European Commission

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and
Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008

Glyphosate

Volume 3 – B.6 (PPP) – MON 52276

Rapporteur Member State : Assessment Group on Glyphosate (AGG) consisting of FR, HU, NL and SE

Version History

When	What
2021/06	Initial RAR

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

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B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS

Table B.6-1: Information on MON 52279

Product name and code	MON 52279
Formulation type	Soluble concentrate [Code: SL]
Active substance(s) (incl. content)	Glyphosate; 360 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	Yes
Product previously evaluated in another MS according to Uniform Principles	Yes

Information on the detailed composition of MON 52276 can be found in the Confidential Section

B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT

MON 52276 exhibits low acute oral, dermal and inhalation toxicity, is slightly irritant to skin, slightly to moderately irritant to eyes and is not a skin sensitizer. No additional classification has to be adopted for MON 52276 due to known toxicological properties of the active substance or any of the co-formulants.

Table B.6.1-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for MON 52276

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 401)	> 5000 mg/kg bw	Yes; study reliable	None	CP 7.1.1/001 Report no 6097-91
LD_{50} dermal, rat (OECD 402)	> 5000 mg/kg bw	Yes; study reliable	None	CP 7.1.2/001 Report no 6098-91
LC_{50} inhalation, rat (OECD 403)	>5.25 mg/L	Yes; study reliable **(new study for AIR 5)**	None	CP 7.1.3/001 Report no 40830
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes; study reliable	None	CP 7.1.4/001 Report no 6099-91
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes; study reliable	None	CP 7.1.5/001 Report no 5999-91
Skin sensitisation, guinea pig (OECD 406, Buehler (9 applications)	Non-sensitising	Yes; study reliable	None	CP 7.1.6/001 Report no [redacted]-2001-153
Skin sensitisation, guinea pig (OECD 406, Buehler	Non-sensitising	No; study unacceptable due to too low number of animals included in the study	N.a.	CP 7.1.6/002 Report no 6100-91

In addition, three *in vitro* mutagenicity assays have been performed with MON 52276. All studies were guideline-compliant and gave negative results. The results are shown in Table B.6.1-2.

Table B.6.1-2: *In vitro* mutagenicity assays performed with MON 52276

Method, guideline, deviations if any	Test substance	Relevant information about the study	Observations /Results	Reference
OECD 471 (1997) GLP Study acceptable	MON 52276 Batch: 11427995 Purity: 30.3 wt% glyphosate acid	TA98, TA100, TA1535, TA1537 and WP2 uvrA strains; 1.5 to 5000 µg/plate (initial assay; duplicate) and 15 to 5000 µg/plate	MON 52276 was negative for the ability to induce reverse mutations in this bacterial mutagenicity assay in the presence and	CP 7.1.7/001; AE60YE-503-BTL; 2016 **(new study for AIR 5)**

		(confirmatory assay, triplicate), both assays ± rat liver S9; adequate positive and negative controls	absence of S9	
OECD487 (2014) Study acceptable but with restrictions The concentration, homogeneity, and stability of the test substance in the vehicle were not analysed. However, the test substance was tested to the maximum appropriate concentration based on records of formulation preparation (weigh tapes, etc.) and the preparation of test substance dilutions occurred immediately before usage. Therefore, lack of verification is not considered to impact the validity of the study.	MON 52276 Batch: 11427995 Purity: 30.3 wt% glyphosate acid	Micronucleus test in Human Lymphocytes, ±S9, 2-2000 µg/mL	Treatment with MON 52276 did not induce a statistically significant increase of micronuclei in human peripheral blood lymphocytes in the presences or absence of metabolic activation under the conditions of this study. The test substance is considered non-clastogenic and non-aneugenic under the conditions of this study.	CP 7.1.7/002; AE60YE.348.BTL; 2016 **(new study for AIR 5)**
OECD487 (2016) GLP Demecolcine (DC) used as positive control. Study acceptable	MON 52276 Batch: 0190A Purity: 30.8% w/w glyphosate acid (41.5% w/w isopropylamine glyphosate) tested, with no correction for purity	Micronucleus test in Human Lymphocytes, ±S9, 321.5-5000 µg/mL	Treatment with MON 52276 did not induce a statistically significant increase of micronuclei in human peripheral blood lymphocytes in the presences or absence of metabolic activation under the conditions of this study. The test substance is considered non-clastogenic and non-aneugenic under the conditions of this study.	CP 7.1.7/003 Report no. WC22PQ; 2020 **(new study for AIR 5)**

B.6.1.1. Oral

1. Information on the study

Data point:	CP 7.1.1/001
Report author	[redacted]
Report year	1991
Report title	Acute Oral Toxicity Study In Rats
Report No	6097-91
Document No	[redacted] 91-261
Guidelines followed in study	US EPA FIFRA guideline 81-1 (1984); OECD 401 (1987 – deleted in 2001) EEC directive 84/449/EEC method B.1 (1984).
Deviations from current test guideline (OECD 401, 1987)	OECD 401 (1987) was deleted in 2001. No major deviations were noted from the 1987 version of the test guideline.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 2a Conclusion AGG: Study acceptable

2. Full summary of the study according to OECD format

The acute oral toxicity of the test substance, MON 52276, was evaluated in Sprague-Dawley albino rats (5 per sex) by administration of 5000 mg/kg bw by gavage at a dose volume of 4.2 mL/kg bw.

No mortality occurred during the study. Clinical signs noted 24 hours after dosing were faecal staining and/ or soft stool, as well as oral and/ or nasal discharge and hypo activity. There was no effect on body weight gain. The gross necropsy conducted at termination of the study revealed no observable abnormalities.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding oral toxicity.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:** Glyphosate
   - Identification: MON 52276
   - Description: Amber liquid
   - Lot/ Batch #: LLN-9105-3135-F
   - Purity: not reported
   - Stability of test compound: Expiry data: May 1992
2. **Vehicle and/ or positive control:** None
3. **Test animals:**
   - Species: Rat albino
   - Strain: Sprague-Dawley [CD-Crl:CD (SD)BR]
   - Source: [redacted]
   - Age: Approx. 9-12 weeks

Sex:	Males and females
Weight at dosing:	Males: 330 - 354 g; females: 253 – 270 g
Acclimation period:	20 days
Diet/ Food:	Purina Laboratory Chow #5001, ad libitum except for approx. 18 h before dosing and 4 hours after dosing
Water:	Tap water, *ad libitum*
Housing:	Individual housing in suspended, wire bottom, stainless steel cages.
Environmental conditions:	Temperature: 19 – 24°C Humidity: 40 – 70% Air changes: not reported Light cycle: 12-hour light/ dark cycle

B. STUDY DESIGN

In life dates: 1991-07-29 to 1991-08-12

Animal assignment and treatment:

Five fasted rats per sex received the test material at a dose level of 5000 mg/kg bw by oral gavage (limit test). Observations for mortality were made twice daily. A check for clinical signs of toxicity was made at least three times on the day of dosing (1, 2 and 4 hours after dosing) and once daily thereafter for 14 days. Individual body weights were recorded just prior to fasting, prior to dosing and on Days 7 and 14. On Day 14 all surviving animals were sacrificed, subjected to gross necropsy and all abnormalities were recorded.

II. RESULTS AND DISCUSSION

A. MORTALITY

There were no mortalities during the study.

B. CLINICAL OBSERVATIONS

Faecal staining and/ or soft stool was noted in all animals after dosing on Day 1. A few animals also showed oral and/ or nasal discharge, as well as hypo activity.

Table B.6.1.1-1: Clinical signs observed after acute oral exposure

Clinical sign	Males*	Duration	Females*	Duration
Dry nasal discharge	2/5	1 hour	1/5	1 hour
Oral discharge	2/5	1 hour	0/5	--
Hypoactivity	1/5	4 hours	0/5	--
Faecal staining	4/5	Day 1	1/5	Day 1
Soft stool	4/5	Day 1	5/5	Day 1
Unthrifty coat	0/5	--	2/5	Day 1
Partially closed eyes	1/5	2 hours	1/5	2 hours

* number affected/ total number

C. BODY WEIGHT

Body weight gain was unaffected by the administration of the test substance and all animals gained weight throughout the observation period.

D. NECROPSY

The gross necropsy conducted at termination of the study revealed no observable abnormalities.

III. CONCLUSIONS

The oral LD_{50} of the test material (MON 52276) in rats was greater than 5000 mg/kg bw.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 401 (1987). However, this guideline was deleted in 2001. There are some deviations according to the most updated version of this guideline but none that could jeopardize the results of this study. Therefore, the outcome can be reported as valid. The acute oral LD_{50} is above 5000 mg/kg bw.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding oral toxicity.

Assessment and conclusion by RMS:

The study is considered acceptable.

Based on the LD50 of >5000 mg/kg bw no classification for acute oral toxicity is required for the formulation MON 52276.

B.6.1.2. Dermal

1. Information on the study

Data point:	CP 7.1.2/001
Report author	[redacted]
Report year	1991
Report title	Acute Dermal Toxicity Study In Rats
Report No	6098-91
Document No	[redacted]-91-262
Guidelines followed in study	US EPA FIFRA guideline 81-2 (1984); OECD 402 (1987); EEC directive 84/449/EEC method B.3 (1984); JMAFF
Deviations from current test guideline (OECD 402, 2017)	The current OECD TG 402, 2017, states the necessity of *in silico* and *in vitro* approaches and weight of evidence evaluations and as last resort prefers the *in vivo* Fixed Dose Method, however, when the study was conducted such methods were not yet available. The study had been performed under occlusive dressing while semi-

	occlusive dressing is being prescribed. After administration the first observation was made after 1 hour instead of during the first 30 minutes.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 2a Conclusion AGG: Study acceptable

2. Full summary of the study according to OECD format

The acute dermal toxicity of the test substance, MON 52276, was evaluated in Sprague-Dawley albino rats (5 per sex) by dermal application of 5000 mg/kg bw for 24 hours.

No mortality occurred during the study. There were no dermal effects or clinical signs of systemic toxicity. Body weight gain was not affected. The gross necropsy conducted at termination of the study revealed no observable abnormalities.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding dermal toxicity.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:**

Identification:	MON 52276
Description:	Amber liquid
Lot/ Batch #:	LLN-9105-3135-F
Purity:	31% glyphosate acid equivalent
Stability of test compound:	Expiry data: May 1992 (estimated)

2. **Vehicle and/ or positive control:** None

3. **Test animals:**

Species:	Rat albino
Strain:	Sprague-Dawley [CD-Crl:CD (SD)BR]
Source:	[redacted]
Age:	Approx. 9-12 weeks
Sex:	Males and females
Weight at dosing:	Males: 312 - 360 g; females: 250 – 262 g
Acclimation period:	21 days
Diet/ Food:	Purina Laboratory Chow #5001, *ad libitum*
Water:	Tap water, *ad libitum*
Housing:	Individual housing in suspended, wire bottom, stainless steel cages.
Environmental conditions:	Temperature: 19 – 24 °C Humidity: 40 – 70 % Air changes: not reported Light cycle : 12-hour light/ dark cycle

B. STUDY DESIGN

In life dates: 1991-07-30 to 1991-08-13

Animal assignment and treatment:

A group of five Sprague-Dawley albino rats per sex received the undiluted test material at a dose level of 5000 mg/kg bw by dermal application to the clipped dorsal skin (approximately 10% of the body surface) under an occlusive dressing for 24 hours. The dosing volume was 4.2 mL/kg bw. After 24 hours the dressing was removed and the application area was wiped free of residual test substance. Observations for mortality were made twice daily. A check for clinical signs of toxicity were made at least three times on the day of dosing (1, 2 and 4 hours) and once daily thereafter for 14 days. Individual body weights were recorded just prior to clipping (one day before dosing), prior to dosing and on Days 7 and 14. On Day 14 all surviving animals were sacrificed, subjected to gross necropsy and all abnormalities were recorded.

II. RESULTS AND DISCUSSION

A. MORTALITY

There were no mortalities during the study.

B. CLINICAL OBSERVATIONS

No severe dermal effects were seen throughout the study. Most animals were free of significant signs of systemic toxicity, although evidence of red ocular discharge was seen in two animals and evidence of red urinary staining was seen in an additional animal at 24 hours.

C. BODY WEIGHT

Body weight gain was unaffected by the administration of the test substance. All animals gained weight throughout the study.

D. NECROPSY

The gross necropsy conducted at termination of the study revealed no observable abnormalities. Two female animals had a swollen uterus.

III. CONCLUSIONS

The dermal LD_{50} of the test material (MON 52276) in rats, under conditions of this study, is greater than 5000 mg/kg bw.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 402 (1987). Therefore, the outcome can be reported as valid. The dermal oral LD_{50} is above 5000 mg/kg bw.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding dermal toxicity.

Assessment and conclusion by RMS:

The study is considered to be acceptable. However, the study has been performed under occlusive dressing whereas a semi-occlusive dressing is being prescribed. This deviation is not considered to have an impact on the study outcome. Based on the LD50 value of >5000 mg/kg bw no classification for acute dermal toxicity is required for the formulation MON 52276.
Additionally, it is noted that the clinical signs of eye irritation in this study are consistent with the results in the eye irritation study (CP 7.1.5/001)

B.6.1.3. Inhalation

1. Information on the study

Data point:	CP 7.1.3/001
Report author	[redacted]
Report year	2015
Report title	MON 52276: Acute Inhalation Toxicity in Rats
Report No	40830
Document No	[redacted]0026415
Guidelines followed in study	US EPA OPPTS 870.1300 (1998), OECD 403 (2009)
Deviations from current test guideline (OECD 403, 2009)	No deviations were noted.
Previous evaluation	New study for AIR5
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 1 Conclusion AGG: Study acceptable

2. Full summary of the study according to OECD format

The acute inhalation toxicity of the test substance, MON 52276, was evaluated in Sprague-Dawley albino rats (5 per sex) via inhalation after aerosolization at a concentration of 5.25 mg/L for 4 hours.

No mortality occurred during the study. Following exposure, all rats exhibited irregular respiration. However, all animals recovered by Day 1 and appeared active and healthy for the remainder of the 14-day observation period. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding inhalation toxicity.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Identification: MON 52276
Description: Amber liquid
Lot/ Batch #: GLP-1503-23897-F
Composition: 30.3 wt % glyphosate

Expiration date March 24, 2016

2. Vehicle and/ or positive control: None

3. Test animals:

Species: Rat

Strain: Sprague-Dawley derived

Source: [redacted]

Age: Approx. 10-11 weeks

Sex: Males (5) and females (5)

Weight at dosing: Males: 336 – 379 g, Females: 219 – 242 g

Acclimation period: 20 days

Diet/ Food: Harlan Teklad Global 16% Protein Rodent Diet® #2016, *ad libitum* (except during exposure)

Water: Filtered tap water, *ad libitum* (except during exposure)

Housing: Individually housed in suspended, stainless steel mesh cages

4. Environmental conditions:

Temperature: 20-23°C

Humidity: 46-59%

Air changes: 13/hour

Photoperiod: 12-hour light/ dark cycle

B. STUDY DESIGN

1. In life dates: 22 April – 12 May 2015

2. Animal assignment and treatment:

Prior to initiation of the full inhalation study, pre-test trials were conducted to establish generation procedures to achieve, to the extent possible, the desired chamber concentration (5 mg/L) and desired particle size distribution (MMAD between 1 and 4 µm). On the day of and prior to exposure, the rats were examined for health and weighed. Ten healthy, naive rats (five males and five females; not previously tested) were selected for test. The animals were exposed to the targeted chamber concentration for at least 4 hours. Chamber concentration and particle size distributions of the test atmosphere were determined periodically during the exposure period. Individual body weights of the animals were recorded prior to test substance exposure (initial) and again on Days 1, 3, 7, and 14 (terminal). All animals were observed for mortality during the exposure period. The animals were examined for signs of gross toxicity, and behavioural changes upon removal from the exposure tube and at least once daily thereafter for 14 days. All rats were euthanized via CO_2 inhalation on Day 14. Gross necropsies were performed on all animals. Tissues and organs of the thoracic and abdominal cavities were examined.

Table B.6.1.3-1: Nominal chamber concentrations

Exposure Concentration (mg/L)	Total Test Substance used (g)	Total Airflow (Lpm)	Total Time of Exposure (min)	Nominal Concentration (mg/L)
5.25	708.5	36.0	244	80.66

II. RESULTS AND DISCUSSION

A. TEST ATMOSPHERE

The chamber and nominal chamber concentrations were 5.25 mg/L and 80.66 mg/L, respectively. The average mass median aerodynamic diameter was estimated to be 2.16 µm based on graphic analysis of the particle size distribution as measured with a 1 ACFM Andersen Ambient Particle Sizing Sampler with an average geometric standard deviation of 1.96.

Table B.6.1.3-2: Concentration(s) and exposure conditions

Target conc. (mg/L air)	Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
5.0	80.66	5.25	2.16	1.96

* MMAD = Mass Median Aerodynamic Diameter
** GSD = Geometric Standard Deviation

B. MORTALITY

There were no mortalities during the study.

C. CLINICAL OBSERVATIONS

Following exposure, all rats exhibited irregular respiration. However, all animals recovered by Day 1 and appeared active and healthy for the remainder of the 14-day observation period.

D. BODY WEIGHT

Animals gained weight throughout the 14-day observation period.

E. NECROPSY

No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

III. CONCLUSIONS

The acute inhalation LC_{50} of MON 52276 in male and female rats was greater than 5.25 mg/L.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 403 (2009). Therefore, the outcome can be reported as valid. The acute inhalation LC_{50} of MON 52276 in rats is greater than 5.25 mg/L.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding inhalation toxicity.

Assessment and conclusion by RMS:

The study was conducted in accordance with OECD 403 and is considered acceptable. Based on the LC50 value of >5.25 mg/L no classification for acute inhalation toxicity is required for the formulation

MON 52276.

B.6.1.4. Skin irritation

1. Information on the study

Data point:	CP 7.1.4/001
Report author	[redacted]
Report year	1991c
Report title	Primary dermal irritation study in rabbits
Report No	6099-91
Document No	[redacted] 91-263
Guidelines followed in study	OECD 404 (1991); Commission Directive 92/69/EEC method B.4 (1984), US EPA FIFRA guideline 81-5 (1984)
Deviations from current test guideline (OECD 404, 2015)	Deviations noted: - The current OECD 404 states the necessity of *in silico* and *in vitro* approaches and weight of evidence evaluations and *in vivo* testing only as last resort. However, when the study was conducted such methods were not yet available. - 6 animals used instead of the maximum recommended of 3 in the latest revision of the guideline. - First response scored at 30 minutes instead of 60 minutes. - Body weights and clinical signs were not recorded. - the test item was applied to two sites on the skin instead of one.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 2a Conclusion AGG: The deviations from OECD 404 are not considered to impact the validity of the study results. Therefore, the study is concluded to be acceptable.

2. Full summary of the study according to OECD format

In a primary dermal irritation study, young adult New Zealand albino rabbits (4 male, 2 females) were dermally exposed to MON 52276. Two sites of clipped, intact skin of the back were exposed to 0.5 mL of the undiluted test substance, for 4 hours under semi-occlusive conditions. The rabbits were observed for 72 hours. Skin irritation was scored using the Draize scheme 0.5, 24, 48 and 72 hours after removal of the test substance.

Very slight to slight erythema was observed in two animals. No oedemas were observed at the application site of any animal at any observation time point. The overall mean for the 24, 48 and 72-hour readings were 0.11 for erythema and 0.0 for oedema.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding skin irritation.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:**

Identification:	MON 52276
Description:	Amber liquid
Lot/ Batch #:	LLN-9105-3135-F
Purity:	not reported
Stability of test compound:	Expiry data: May 1992 (estimated)

2. **Vehicle and/ or positive control:** None

3. **Test animals:**

Species:	Rabbit
Strain:	New Zealand White
Source:	[redacted]
Age:	At least 8 weeks
Sex:	Males (4) and females (2)
Weight at dosing:	Not available
Acclimation period:	49 days
Diet/ Food:	Lab Rabbit Chow HF (Purina #5326)
Water:	Tap water, *ad libitum*
Housing:	Individual housing in suspended, wire bottom, stainless steel cages.
Environmental conditions:	Temperature: 15 – 21°C Humidity: 40 – 60% Air changes: not reported Light cycle : 12-hour light/ dark cycle

B. STUDY DESIGN

In life dates: 1991-07-22 to 1991-07-25

Animal assignment and treatment:

The test was conducted using young adult New Zealand albino rabbits (4 male, 2 females). An amount of 0.5 mL of the undiluted test substance was applied to the intact skin on two sites of the clipped back of the rabbits on a 1’’x1’’ gauze square. The patch was covered with a semi-occlusive dressing. After 4 hours of exposure the dressing was removed and the skin was cleaned with water.
Skin reactions were assessed approximately 0.5, 24, 48 and 72 hours after removal of the patch. The animals were observed for mortality and clinical signs twice daily.

II. RESULTS AND DISCUSSION

A. MORTALITY

No mortality occurred.

B. CLINICAL OBSERVATIONS

Clinical signs were not monitored.

D. NECROPSY

No necropsy was performed.

E. SKIN OBSERVATIONS

All six animals exhibited very slight to slight erythema with no oedema. Five of the six animals were free of dermal irritation by 24-hours with the remaining animal free of irritation by 72-hours.

Table B.6.1.4-1: Skin irritation scores

Animal No.			Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
			0.5 h	24 h	48 h	72 h		
0259M	Erythema Oedema	Right side	0 0	0 0	0 0	0 0	0 0	NA
		Left side	1 0	0 0	0 0	0 0	0 0	NA
0249M	Erythema Oedema	Right side	1 0	0 0	0 0	0 0	0 0	NA
		Left side	2 0	0 0	0 0	0 0	0 0	NA
0252F	Erythema Oedema	Right side	2 0	1 0	1 0	0 0	0.66 0	3
		Left side	1 0	1 0	1 0	0 0	0.66 0	3
0261M	Erythema Oedema	Right side	1 0	0 0	0 0	0 0	0 0	NA
		Left side	1 0	0 0	0 0	0 0	0 0	NA
0255M	Erythema Oedema	Right side	1 0	0 0	0 0	0 0	0 0	NA
		Left side	1 0	0 0	0 0	0 0	0 0	NA
0238F	Erythema Oedema	Right side	1 0	0 0	0 0	0 0	0 0	NA
		Left side	1 0	0 0	0 0	0 0	0 0	NA

* scores in the range of 0 to 4

III. CONCLUSIONS

MON 52276 produced mild, transient dermal irritation. The FIFRA Primary Irritation Index of MON 52276 is 0.3; therefore, this material would be classified as Essentially Non irritating.

According to the OECD Globally Harmonized System (GHS) classification criteria MON 52276 is also not classified for skin irritation.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 404 (1992). Despite some deviations compared to the most updated version of this guideline, none of them could jeopardize the results of this study. Therefore, the outcome can be reported as valid.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding skin irritation.

Assessment and conclusion by RMS:

Although some minor deviations were noted overall the study is considered to be acceptable.

The mean scores were 0 for oedema in all animals and 0.66 for erythema in one animals and 0 in the remaining animals. Therefore, classification for skin irritation is not required.

B.6.1.5. Eye irritation

1. Information on the study

Data point:	CP 7.1.5/001
Report author	[redacted]
Report year	1992
Report title	Primary eye irritation study in rabbits
Report No	5999-91
Document No	[redacted]91-60
Guidelines followed in study	OECD 405 (1987); EC Directive 92/69/EEC method B.5 (1987), US EPA FIFRA guideline 81-4 (1984)
Deviations from current test guideline (OECD 405, 2020)	Deviations noted: - 6 animals used instead of the maximum recommended of 3 in the latest revision of the guideline. - No use of analgesics and anaesthetics - The current OECD 405 states the necessity of *in silico* and *in vitro* approaches and weight of evidence evaluations and *in vivo* testing only as last resort. However, when the study was conducted such methods were not yet available. - Body weight and clinical signs not investigated. - The temperature and humidity were recorded, but not reported in the study.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 2a Conclusion AGG: The deviations from OECD 405 are not considered

	to impact the validity of the study results. Therefore, the study is concluded to be acceptable.

2. Full summary of the study according to OECD format

In an eye irritation study, 0.1 mL of the undiluted test substance was instilled into the right conjunctival sac of six young adult New Zealand albino rabbits. Animals were observed for 7 days. Eye irritation was scored 1, 24, 48 and 72 hours and 7 days after test item instillation.

Application of MON 52276 into the rabbit eye resulted in slight to moderate conjunctival irritation in all animals. Iridial changes were noted in one animal 1 hour after instillation. There were no corneal effects noted. All eye effects were reversible within 7 days after instillation. The overall mean irritation scores (24 to 72 hours) of the six rabbits were as follows:

- for corneal opacity: 0.0;
- for iris lesions: 0.0
- for conjunctival redness: 1.1
- for chemosis of the conjunctiva: 0.0

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding eye irritation.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:**

Identification:	MON 52276
Description:	Clear, amber liquid
Lot/ Batch #:	LLN-9102-2794-F
Purity:	not reported
Stability of test compound:	Expiry date: February 1992 (estimated)

2. **Vehicle and/ or positive control:** None

3. **Test animals:**

Species:	Rabbit
Strain:	New Zealand White
Source:	[redacted]
Age:	At least 8 weeks
Sex:	Males (3) and females (3)
Weight at dosing:	2.6 – 2.8 kg
Acclimation period:	49 days
Diet/ Food:	Lab Rabbit Chow HF (Purina #5326)
Water:	Tap water, *ad libitum*
Housing:	Individual housing in suspended, wire bottom, stainless steel cages.
Environmental conditions:	Temperature: 15 – 21 °C Humidity: 40 – 60% Air changes: not reported Light cycle : 12-hour light/ dark cycle

B. STUDY DESIGN

In life dates: 1991-01-14 to 1991-03-11

Animal assignment and treatment:

The test was conducted using six (3 per sex) young adult New Zealand white rabbits. An amount of 0.1 mL of the undiluted test substance was applied into the conjunctival sac of the right eye of the rabbits. The treated eyes were not rinsed after instillation. The right left remained untreated and served as the reference control.
Eye reactions were assessed approximately 1, 24, 48 and 72 hours, and 7 days after instillation. Eye examinations using fluorescein were done one day prior to instillation, and at each examination time-point starting with the 24-hour observation until there was no stain retention for two observations. The animals were observed for mortality and clinical signs daily.

II. RESULTS AND DISCUSSION

A. MORTALITY

No mortality occurred.

B. CLINICAL OBSERVATIONS

Not evaluated.

C. BODY WEIGHT

Not evaluated.

D. NECROPSY

No necropsy was performed.

E. EYE OBSERVATIONS

Slight to moderate conjunctival irritation (redness, chemosis, discharge) was noted in all rabbits. Slight iridial changes were observed in one animal at the 1-hour reading only. There were no corneal effects noted. Three of the six animals were free of all ocular irritation within 24 to 72 hours with the remaining three animals free of irritation by Day 7.
The group mean irritation scores (24 to 72 hours) were calculated to be 0.0 for corneal opacity, 0.0 for iris lesions, and 1.1 for conjunctival redness, and 0.0 for chemosis of the conjunctiva.

The individual scores for each time point, individual mean and group mean scores (24 to 72 hours) are presented in the following table.

Table B.6.1.5-1: Eye irritation scores

Animal No.		Scores after treatment*				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
9870 F	Corneal opacity	0	0	0	0	0	3
	Iritis	0	0	0	0	0	
	Redness conjunctivae	1	1	1	0	0.66	
	Chemosis conjunctivae	1	0	0	0	0	

Table B.6.1.5-1: Eye irritation scores

Animal No.		Scores after treatment*				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
	Discharge	2	0	0	0	0	
9871 M	Corneal opacity	0	0	0	0	0	3
	Iritis	0	0	0	0	0	
	Redness conjunctivae	1	1	1	0	0.66	
	Chemosis conjunctivae	1	0	0	0	0	
	Discharge	1	0	0	0	0	
9876 F	Corneal opacity	0	0	0	0	0	NA
	Iritis	0	0	0	0	0	
	Redness conjunctivae	2	0	0	0	0	
	Chemosis conjunctivae	1	0	0	0	0	
	Discharge	1	0	0	0	0	
9879 M	Corneal opacity	0	0	0	0	0	7
	Iritis	+	0	0	0	0	
	Redness conjunctivae	2	2	2	1	1.66	
	Chemosis conjunctivae	1	0	0	0	0	
	Discharge	2	0	0	0	0	
9880 F	Corneal opacity	0	0	0	0	0	7
	Iritis	0	0	0	0	0	
	Redness conjunctivae	1	2	2	1	1.66	
	Chemosis conjunctivae	1	0	0	0	0	
	Discharge	2	0	0	0	0	
9887 M	Corneal opacity	0	0	0	0	0	7
	Iritis	0	0	0	0	0	
	Redness conjunctivae	1	2	2	2	2	
	Chemosis conjunctivae	1	0	0	0	0	
	Discharge	3	0	0	0	0	

* Scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis
+ Slight iridial effect

III. CONCLUSIONS

MON 52276 produced mild, transient ocular irritation. This material would be considered to produce eye irritation as defined in the EPA test guidelines (see Report Section VIII). However, MON 52276 did not cause significant ocular lesions and therefore, is not classified according to Annex VI of EEC Council Directive 67/548/EEC (L 180, 91/325, 08 July 1991).

According to EU and GHS classification criteria the test substance MON 52276 is not to be classified for eye irritation.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 405 (1987). Despite some deviations compared to the most updated version of this guideline, none of them could jeopardize the results of this study. Therefore, the outcome can be reported as valid.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding eye irritation.

Assessment and conclusion by RMS:

Although some minor deviations were noted overall the study is considered to be acceptable.

Since no corneal effects, iris effect or oedema was observed between 24-72 hours and since the mean conjunctivae redness scores were below 2 in 5 out of 6 animals no classification for eye irritation is required.

B.6.1.6. Skin sensitization

Study 1

1. Information on the study

Data point:	CP 7.1.6/001
Report author	[redacted]
Report year	2001
Report title	Skin sensitization test in guinea pigs (Modified Buehler test: 9 applications)
Report No	[redacted]-2001-153
Document No	Not reported
Guidelines followed in study	OECD 406 (1992); EC Directive 96/54/EEC method B.6 (1996)
Deviations from current test guideline (OECD 406, 1992)	None
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 2a Conclusion AGG: The study is considered acceptable. Regulation 284/2013 requires the use of an LLNA test or if not possible the Maximisation test. No adequate justification was provided for using the Buehler method while it is noted that the provided study was already performed in 2001. However, it is noted that glyphosate nor its co-formulants are classified for skin sensitisation. Therefore, based on a weight-of-evidence approach the negative Buehler assay is accepted.

2. Full summary of the study according to OECD format

MON 52276 was tested for its sensitizing effect on the skin of the guinea pig in the modified Buehler test with nine induction treatments. The test-substance concentrations for the main test were selected based on the results of the pre-test. Both induction and challenge applications were performed with undiluted test substance. The study was performed using one control group consisting of 10 animals, and one test group consisting of 20 animals.

None of the animals exhibited a positive skin reaction (defined as scores of ≥ 1) after the challenge treatment. Under the test conditions MON 52276 did not show a potential for skin sensitisation.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Identification:	Mon 52276
Description:	Yellowish liquid
Lot/ Batch #:	A1C1204104
Purity:	30.88 %
Stability of test compound:	Expiry date: May 2003

2. Vehicle and/ or positive control: Purified water/ mercaptobenzothiazole

3. Test animals:

Species:	Guinea pig
Strain:	Hartley, CRL:(HA)BR, (COBS-VAF)
Source:	[redacted]
Age:	1 – 3 months
Sex:	Males and females
Weight at dosing:	males: 366 ± 18 g; females: 348 ± 17 g
Acclimation period:	at least 5 days
Diet/ Food:	Pelleted diet (UAR, France), *ad libitum*
Water:	Filtered drinking water, *ad libitum*
Housing:	Individually in polycarbonate cages with autoclaved sawdust bedding
Environmental conditions:	Temperature: 21 ± 2 °C Humidity: 30 – 70 % Air changes: 12/hour Light cycle: 12 hours light/ dark cycle

B. STUDY DESIGN

In life dates: 2001-06-19 to 2001-08-01

Animal assignment and treatment:

MON 52276 was tested for its sensitising effect on the skin of the guinea pig using the modified Buehler method with nine induction treatments. Male and female Hartley guinea pigs, young adults were used. The test substance concentrations for the main study were selected based on the results of a preliminary test on one male and one female guinea pig using test substance concentrations of 100 % and 75 % for both induction and challenge treatments. The main study was performed in 20 test animals and 10 control animals.

In the main study the nine inductions were done on Days 1, 3, 5, 8, 10, 12, 15, 17 and 19 on the same intact flanks of the animals. 24 hours before the applications, the treatment area was clipped. All inductions were performed under occlusive conditions with 4×4 cm test patches soaked with the undiluted test substance (100%) for 6 hours each. On Day 29, the challenge applications with undiluted test substance and vehicle were done to the clipped posterior right and left flanks of the animals under the same conditions as for the inductions. The control animals were treated with purified water for the induction treatments.
Skin reactions were assessed 24 and 48 hours after each induction and challenge treatment.
Body weights were determined at the first day of treatment of the main study and at termination. Mortality and clinical signs were recorded daily during the study period.

A positive control (reliability check) with a known sensitizer was performed in June 2001 in the laboratory according to the modified Buehler method. The positive control with mercaptobenzothiazole (20%) showed that the chosen guinea pig strain was able to detect sensitizing compounds under the laboratory conditions chosen.

Evaluation criteria for classification as a potential skin sensitizer:
At the 24-hour and/ or 48-hour reading, 15% or more of the test animals exhibit a positive response (scores ≥ 1) in the absence of similar results in the vehicle control group.

II. RESULTS AND DISCUSSION

A. MORTALITY

No deaths occurred.

B. CLINICAL OBSERVATIONS

No signs of systemic toxicity were observed.

C. BODY WEIGHT

The body weight was not affected.

D. NECROPSY

No necropsy was performed.

E. SKIN REACTIONS

After the induction treatments discrete erythema (grade 1) were observed in a few animals. After challenge application, except for dryness of the skin at the 24-hour reading in one animal, no skin reactions were observed (see following table).

Table B.6.1.6-1: Summary of positive skin responses after challenge exposure

Group	Test substance concentration	Reading time (h)	Number of animals with positive skin responses*
Test substance	100 % MON 52276	24	0/20
		48	0/20
Negative control	Purified water	24	0/10
		48	0/10
Positive control**	20 % MBT***	48	7/10

* Number of animals with skin reactions/ total number of animals
** Study performed in June 2001
*** MBT = mercaptobenzothiazole

III. CONCLUSIONS

Under the experimental conditions and according to the modified Buehler method, the test substance MON 52276 does not induce delayed contact hypersensitivity in guinea pigs.

According to the classification criteria laid down in Commission Directive 93/21/EEC, the test substance should not be classified, as sensitizing to the skin.

Based on the EU classification criteria, MON 52276 is not to be classified for skin sensitisation. According to the OECD Globally Harmonized System (GHS) classification criteria MON 52276 is also not classified for skin sensitization.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 406 (1992). Despite the fact that the LLNA, or, if not possible, the M&K test are clearly preferred to the Buehler test, the provided Buehler test is valid and is to be accepted against the background of animal welfare.
The results of this GLP study confirm the results of the previously submitted study evaluated by the rapporteur in 2001, which followed the previous OECD 406 (1987) test guideline.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding skin sensitisation.

Assessment and conclusion by RMS:

The study is considered acceptable. Under the test conditions the formulation MON 52276 did not show a potential for skin sensitisation.

Study 2

1. Information on the study

Data point:	CP 7.1.6/002
Report author	[redacted]
Report year	1992b
Report title	Closed-patch repeated insult dermal sensitization study in guinea pigs (Buehler method)
Report No	6100-91
Document No	[redacted] 91-264
Guidelines followed in study	OECD 406 (1987) EC Directive 96/54/EEC method B.6 (1984)
Deviations from current test guideline (OECD 406, 1992)	A minimum of 20 animals should be used in the treatment group, 10 animals were used in this study.
Previous evaluation	No, not accepted in RAR (2015)
GLP/ Officially recognised testing facilities	No
Acceptability/ Reliability:	Conclusion GRG: Supportive, Category 3a Conclusion AGG: Since the number of animals tested is too low the study is concluded to be unacceptable.

2. Full summary of the study according to OECD format

This study was conducted to assess the potential of MON 52276 (Lot No. LLN-9105-31354F) to produce hypersensitivity subsequent to repeated dermal exposure. This was accomplished by repetitive dermal application of the test chemical for a defined period of time (induction phase), followed by a rest period and challenge of the animals with a non-irritating dose to test for hypersensitivity. This method is a modification of that originally described by Buehler.

A range-finding irritation screen was conducted to determine appropriate induction and challenge dose levels. For the induction phase, 0.3 mL of 100 % MON 52276 was administered dermally to the shaved backs of 5 males and 5 female Hartley guinea pigs. Induction consisted of 3 applications, once per week for 3 weeks, each of 6 hours duration. A 14-day rest period followed the third induction dose, after which, each animal was challenged on a previously untreated area of skin using the same exposure technique. The challenge dose administered was the same as for induction. An additional group of naïve animals (5/sex) received the identical challenge dose and served as irritation controls.

Body weights were recorded pre-test and at study termination. Dermal irritation was scored at 24 and 45 hours after each induction and challenge application.
Although no positive control group was included in this study, [redacted] frequently includes animals treated with dinitrochlorobenzene (DNCB), a known sensitizer, in sensitization studies. A file of historical control data is maintained, demonstrating the validity of this protocol for detecting known sensitizers. These data are appended to the report.

All animals survived and exhibited normal weight gain over the course of the study. No irritation responses were seen following administration of the induction doses. Following administration of the challenge dose, no dermal irritation responses were observed in any of the ten test animals or ten naïve control animals.

Under the conditions of this study, MON 52276 exhibited no potential to produce dermal sensitization in guinea pigs. However, considering the low number of animals the study is concluded to be unacceptable.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Identification:	Mon 52276
Description:	Amber liquid
Lot/ Batch #:	LLN-9105-3135-F
Purity:	not reported
Stability of test compound:	Expiry date: May 1992
2. Vehicle and/ or positive control:	Purified water, dinitrochlorobenzene (positive control)
3. Test animals:	
Species:	Guinea pig
Strain:	Hartley, CRL:(HA)BR
Source:	[redacted]
Age:	2-3 weeks at receipt, 4-5 weeks at study initiation
Sex:	Males and females
Weight at dosing:	males: 313-362 g; females: 305-370 g
Acclimation period:	8 days for the range-finding, 15 days for the sensitization study
Diet/ Food:	Agway Prolab Guinea Pig Diet, *ad libitum*
Water:	Automatic watering system, *ad libitum*
Housing:	Individually in stainless steel cages with wire mesh bottoms
Environmental conditions:	Temperature: 19-24 °C Humidity: 30 – 91% Air changes: NA Light cycle: 12 hours light/ dark cycle

[redacted] has a historical data base of data for animals form the same source as those used in the study demonstrating susceptibility to dermal sensitization with a known sensitizer (dinitrochlorobenzene) when tested using procedures described in this report.

B. STUDY DESIGN

In life dates: 1991-08-26 to 1991-10-3

Animal assignment and treatment:

Prior to initiation of the study, a range-finding study was performed in order to select a slightly irritating concentration for topical induction and a non-irritating concentration for the challenge application. Six animals were treated topically with undiluted test material (100%) and with concentrations of 50%, 25% and 10% v/v of the test material in distilled water (one concentration/ site).
Based on results of the range-finding study, the undiluted material was found to be non-irritating and was, therefore, administered at a 100% concentration for both induction and challenge.

In the main study, the test material was applied to saturation (approximately 0.3 mL) beneath a Hilltop Chamber® placed directly on the test site. The test site was on the right side of the midline, as close to the midline as possible. The chamber was covered by overlapping, impermeable plastic. This was firmly secured by an elastic adhesive bandage which was wound around the torso of the animal. The chamber was left in place for six hours after which it was removed and the skin was wiped free of any excess material with gauze and water. This was performed once a week, for three weeks, for a total of three exposures.

Fourteen days after the last induction exposure, the challenge treatment was administered. The test material was administered in the same manner as in the induction phase, but at a second site, on the left side of the midline. After six hours of exposure, the chambers were removed and the skin wiped free of any excess material.
In order to differentiate dermal reactions produced by irritation from those produced by sensitization, ten previously untreated animals (five/ sex) were subjected to the same challenge procedures as the animals which received the three induction exposures.

Table B.6.1.6-2: Experimental design

Group	Test material	Number of animals	Concentration (%)	
			Induction	Challenge
I	MON 52276	10 (5/ sex)	100	100
II	MON 52276 (irritation control)	10 (5/ sex)	NR*	100

* The irritation control group was treated at challenge only

Dermal evaluations were made approximately 24 and 48 hours after the induction exposure to confirm that an appropriate concentration of the test material had been selected and to evaluate response for possible preliminary indication of sensitization. For challenge, dermal evaluations were made 24 and 48 hours after dosing.

Viability was checked twice daily and body weight was checked on the day prior to the first induction and at termination.

II. RESULTS AND DISCUSSION

A. MORTALITY

All animals survived throughout the study.

B. CLINICAL OBSERVATIONS

No signs of systemic toxicity were observed.

C. BODY WEIGHT

All animals gained weight by study termination

D. NECROPSY

No necropsy was performed.

E. SKIN REACTIONS

No dermal irritation was seen during induction exposures. Animals challenged with MON 52276 (Group I) exhibited no dermal response at challenge to a non-irritating concentration, as confirmed by a lack of dermal response in irritation control animals (Group II). The Incidence Index of sensitization to the test material was 0 %. The Severity Indices at 24 and 48 hours were 0 for both the test material-treated animals and for the irritation controls.

Table B.6.1.6-3: Summary of positive skin responses after challenge exposure

Group	Test substance concentration	Reading time (h)	Number of animals with positive skin responses*
Test substance	100 % MON 52276	24	0/10
		48	0/10
Negative control	Purified water	24	0/10
		48	0/10

* Number of animals with skin reactions/ total number of animals

III. CONCLUSIONS

Under the conditions of this study, MON 52276 exhibited no potential to produce dermal sensitization in guinea pigs.

3. Assessment and conclusion

Assessment and conclusion by applicant:

This study was performed following the previous OECD 406 (1987) test guideline. However, due to major deviations with the current guideline, the results cannot be interpreted and the study is not acceptable. Therefore, another skin sensitisation study [redacted], 2001) was performed.

Assessment and conclusion by RMS:

Under the test conditions the formulation MON 52276 did not show any skin sensitisation potential. However, due to the low number of animals test the study is concluded to be unacceptable.

B.6.1.7. Supplementary studies on the plant protection product

B.6.1.7.1. Bacterial Reverse Mutation Assay with MON 52276

1. Information on the study

Data point:	CP 7.1.7/001
Report author	[redacted]
Report year	2016
Report title	MON 52276: Bacterial Reverse Mutation Assay
Report No	AE60YE-503-BTL
Document No	MSL0027853
Guidelines followed in study	OECD 471 (1997)
Deviations from current test guideline (OECD 471, 2020)	The concentration, homogeneity, and stability of the test substance in the vehicle were not analyzed. However, the study director indicated that it is believed that the test substance was tested to the maximum appropriate concentration based on the laboratory records of formulation preparation (weigh tapes, etc.) and the preparation of test substance dilution occurred

	immediately before usage. Therefore, lack of stability, homogeneity and concentration verification is not considered to impact the validity of the study. 2-Aminoanthracene was used as sole positive control in the presence of metabolic activation, but the functionality of the S9 batch was routinely checked with benzo(a)pyrene according to the study author. Furthermore, the positive controls showed marked increases in the number of revertants. The deviation is not expected to significantly impact the study outcome.
Previous evaluation	New study for AIR5
GLP/ Officially recognised testing facilities	Yes The study was claimed to be conducted under GLP, but no GLP authority statement was included. The GLP status of the conducting lab was checked by the RMS and found to be acceptable (an inspection was conducted 8 months prior to the start of the study).
Acceptability/ Reliability:	Conclusion GRG : Yes, valid study, Category 1 Conclusion AGG: study acceptable

2. Full summary

The test substance, MON 52276, was tested to evaluate its mutagenic potential by measuring its ability to induce reverse mutations at selected loci of several strains of *Salmonella typhimurium* and at the tryptophan locus of *Escherichia coli* strain WP2 *uvr*A in the presence and absence of an exogenous metabolic activation system. Water was used as the vehicle.

In the initial toxicity-mutation assay, the dose levels tested were 1.50, 5.00, 15.0, 50.0, 150, 500, 1500 and 5000 µg per plate. Neither precipitate nor toxicity was observed. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation. Based upon these results, the maximum dose tested in the confirmatory mutagenicity assay was 5000 µg per plate.

In the confirmatory mutagenicity assay, the dose levels tested were 15.0, 50.0, 150, 500, 1500 and 5000 µg per plate. Neither precipitate nor background lawn toxicity was observed. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation.

These results indicate MON 52276 was negative for the ability to induce reverse mutations at selected loci of several strains of *Salmonella typhimurium* and at the tryptophan locus of *Escherichia coli* strain WP2 *uvr*A in the presence and absence of an exogenous metabolic activation system.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material: MON 52276
Description: Yellow-orange liquid
Lot/ Batch#: 11427995
Purity: 30.3 wt% glyphosate acid
Expiration Date: 08 February 2018

2. Control Materials:
Vehicle: Deionized water
Positive:
non-activation: 2-nitrofluorene: 1.0 µg/plate TA98
sodium azide: 1.0 µg/plate TA100, TA1535
9-aminoacridine: 75 µg/plate TA1537
methyl methanesulfonate: 1,000 µg/plate WP2 *uvr*A
activation: 2-aminoanthracene: 1.0 µg/plate TA98, TA1535;
2.0 µg/plate TA100, TA1537; 15 µg/plate WP2 *uvr*A
All positive controls were diluted in dimethyl sulfoxide (DMSO) except for sodium azide, which was diluted in sterile water.

3. Activation

The S9 preparations were from livers of Aroclor 1254-induced rats [redacted]. The S9 mix was composed of water, phosphate buffer, glucose 6-phosphate, β-nicotinamide-adenine dinucleotide phosphate, potassium chloride/ magnesium chloride buffer, and S9 homogenate. Each bulk preparation of S9 was assayed for its ability to metabolize benzo(a)pyrene and 2-aminoanthracene to forms mutagenic to *Salmonella typhimurium* TA100.

4. Test Concentrations:

a. Initial toxicity-mutation assay:

The initial toxicity-mutation assay was used to establish the dose-range for the confirmatory mutagenicity assay and to provide a preliminary mutagenicity evaluation. TA98, TA100, TA1535, TA1537 and WP2 *uvr*A were exposed to the vehicle alone, positive controls and eight dose levels of the test substance ranging from 1.5 to 5000 µg/plate, in duplicate, in the presence and absence of Aroclor-induced rat liver S9.

b. Confirmatory mutagenicity assay:

The confirmatory mutagenicity assay was used to evaluate and confirm the mutagenic potential of the test substance. TA98, TA100, TA1535, TA1537 and WP2 *uvr*A were exposed to the vehicle alone, positive controls and six dose levels of the test substance ranging from 15 to 5000 µg/plate, in triplicate, in the presence and absence of Aroclor-induced rat liver S9.

B. STUDY DESIGN

1. In-life dates: 17 June 2016 to 05 July 2016

2. Plate incorporation method

One-half (0.5) milliliter of S9 or Sham mix, 100 µL of tester strain (cells seeded) and 100 µL of vehicle or test substance dilution were added to 2.0 mL of molten selective top agar at 45±2 °C. When plating the positive controls, the test substance aliquot was replaced by a 50.0 µL aliquot of appropriate positive control. After vortexing, the mixture was overlaid onto the surface of 25 mL of minimal bottom agar. After the overlay had solidified, the plates were inverted and incubated for 48 to 72 hours at 37±2°C. The condition of the bacterial background lawn was evaluated for evidence of test substance toxicity by using a dissecting microscope. Precipitate was evaluated after the incubation period by visual examination without magnification. Toxicity and degree of precipitation were scored relative to the vehicle control plate.

3. Statistics

None.

4. Evaluation Criteria

For the test substance to be evaluated positive, it must cause a dose-related increase in the mean revertants per plate of at least one tester strain over a minimum of two increasing concentrations of test substance as specified:
- Strains TA1535 and TA1537: data sets were judged positive if the increase in mean revertants at the peak of the dose response was equal to or greater than 3.0-times the mean vehicle control value;
- Strains TA98, TA100 and WP2 *uvr*A: data sets were judged positive if the increase in mean revertants at the peak of the dose response was equal to or greater than 2.0-times the mean vehicle control value.

An equivocal response is a biologically relevant increase in a revertant count that partially meets the criteria for evaluation as positive. This could be a dose-responsive increase that does not achieve the respective threshold cited above or a non-dose responsive increase that is equal to or greater than the

respective threshold cited. A response was evaluated as negative if it was neither positive nor equivocal.

II. RESULTS AND DISCUSSION

A. Initial toxicity-mutation assay

Neither precipitate nor toxicity was observed. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation.

B. Confirmatory mutagenicity assay

Neither precipitate nor background lawn toxicity was observed. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation.
Results are presented in the table below:

Table B.6.1.7.-1: **Results of the mutagenicity assays**

MON 52276 [µg/plate]		Strain									
		TA 98		TA 100		TA 1535		TA 1537		WP2uvrA	
S9:		-	+	-	+	-	+	-	+	-	+
acceptable range of historical control (95 % CL)		6-26	9-37	66-114	68-128	3-23	3-23	1-13	3-15	9-41	12-44
Initial toxicity – mutation assay											
Negative controls		11	19	103	92	15	21	6	12	22	28
1.50		11	23	86	82	15	20	6	10	16	36
5.00		14	22	92	84	11	11	7	11	22	25
15.0		10	17	94	77	17	18	8	11	22	18
50.0		13	15	102	85	13	16	8	15	27	29
150		12	16	110	104	11	14	6	9	21	31
500		9	15	91	92	13	21	7	13	21	28
1000		13	16	100	98	16	15	6	12	26	28
5000		7	10	115	109	15	15	6	11	26	34
Positive controls [µg/plate]											
2-aminoanthracene:	1.0		249				126				
	2.0				612				46		
	15										306
2-nitrofluorene:	1.0	141									
sodium azide:	1.0			640		593					
9-aminoacridine:	75							135			
methyl methanesulfonate	1000									410	
Confirmatory mutagenicity assay											
Negative controls		10	21	104	100	14	12	8	7	24	25
15		10	21	104	98	13	16	7	5	31	29
50		9	23	98	101	18	13	10	7	22	20
150		9	32	87	95	12	18	7	8	20	36
500		10	19	101	84	17	10	7	7	18	26
1000		8	21	59	88	15	10	7	5	18	24
5000		8	5	77	78	11	13	5	5	17	23
Positive controls [µg/plate]											
2-aminoanthracene:	1.0		129				63				
	2.0				447				53		
	15										356
2-nitrofluorene:	1.0	306									
sodium azide:	1.0			663		507					
9-aminoacridine:	75							122			
methyl methanesulfonate	1000									392	

Historical negative and positive control values are presented in the table below:

Historical Negative and Positive Control Values
2015
Revertants per plate

Strain	Control	Activation									
		None					Rat Liver				
		Mean	SD	Min	Max	95% CL	Mean	SD	Min	Max	95% CL
TA98 (2015)	Neg	16	5	6	43	6-26	23	7	5	53	9-37
	Pos	190	191	42	2468		329	176	51	1786	
TA100 (2015)	Neg	90	12	62	233	66-114	98	15	63	157	68-128
	Pos	697	172	239	1767		671	284	138	2692	
TA1535 (2015)	Neg	13	5	2	35	3-23	13	5	3	33	3-23
	Pos	624	196	50	2509		137	110	24	1060	
TA1537 (2015)	Neg	7	3	1	20	1-13	9	3	2	23	3-15
	Pos	392	292	24	2887		73	53	19	574	
WP2 *uvr*A (2015)	Neg	25	8	7	73	9-41	28	8	10	96	12-44
	Pos	336	112	89	1026		352	117	78	1409	

SD=standard deviation; Min=minimum value; Max=maximum value; 95% CL = Mean ±2 SD (but not less than zero); Neg=negative control (including but not limited to deionized water, dimethyl sulfoxide, ethanol and acetone); Pos=positive control

III. CONCLUSIONS

Based on the results of this study, MON 52276 is considered to be negative (not mutagenic) in the Bacterial Reverse Gene Mutation Assay.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The study is in concordance with the OECD guideline 471 (1997). Despite some deviations, the test was considered acceptable.
MON 52276 is considered to be negative (not mutagenic) with and without metabolic activation in this gene mutation in bacteria.

According to CLP Regulation (EC) 1272/2008, MON 52276 (Glyphosate 360 g/L SC) does not require classification regarding genotoxicity.

Assessment and conclusion by RMS:

The study is considered to be acceptable.

Under the test conditions the formulation MON 52276 was negative for mutagenicity with and without metabolic activation.

B.6.1.7.2. In vitro Micronucleus Assay with MON 52276 – study 1

1. Information on the study

Data point:	CP 7.1.7/002
Report author	[redacted]
Report year	2016
Report title	*In Vitro* Mammalian Cell Micronucleus Assay in Human Peripheral Blood Lymphocytes (HPBL)
Report No	AE60YE.348.BTL
Document No	MSL0027858
Guidelines followed in study	OECD 487 (2014)
Deviations from current test guideline (OECD 487, 2016)	Deviations from current test guideline (2016): - The concentration, homogeneity, and stability of the test substance in the vehicle were not analysed. However, the study director indicated that it is believed that the test substance was tested to the maximum appropriate concentration based on the laboratory records of formulation preparation (weigh tapes, etc.) and the preparation of test substance dilutions occurred immediately before usage. Therefore, lack of stability, homogeneity and concentration verification is not considered to impact the validity of the study.
Previous evaluation	New study for AIR5
GLP/ Officially recognised testing facilities	Yes The study was claimed to be conducted under GLP, but no GLP authority statement was included. The GLP status of the conducting lab was checked by the RMS and found to be acceptable (an inspection was conducted 8 months prior to the start of the study).
Acceptability/ Reliability:	Conclusion GRG: Supportive, Category 1 Conclusion AGG: Study acceptable but with restrictions (reliable with restrictions)

2. Full summary

The test substance, MON 52276, was tested to evaluate the potential to induce micronuclei in human peripheral blood lymphocytes (HPBL) in both the absence and presence of an exogenous metabolic activation system. Water was used as the vehicle.

In the preliminary toxicity assay, the doses tested ranged from 0.2 to 2000 µg/mL, which was the limit dose for this assay. Cytotoxicity [defined as 55 ± 5% cytokinesis-blocked proliferation index (CBPI) relative to the vehicle control] was not observed at any dose for the non-activated and S9-activated 4-hour treatment conditions. Cytotoxicity was observed at 2000 µg/mL in the non-activated 24-hour treatment condition. Based upon these results, the doses chosen for the micronucleus assay ranged from 2 to 2000 µg/mL for the non-activated 4-hour exposure group; from 6 to 2000 µg/mL for the S9-activated 4-hour and the non-activated 24-hour exposure group.

In the micronucleus assay, cytotoxicity was not observed at any dose of the non-activated and S9-activated 4-hour treatment conditions. Cytotoxicity was observed at 2000 µg/mL in the non-activated 24-hour treatment condition. The doses selected for microscopic evaluation were 200, 600, and 2000 µg/mL for the non-activated and S9-activated 4-hour exposure groups; and 200, 1000, and 2000 µg/mL for the non-activated 24-hour exposure group.

No significant or dose-dependent increases in micronuclei induction were observed in treatment groups with or without S9 ($p > 0.05$; Fisher's Exact and Cochran-Armitage tests).

Based on above findings MON 52276 was considered negative for the induction of micronuclei in the presence and absence of the exogenous metabolic activation system.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material: MON 52276
Description: Yellow-orange liquid
Lot/ Batch #: 11427995
Purity: 30.3 wt % glyphosate acid
Expiration Date: 08 February 2018

2. Control Materials:
Vehicle control: Water
Positive control: Cyclophosphamide (2.5, 5, and 7.5 µg/mL)
Vinblastine (5, 7.5, and 10 ng/mL)

3. Metabolic activation system: Rat liver S9 mix

4. Test organisms: Human peripheral blood lymphocytes were obtained from a healthy non-smoking individual (32 year old male)

B. STUDY DESIGN

1. **In-life dates:** 27 June 2016 to 30 July 2016

2. Test concentrations

a. Preliminary Toxicity Test

0.2, 0.6, 2, 6, 20, 60, 200, 600, and 2000 µg/mL for non-activated, 4 hour treatment, 24 hour harvest; non-activated, 24 hour treatment, 24 hour harvest; S9-activated, 4 hour treatment, 24 hour harvest

b. Micronucleus Assay

2, 60, 200, 600, and 2000 µg/mL for the non-activated, 4 hour treatment, 24 hour harvest; 6, 60, 200, 600, and 2000 µg/mL for the S9-activated, 4 hour treatment, 24 hour harvest; 6, 200, 600, 1000, 1200, 1400, 1600, 1800, and 2000 µg/mL for non-activated, 24 hour treatment, 24 hour harvest

c. Micronucleus Evaluation

200, 600, and 2000 µg/mL for non-activated, 4 hour treatment, 24 hour harvest and S9-activated, 4 hour treatment, 24 hour harvest; 200, 1000, and 2000 for non-activated, 24 hour treatment, 24 hour harvest

3. Collection of Cells

In non-activated 24 hr treatment, cells were collected after being exposed to cytochalasin B (cyto B) for 24 hours (± 30 minutes), 1.5 to 2 normal cell cycles, to ensure identification and selective analysis of micronucleus frequency in cells that have completed one mitosis evidenced by binucleated cells. The cyto B exposure time for the 4 hour treatment in the non-activated and the S9-activated studies was 20 hours (± 30 minutes). Cell suspension slides were prepared and coded for scoring.

4. Cell Cycle Kinetics Scoring

For the preliminary toxicity test, at least 500 cells were evaluated to determine the cytokinesis-blocked proliferation index (CBPI) at each dose level and the control. For the micronucleus assay, at least 1,000 cells (500 cells per culture were evaluated to determine the CBPI at each dose level and the control).

5. Micronucleus Scoring

A minimum of 2000 binucleated cells from each concentration (1000 binucleated cells from each culture) were examined and scored for the presence of micronuclei.

6. Statistics

Statistical analysis was performed using the Fisher's exact test ($p \leq 0.05$) for a pairwise comparison of the percentage of micronucleated cells in each treatment group with that of the vehicle control. The Cochran-Armitage trend test was used to assess dose-responsiveness.

7. Evaluation Criteria

The test substance was considered to have induced a positive response if: at least one of the test concentrations exhibited a statistically significant increase when compared with the concurrent negative control ($p \leq 0.05$), and the increase was concentration-related ($p \leq 0.05$), and results were outside the 95 % control limit of the historical negative control data. The test substance was considered to have induced a clear negative response if none of the criteria for a positive response were met.

II. RESULTS AND DISCUSSION

In the preliminary toxicity test, cytotoxicity [defined as 55 ± 5% cytokinesis-blocked proliferation index (CBPI) relative to the vehicle control] was not observed at any dose the non-activated and S9-activated 4-hour treatment conditions. Cytotoxicity was observed at 2000 µg/mL in the non-activated 24-hour treatment condition. The test substance was soluble in the treatment medium at all doses tested at the beginning and conclusion of the treatment period.

In the micronucleus assays, the test substance was soluble in the treatment medium at all doses tested at the beginning and conclusion of the treatment period. Cytotoxicity was not observed at any dose the non-activated and S9-activated 4-hour treatment conditions; cytotoxicity was observed at 2000 µg/mL in the non-activated 24-hour treatment condition. No significant or dose-dependent increases in micronuclei induction were observed in treatment groups with or without S9.

Results are presented in the table below:

Table B.6.1.7-2: Results of the micronucleus assay

Concentration (µg/mL)	CBPI	Cytotoxicity	Micronucleated binucleated cells (%)	95% Control Limits HCD	Range HCD [min-max]
4 h treatment without S9					
Water	1.725	-	0.4	0.00-0.82	0.05-1.43
MON 52276, 200	1.679	6 %	0.3		
MON 52276, 600	1.613	15 %	0.3		
MON 52276, 2000	1.616	15 %	0.4		
4 h treatment with S9					
Water	1.553	-	0.3	0.00-0.78	0.10-1.50
MON 52276, 200	1.621	-12 %	0.4		
MON 52276, 600	1.615	-11 %	0.4		
MON 52276, 2000	1.545	1 %	0.3		
CP, 5	1.301	46 %	1.4**	0.50-2.51	0.40-3.30
24 h treatment without S9					
Water	1.814	-	0.4	0.00-1.01	0.10-2.00
MON 52276, 200	1.805	1 %	0.4		

Concentration (µg/mL)	CBPI	Cytotoxicity	Micronucleated binucleated cells (%)	95% Control Limits HCD	Range HCD [min-max]
MON 52276, 1000	1.605	26 %	0.3		
MON 52276, 2000	1.394	52 %	0.6		
VB, 10	1.141	83 %	1.6**	0.04-3.48	0.50-5.70

CBPI: Cytokinesis-blocked proliferation index
CP: Cyclophosphamide
VB: Vinblastine

Historical negative and positive control values are presented below:

HISTORICAL CONTROL VALUES
MICRONUCLEUS INDUCTION
2013-2015

NON-ACTIVATED TEST SYSTEM

Historical Values	Micronucleated Binucleated Cells (%)			
	Negative Control[1]		Positive Controls	
	4-hour	24-hour	4-hour [2]	24-hour [3]
Mean	0.36	0.39	3.77	1.76
Standard Deviation	±0.23	±0.31	±1.66	±0.86
95% Control Limits	0.00-0.82	0.00-1.01	0.46-7.08	0.04-3.48
Range [5]	0.05-1.43	0.10-2.00	1.00-10.10	0.50-5.70

S9-ACTIVATED TEST SYSTEM

Historical Values	Micronucleated Binucleated Cells (%)	
	Negative Control[1]	Positive Control [4]
Mean	0.33	1.51
Standard Deviation	±0.23	±0.50
95% Control Limits	0.00-0.78	0.50-2.51
Range [5]	0.10-1.50	0.40-3.30

1. Solvents include water, saline, DMSO, ethanol, acetone, and other non-standard and Sponsor supplied vehicles.
2. Positive control for non-activated 4 hour studies, Mitomycin C (MMC).
3. Positive control for non-activated 24 hour studies, Vinblastine (VB).
4. Positive control for S9-activated studies, Cyclophosphamide (CP).
5. Range from minimum to maximum.

III. CONCLUSIONS

Based on these results, MON 52276 was considered to be negative for the induction of micronuclei in the non-activated and S9-activated test systems in the *in vitro* mammalian micronucleus test using human peripheral blood lymphocytes.

3. Assessment and conclusion

Assessment and conclusion by applicant:
The study is in concordance with the OECD guideline 487 (2014). Under the experimental conditions reported, the test item did not induce micronuclei as determined by the *in vitro* micronucleus test in human lymphocytes. Therefore, MON 52276 is considered to be non-mutagenic in this *in vitro* micronucleus test when tested up to cytotoxic concentrations.
However, considering the deviations identified in the study, the study is considered supportive only.

Assessment and conclusion by RMS:
The study is considered to be acceptable, but with restrictions. Some minor deviations were noted but none were considered to impact the validity of the study.

No statistically significant increase in micronucleated cells and no dose-response was observed in the conducted experiments. Furthermore, results of the cultures treated with the test item were all within the range of the negative concurrent control. Therefore, under the test conditions the formulation MON 52276 was negative for clastogenicity and aneugenicity with and without metabolic activation.

B.6.1.7.3. In vitro Micronucleus Assay with MON 52276 – study 2

1. Information on the study

Data point:	CP 7.1.7/003
Report author	[redacted]
Report year	2020
Report title	MON 52276: Micronucleus Test in Human Lymphocytes *in vitro*
Report No	WC22PQ
Document No	CV-2019-0628
Guidelines followed in study	OECD 487 (2016)
Deviations from current test guideline (OECD 487, 2016)	Demecolcine (DC) is not one of the suggested positive control substances listed in the OECD 487 guideline but the substances are recommendations only, and DC is a derivative of Colchicine, one of the recommended substances. There is sufficient laboratory historical control data to demonstrate its effectiveness and suitability as an aneugen. The highest test concentration exceeds the limit concentration stated in the OECD guideline. Modification of the suggested extended treatment schedule (see study summary). The deviations were not expected to significantly impact the study outcome.
Previous evaluation	New study for AIR5
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	Conclusion GRG: Valid, Category 1 Conclusion AGG : study acceptable

2. Full summary

The test substance, MON 52276, was tested to evaluate the potential to induce micronuclei in human peripheral blood lymphocytes (HPBL) in both the absence and presence of an exogenous metabolic activation system. Minimal Essential Medium was used as the vehicle.

The doses tested in the Preliminary Toxicity Test ranged from 19.53 to 5000 µg/mL. No precipitate of the test item was observed in the parallel blood-free cultures at the end of the exposure in the 4-hour exposure groups or in the 24-hour continuous exposure group. Microscopic assessment of the slides prepared from the exposed cultures showed that binucleate cells were present at up to 5000 µg/mL in all three exposure groups. The test

item induced some evidence of toxicity in the 4-hour exposure group in the absence of S9 and in the 24-hour exposure group. There was no marked toxicity demonstrated in the 4-hour exposure group in the presence of S9. The maximum dose level selected for the Main Experiment was the maximum recommended dose level and was 5000 µg/mL for all three exposure groups.

The dose levels used in the Main Experiment were selected using data from the Preliminary Toxicity Test where the results indicated that the maximum concentration should be limited by toxicity. The doses selected for the Main Experiment ranged from 321.5 to 5000 µg/mL for the 4-hour treatment without S9, 4-hour treatment in the presence of S9, and 24-hour treatment in the absence of S9.

The test item demonstrated some modest toxicity in the 4-hour exposure in the absence of S9 and achieved near optimum toxicity at the maximum recommended dose level in the 24-hour exposure. There was no marked toxicity demonstrated in the 4-hour exposure group in the presence of S9 up to the maximum recommended dose level.

The test item did not induce any statistically significant increases in the frequency of binucleate cells containing micronuclei in the 4-hour exposure group in the presence of S9 or in the 24-hour continuous exposure group where the maximum dose was the maximum recommended dose level.

The 4-hour group in the absence of S9 included a dose level (1250 µg/mL) which induced a small but statistically significant increase in binucleate cells containing micronuclei. However, since this increase was well within the laboratory historical control range (within 95% control limits) for a vehicle and was not part of a dose related response it was considered to be of no toxicological significance.

The dose formulation analysis performed for the Main Experiment demonstrated that the test item formulations were accurate and within acceptable limits.

The test item, MON 52276 was considered to be non-clastogenic and non-aneugenic to human lymphocytes *in vitro*.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material: MON 52276
Description: Yellow liquid
Lot/Batch #: AZE200810A
Purity: 30.8% w/w glyphosate acid (41.5% w/w isopropylamine glyphosate); tested as received, with no correction for purity
Expiration Date: 2023-05-20

2. Control Materials:
Vehicle control: Minimal Essential Medium (MEM) (Batch No. 2091547)
Positive controls: Mitomycin C (MMC) (Batch No. SLBR6518V): 0.2 µg/mL for 4-hour/-S9 exposure
Demecolcine (DC) (Batch No. BCBV3422): 0.075 µg/mL for 24-hour/-S9 exposure*
Cyclophosphamide (CP) (Batch No. A0389648): 6 µg/mL for 4-hour/+S9 exposure
**Demecolcine (DC) is not one of the suggested positive control substances listed in the OECD 487 guideline but the substances are recommendations only, and DC is a derivative of Colchicine, one of the recommended substances. There is sufficient laboratory historical control data to demonstrate its effectiveness and suitability as an aneugen.*

3. Metabolic activation system: Rat liver S9 mix

4. Test organisms: Human peripheral blood lymphocytes were obtained from healthy non-smoking individuals: 25 year old female for Preliminary Toxicity Test and 35 year old female for Main Experiment

B. METHODS

1. **In-life dates:** 2020-01-31 to 2020-03-25

2. Test concentrations

a. Preliminary Toxicity Test

0, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250, 2500 and 5000 µL/mL for 4-hour treatment without S9, 4-hour treatment with S9, and 24-hour treatment without S9.

b. Micronucleus Assay

0, 312.5, 625, 1250, 2500, 3750, 5000 µg/mL for the 4-hour treatment without S9, 4-hour treatment with S9, and 24-hour treatment without S9.

c. Micronucleus Evaluation

0, 1250, 2500, 3750, 5000 µg/mL for the 4-hour treatment without S9, 4-hour treatment with S9, and the 24-hour treatment without S9.

3. Collection and Treatment of Cells

For each experiment, sufficient whole blood was drawn from the peripheral circulation of a non smoking volunteer (18-35) who had been previously screened for suitability. The volunteer had not knowingly been exposed to high levels of radiation or hazardous chemicals and had not knowingly recently suffered from a viral infection.

Cells (whole blood cultures) were grown in Eagle's minimal essential medium with HEPES buffer (MEM), supplemented “in-house” with L-glutamine, penicillin/streptomycin, amphotericin B and 10% fetal bovine serum (FBS), at approximately 37 ºC with 5% CO_2 in humidified air. The lymphocytes of fresh heparinized whole blood were stimulated to divide by the addition of phytohaemagglutinin (PHA).

The Preliminary Toxicity Test was performed using the exposure conditions as described for the Main Experiment but using single cultures for the test item dose levels and duplicate cultures for the vehicle controls, whereas the Main Experiment used duplicate cultures for the test item and quadruplicate cultures for the vehicle controls. Parallel flasks, containing culture medium without whole blood, were established for the three exposure conditions so that test item precipitate observations could be made. Precipitate observations were recorded at the beginning and end of the exposure periods.

a. 4-Hour Exposure With Metabolic Activation (S9)

After approximately 48 hours incubation at approximately 37 ºC, 5% CO_2 in humidified air, the cultures were transferred to tubes and centrifuged. Approximately 9 mL of the culture medium was removed, reserved, and replaced with the required volume of MEM (including serum) and 1.0 mL of the appropriate solution of vehicle control or test item was added to each culture. For the positive control, 0.1 mL of the appropriate solution was added to the cultures. 1.0 mL of 20% S9-mix (i.e. 2% final concentration of S9 in standard co factors) was added to the cultures of the Preliminary Toxicity Test and the Main Experiment. All cultures were then returned to the incubator. The nominal total volume of each culture was 10 mL.

After 4 hours at approximately 37 ºC, the cultures were centrifuged, the treatment medium removed by suction and replaced with an 8 mL wash of MEM culture medium. After a further centrifugation the wash medium was removed by suction and replaced with the reserved original culture medium, supplemented with Cytochalasin B at a final concentration of 4.5 µg/mL, and then incubated for a further 24 hours.

b. 4-Hour Exposure Without Metabolic Activation (S9)

After approximately 48 hours incubation at approximately 37 ºC with 5% CO_2 in humidified air, the cultures were decanted into tubes and centrifuged. Approximately 9 mL of the culture medium was removed and reserved. The cells were then resuspended in the required volume of fresh MEM (including serum) and dosed with 1.0 mL of the appropriate vehicle control, test item solution or 0.1 mL of positive control solution. The nominal total volume for each culture was 10 mL.

After 4 hours at approximately 37 ºC, the cultures were centrifuged, the treatment medium was removed by suction and replaced with an 8 mL wash of MEM culture medium. After a further centrifugation the wash medium was removed by suction and replaced with the reserved original culture medium, supplemented with Cytochalasin B, at a final concentration of 4.5 µg/mL, and then incubated for a further 24 hours.

c. 24-Hour Exposure Without Metabolic Activation (S9)

The exposure was continuous for 24 hours in the absence of metabolic activation. Therefore, when the cultures were established the culture volume was a nominal 9 mL. After approximately 48 hours incubation, the cultures were removed from the incubator and dosed with 1.0 mL of vehicle control, test item dose solution or 0.1 mL of positive control solution. The nominal total volume of each culture was 10 mL. The cultures were then incubated for 24 hours, the tubes and the cells washed in MEM before resuspension in fresh MEM with serum. At this point Cytochalasin B was added at a final concentration of 4.5 µg/mL, and then the cells were incubated for a further 24 hours.

The RMS notes the following: The extended exposure for the extended treatment (24 hours without S9 mix) detailed above is a modification of the suggested cell treatment schedule in the OECD Guideline 487. According to the study director, this is considered to be an acceptable alternative because it avoids any potential interaction between cytochalasin B and the test item during exposure and any effect this may have on the activity or response. Additionally, the study directed stated that as the stability or reactivity of the test item is unknown prior to the start of the study this modification of the schedule is considered more effective and reproducible by the study director due to the in-house observations on human lymphocytes and their particular growth characteristics in this study type and also the significant laboratory historical control data using the above format. The RMS agrees with this justification on the modification of the suggested cell treatment schedule.

At the end of the Cytochalasin B treatment period the cells were centrifuged, the culture medium was drawn off and discarded, and the cells resuspended in MEM. The cells were then treated with a mild hypotonic solution (0.0375M KCl) before being fixed with fresh methanol/glacial acetic acid (19:1 v/v). The fixative was changed at least three times and the cells stored at approximately 4 ºC prior to slide making.

The lymphocytes were re-suspended in several mL of fresh fixative before centrifugation and re suspension in a small amount of fixative. Several drops of this suspension were dropped onto clean, wet microscope slides and left to air dry with gentle warming. Each slide was permanently labeled with the appropriate identification data. When the slides were dry they were stained in 5% Giemsa for 5 minutes, rinsed, dried and a cover slip applied using mounting medium.

4. Cell Cycle Kinetics Scoring

A minimum of approximately 500 cells per culture were scored for the incidence of mononucleate, binucleate and multinucleate cells and the cytokinesis block proliferation index (CBPI) value expressed

as a percentage of the vehicle controls. The CBPI indicates the number of cell cycles per cell during the period of exposure to Cytochalasin B.

5. Micronucleus Scoring

The micronucleus frequency in 1000 binucleated cells was analyzed per culture (2000 binucleated cells per concentration for the test item and positive control and 4000 binucleated cells for the vehicle controls). Cells with 1, 2 or more micronuclei were recorded and included in the total.

The criteria for identifying micronuclei were that they were round or oval in shape, non refractile, not linked to the main nuclei and with a diameter that was approximately less than a third of the mean diameter of the main nuclei. Binucleate cells were selected for scoring if they had two nuclei of similar size with intact nuclear membranes situated in the same cytoplasmic boundary. The two nuclei could be attached by a fine nucleoplasmic bridge which was approximately no greater than one quarter of the nuclear diameter.

6. Statistics

The frequency of binucleate cells with micronuclei was compared, where necessary, with the concurrent vehicle control value using the Chi-squared Test on observed numbers of cells with micronuclei. A toxicologically significant response was recorded when the p value calculated from the statistical analysis of the frequency of binucleate cells with micronuclei was less than 0.05 and there was a dose-related increase in the frequency of binucleate cells with micronuclei.

The dose-relationship (trend-test) was assessed using a linear regression model. An arcsine square-root transformation was applied to the percentage of binucleated cells containing micronuclei (excluding positive controls). A linear regression model was then applied to these transformed values with dose values fitted as the explanatory variable. The F-value from the model was assessed at the 5% statistical significance level.

7. Evaluation Criteria

Providing that all of the acceptability criteria are fulfilled, a test item is considered to be clearly negative if, in most/all of the experimental conditions examined:

1. None of the test concentrations exhibits a statistically significant increase compared with the concurrent negative control.
2. There is no dose-related increase when evaluated with an appropriate trend test.
3. The results in all evaluated dose groups are within the range of the laboratory historical control data.

The test system is then considered to be unable to induce chromosome breaks and/or gain or loss.

Providing that all of the acceptability criteria are fulfilled, a test item may be considered to be clearly positive, if in any of the experimental conditions examined, there is one or more of the following applicable:

1. At least one of the test concentrations exhibits a statistically significant increase compared with the concurrent negative control.
2. The increase is dose-related in at least one experimental condition when evaluated with an appropriate trend test.
3. The results are substantially outside the range of the laboratory historical negative control data.

When all the criteria are met, the test item is considered able to induce chromosome breaks and/or gain or loss in this test system.

There is no requirement for verification of a clear positive or negative response.

In case the response is neither clearly negative nor clearly positive as described above or in order to assist in establishing the biological relevance of a result, the data should be evaluated by expert judgement and/or further investigations. The Study Director may make a judgement based on

experience and the biological relevance of the data and any justification for acceptance of the data will be included in the report. Scoring additional cells (where appropriate) or performing a repeat experiment possibly using modified experimental conditions (e.g. concentration spacing, other metabolic activation conditions (i.e. S9 concentration or S9 origin)) could be useful.

II. RESULTS AND DISCUSSION

The test item was formulated within two hours of it being applied to the test system. Stability and homogeneity was evaluated, and the test item formulations were shown to be stable for up to 24 hours. Dose formulation analysis was performed on the dose formulations of the Main Experiment, which demonstrated that the test item formulations were accurate and within acceptable limits.

The dose range for the Preliminary Toxicity Test was 0, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250, 2500 and 5000 µg/mL. The maximum dose was the maximum recommended dose level.

No precipitate of the test item was observed in the parallel blood-free cultures at the end of the exposure in the 4-hour exposure groups or in the 24-hour continuous exposure group. Microscopic assessment of the slides prepared from the exposed cultures showed that binucleate cells were present at up to 5000 µg/mL in all three exposure groups.

The test item induced some evidence of toxicity in the 4-hour exposure group in the absence of S9 and in the 24-hour exposure group. There was no marked toxicity demonstrated in the 4-hour exposure group in the presence of S9.

The maximum dose level selected for the Main Experiment was the maximum recommended dose level and was 5000 µg/mL for all three exposure groups.

Table B.6.1.7-3: CBPI Data: Preliminary Toxicity Test, 4-hour exposure without metabolic activation

Treatment/ Concentration (µg/mL)	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI[c]	Cytostasis (%)
Vehicle (MEM)	137	319	44	1.81	0
	139	317	44		
19.53	-	-	-	-	-
39.06	-	-	-	-	-
78.13	-	-	-	-	-
156.25	-	-	-	-	-
312.5	-	-	-	-	-
625	168	286	46	1.76	6
1250	179	291	30	1.70	14
2500	169	295	36	1.73	10
5000	216	271	13	1.59	27

[c] Mean value for vehicle

\- Not selected for scoring

MEM Minimal Essential Medium

Table B.6.1.7-4: CBPI Data: Preliminary Toxicity Test, 4-hour exposure with metabolic activation

Treatment / Concentration (µg/mL)	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI[c]	Cytostasis (%)
Vehicle (MEM)	177	285	38	1.73	0
	184	262	54		
19.53	-	-	-	-	-
39.06	-	-	-	-	-
78.13	-	-	-	-	-
156.25	-	-	-	-	-
312.5	-	-	-	-	-
625	223	242	35	1.62	15
1250	204	259	37	1.67	8
2500	154	303	43	1.78	0‡
5000	187	277	36	1.70	4

[c] Mean value for vehicle

\- Not selected for scoring

‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control

MEM Minimal Essential Medium

Table B.6.1.7-5: CBPI Data: Preliminary Toxicity Test, 24-hour exposure without metabolic activation

Treatment / Concentration (µg/mL)	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI[c]	Cytostasis (%)
Vehicle (MEM)	104	339	57	1.86	0
	132	332	36		
19.53	-	-	-	-	-
39.06	-	-	-	-	-
78.13	-	-	-	-	-
156.25	-	-	-	-	-
312.5	-	-	-	-	-
625	148	320	32	1.77	10
1250	137	348	15	1.76	12
2500	218	280	2	1.57	34
5000	285	215	0	1.43	50

c Mean value for vehicle
- Not selected for scoring
MEM Minimal Essential Medium

In the micronucleus test, the qualitative assessment of the slides determined that the toxicity was similar to that observed in the Preliminary Toxicity Test, and that there were binucleated cells suitable for scoring at the maximum dose level of test item, 5000 µg/mL, in all three exposure groups.

The CBPI data confirm the qualitative observations in that a dose-related toxicity was observed in the 4-hour exposure group in the absence of S9 and in the 24-hour exposure group and no marked toxicity was observed in the 4-hour exposure group in the presence of S9.

The vehicle control cultures had frequencies of cells with micronuclei within the expected range and were considered acceptable for addition to the laboratory historical negative control data range.

The positive control items induced statistically significant increases in the frequency of cells with micronuclei with responses that were compatible with those in the laboratory historical positive control data range. Thus, the sensitivity of the assay and the efficacy of the S9-mix were validated.

The test item demonstrated some modest toxicity in the 4-hour exposure in the absence of S9 at the maximum dose level and achieved near optimum toxicity at the maximum recommended dose level in the 24-hour exposure. There was no marked toxicity demonstrated in the 4-hour exposure group in the presence of S9 up to the maximum recommended dose level.

The test item did not induce any statistically significant increases in the frequency of binucleate cells containing micronuclei in the 4-hour exposure group in the presence of S9 or in the 24-hour continuous exposure group where the maximum dose was the maximum recommended dose level.

The 4-hour group in the absence of S9 included a dose level (1250 µg/mL) which induced a small but statistically significant increase in binucleate cells containing micronuclei. However, since this increase was well within the laboratory historical control range (within 95% control limits) for a vehicle and was not part of a dose related response, it was considered to be of no toxicological significance.

Cytostasis and micronucleus data are presented in the tables below.

Table B.6.1.7-6: CBPI Data: Main Experiment, 4-hour exposure without metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI	Mean CBPI	Mean Cytostasis (%)
Vehicle (MEM)	A_1	193	262	45	1.70	1.66	0
	A_2	189	273	38	1.70		
	B_1	220	251	29	1.62		
	B_2	234	220	46	1.62		
312.5	A	-	-	-	-	-	-
	B	-	-	-	-		
625	A	-	-	-	-	-	-
	B	-	-	-	-		
1250	A	180	288	32	1.70	1.71	0‡
	B	196	253	51	1.71		
2500	A	180	302	18	1.68	1.68	0‡
	B	193	275	32	1.68		
3750	A	238	240	22	1.57	1.52	22
	B	283	206	11	1.46		
5000	A	299	190	11	1.42	1.41	39
	B	311	181	8	1.39		
MMC 0.2	A	267	227	6	1.48	1.48	27
	B	266	230	4	1.48		

MMC Mitomycin C
\- Not selected for scoring
‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control
MEM Minimal Essential Medium

Table B.6.1.7-7: CBPI Data: Main Experiment, 4-hour exposure with metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI	Mean CBPI	Mean Cytostasis (%)
Vehicle (MEM)	A_1	139	300	61	1.84	1.77	0
	A_2	165	282	53	1.78		
	B_1	162	294	44	1.76		
	B_2	192	273	35	1.69		
312.5	A	-	-	-	-	-	-
	B	-	-	-	-		
625	A	-	-	-	-	-	-
	B	-	-	-	-		
1250	A	203	255	42	1.68	1.74	4
	B	149	305	46	1.79		
2500	A	199	268	33	1.67	1.73	6
	B	161	288	51	1.78		
3750	A	180	275	45	1.73	1.77	0‡
	B	147	300	53	1.81		
5000	A	163	295	42	1.76	1.76	1
	B	163	294	43	1.76		
CP 6	A	267	229	4	1.47	1.47	39
	B	279	214	7	1.46		

CP Cyclophosphamide
- Not selected for scoring
‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control
MEM Minimal Essential Medium

Table B.6.1.7-8: CBPI Data: Main Experiment, 24-hour exposure without metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mononucleate Cells	Binucleate Cells	Multinucleate Cells	CBPI	Mean CBPI	Mean Cytostasis (%)
Vehicle (MEM)	A_1	120	377	3	1.77	1.69	0
	A_2	171	321	8	1.67		
	B_1	180	314	6	1.65		
	B_2	175	321	4	1.66		
312.5	A	-	-	-	-	-	-
	B	-	-	-	-		
625	A	-	-	-	-	-	-
	B	-	-	-	-		
1250	A	141	359	0	1.72	1.70	0‡
	B	164	333	3	1.68		
2500	A	220	280	0	1.56	1.60	13
	B	184	315	1	1.63		
3750	A	303	196	1	1.40	1.44	36
	B	261	239	0	1.48		
5000	A	385	115	0	1.23	1.27	61
	B	346	154	0	1.31		
DC 0.075	A	354	111	35	1.36	1.36	48
	B	360	106	34	1.35		

DC Demecolcine
- Not selected for scoring
‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control
MEM Minimal Essential Medium

Table B.6.1.7-9: Cytostasis and Micronucleus Data: Main Experiment, 4-hour exposure without metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mean Cytostasis (%)	Binucleated cells containing micronuclei			
			%	Mean %	*p* -value[b]	Trend test *p* -value[d]
Vehicle (MEM)	A_1	0	0.40	0.43	-	0.059
	A_2		0.30			
	B_1		0.50			
	B_2		0.50			
1250	A	0‡	0.90	0.90	0.0228*	
	B		0.90			
2500	A	0‡	0.60	0.55	-	
	B		0.50			
3750	A	22	0.60	0.80	0.0641	
	B		1.00			
5000	A	39	0.80	0.75	-	
	B		0.70			
MMC 0.2	A	27	4.50	4.05	1.58E-25***	-
	B		3.60			

[b] *p*-values are for comparison with the control using Chi-square test

[d] Trend test *p*-values using Linear regression model applied to control and test item concentrations

MMC Mitomycin C

MEM Minimal Essential Medium

* P<0.05

*** P<0.001

‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control

Table B.6.1.7-10: Cytostasis and Micronucleus Data: Main Experiment, 4-hour exposure with metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mean Cytostasis (%)	Binucleated cells containing micronuclei			
			%	Mean %	*p* -value[b]	Trend test *p* -value[d]
Vehicle (MEM)	A_1	0	0.10	0.50	-	0.365
	A_2		0.30			
	B_1		0.60			
	B_2		1.00			
1250	A	4	0.90	0.65	0.4589	
	B		0.40			
2500	A	6	0.30	0.40	-	
	B		0.50			
3750	A	0‡	0.20	0.25	-	
	B		0.30			
5000	A	1	0.30	0.35	-	
	B		0.40			
CP 6	A	39	2.60	2.50	1.04E-11***	-
	B		2.40			

[b] *p*-values are for comparison with the control using Chi-square test

[d] Trend test *p*-values using Linear regression model applied to control and test item concentrations

CP Cyclophosphamide

MEM Minimal Essential Medium

*** P<0.001

‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control

Table B.6.1.7-12: Cytostasis and Micronucleus Data: Main Experiment, 24-hour exposure without metabolic activation

Treatment/ Concentration (µg/mL)	Replicate	Mean Cytostasis (%)	Binucleated cells containing micronuclei			
			%	Mean %	*p* -value[b]	Trend test *p* -value[d]
Vehicle (MEM)	A_1	0	0.00	0.03	-	0.588
	A_2		0.10			
	B_1		0.00			
	B_2		0.00			
1250	A	0‡	0.20	0.20	-	
	B		0.20			
2500	A	13	0.30	0.30	-	
	B		0.30			
3750	A	36	0.00	0.05	-	
	B		0.10			
5000	A	61	0.20	0.10	-	
	B		0.00			
DC 0.075	A	48	4.30	4.70	1.43E-42***	-
	B		5.10			

[b] *p*-values are for comparison with the control using Chi-square test

[d] Trend test *p*-values using Linear regression model applied to control and test item concentrations

DC Demecolcine

MEM Minimal Essential Medium

*** P<0.001

‡ Cytostasis reported as 0 as the CBPI value is equal to or higher than the solvent control

Historical Control Data

Many experiments with human lymphocytes have established a range of micronucleus frequencies for control cultures. The current in-house historical ranges (July 2016 to May 2018) are presented below.

Table B.6.1.7-13: Historical range for vehicle control cultures

	4 hour exposure without S9	4 hour exposure with S9	24 hour exposure without S9
	% binucleate cells with micronuclei	% binucleate cells with micronuclei	% binucleate cells with micronuclei
Minimum	0.05	0.05	0.15
Maximum	1.20	1.30	0.90
Mean	0.56	0.51	0.47
Standard Deviation	0.29	0.29	0.19
95% Control Limits	0 – 1.43	0 – 1.38	0 – 1.04
Number of Experiments	50	50	50

Table B.6.1.7-14: Historical range for positive control cultures

	4 hour exposure without S9 (MMC)	4 hour exposure with S9 (CP)	24 hour exposure without S9 (DC)
	% binucleate cells with micronuclei	% binucleate cells with micronuclei	% binucleate cells with micronuclei
Minimum	1.33	1.75	1.80
Maximum	11.80	8.15	6.70
Mean	5.51	3.79	3.41
Standard Deviation	2.43	1.39	1.04
95% Control Limits	0 – 12.8	0 – 7.96	0.29 – 6.53
Number of Experiments	50	50	50

III. CONCLUSIONS

MON 52276 did not induce any toxicologically significant increases in the frequency of binucleate cells with micronuclei in either the absence or presence of a metabolizing system. MON 52276 was therefore considered to be non-clastogenic and non-aneugenic to human lymphocytes *in vitro*.

3. Assessment and conclusion

Assessment and conclusion by applicant:
MON 52276 was tested in a guideline study on its clastogenic and aneugenic potential in human lymphocytes *in vitro*. MON 52276 did not induce any toxicologically significant increases in the frequency of binucleate cells with micronuclei in either the absence or presence of a metabolizing system. MON 52276 was therefore considered to be non-clastogenic and non-aneugenic to human lymphocytes *in vitro*.

Assessment and conclusion by RMS:
The study is considered to be acceptable.

Based on the results of the study (i.e. the small, but statistical significant increase in micronucleated cells at 1250 µg/mL in combination with incidences well in line with the negative HCD and the lack of a dose-response relationship), the test item is considered negative for induction of chromosome breaks and/or gain or loss under the condition of this *in vitro* micronucleus assay in human lymphocytes with and without metabolic activation.

B.6.1.8. Supplementary studies for combinations of plant protection products

Not required as no combination of plant protection products is recommended on the label.

B.6.2. DERMAL ABSORPTION

The percentage absorptions used in the exposure assessment are in Table B.6.2-1.

Table B.6.2-1: Dermal absorption end-points for the risk assessment

	Concentration	Adapted values used in calculations for risk assessment	Reference
Concentrate	360 g/L	0.096%	[redacted] 2010 EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)
Dilution (1:12.5)	28.8 g/L	0.23%	[redacted] 2010 EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)
Dilution (1:150)	2.4 g/L	0.68%	[redacted] 2010 EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)

B.6.2.1. Dermal absorption study

Data point:	CP 7.3.1/001
Report author	[redacted]
Report year	2010
Report title	360 g/L Glyphosate SL Formulation (MON 52276) *In Vitro* Absorption of Glyphosate through Human Epidermis
Report No	JV2084-REG
Document No	DTL-09-094
Guidelines followed in study	OECD 428 (2004); OECD (Guidance Document No. 28 (2004)). The Conduct of Skin Absorption Studies; European Commission Guidance Document on Dermal Absorption (2004)
Deviations from current test guideline (OECD 428, 2004)	Detailed information on the tested skin samples is missing in the study report (source and site of the skin, thickness, donor age *etc.*). Receptor fluid solubility was not experimentally determined within the study; instead it is referred to publicly available data.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/ Officially recognised testing facilities	Yes
Acceptability/ Reliability:	**Conclusion GRG:** Valid, Category 2a **Conclusion AGG:** The study is considered to be acceptable.

Summary
The objective of this study was to evaluate the potential dermal absorption of glyphosate from a 360 g/L SL formulation concentrate (MON 52276), as well as from two representative in-use dilutions prepared as 1/12.5 (v/v) and 1/150 (v/v) aqueous dilutions, corresponding to 28.8 and 2.4 g glyphosate/L, respectively. ^{14}C-glyphosate was incorporated into the concentrate formulation and dilutions prior to application. The doses were applied to human epidermal membranes at a rate of 10 µL/cm^2 and left unoccluded for an exposure period of 24 hours. The absorption process was followed by taking samples of the receptor fluid (physiological saline) at recorded intervals throughout the exposure period. The distribution of glyphosate within the test system and a 24-hour absorption profile were determined. All samples were analysed by liquid scintillation counting (LSC).

According to the EFSA Guidance on Dermal Absorption (2017), the dermal absorption estimates to be used for risk assessment were estimated at 0.096% for the concentrate (360 g/L), 0.23% for the intermediate dose (28.8 g/L) and 0.68% for the low dose (2.4 g/L) in human skin.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test materials:

a) Non radio-labelled test substance:

Identification:	Isopropylamine salt of glyphosate technical material (glyphosate-IPA)
Description:	Clear, water white to light amber viscous liquid (solution in water)
Lot/ Batch #:	A8B60170S0
Chemical purity:	Glyphosate-IPA: 63.81% Glyphosate acid: 47.28%
Stability of test compound:	Stable under ambient conditions; Expiry date: 2012-01-25

b) Analytical reference standard:

Identification:	Glyphosate acid
Description:	White solid
Lot/ Batch #:	GLP-0810-19515-A
Chemical purity:	99.8 %
Stability of test compound:	Expiry date: 2011-01-31

c) Radio-labelled test substance

Identification:	^{14}C-glyphosate (as glyphosate acid)
Lot/ Batch #:	53463-3-23
Chemical purity:	99.8%
Radiochemical purity:	97.8% (confirmed by analysis)
Specific activity:	47 mCi/mmol; 1739 MBq/mmol; 277.9 µCi/mg; 10.28 MBq/mg
Stability of test compound:	Stable under deep freeze (-20 °C)

c) Blank formulation

Identification:	Proprietary surfactant blend (MON 8153)
Concentration of a.s.:	0 %
Description:	Not reported
Lot/ Batch #:	Not reported
Stability of test compound:	Not reported

d) Formulated test substance

Identification:	MON 52276 The formulation concentrate used was not supplied as complete formulation, but had to be prepared from the ingredients a) and c) described above, to allow the incorporation of the radiolabel. The test substance concentration in the prepared formulation was confirmed by analysis.

2. Test skin source:

Species:	Human excised skin
Source:	Tissue bank (not further specified)

3. Test system: Glass diffusion cells; physiological saline

B. STUDY DESIGN

1. In life dates: 9 June to 26 August 2009

2. Test Apparatus and treatment

a) Assembly of diffusion cells
The type of glass diffusion cell used in this study had an exposed membrane area of 2.54 cm^2. Discs of approximately 3.3 cm diameter of prepared skin membrane from several different skin samples were mounted, dermal side down, in diffusion cells held together with individually numbered clamps. The total volume of the receptor fluid chamber was approximately 4.5 mL.

b) Assessment of membrane integrity
Membrane integrity was assessed by measurement of electrical resistance across the membrane. Membranes with a resistance <10 kΩ were discarded. After the completion of the integrity assessment, the contents of the donor and receptor chambers were discarded.

c) Selection of cells and dosing
Each dose (concentrate, 1:12.5 dilution and 1:150 dilution) was represented by six diffusion cells with intact membranes from at least three different donors. The receptor chambers of the cells containing small magnetic stirrer bars were filled with a recorded volume of receptor fluid (physiological saline) and placed in a water bath maintained at a temperature of 32 ºC ± 1 ºC. The physiological saline receptor fluid was chosen to ensure that the test substance could freely partition into the receptor fluid from the skin membrane and never reached a concentration that would limit its diffusion. The receptor fluid (saline) provided adequate solubility because glyphosate has high aqueous solubility (water solubility of glyphosate acid = 10.5 g/L at 20° C; The Pesticides Manual, 2006; EFSA conclusion, 2015). The area of epidermis exposed to the test formulation in each cell was 2.54 cm^2, with 10 µL/cm^2 applied to each diffusion cell. Glyphosate concentrations for each dose were 3693 µg a.s./cm^2 (formulation concentrate), 296 µg a.s./cm^2 (1:12.5 dilution) and 25.1 µg a.s./cm^2 (1:150 dilution). After dosing, the cells were replaced in a water bath maintained at 32 °C ± 1 °C. The formulation was applied to the skin membranes and left unoccluded for the duration of the exposure period (24 hours).

d) Sampling of receptor fluid
Samples of the receptor fluid (500 µL) were taken from the receptor chambers at 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 16, 20 and 24 hours after application. The receptor chambers were stirred continuously and the volume of fluid in the receptor chamber maintained by the replacement of a volume of fresh receptor fluid, equal to the sample volume, after each sample was taken.

e) Measurement of mass balance
All apparatus and epidermis upper surface were washed with deionised water and Teepol® L and sponged thoroughly until decontamination appeared complete or until it was apparent that radiolabel may be being extracted from the epidermis using a Geiger counter. All sponges were digested in Soluene 350®. The digests made up to a recorded volume and a sample taken for analysis.
To assess penetration through human *stratum corneum*/epidermis, a tape stripping technique was employed. The surface of the skin was allowed to dry naturally, prior to the removal of successively deeper layers of the *stratum corneum* by the repeated application of adhesive tape (Scotch 3M Magic Tape, 1.9 cm wide) up to a maximum of 5 strips. The strips were extracted individually for approximately 20 hours in a solution of 30 % v/v methanol in water. The extracts were sequentially numbered and analysed by liquid scintillation counting (LSC). If the epidermis started to tear and/ or pieces came away during the tape stripping procedure, the process was terminated as soon as noticed. In such cases, the last strip taken was digested with the remaining epidermis to avoid underestimating residual penetrant in the epidermis. The total number of tape strips was recorded for each epidermis sample. The remaining epidermis was then carefully removed from the receptor chamber and digested in Soluene 350®, together with the final tape strip taken if tearing had occurred, and analysed by LSC.

3. Statistics
The data did not warrant statistical analysis, other than group means and standard deviations.

II. RESULTS AND DISCUSSION

In order to add all the data for the cells that had been excluded in the study report for the neat formulation and the 1/150 dilution, it was necessary to reconstruct the results from the raw data files. The following tables and figures are derived from this work and may differ slightly from previously presented tables due to rounding differences. The data have been evaluated according to the latest EFSA guidance (2017). The RMS notes that the data from the raw files are not included in the study report and therefore the RMS requested these data from the applicant. The results as presented in this summary include also the data from the cells that were excluded in the study report.

Table B.6.2.1-1 presents the data from all the cells used for the neat or concentrate (high dose) formulation test expressed in terms of percentage of radioactivity or dose applied. Table B.6.2.1-2 presents the data from the high dose group cells excluding the two cells considered to be outliers for the neat or concentrate formulation test expressed in terms of percentage of radioactivity or dose applied. Cells 20 and 27, which were from the same human donor, showed considerable higher diffusion into the receptor fluid compared with the other cells of that treatment group, which indicated either fragility of that donor specimen or membrane damage during dose application. Further support for the exclusion of these cells is provided by the spray dilution results which also presented much lower proportions of radioactivity in the receptor fluid than observed for cells 20 and 27 when the trend would have been expected to be in the opposite direction i.e. higher proportional absorption from the spray dilutions.

Table B.6.2.1-3 presents the data from all the cells used for the 28.8 g/L (1 in 12.5 dilution) representative spray dilution expressed in terms of percentage of radioactivity or dose applied. No cells required exclusion from this test group.

Table B.6.2.1-4 presents the data from all the cells used for the 2.4 g/L (1 in 150 dilution) representative spray dilution expressed in terms of percentage of radioactivity or dose applied. Table B.6.2.1-5 presents the data from the low (2.4 g/L) dose group cells excluding the two cells considered to be outliers expressed in terms of percentage of radioactivity or dose applied. Cell numbers 25 and 28 required exclusion from this test group as the receptor fluid profiles clearly showed immediate break-through of radioactivity implying that the membrane had been damaged during application. The duplicate cells (16 and 30) displayed much lower levels of absorption and normal absorption profiles.

Table B.6.2.1-1: Distribution of radioactivity at 24 hours after dose application of [^{14}C]-glyphosate in a SL 360 formulation at the rate of 360 g/L to human skin samples (HD (high dose); all cells)

% dose applied	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD N = 6 K N° = 1	
Donor N°	1124L	1124L	1115B	1105	1110E	1105		
Sex	Female	Female	Female	Female	Female	Female		
Cell N°	Cell 2	Cell 3	Cell 13	Cell 20	Cell 23	Cell 27	MEAN	SD
Dislodgeable dose								
Skin wash (24 h)	92.94	102.81	103.12	92.26	97.12	100.84	98.18	4.83
Donor chamber wash	9.030	n.d.	n.d.	n.d.	n.d.	n.d.	1.505	3.686
Skin associated dose								
SC1	0.013	0.062	0.023	0.005	0.023	0.011	0.023	0.021
SC2	0.005	0.016	0.008	0.006	0.020	0.009	0.011	0.006
SC3	0.003	0.005	0.008	n.d.	0.004	0.017	0.006	0.006
SC4	n.d.	0.004	0.006	n.d.	0.010	n.d.	0.003	0.004
SC5	0.043	0.004	n.d.	n.d.	0.002	n.d.	0.008	0.017
TOTAL SC3-5	0.046	0.012	0.014	n.d.	0.016	0.017	0.018	0.015
Skin preparation	0.032	0.074	0.073	0.027	0.039	0.122	0.061	0.036
Absorbed dose								
Receptor fluid (24 h)	0.006	0.003	0.004	9.438	0.021	0.995	1.745	3.789

% dose applied	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD N = 6 K N° = 1	
Donor N°	1124L	1124L	1115B	1105	1110E	1105		
Sex	Female	Female	Female	Female	Female	Female		
Receptor chamber wash	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total recovery	102.07	102.97	103.24	101.73	97.24	101.99	101.54	2.19
Evaluation according to EFSA Guidance (2017)								
LLC of t_0.5 absorption							53.60	14.69
Absorption complete?							No	
Measured absorption, if LLC of t_0.5<=75%							1.82	3.77
Measured absorption, if LLC of t_0.5>75%							N/A	N/A
Measured absorption corrected							1.82	3.77
Relevant absorption estimate							5.590	
Final estimate (rounded)							5.6	

Table B.6.2.1-2: Distribution of radioactivity at 24 hours after dose application of [14C]-glyphosate in a SL 360 formulation at the rate of 360 g/L to human skin samples (HD (high dose); excluding cells 20 and 27)

% dose applied	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD N = 4 K N° = 1.6	
Donor N°	1124L	1124L	1115B	1110E		
Sex	Female	Female	Female	Female		
Cell N°	Cell 2	Cell 3	Cell 13	Cell 23	MEAN	SD
Dislodgeable dose						
Skin wash (24 h)	92.94	102.81	103.12	97.12	98.994	4.890
Donor chamber wash	9.030	n.d.	n.d.	n.d.	2.257	4.515
Skin associated dose						
SC1	0.013	0.062	0.023	0.023	0.030	0.022
SC2	0.005	0.016	0.008	0.020	0.012	0.007
SC3	0.003	0.005	0.008	0.004	0.005	0.002
SC4	n.d.	0.004	0.006	0.010	0.005	0.004
SC5	0.043	0.004	n.d.	0.002	0.012	0.021
TOTAL SC3-5	0.046	0.012	0.014	0.016	0.022	0.016
Skin preparation	0.032	0.074	0.073	0.039	0.055	0.022
Absorbed dose						
Receptor fluid (24 h)	0.006	0.003	0.004	0.021	0.009	0.009
Receptor chamber wash	N/A	N/A	N/A	N/A	N/A	N/A
Total recovery	102.07	102.97	103.24	97.24	101.38	2.80
Evaluation according to EFSA Guidance (2017)						
LLC of t_0.5 absorption					53.53	6.13
Absorption complete?					No	
Measured absorption, if LLC of t_0.5<=75%					0.086	0.006

% dose applied	Group Human HD	Group Human HD	Group Human HD	Group Human HD	Group Human HD N = 4 K N° = 1.6	
Donor N°	1124L	1124L	1115B	1110E		
Sex	Female	Female	Female	Female		
Measured absorption, if LLC of t_0.5>75%					N/A	N/A
Measured absorption corrected					0.086	0.006
Relevant absorption estimate					0.096	
Final estimate (rounded)					0.096	

Table B.6.2.1-3: Distribution of radioactivity at 24 hours after dose application of [14C]-glyphosate in a SL 360 formulation at the nominal rate of 28.8 g/L to human skin (ID (intermediate dose); all cells)

% dose applied	Group Human ID	Group Human ID	Group Human ID	Group Human ID	Group Human ID	Group Human ID	Group Human HD N = 6 K N° = 1	
Donor N°	1124A	1124A	1115B	1105	1110E	1110E		
Sex	Female	Female	Female	Female	Female	Female		
Cell N°	Cell 4	Cell 5	Cell 14	Cell 21	Cell 24	Cell 29	MEAN	SD
Dislodgeable dose								
Skin wash (24 h)	100.42	98.15	97.48	97.41	96.42	94.77	97.44	1.87
Donor chamber wash	n.d.	1.837	4.439	0.008	2.503	4.749	2.256	2.067
Skin associated dose								
SC1	0.028	0.005	0.040	0.002	0.181	0.112	0.061	0.071
SC2	0.024	0.005	0.013	0.006	0.091	0.066	0.034	0.036
SC3	0.009	0.007	0.012	0.000	0.031	0.029	0.014	0.013
SC4	0.016	0.009	0.010	0.000	0.016	0.015	0.011	0.006
SC5	0.002	0.020	0.005	0.000	0.010	0.018	0.009	0.008
TOTAL SC3-5	0.027	0.035	0.026	0.000	0.057	0.063	0.035	0.023
Skin preparation	0.136	0.119	0.062	0.028	0.146	0.138	0.105	0.048
Absorbed dose								
Receptor fluid (24 h)	0.019	0.020	0.025	0.054	0.034	0.021	0.029	0.014
Receptor chamber wash	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total recovery	100.65	100.17	102.08	97.51	99.43	99.92	99.96	1.50
Evaluation according to EFSA Guidance (2017)								
LLC of t_0.5 absorption							38.77	17.25
Absorption complete?							No	
Measured absorption, if LLC of t_0.5<=75%							0.17	0.06
Measured absorption, if LLC of t_0.5>75%							N/A	N/A
Measured absorption corrected							0.17	0.06
Relevant absorption estimate							0.228	
Final estimate (rounded)							0.23	

Table B.6.2.1-4: Distribution of radioactivity at 24 hours after dose application of [^{14}C]-glyphosate in a SL 360 formulation at the rate of 2.4 g/L to human skin (LD (low dose); all cells)

% dose applied	Group Human LD	Group Human LD	Group Human LD	Group Human LD	Group Human LD	Group Human LD	Group Human HD N = 6 K N° = 1	
Donor N°	1124A	1115B	1105	1110E	1105	1110E		
Sex	Female	Female	Female	Female	Female	Female		
Cell N°	Cell 6	Cell 15	Cell 16	Cell 25	Cell 28	Cell 30	MEAN	SD
Dislodgeable dose								
Skin wash (24 h)	99.49	100.46	95.99	84.40	83.58	97.78	93.62	7.62
Donor chamber wash	n.d.	n.d.	0.029	0.000	0.414	0.005	0.075	0.167
Skin associated dose								
SC1	0.483	0.166	0.032	0.017	0.507	0.086	0.215	0.223
SC2	0.174	0.042	0.010	0.069	n.d.	0.030	0.054	0.064
SC3	0.056	0.024	0.010	n.d.	n.d.	0.024	0.015	0.020
SC4	0.049	0.018	n.d.	n.d.	n.d.	0.025	0.009	0.013
SC5	0.030	0.005	n.d.	n.d.	n.d.	0.019	0.043	0.053
TOTAL SC3-5	0.135	0.047	0.010	n.d.	n.d.	0.068	0.067	0.085
Skin preparation	0.414	0.027	0.134	0.174	1.057	0.165	0.328	0.379
Absorbed dose								
Receptor fluid (24 h)	0.082	0.039	0.179	12.535	11.470	0.050	4.059	6.162
Receptor chamber wash	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total recovery	100.78	100.78	96.38	97.19	97.03	98.19	98.39	1.94
Evaluation according to EFSA Guidance (2017)								
LLC of t_0.5 absorption							67.87	14.61
Absorption complete?							No	
Measured absorption, if LLC of t_0.5<=75%							4.43	6.34
Measured absorption, if LLC of t_0.5>75%							N/A	N/A
Measured absorption corrected							4.43	6.34
Relevant absorption estimate							10.775	
Final estimate (rounded)							11	

Table B.6.2.1-5: Distribution of radioactivity at 24 hours after dose application of [14C]-glyphosate in a SL 360 formulation at the rate of 2.4 g/L to human skin samples (LD (low dose); excluding cells 25 and 28)

% dose applied	Group Human LD	Group Human LD	Group Human LD	Group Human LD	Group Human HD N = 4 K N° = 1.6	
Donor N°	1124A	1115B	1105	1110E		
Sex	Female	Female	Female	Female		
Cell N°	Cell 6	Cell 15	Cell 16	Cell 30	MEAN	SD
Dislodgeable dose						
Skin wash (24 h)	99.49	100.46	95.99	97.78	98.43	1.97
Donor chamber wash	n.d.	n.d.	0.029	0.005	0.008	0.014
Skin associated dose						

% dose applied	Group Human LD	Group Human LD	Group Human LD	Group Human LD	Group Human HD N = 4 K N° = 1.6	
Donor N°	1124A	1115B	1105	1110E		
Sex	Female	Female	Female	Female		
SC1	0.483	0.166	0.032	0.086	0.192	0.202
SC2	0.174	0.042	0.010	0.030	0.064	0.075
SC3	0.056	0.024	0.010	0.024	0.029	0.020
SC4	0.049	0.018	n.d.	0.025	0.023	0.020
SC5	0.030	0.005	n.d.	0.019	0.013	0.014
TOTAL SC3-5	0.135	0.039	0.010	0.068	0.065	0.053
Skin preparation	0.414	0.027	0.134	0.165	0.185	0.164
Absorbed dose						
Receptor fluid (24 h)	0.082	0.039	0.179	0.050	0.088	0.064
Receptor chamber wash	N/A	N/A	N/A	N/A	N/A	N/A
Total recovery	100.86	100.80	96.38	98.23	99.03	2.15
Evaluation according to EFSA Guidance (2017)						
LLC of t_0.5 absorption					64.65	8.81
Absorption complete?					No	
Measured absorption, if LLC of t_0.5<=75%					0.34	0.22
Measured absorption, if LLC of t_0.5>75%					N/A	N/A
Measured absorption corrected					0.34	0.22
Relevant absorption estimate					0.684	
Final estimate (rounded)					0.68	

III. CONCLUSIONS

The dermal penetration through human dermatomed skin of [^{14}C]-glyphosate in the SL 360 formulation was investigated at three nominal concentrations corresponding to the neat product (360 g/L) and to two representative spray dilutions of 28.8 g/L and 2.4 g/L, respectively.

For the concentrate and the low dose, two out of six cells were excluded from the data analysis since results indicated fragility of the donor specimen or membrane damage during dose application. For the intermediate dose, all six cells could be used for analysis.

Based on the performed experiments, dermal absorption values for the concentrate (360 g/L), intermediate dose (28.8 g/L), and low dose (2.4 g/L) were estimated to be 0.096%, 0.23%, and 0.68%, respectively, according to the EFSA guidance on dermal absorption (2017).

3. Assessment and conclusion

Assessment and conclusion by applicant:
The study is in concordance with the OECD guideline 428 (2004) and GLP compliant. Therefore, the study is considered acceptable.
According to the EFSA Guidance on Dermal Absorption (2017), the dermal absorption estimates to be used for risk assessment are set at 0.096 % for the concentrate, 0.23 % for the intermediate dose and 0.69 % for the low dose in human skin.

Assessment and conclusion by RMS:
The study is considered to be acceptable. Minor deviations from the OECD guideline 428 (2004) were noted, however, these are not considered to affect the study outcome significantly. It is agreed with the explanations

from the applicant why two out of six cells were excluded from data analysis from the concentrate and low dose test conditions.
According to the EFSA Guidance on Dermal Absorption (2017), the dermal absorption estimates to be used for risk assessment were estimated at 0.096% for the concentrate (360 g/L), 0.23% for the intermediate dose (28.8 g/L) and 0.68% for the low dose (2.4 g/L) in human skin.

B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS

CONFIDENTIAL information - data provided separately in Volume 4.

B.6.4. EXPOSURE DATA

Below follows a table that summarizes the critical uses of glyphosate (referring to the use numbers in the GAP table) and the overall conclusions regarding exposure for operators, workers, bystanders and residents. All uses are for F = professional field use. The exposure model is according to "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products"; EFSA Journal 2014;12(10):3874.

Table B.6.4-1: Critical uses and overall conclusion of exposure assessment

		Application		Application rate		Pre-harvest interval (PHI) (d)	Acceptability of exposure assessment			
Use-No. in accordance with the list of all intended GAPs	Crops and situation (e.g. growth stage of crop)	Method/ Kind (incl. application technique)	Max. number (min. interval between applica-tions) a) per use b) per crop/ season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ max		Operator	Worker	Bystander	Residents
1	Pre emergence of crops	Spraying, low crops, tractor mounted (LCTM)	a) 1 b) 1	a) 1.44 b) 1.44	100–400	NA				
2a	Vegetables	Spraying, low crops, tractor mounted (LCTM)	a) 1-2 (28 d) (3-4 L/ha) b) 2 (28d) (6 L/ha)	a) 1.44 b) 2.16	100–400	NA				
2b,c-3-6-10	Vegetables	Spraying, low crops, tractor mounted (LCTM)	a) 1-3 b) 1-3 (28 d)	a)1.08 0.72 b) 2.16	100–400	NA				
4	Orchards	Ground directed, shielded spray, band application	a) 1-3 b) 1-3 (28 d)	a) 1.44 1.08 b) 2.88	100–400	7				
5	Vines	Ground directed, shielded spray, band application	a) 1-3 b) 1-3 (28 d)	a) 1.44 0.72 b) 2.88	100–400	7				

7	Railroad tracks	Ground directed, shielded spray	a) 2 (90 d) b) 2 (90 d)	a) 1.8 b) 3.6	100–400	NA				
8-9	Invasive species in agricultural and non-agricultural areas	Spot treatment (shielded)	a) 1 b) 1	a) 1.8 b) 1.8	5–400	NA				

Explanation for column "Acceptability of exposure assessment"

A	Exposure acceptable without PPE/ risk mitigation measures
R	Further refinement and/ or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

In the table below the uses are presented that cover the different scenarios in the GAPs (risk envelope). The calculations are performed considering that the total area is treated which is a worst case compared to the real conditions for band and spot application.

Table B.6.4-2: Summary of representative uses (risk envelope approach)

Crop	Application method	Water volume [L/ha]	Number of applications	Application rate [L product / ha and year]	Application rate a) max. rate per appl b) max total application rate per year [kg a.s./ha]	Minimum application interval [days]	Application timing [e.g. BBCH]
All crops (pre-sowing, pre-planting)	Field spraying, tractor-mounted	100-400	1	4	a) 1.44 b) 1.44	Not applicable	Pre-emergence
Vegetables	Field spraying, tractor-mounted	100-400	1 and 2[1]	6	a) 1.08-1.44 b) 2.16	28	Post-harvest, pre-sowing, pre-planting
Orchards	Ground directed, shielded spray, band application[2]	100-400	2[1]	8	a) 1.44 b) 2.88	28	Post-emergence of weeds
Vines	Ground directed, shielded spray, band application[3]	100-400	2[1]		a) 1.44 b) 2.88	28	Post-emergence of weeds
Railroad tracks	Ground directed,	100-400	2	10	a) 1.8 b) 3.6	90	Post-emergence

	spray						of weeds
Invasive species in agricultural and non-agricultural areas	Spot treatment (shielded)	5 - 400	1	5	a) 1.8 b) 1.8	Not applicable	Post-emergence of weeds

1 2 applications at higher rates are worst case compared to 3 application at a lower dose rate, hence the selection of the GAP with 2 applications for a risk envelope approach. However, for vegetables a calculation has also been done with one application at the highest dose (1.44 kg as /ha) as this scenario gave higher exposure values for operators and residents.
2 Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.
3 Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50 % of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.

The following table provides the endpoints used in the risk assessment.

Table B.6.4-3: Endpoints used for risk assessment

Endpoint	Endpoints used for risk assessment
Dermal penetration	Concentrate: 0.096 % Dilution (1:150): 0.68 %
AOEL	0.03 mg/kg bw/day
AAOEL	0.3 mg/kg bw Since the AAOEL is based on fetal effects, it is only applicable to exposure scenarios for adults and not for children.
Oral bioavailability	20 %

B.6.4.1. Operator exposure

Risk assessment for operator
MON 52276 is formulated as a soluble liquid (SL) containing nominal 360 g glyphosate acid/L as the active substance. The product is used as herbicide for the control of annual, perennial, and biennial weeds.

Applications are made pre-sowing, pre-planting and post-harvest of the crops, as well as post-emergence of weeds.

The formulation MON 52276 is commercialised in 1 L bottle, 5 – 20 L container, 60 – 120 – 200 – 640 and 1000 L for agricultural and amenities uses.

The product is used on bare soil, on vegetables, orchard crops, vines, railroad tracks and on invasive species in non-agricultural and agricultural areas.

Railway tracks
With respect to the intended use on railway tracks, the product is applied using special designed spray trains releasing the product as a coarse spray and with low risk of spray drift.

For this use the maximum recommended application rate is 1.8 kg a.s./ha twice a year. Recommended spray volumes are in the range of 100 – 400 L/ha.

When loading of the formulation tank of the spray train, before the application with a spray train, 1000 L bulk containers (IBCs) are used. The transfer of the product to the formulation tank is performed in a closed system via a hose connecting the product container to the formulation tank. For this purpose, both the product containers

as well as the formulation tank of the spray train are equipped with a fast couple system, using dry-break couplings. With this system, the transfer/loading process is a vacuum operation (not pumped) and therefore if there is any break in a hose, only air will get sucked in rather than chemical being pumped out. This makes operator exposure during loading unlikely to occur. Furthermore, the spray train protects the operator from exposure to the spray. Thus, it can reasonably be concluded that with the use of a train-multi-purpose-vehicle significant operator exposure to MON 52276 is unlikely to occur.

In this respect, the intended use with vehicle mounted ground boom spray equipment represents a worst case as for this type of application the mixing and loading is done manually by the operator. In addition, with regard to the model approach used for the assessment, i.e. the EFSA model, it has to be noted that large scale spray conditions in the field are assumed (boom sizes >24 m) which obviously represents a worst case as compared to an application with a spray train (treatment width about 5 m). Furthermore, with that use the maximum application rate relevant for the railway use is covered. Therefore, it is concluded that the assessment being conducted regarding the intended vehicle mounted ground boom spray application in the field covers the intended application on railway ballast with a spray train.

When the product is applied with a knapsack to the railroad tracks, it is not different to when the product is applied with knapsack type application equipment in other places. Therefore, it is concluded that the intended application to railway ballast using knapsack type application equipment is covered by the assessment being conducted regarding the intended hand held uses.

Estimation of operator exposure
The estimated operator exposure to Glyphosate according to the EFSA OPEX is summarised in Table B.6.4.1-1 and 2 and detailed calculations are in the Appendix.

Table B.6.4.1-1: Estimated long term operator exposure to Glyphosate

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Pre-emergence of crops (bare soil) Tractor mounted boom spray application outdoors (downward spraying)			
Application rate		1.44 kg a.s./ha (4 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0055905	18.63
	Work wear – arms, body and legs covered (no gloves)	0.0037956	12.65
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors (downward spraying)			
Application rate		1.44 kg a.s./ha (6 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0055905	18.63
	Work wear – arms, body and legs covered (no gloves)	0.0037956	12.65
Application rate		2 x 1.08 kg a.s./ha (6 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0044314	14.77
	Work wear – arms, body and legs covered (no gloves)	0.0030085	10.03
Orchard crops Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus Outdoor, downward spraying, vehicle-mounted			
Application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0077576	25.86
	Work wear – arms, body and legs covered (no gloves)	0.0038067	12.69
Outdoor, downward spraying, manual hand-held			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0416198	138.73
	Work wear – arms, body and legs covered (no gloves)	0.0066254	22.08
Outdoor, downward spraying, manual knapsack			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0112629	37.54
	Work wear – arms, body and legs covered (no gloves)	0.0021878	7.29
Vines Ground directed, shielded spray Outdoor, downward spraying, vehicle-mounted			
Application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0077576	25.86
	Work wear – arms, body and legs covered (no gloves)	0.0038067	12.69
Outdoor, downward spraying, manual hand-held			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0416198	138.73
	Work wear – arms, body and legs covered (no gloves)	0.0066254	22.08
Outdoor, downward spraying, manual knapsack			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0112629	37.54
	Work wear – arms, body and legs covered (no gloves)	0.0021878	7.29
Railroad tracks (bare soil) Ground directed, spray – application by spray train			
Application rate		2 x 1.8 kg a.s./ha (10 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0067055	22.35
	Work wear – arms, body and legs covered (no gloves)	0.0045539	15.18
Invasive species in non-agricultural areas – manual knapsack			
Application rate		1.8 kg a.s./ha (5 L MON 52276/ha) Here RMS has used the value 0.68 % for dermal absorption of in-use dilution (used in all other calculations) instead of 0.1 % that the applicant used. 0.68 % represents a worst-case assumption.	
Spray application	Potential exposure	0.0135155	45.05

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
(AOEM; 75th percentile) Body weight: 60 kg	Work wear – arms, body and legs covered (no gloves)	0.0026253	8.75
Invasive species in agricultural areas – manual knapsack			
Application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0137046	45.05
	Work wear – arms, body and legs covered (no gloves)	0.0026253	8.75

AOEM = Agricultural operator exposure model

Table B.6.4.1-2: Estimated acute operator exposure to Glyphosate

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Pre-emergence of crops (bare soil) Tractor mounted boom spray application outdoors (downward spraying)			
Application rate		1.44 kg a.s./ha (4 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0229126	7.64
	Work wear – arms, body and legs covered (no gloves)	0.0156460	5.22
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors (downward spraying)			
Application rate		1.44 kg a.s./ha (6 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0229126	7.64
	Work wear – arms, body and legs covered (no gloves)	0.0156460	5.22
Application rate		2 x 1.08 kg a.s./ha (6 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0187962	6.7
	Work wear – arms, body and legs covered (no gloves)	0.0126683	4.22
Orchard crops Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus Outdoor, downward spraying, vehicle-mounted			
Application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0163224	5.44
	Work wear – arms, body and legs covered (no gloves)	0.0093113	3.10
Outdoor, downward spraying, manual hand-held			
Spray application (AOEM; 95th percentile)	Potential exposure	0.0667148	22.24
	Work wear – arms, body	0.0324429	10.81

Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Body weight: 60 kg	and legs covered (no gloves)		
Outdoor, downward spraying, manual knapsack			
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0173337	5.78
	Work wear – arms, body and legs covered (no gloves)	0.0088614	2.95
Vines Ground directed, shielded spray Outdoor, downward spraying, vehicle-mounted			
Application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0163224	5.44
	Work wear – arms, body and legs covered (no gloves)	0.0093113	3.10
Outdoor, downward spraying, manual hand-held			
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0667148	22.24
	Work wear – arms, body and legs covered (no gloves)	0.0324429	10.81
Outdoor, downward spraying, manual knapsack			
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0173337	5.78
	Work wear – arms, body and legs covered (no gloves)	0.0088614	2.95
Railroad tracks (bare soil) Ground directed, spray – application by spray train			
Application rate		2 x 1.8 kg a.s./ha (10 L MON 52276/ha)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0268056	8.94
	Work wear – arms, body and legs covered (no gloves)	0.0184530	6.15
Invasive species in non-agricultural areas – manual knapsack			
Application rate		1.8 kg a.s./ha (5 L MON 52276/ha) Here RMS has used the value 0.68 % for dermal absorption of in-use dilution (used in all other calculations) instead of 0.1 % that the applicant used.	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.0208005	6.93
	Work wear – arms, body and legs covered (no gloves)	0.0106337	3.54
Invasive species in agricultural areas – manual knapsack			
Application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	
Spray application	Potential exposure	0.0208005	6.93

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
(AOEM; 95th percentile) Body weight: 60 kg	Work wear – arms, body and legs covered (no gloves)	0.0106337	3.54

Conclusion
Based on the EFSA model predictions for tractor-mounted and hand-held application techniques, the operator exposure is predicted to be within acceptable limits and below 22.1 % of the AOEL and 10.8 % of the AAOEL for an operator having work wear (arms, body and legs covered) and no further PPE.

Thus, according to the EFSA Guidance calculations, a safe use could be demonstrated for operators using MON 52276 for proposed uses, without PPE.

Measurement of operator exposure
Since the operator exposure estimations carried out indicated that the acceptable operator exposure levels (AAOEL and AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

B.6.4.2. Bystander and resident exposure

Risk assessment for bystander and resident
The estimation of bystander and resident exposure was performed according to the EFSA (EFSA Journal 2014;12(10):3874).

Regarding the spray train application, spray drift (direct drift and drift deposition in adjacent areas) can be regarded as the most relevant source for exposure for resident/ bystander. In this context, it has to be taken into consideration that spray trains are specifically designed to release the spray as a very coarse spray with an accordingly very low risk of spray drift. Hence, it is concluded that in terms of spray drift and subsequently drift deposition in adjacent areas, the application with a tractor mounted ground boom field crop sprayer represents a worst-case surrogate and accordingly covers the application with a spray train.

Regarding the intended applications of MON 52276 using vehicle mounted ground boom spray equipment, resident/ bystander exposure was assessed using the EFSA model. Beside exposure via spray drift, the model also considers the possibility of re-entry into treated crops which can reasonably be excluded as far as applications on railway tracks are concerned. Furthermore, the model assumes exposure via vapour whereby the exposure values proposed by the model refer to large scale applications performed in the field. This covers the worst-case conditions with regard to a railway ballast treatment which can be characterised as a band treatment.

Accordingly, it is concluded that the intended application to railway ballast using a spray train or other vehicle mounted boom equipment is covered by the assessment conducted regarding spray applications in the field using vehicle mounted ground boom spray equipment. For this conclusion, it is also taken into account that, as far as applications performed on railway ballast are concerned, maximum application rates as well as maximum in use concentrations are covered.

Concerning applications performed with hand held spray equipment, the EFSA guidance indicates: “It is noted that no data are available for manual application. Therefore, the WoG (ad hoc EFSA working group) proposes that the same data be used for manual application as for vehicle application as a first tier assessment (i.e. deposition values for broadcast air-assisted sprayers for upwards manual application, and field crop sprayer values for downwards manual application)”. Hence, with the assessment conducted to assess the vehicle mounted application, the application with knapsack type application equipment is covered as well.

Regarding the use in invasive species, the scenario “golf course, turf or other sports lawns” was selected for non-agricultural areas as it is the appropriate model to evaluate recreational exposure for non-agricultural areas according to the EFSA model. The application is made by spot treatment with a knapsack sprayer.

For invasive species in agricultural areas, scenarios for cereals, low berries and small fruits, etc. were selected to cover this use.

A default value of dissipation half-life (DT50) of 30 days has been used in the calculations, as no experimental data is available (this is in accordance with EFSA guidance).

The outcome of the estimations is presented in Table B.6.4.2-1. Detailed calculations are in the Appendix.

Estimation of resident exposure
The estimated resident exposure to Glyphosate is summarised in the following table.

Table B.6.4.2-1: Estimated resident exposure to Glyphosate

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Pre-emergence of crops (bare soil) Tractor mounted boom spray application outdoors Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2			
Number of applications and application rate		1.44 kg a.s./ha (4 L MON 52276/ha)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0029424	9.81
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0003764	1.25
	Re-entry (75th perc.)	0.0016524	5.51
	Sum (mean)	**0.0043532**	**14.51**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006530	2.18
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0000667	0.22
	Re-entry (75th perc.)	0.0009180	3.06
	Sum (mean)	**0.001311**	**4.44**
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2			
Number of applications and application rate		**1.44 kg a.s./ha (6 L MON 52276/ha)**	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0029424	9.81
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0003764	1.25
	Re-entry (75th perc.)	0.0016524	5.51
	Sum (mean)	**0.0043532**	**14.51**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006530	2.18
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0000667	0.22
	Re-entry (75th perc.)	0.0009180	3.06
	Sum (mean)	**0.0013311**	**4.44**
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors Buffer zone: 2-3 (m)			

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Drift reduction technology: no DT_{50}: 30 days DFR: 3.24 µg/cm^2 28 days between applications			
Number of applications and application rate		**2 x 1.08 kg a.s./ha (6 L MON 52276/ha)**	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0220682	7.36
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0004302	1.43
	Re-entry (75th perc.)	0.0018883	6.29
	Sum (mean)	**0.0041581**	**13.86**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0004897	1.63
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.000762	0.25
	Re-entry (75th perc.)	0.0010490	3.50
	Sum (mean)	**0.0013624**	**4.54**
Orchard crops Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus Ground directed, shielded spray, band application Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2 28 days between applications			
Number of applications and application rate	2 x 1.44 kg a.s./ha (8 L MON 52276/ha)		
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0029424	9.81
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0024539	8.18
	Re-entry (75th perc.)	0.0025177	8.39
	Sum (mean)	**0.0067094**	**22.36**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006530	2.18
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0004349	1.45
	Re-entry (75th perc.)	0.0013987	4.66
	Sum (mean)	**0.0020097**	**6.70**
Vines Ground directed, shielded spray Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2 28 days between applications			
Number of applications and application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0029424	9.81
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0007067	2.36
	Re-entry (75th perc.)	0.0025177	8.39
	Sum (mean)	**0.0053052**	**17.68**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006530	2.18
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0001252	0.42
	Re-entry (75th perc.)	0.0013987	4.66
	Sum (mean)	**0.0017608**	**5.87**
Railroad tracks (bare soil)			

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Ground directed, spray Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2 90 days between applications			
Number of applications and application rate		2 x 1.8 kg a.s./ha (10 L MON 52276/ha)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0036780	12.26
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0005294	1.76
	Re-entry (75th perc.)	0.0023237	7.75
	Sum (mean)	**0.0054229**	**18.08**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0008162	2.72
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0000938	0.31
	Re-entry (75th perc.)	0.0012909	4.30
	Sum (mean)	**0.0017283**	**5.76**
Invasive species in non-agricultural areas (golf course, turf or other sports lawns) Spot treatment (shielded)/spray application Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2			
Number of applications and application rate		1.8 kg a.s./ha (5 L MON 52276/ha) Here RMS has used the value 0.68 % for dermal absorption of in-use dilution (used in all other calculations) instead of 0.1 % that the applicant used. 0.68 % represents a worst-case assumption.	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0735607	245.20
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0004705	1.57
	Re-entry (75th perc.)	0.0026253	8.75
	Sum (mean)	**0.0440648**	**146.88**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0163243	54.41
	Vapour (75th perc.)	0.0002300	0.77
	Deposits (75th perc.)	0.0000834	0.28
	Re-entry (75th perc.)	0.0001862	0.62
	Sum (mean)	**0.0084839**	**28.28**
Invasive species in agricultural areas Spot treatment (shielded)/spray application Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2			
Number of applications and application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0735607	245.20
	Vapour (75th perc.)	0.0010700	3.57
	Deposits (75th perc.)	0.0004705	1.57
	Re-entry (75th perc.)	0.0020655	6.89
	Sum (mean)	**0.0453139**	**151.05**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0163243	54.41
	Vapour (75th perc.)	0.0002300	0.77

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Deposits (75th perc.)	0.0000834	0.28
	Re-entry (75th perc.)	0.0011475	3.83
	Sum (mean)	**0.0092127**	**30.71**

Results
According to the EFSA Guidance, the total estimated systemic resident exposure of children and adults to glyphosate, after application on bare soil, vegetables, orchards, vines, and railroad tracks, are lower than 100 % the AOEL. The exposure is higher for children than for adults. The highest exposure for the residents is expected for orchards and it is 22.4 % and 6.7% of the AOEL for child and adult, respectively. However, during exposure to invasive species in both agricultural and non-agricultural areas the AOEL is exceeded for children. The values are 151 respective 147 % of AOEL for agricultural respective non-agricultural areas. The AOEL is not exceeded for adults.

Estimation of bystander exposure
An acute acceptable operator exposure level (AAOEL) has been set at 0.3 mg/kg bw. However, the AAOEL is based on fetal effects and is therefore only applicable to exposure scenarios for adults and not for children. The resident exposure which considers the long-term risk is supposed to also cover the bystander exposure for children.

The AAOEL has been used to compare with the estimated bystander exposure of adults, see the table below.

Table B.6.4.2-2: Estimated adult bystander exposure to Glyphosate

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Pre-emergence of crops (bare soil) Tractor mounted boom spray application outdoors Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2			
Number of applications and application rate		1.44 kg a.s./ha (4 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.58
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.07
	Re-entry (95th perc.)		0.31
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2			
Number of applications and application rate		1.44 kg a.s./ha (6 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.58
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.07
	Re-entry (95th perc.)		0.31
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Tractor mounted boom spray application outdoors			

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3.24 µg/cm^2 28 days between applications			
Number of applications and application rate		2 x 1.08 kg a.s./ha (6 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.43
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.08
	Re-entry (95th perc.)		0.35
Orchard crops Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus Ground directed, shielded spray, band application Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2 28 days between applications			
Number of applications and application rate	2 x 1.44 kg a.s./ha (8 L MON 52276/ha)		
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.58
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.35
	Re-entry (95th perc.)		0.47
Vines Ground directed, shielded spray Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 4.32 µg/cm^2 28 days between applications			
Number of applications and application rate		2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.58
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.10
	Re-entry (95th perc.)		0.47
Railroad tracks (bare soil) Ground directed, spray Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2 90 days between applications			
Number of applications and application rate		2 x 1.8 kg a.s./ha (10 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		0.72
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.09
	Re-entry (95th perc.)		0.43
Invasive species in non-agricultural areas (golf course, turf or other sports lawns) Spot treatment (shielded)/spray application Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2			
Number of applications and application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	

		Glyphosate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
		Here RMS has used the value 0.68 % for dermal absorption of in-use dilution (used in all other calculations) instead of 0.1 % that the applicant used. 0.68 % represents a worst-case assumption.	
bystander adult Body weight: 60 kg	Drift (95th perc.)		14.49
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.08
	Re-entry (95th perc.)		0.12
Invasive species in agricultural areas Spot treatment (shielded)/spray application Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 5.4 µg/cm^2			
Number of applications and application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	
bystander adult Body weight: 60 kg	Drift (95th perc.)		14.49
	Vapour (95th perc.)		0.08
	Deposits (95th perc.)		0.08
	Re-entry (95th perc.)		0.38

Results
The bystander exposure is acceptable for all intended uses. The highest exposure is 14.49 % of the AAOEL for spray drift when treating invasive species in agricultural and non-agricultural areas.

Estimated recreational exposure (EFSA Guidance)

Table B.6.4.2-3: Estimated recreational exposure to Glyphosate

Model data		**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Invasive species in non-agricultural areas, knapsack sprayer application outdoors to low crops[1]			
Application rate:		1.8 kg a.s./ha (5 L MON 52276/ha) Here RMS has used the value 0.68 % for dermal absorption of in-use dilution (used in all other calculations) instead of 0.1 % that the applicant used.	
Child Body weight: 10 kg	Recreational exposure	0.0084024	28.01
Adult Body weight: 60 kg	Recreational exposure	0.0014892	4.96

1 As a worst case, in the EFSA Guidance calculator the crop type "golf course, turf and other sports lawns" was chosen in order to present the corresponding recreational exposure scenario.

Results
According to the EFSA Guidance, the total estimated systemic recreational exposure after application on non-crop areas (recreation area) of children and adults to glyphosate amounts to 0.0084024 mg/kg bw/day and 0.0014892 mg/kg bw/day, respectively. These values correspond to 28.01 % and 4.96 % of the AOEL of glyphosate, respectively.

Conclusion
Based on the EFSA model predictions for tractor-mounted and hand-held application techniques, the resident exposure is predicted to be within acceptable limits after application on bare soil, vegetables, orchards, vines and railroad tracks. The recreational exposure is also estimated to be under 100 % of the AOEL and the bystander exposure is under 100 % of the AAOEL.

The AOEL is not exceeded for resident adults during exposure to invasive species in both agricultural and non-agricultural areas. However due to the high spray drift exposure, the AOEL is exceeded for resident children.

Therefore, it is concluded that bystander exposure is acceptable for all uses and resident exposure to MON 52276 is acceptable on bare soil, vegetables, orchards, vines and railroad tracks for adults and children, but the exposure is not acceptable for use on invasive species in agricultural or non-agricultural areas.

Measurement of bystander and resident exposure
Since the resident and/ or bystander exposure estimations carried out by the applicant indicated that the acceptable operator exposure level (AOEL) for Glyphosate will not be exceeded under conditions of intended uses, a study to provide measurements of resident/ bystander exposure was not necessary and was therefore not been performed.

B.6.4.3. Worker exposure

The estimation of worker exposure was performed according to the EFSA Guidance (EFSA Journal 2014;12(10):3874).

According to the applicant there are no foreseen re-entry activities for the scenarios pre-emergence of crops (bare soil) and railroad tracks (bare soil).

The Applicant also says that the only re-entry scenario is for orchards and grapes and it is just about inspection of the crops and it doesn't normally require dermal contact to the foliage but consists of a visual inspection. RMS is of the opinion that inspection is not the "worst case" worker task, but rather hand harvesting. RMS has therefore made calculations for exposure at hand harvest. It is noted that it is not the fruit trees and grapes, but the weeds that are sprayed. However, the EFSA calculator gives the same exposure values in vines for downward and upward spraying which makes this calculation overly conservative. As a refinement the decline at the proposed minimum pre-harvest interval (PHI) has been used. A PHI of 7 days is used for the use on vines. Please, see the decline calculator in the Appendix Detailed exposure calculations, section A1.4 Worker exposure calculations.

The RMS has also made a calculation of the inspection scenario as suggested by the applicant. Glyphosate is a herbicide that is applied on the ground and not on the foliage of fruit trees and vines. Therefore, it does not make sense to use TC values of orchards and vines. The RMS agrees with the proposal of the applicant to use TC values of crop inspection in cereals and grasslands (potential 12500 cm^2/h and work wear 1400 cm^2/h). The RMS has calculated the exposure both for two- and eight-hours exposure.

The estimation of worker exposure after entry into a previously treated area or handling a crop treated with MON 52276 according to the critical uses is summarised in table B.6.4.3-1. Detailed calculations are in the Appendix.

Table B.6.4.3-1: Estimated worker exposure to Glyphosate

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pre-emergence of crops (bare soil) No worker's tasks and therefore no calculation has been made			
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 4.32 µg/cm^2 Dermal absorption 0.68 %			
Number of applications and application rate		**1.44 kg a.s./ha (6 L MON 52276/ha)**	

Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Body weight: 60 kg	Potential **TC: 5800 cm²/person/h**		0.0227174	75.72
	Work wear (arms, body and legs covered) **TC: 2500 cm²/person/h**		0.0097920	32.64
	Work wear (arms, body and legs covered) and gloves **TC: 580 cm²/person/h**		0.0022717	7.57
Vegetables Including: Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet) Reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3.24 µg/cm² Dermal absorption 0.68 % 28 days between applications				
Number of applications and application rate			**2 x 1.08 kg a.s./ha (6 L MON 52276/ha)**	
Body weight: 60 kg	Potential **TC: 5800 cm²/person/h**		0.0259600	86.53
	Work wear (arms, body and legs covered) **TC: 2500 cm²/person/h**		0.0111897	37.30
	Work wear (arms, body and legs covered) and gloves **TC: 580 cm²/person/h**		0.0025960	8.65
Orchards Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus **Hand harvesting** Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 4.32 µg/cm² Dermal absorption 0.68 % 28 days between applications				
Number of applications and application rate			2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 22500 cm²/person/h**	8 hours/day	0.1342760	447.59
	Work wear (arms, body and legs covered) **TC: 4500 cm²/person/h**	8 hours/day	0.0268552	89.52
	Work wear (arms, body and legs	8 hours/day	0.0134276	44.76

Model data	Level of PPE		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	covered) and gloves **TC: 2250 cm²/person/h**			
Orchards Including: stone and pome fruits, kiwi, tree nuts, banana, and table olives, citrus **inspection** Outdoor Work rate: 2 or 8 hours/day DT_{50}: 30 days DFR: 4.32 µg/cm² Dermal absorption 0.68 % 28 days between applications				
Number of applications and application rate			2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 12500 cm²/person/h**	2 hours/day	0.0186494	62.16
		8 hours/day	0.0745976	248.64
	Work wear (arms, body and legs covered) **TC: 1400 cm²/person/h**	2 hours/day	0.0020887	6.96
		8 hours/day	0.0083548	27.84
Vines **Hand harvesting** Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 4.32 µg/cm² Dermal absorption 0.68 % 28 days between applications				
Number of applications and application rate			2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 30000 cm²/person/h**	8 hours/day	0.1790346	596.78
	Work wear (arms, body and legs covered) **TC: 10100 cm²/person/h**	8 hours/day	0.0602750	200.92
	Work wear (arms, body and legs covered) and gloves TC: **NA**		NA	NA
Using the decline calculator as a refinement				
Body weight: 60 kg	Work wear	8 hours/day	0.051	170.91 (using PHI=7 days)

Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	(arms, body and legs covered) **TC: 10100 cm²/person/h**			Comment: If instead a PHI value of 30 days is used the result would be 100.46 % of AOEL and therefore, based on agricultural practices and timing of application in vineyards and harvesting, it is unlikely that exposure of workers exceeds AOEL.
Vines **Inspection** Outdoor Work rate: 2 or 8 hours/day DT_{50}: 30 days DFR: 4.32 µg/cm² Dermal absorption 0.68 % 28 days between applications				
Number of applications and application rate			2 x 1.44 kg a.s./ha (8 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 12500 cm²/person/h**	2 hours/day	0.0186494	62.16
		8 hours/day	0.0745976	248.64
	Work wear (arms, body and legs covered) **TC: 1400 cm²/person/h**	2 hours/day	0.0020887	6.96
		8 hours/day	0.0083548	27.84
Railroad tracks (bare soil) No worker's tasks and therefore no calculation has been made				
Invasive species in <u>non</u>-agricultural areas Maintenance Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 5.4 µg/cm² Dermal absorption 0.68 %				
Number of applications and application rate			1.8 kg a.s./ha (5 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 5800 cm²/person/h**		0.0283968	94.66
	Work wear (arms, body and legs covered) **TC: 2500 cm²/person/h**		0.0122400	40.80
	Work wear (arms, body and legs covered) and gloves **TC: 580 cm²/person/h**		0.0028397	9.47
Invasive species in agricultural areas Inspection, irrigation Outdoor				

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Work rate: 8 hours/day, DT_{50}: 30 days DFR: 5.4 µg/cm^2 Dermal absorption 0.68 %			
Number of applications and application rate		1.8 kg a.s./ha (5 L MON 52276/ha)	
Body weight: 60 kg	Potential **TC: 12500 cm^2/person/h**	0.0153000	51.00
	Work wear (arms, body and legs covered) **TC: 1400 cm^2/person/h**	0.0017136	5.71
	Work wear (arms, body and legs covered) and gloves TC: **NA**	NA	NA

Conclusion
With respect to the intended use of MON 52276 on pre emergence crops and railway tracks, it is concluded that worker exposure is not relevant as no re-entry and worker's tasks are expected.

For the scenarios vegetables, orchards, invasive species in agricultural and non-agricultural areas, the estimated systemic exposure of workers to glyphosate is lower than 100 % the AOEL for a 8 hour work day and without PPE. The highest exposure is in the hand harvesting orchard scenario, 90 and 45 % of AOEL without and with gloves, respectively. For a worker wearing adequate work clothing, but no further PPE, the exposure in the hand harvesting vine scenario is exceeded as it is 201 % of AOEL when performing re-entry activities. However, as stated above, the hand harvesting scenario is considering being overly conservative as the EFSA calculator uses upward spraying instead of downwards spraying that is the realistic use. Therefore, RMS has used the inspection scenario for crop grassland and lawns. When this scenario is used to calculate the exposure risk for workers in vineyards the exposure is acceptable, 27.84 % of AOEL when work wears are used.

Therefore, it is concluded that for all scenarios; vegetables, orchards, vines, invasive species in agricultural and non-agricultural areas there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no further PPE), when re-entering crops treated with MON 52276.

Measurement of worker exposure
Since the worker exposure estimations carried out by the applicant, indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and has therefore not been performed.

B.6.4.4. Review from open literature

Data point	CA 9
Author	Solomon K.R.
Year	2019
Title	Estimated exposure to glyphosate in humans via environmental, occupational, and dietary pathways: an updated review of the scientific literature
Document source	Pest Management Science, (2020) Vol. 76, pp. 2878 2885. Published online: 28 December 2019
Short description of literature article	Glyphosate is one of the most widely used herbicides in the world, but it has also been the focus of discussion and restrictions in several countries since it was declared 'probably carcinogenic to humans (Group 2A)' by the International

	Agency for Research on Cancer in 2015. Since that time, several regulatory agencies have reviewed the public literature and guideline studies submitted for regulatory purposes and have concluded that it is not a carcinogen, and revised acceptable daily intakes (ADIs) and the reference dose (RfD) have been published. Also, restrictions on use have been lifted in many locations. Risk assessment for any pesticide requires knowledge of exposure in humans and the environment, and this paper is an update on a previous review in 2016 and includes papers published after 2016. These exposure data for air, water, bystanders, the general public, domesticated animals, pets, and applicators were combined and compared to the revised exposure criteria published by regulatory agencies. In all cases, measured and estimated systemic exposures to glyphosate in humans and animals were less than the ADIs and the RfD. Based on this large dataset, these exposures represent a *de minimis* risk.
Short description of findings	The author concludes: Regardless of source and pathway, exposures to glyphosate in the general public were less than the revised and updated ADIs or RfD from USEAP, FAO, EFSA, FSCJ, and the APVMA. Based on the new RfD and ADIs, the risk from the good agricultural and landscape practice use glyphosate for the management of weeds and production of crops is considered *de minimis*.
Justification as provided in the AIR5 dossier (KCA 9)	Not relevant by title/abstract: Secondary information including human biomonitoring results and regulatory reviews.

Assessment and conclusion by RMS:

RMS agree with the applicant that this is a review with secondary information and the study is not considered further for the renewal of glyphosate. The work is based on published literature and unpublished reports of studies on exposure to glyphosate in applicators working in agriculture, landscape, and forestry. Regardless of source and pathway, exposures to glyphosate in the general public were less than the revised and updated ADIs or RfD from USEAP, FAO, EFSA, FSCJ, and the APVMA.

Additional comment: As stated in the summary above, the paper was an update of a previous review in 2016 (Solomon K.R. (2016) Glyphosate in the general population and in applicators: a critical review of studies on exposures. Critical Reviews in Toxicology, 46(S1) pp. 21–27). A corrigendum (Critical Reviews in Toxicology 2018, 48, No. 10, 896) to that article stated: " […] This article is part of a supplement, sponsored and supported by Intertek Scientific & Regulatory Consultancy. Funding for the sponsorship of this supplement was provided to Intertek by the Monsanto Company, which is a primary producer of glyphosate and products containing this active ingredient. […]"

B.6.5. EXPOSURE AND RISK ASSESSMENT

The operator, worker, bystanders, and resident exposure estimations according to the EFSA model (EFSA calculator) indicate that the levels of exposure will be within acceptable levels of the proposed systemic AAOEL and AOEL of glyphosate (0.3 and 0.03 mg/kg bw/day respectively) for the use on bare soil, vegetables, orchards, vines, and railroad.

For tractor-mounted and hand-held application techniques, the operator and bystander exposure was predicted to be within acceptable limits and below the AOELs without PPE.

The total estimated systemic resident exposure of children to glyphosate, are unacceptable for invasive species in non-agricultural and agricultural use for which the exposure levels were 146.88 and 151.05 % of AAOEL respectively whereas the exposure to adults is acceptable.

In the EFSA calculator the crop type “golf course, turf and other sports lawns” was chosen to present the recreational exposure scenario. The total estimated systemic recreational exposure after application on these non-crop areas, was acceptable for children and adults.

With respect to the intended use of MON 52276 on pre emergence crops and railway tracks, it is concluded that worker exposure is not relevant as no re-entry and worker’s tasks are expected.

Conclusion
The exposure is acceptable for bare soil, vegetables, orchards, vines, and railroad and un-acceptable for invasive species in non-agricultural and agricultural areas.

B.6.6. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 7.1.1-001	[redacted]	1991	Acute Oral Toxicity Study In Rats Report No.: 6097-91 Document No.: [redacted]-91-261 [redacted] GLP/GEP: Y Published: N	Y	N	-	BCS	Y RAR 2017: IIIA, 7.1.1
KCP 7.1.2-001	[redacted]	1991	Acute Dermal Toxicity Study In Rats Report No.: 6098-91 Document No.: [redacted]-91-262 [redacted] GLP/GEP: Y Published: N	Y	N	-	BCS	Y RAR 2017: IIIA, 7.1.2
KCP 7.1.3-001	[redacted]	2015	MON 52276: Acute Inhalation Toxicity in Rats Report No.: 40830 Document No.: [redacted]0026415 [redacted] GLP/GEP: Y Published: N	Y	Y	First submission in EU	BCS	N
KCP 7.1.4-001	[redacted]	1991	Primary dermal irritation study in rabbits Report No.: 6099-91 Document No.: [redacted]-91-263 [redacted] GLP/GEP: Y Published: N	Y	N	-	BCS	Y RAR 2017: IIIA 7.1.4

KCP 7.1.5-001	[redacted]	1992	Primary eye irritation study in rabbits Report No.: 5999-91 Document No.: [redacted]-91-60 [redacted] GLP/GEP: Y Published: N	Y	N	-	BCS	Y RAR 2017: IIIA 7.1.5
KCP 7.1.6-001	[redacted]	2001	Skin sensitization test in guinea pigs (Modified Buehler test: 9 applications) Report No.: 22008 TSG Document No.: [redacted]-2001-153 [redacted] GLP/GEP: Y Published: N	Y	N	-	BCS	Y RAR 2017: IIIA 7.1.6
KCP 7.1.7-001	[redacted]	2016	MON 52276: Bacterial Reverse Mutation Assay Report No.: AE60YE-503-BTL Document No.: MSL0027853 BioReliance GLP/GEP: Y Published: N	N	Y	First submission in EU	BCS	N
KCP 7.1.7-002	[redacted]	2016	*In Vitro* Mammalian Cell Micronucleus Assay in Human Peripheral Blood Lymphocytes (HPBL) Report No.: AE60YE-348-BTL Document No.: MSL0027858 BioReliance GLP/GEP: Y Published: N	N	Y	First submission in EU	BCS	N
KCP 7.1.7-003	[redacted]	2020	MON 52276: Micronucleus Test in Human Lymphocytes *in vitro* Report No.: WC22PQ Document No.: TRR0000171 Covance Laboratories Limited. GLP/GEP: Y Published: N	N	Y	First submission in EU	BCS	N

KCP 7.3.1-001	[redacted]	2010	In Vitro Absorption of Glyphosate through Human Epidermis Report No.: JV2084-REG Document No.: DTL-09-094 Dermal Technology Laboratory Ltd. GLP/GEP: Y Published: N	N	N	-	BCS	Y RAR 2017: IIIA 7.3

APPENDIX: DETAILED EXPOSURE CALCULATIONS

A 1.1 Operator exposure calculation (Table 1-12)

Table 1a: Input parameters considered for the estimation of operator exposure in bare soil
Table 1b: Estimation of operator exposure towards Glyphosate in bare soil
Table 2a: Input parameters considered for the estimation of operator exposure in vegetables one application
Table 2b: Estimation of operator exposure towards Glyphosate in vegetables one application
Table 3a: Input parameters considered for the estimation of operator exposure in vegetables two application
Table 3b: Estimation of operator exposure towards Glyphosate in vegetables two application
Table 4a: Input parameters considered for the estimation of operator exposure in orchards, vehicle-mounted
Table 4b: Estimation of operator exposure towards Glyphosate in orchards, vehicle-mounted
Table 5a: Input parameters considered for the estimation of operator exposure in orchards, manual hand-held
Table 5b: Estimation of operator exposure towards Glyphosate in orchards, manual hand-held
Table 6a: Input parameters considered for the estimation of operator exposure in orchards, manual knapsack
Table 6b: Estimation of operator exposure towards Glyphosate in orchards, manual knapsack
Table 7a: Input parameters considered for the estimation of operator exposure in vines vehicle-mounted
Table 7b: Estimation of operator exposure towards Glyphosate in vines vehicle-mounted
Table 8a: Input parameters considered for the estimation of operator exposure in vines manual hand-held
Table 8b: Estimation of operator exposure towards Glyphosate in vines manual hand-held
Table 9a: Input parameters considered for the estimation of operator exposure in vines manual knapsack
Table 9b: Estimation of operator exposure towards Glyphosate in vines manual knapsack
Table 10a: Input parameters considered for the estimation of operator exposure in railroad tracks
Table 10b: Estimation of operator exposure towards Glyphosate in railroad tracks
Table 11a: Input parameters considered for the estimation of operator exposure for invasive species in non-agricultural areas
Table 11b: Estimation of operator exposure for invasive species in non-agricultural areas
Table 12a: Input parameters considered for the estimation of operator exposure for invasive species in agricultural areas
Table 12b: Estimation of operator exposure for invasive species in agricultural areas

A 1.2 Resident exposure calculation (Table 13-21)

Table 13a: Input parameters considered for the estimation of resident exposure in bare soil
Table 13b: Estimation of resident exposure towards Glyphosate in bare soil
Table 14a: Input parameters considered for the estimation of resident exposure in vegetables one application
Table 14b: Estimation of resident exposure towards Glyphosate in vegetables one application
Table 15a: Input parameters considered for the estimation of resident exposure in vegetables two application
Table 15b: Estimation of resident exposure towards Glyphosate in vegetables two application
Table 16a: Input parameters considered for the estimation of resident exposure in orchards
Table 16b: Estimation of resident exposure towards Glyphosate in orchards
Table 17a: Input parameters considered for the estimation of resident exposure in vines
Table 17b: Estimation of resident exposure towards Glyphosate in vines
Table 18a: Input parameters considered for the estimation of resident exposure in railroad tracks
Table 18b: Estimation of resident exposure towards Glyphosate in railroad tracks
Table 19a: Input parameters considered for the estimation of resident exposure for invasive species in non-agricultural areas
Table 19b: Estimation of resident exposure towards Glyphosate for invasive species in non-agricultural areas
Table 20a: Input parameters considered for the estimation of resident exposure for invasive species in agricultural areas
Table 20b: Estimation of resident exposure towards Glyphosate for invasive species in agricultural areas
Table 21a: Input parameters considered for the estimation of recreational exposure for invasive species in non-agricultural areas
Table 21b: Estimation of recreational exposure for invasive species in non-agricultural areas

A 1.3 Adult bystander exposure calculation (Table 22-29)

Table 22a: Input parameters considered for the estimation of adult bystander exposure in bare soil
Table 22b: Estimation of adult bystander exposure towards Glyphosate in bare soil
Table 23a: Input parameters considered for the estimation of bystander exposure in vegetables one application
Table 23b: Estimation of adult bystander exposure towards Glyphosate in vegetables one application

Table 24a: Input parameters considered for the estimation of adult bystander exposure in vegetables two applications
Table 24b: Estimation of adult bystander exposure towards Glyphosate in vegetables two applications
Table 25a: Input parameters considered for the estimation of adult bystander exposure in in orchards
Table 25b: Estimation of adult bystander exposure towards Glyphosate in in orchards
Table 26a: Input parameters considered for the estimation of adult bystander exposure in vines
Table 26b: Estimation of adult bystander exposure towards Glyphosate in vines
Table 27a: Input parameters considered for the estimation of adult bystander exposure for invasive species in non-agricultural areas
Table 27b: Estimation of adult bystander exposure towards Glyphosate for invasive species in non-agricultural areas
Table 28a: Input parameters considered for the estimation of adult bystander exposure for invasive species in agricultural areas
Table 28b: Estimation of adult bystander exposure towards Glyphosate for invasive species in agricultural areas
Table 29a: Input parameters considered for the estimation of adult bystander exposure in railroad tracks
Table 29b: Estimation of adult bystander exposure towards Glyphosate in railroad tracks

A1.4 Worker exposure calculations (Table 30-37)

Table 30a: Input parameters considered for the estimation of worker exposure in vegetables one application
Table 30b: Estimation of worker exposure towards Glyphosate in vegetables one application
Table 31a: Input parameters considered for the estimation of worker exposure in vegetables two applications
Table 31b: Estimation of worker exposure towards Glyphosate in vegetables two applications
Table 32a: Input parameters considered for the estimation of worker exposure in orchards, hand harvesting
Table 32b: Estimation of worker exposure towards Glyphosate in orchards, hand harvesting
Table 32c: Estimation of worker exposure towards Glyphosate in orchards, hand harvesting and using the decline calculator
Table 33a: Input parameters considered for the estimation of worker exposure in orchards, inspection
Table 33b: Estimation of worker exposure towards Glyphosate in orchards, inspection
Table 34a: Input parameters considered for the estimation of worker exposure in vines, hand harvesting
Table 34b: Estimation of worker exposure towards Glyphosate in vines, hand harvesting
Table 34c: Estimation of worker exposure towards Glyphosate in vines, hand harvesting and using the decline calculator
Table 35a: Input parameters considered for the estimation of worker exposure in vines, inspection
Table 35b: Estimation of worker exposure towards Glyphosate in vines, inspection
Table 36a: Input parameters considered for the estimation of worker exposure for invasive species in non-agricultural areas
Table 36b: Estimation of worker exposure towards Glyphosate for invasive species in non-agricultural areas
Table 37a: Input parameters considered for the estimation of worker exposure for invasive species in agricultural areas
Table 37b: Estimation of worker exposure towards Glyphosate for invasive species in agricultural areas

A 1.1 Operator exposure calculation (Table 1-12)

Table 1a: Input parameters considered for the estimation of operator exposure in bare soil

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha		*i_AppRate*
Assumed area treated	50 ha/day		*d_AreaTreated*
Amount of active substance applied	72 kg a.s./day		*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		
	OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	130674	497229	AOEM	
	Body	72095	249504	AOEM	
	Head	3736	20488	AOEM	
	Protected hands (gloves)	557	14261	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1053	10530	AOEM	
	Protected head (hood and face shield)	60	1160	AOEM	
	Inhalation	13	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	10679	52541	AOEM	
	Body	5971	30781	AOEM	
	Head	282	851	AOEM	
	Protected hands (gloves)	432	5488	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	164	402	AOEM	
	Inhalation	9	34	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 1b: Estimation of operator exposure towards Glyphosate in bare soil

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3354290	0,2277384	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0055905	0,0037956	
% of RVNAS	18,63%	12,65%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,3747544	0,9387593	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0229126	0,0156460	
% of RVAAS	7,64%	5,22%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	125,4473550	2,0907892	*D15*i_AbsorpProduct*
Body	69,2111340	1,1535189	*D16*i_AbsorpProduct*
Head	3,5861936	0,0597699	*D17*i_AbsorpProduct*
Inhalation	13,2172818	0,2202880	*D21*i_AbsorpInhalation*
Sum	211,4619644	3,5243661	
With RPE/PPE (as selected above)			
Hands	125,4473550	2,0907892	*D18*i_AbsorpProduct*
Body	1,0105203	0,0168420	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	3,5861936	0,0597699	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	13,2172818	0,2202880	*D21*i_AbsorpInhalation*G25*
Sum	143,2613507	2,3876892	
Water soluble bag	143,2613507	2,3876892	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	72,6191268	1,2103188	*D30*i_AbsorpInuse*
Body	40,6038359	0,6767306	*D31*i_AbsorpInuse*
Head	1,9190764	0,0319846	*D32*i_AbsorpInuse*
Inhalation	8,8250050	0,1470834	*D35*i_AbsorpInhalation*
Sum	123,9670441	2,0661174	
With RPE/PPE (as selected above)			
Hands	72,6191268	1,2103188	*D33*i_AbsorpInuse*
Body	1,1138317	0,0185639	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	1,9190764	0,0319846	*D32*i_AbsorpInuse*F39*
Inhalation	8,8250050	0,1470834	*D35*i_AbsorpInuse*G39*
Sum	84,4770400	1,4079507	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	477,3400048	7,9556667	*E15*i_AbsorpProduct*
Body	239,5243125	3,9920719	*E16*i_AbsorpProduct*
Head	19,6686127	0,3278102	*E17*i_AbsorpProduct*
Inhalation	31,7943947	0,5299066	*E21*i_AbsorpInhalation*
Sum	768,3273248	12,8054554	
With RPE/PPE (as selected above)			
Hands	477,3400048	7,9556667	*E18*i_AbsorpProduct*
Body	10,1088960	0,1684816	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	19,6686127	0,3278102	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,7943947	0,5299066	*E21*i_AbsorpInhalation*G25*
Sum	538,9119083	8,9818651	
Water soluble bag	538,9119083	8,9818651	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	357,2759747	5,9545996	*E30*i_AbsorpInuse*
Body	209,3114403	3,4885240	*E31*i_AbsorpInuse*
Head	5,7872021	0,0964534	*E32*i_AbsorpInuse*
Inhalation	34,0524615	0,5675410	*E35*i_AbsorpInhalation*
Sum	606,4270786	10,1071180	
With RPE/PPE (as selected above)			
Hands	357,2759747	5,9545996	*E33*i_AbsorpInuse*
Body	2,7317947	0,0455299	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	5,7872021	0,0964534	*E32*i_AbsorpInuse*F39*
Inhalation	34,0524615	0,5675410	*E35*i_AbsorpInhalation*G39*
Sum	399,8474330	6,6641239	

Table 2a: Input parameters considered for the estimation of operator exposure in vegetables one application

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	72	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	130674	497229	AOEM	
	Body	72095	249504	AOEM	
	Head	3736	20488	AOEM	
	Protected hands (gloves)	557	14261	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1053	10530	AOEM	
	Protected head (hood and face shield)	60	1160	AOEM	
	Inhalation	13	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	10679	52541	AOEM	
	Body	5971	30781	AOEM	
	Head	282	851	AOEM	
	Protected hands (gloves)	432	5488	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	164	402	AOEM	
	Inhalation	9	34	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 2b: Estimation of operator exposure towards Glyphosate in vegetables one application

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3354290	0,2277384	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0055905	0,0037956	
% of RVNAS	18,63%	12,65%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,3747544	0,9387593	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0229126	0,0156460	
% of RVAAS	7,64%	5,22%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	125,4473550	2,0907892	*D15*i_AbsorpProduct*
Body	69,2111340	1,1535189	*D16*i_AbsorpProduct*
Head	3,5861936	0,0597699	*D17*i_AbsorpProduct*
Inhalation	13,2172818	0,2202880	*D21*i_Absorpinhalation*
Sum	211,4619644	3,5243661	
With RPE/PPE (as selected above)			
Hands	125,4473550	2,0907892	*D18*i_AbsorpProduct*
Body	1,0105203	0,0168420	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	3,5861936	0,0597699	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	13,2172818	0,2202880	*D21*i_Absorpinhalation*G25*
Sum	143,2613507	2,3876892	
Water soluble bag	143,2613507	2,3876892	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	72,6191268	1,2103188	*D30*i_Absorpinuse*
Body	40,6038359	0,6767306	*D31*i_Absorpinuse*
Head	1,9190764	0,0319846	*D32*i_Absorpinuse*
Inhalation	8,8250050	0,1470834	*D35*i_Absorpinhalation*
Sum	123,9670441	2,0661174	
With RPE/PPE (as selected above)			
Hands	72,6191268	1,2103188	*D33*i_Absorpinuse*
Body	1,1138317	0,0185639	*D34*i_Absorpinuse or D31*i_Absorpinuse*F38*
Head	1,9190764	0,0319846	*D32*i_Absorpinuse*F39*
Inhalation	8,8250050	0,1470834	*D35*i_Absorpinuse*G39*
Sum	84,4770400	1,4079507	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	477,3400048	7,9556667	*E15*i_AbsorpProduct*
Body	239,5243125	3,9920719	*E16*i_AbsorpProduct*
Head	19,6686127	0,3278102	*E17*i_AbsorpProduct*
Inhalation	31,7943947	0,5299066	*E21*i_AbsorpInhalation*
Sum	768,3273248	12,8054554	
With RPE/PPE (as selected above)			
Hands	477,3400048	7,9556667	*E18*i_AbsorpProduct*
Body	10,1088960	0,1684816	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	19,6686127	0,3278102	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,7943947	0,5299066	*E21*i_AbsorpInhalation*G25*
Sum	538,9119083	8,9818651	
Water soluble bag	538,9119083	8,9818651	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	357,2759747	5,9545996	*E30*i_AbsorpInuse*
Body	209,3114403	3,4885240	*E31*i_AbsorpInuse*
Head	5,7872021	0,0964534	*E32*i_AbsorpInuse*
Inhalation	34,0524615	0,5675410	*E35*i_AbsorpInhalation*
Sum	606,4270786	10,1071180	
With RPE/PPE (as selected above)			
Hands	357,2759747	5,9545996	*E33*i_AbsorpInuse*
Body	2,7317947	0,0455299	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	5,7872021	0,0964534	*E32*i_AbsorpInuse*F39*
Inhalation	34,0524615	0,5675410	*E35*i_AbsorpInhalation*G39*
Sum	399,8474330	6,6641239	

Table 3a: Input parameters considered for the estimation of operator exposure in vegetables two application

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,08	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	54	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	104715	397440	AOEM	
	Body	58895	229499	AOEM	
	Head	2802	15366	AOEM	
	Protected hands (gloves)	462	10696	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	816	7898	AOEM	
	Protected head (hood and face shield)	45	870	AOEM	
	Inhalation	12	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	8009	42559	AOEM	
	Body	4478	23086	AOEM	
	Head	212	638	AOEM	
	Protected hands (gloves)	370	5307	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	123	301	AOEM	
	Inhalation	8	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 3b: Estimation of operator exposure towards Glyphosate in vegetables two application

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,2658854	0,1805114	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0044314	0,0030085	
% of RVNAS	14,77%	10,03%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,1277719	0,7600998	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0187962	0,0126683	
% of RVAAS	6,27%	4,22%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	100,5263516	1,6754392	*D15*i_AbsorpProduct*
Body	56,5396061	0,9423268	*D16*i_AbsorpProduct*
Head	2,6896452	0,0448274	*D17*i_AbsorpProduct*
Inhalation	12,1327817	0,2022130	*D21*i_AbsorpInhalation*
Sum	171,8883846	2,8648064	
With RPE/PPE (as selected above)			
Hands	100,5263516	1,6754392	*D18*i_AbsorpProduct*
Body	0,7830745	0,0130512	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	2,6896452	0,0448274	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	12,1327817	0,2022130	*D21*i_AbsorpInhalation*G25*
Sum	116,1318530	1,9355309	
Water soluble bag	116,1318530	1,9355309	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	54,4643451	0,9077391	*D30*i_AbsorpInuse*
Body	30,4528769	0,5075479	*D31*i_AbsorpInuse*
Head	1,4393073	0,0239885	*D32*i_AbsorpInuse*
Inhalation	7,6404802	0,1273413	*D35*i_AbsorpInhalation*
Sum	93,9970095	1,5666168	
With RPE/PPE (as selected above)			
Hands	54,4643451	0,9077391	*D33*i_AbsorpInuse*
Body	0,8353738	0,0139229	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	1,4393073	0,0239885	*D32*i_AbsorpInuse*F39*
Inhalation	7,6404802	0,1273413	*D35*i_AbsorpInuse*G39*
Sum	64,3795064	1,0729918	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	381,5425828	6,3590430	*E15*i_AbsorpProduct*
Body	220,3189968	3,6719833	*E16*i_AbsorpProduct*
Head	14,7514596	0,2458577	*E17*i_AbsorpProduct*
Inhalation	31,5772448	0,5262874	*E21*i_Absorpinhalation*
Sum	648,1902840	10,8031714	
With RPE/PPE (as selected above)			
Hands	381,5425828	6,3590430	*E18*i_AbsorpProduct*
Body	7,5816720	0,1263612	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	14,7514596	0,2458577	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,5772448	0,5262874	*E21*i_Absorpinhalation*G25*
Sum	435,4529592	7,2575493	
Water soluble bag	435,4529592	7,2575493	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	289,3984384	4,8233073	*E30*i_Absorpinuse*
Body	156,9835802	2,6163930	*E31*i_Absorpinuse*
Head	4,3404016	0,0723400	*E32*i_Absorpinuse*
Inhalation	28,8591642	0,4809861	*E35*i_Absorpinhalation*
Sum	479,5815843	7,9930264	
With RPE/PPE (as selected above)			
Hands	289,3984384	4,8233073	*E33*i_Absorpinuse*
Body	2,0488461	0,0341474	*E34*i_Absorpinuse or E31*i_Absorpinuse*F38*
Head	4,3404016	0,0723400	*E32*i_Absorpinuse*F39*
Inhalation	28,8591642	0,4809861	*E35*i_Absorpinhalation*G39*
Sum	324,6468502	5,4107808	

Table 4a: Input parameters considered for the estimation of operator exposure in orchards, vehicle-mounted

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha	*i_AppRate*
Assumed area treated	10 ha/day	*d_AreaTreated*
Amount of active substance applied	14,4 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	37853	142003	AOEM	
	Body	23258	156319	AOEM	
	Head	747	4098	AOEM	
	Protected hands (gloves)	195	2852	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	253	2106	AOEM	
	Protected head (hood and face shield)	12	232	AOEM	
	Inhalation	8	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	23333	26437	AOEM	This scenario assumes that small area equipment is used
	Body	32013	40565	AOEM	
	Head	192	2250	AOEM	
	Protected hands (gloves)	93	29	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	400	473	AOEM	
	Inhalation	20	188	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 4b: Estimation of operator exposure towards Glyphosate in orchards, vehicle-mounted

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4654531	0,2284004	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0077576	0,0038067	
% of RVNAS	25,86%	12,69%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,9793463	0,5586767	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0163224	0,0093113	
% of RVAAS	5,44%	3,10%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	36,3390384	0,6056506	*D15*i_AbsorpProduct*
Body	22,3279566	0,3721326	*D16*i_AbsorpProduct*
Head	0,7172387	0,0119540	*D17*i_AbsorpProduct*
Inhalation	8,1870733	0,1364512	*D21*i_AbsorpInhalation*
Sum	67,5713070	1,1261884	
With RPE/PPE (as selected above)			
Hands	36,3390384	0,6056506	*D18*i_AbsorpProduct*
Body	0,2426604	0,0040443	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,7172387	0,0119540	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	8,1870733	0,1364512	*D21*i_AbsorpInhalation*G25*
Sum	45,4860108	0,7581002	
Water soluble bag	45,4860108	0,7581002	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	158,6623907	2,6443732	*D30*i_AbsorpInuse*
Body	217,6897984	3,6281633	*D31*i_AbsorpInuse*
Head	1,3033579	0,0217226	*D32*i_AbsorpInuse*
Inhalation	20,2262733	0,3371046	*D35*i_AbsorpInhalation*
Sum	397,8818203	6,6313637	
With RPE/PPE (as selected above)			
Hands	158,6623907	2,6443732	*D33*i_AbsorpInuse*
Body	2,7223598	0,0453727	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	1,3033579	0,0217226	*D32*i_AbsorpInuse*F39*
Inhalation	20,2262733	0,3371046	*D35*i_AbsorpInuse*G39*
Sum	182,9143816	3,0485730	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	136,3225593	2,2720427	*E15*i_AbsorpProduct*
Body	150,0659945	2,5010999	*E16*i_AbsorpProduct*
Head	3,9337225	0,0655620	*E17*i_AbsorpProduct*
Inhalation	30,5984548	0,5099742	*E21*i_Absorpinhalation*
Sum	320,9207311	5,3486789	
With RPE/PPE (as selected above)			
Hands	136,3225593	2,2720427	*E18*i_AbsorpProduct*
Body	2,0217792	0,0336963	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	3,9337225	0,0655620	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	30,5984548	0,5099742	*E21*i_Absorpinhalation*G25*
Sum	172,8765159	2,8812753	
Water soluble bag	172,8765159	2,8812753	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	179,7749145	2,9962486	*E30*i_Absorpinuse*
Body	275,8425388	4,5973756	*E31*i_Absorpinuse*
Head	15,2999155	0,2549986	*E32*i_Absorpinuse*
Inhalation	187,5081592	3,1251360	*E35*i_Absorpinhalation*
Sum	658,4255279	10,9737588	
With RPE/PPE (as selected above)			
Hands	179,7749145	2,9962486	*E33*i_Absorpinuse*
Body	3,2171451	0,0536191	*E34*i_Absorpinuse or E31*i_Absorpinuse*F38*
Head	15,2999155	0,2549986	*E32*i_Absorpinuse*F39*
Inhalation	187,5081592	3,1251360	*E35*i_Absorpinhalation*G39*
Sum	385,8001342	6,4300022	

Table 5a: Input parameters considered for the estimation of operator exposure in orchards, manual hand-held

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha	*i_AppRate*
Assumed area treated	4 ha/day	*d_AreaTreated*
Amount of active substance applied	5,76 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Hand held	
Season	not relevant	

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Hand held

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	18696	69573	AOEM	
	Body	12214	119784	AOEM	
	Head	299	1639	AOEM	
	Protected hands (gloves)	108	1141	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	112	842	AOEM	
	Protected head (hood and face shield)	5	93	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	5929	16178	AOEM	
	Body	341253	526107	AOEM	
	Head	46	326	AOEM	
	Protected hands (gloves)	19	84	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	34188	240499	AOEM	
	Inhalation	100	100	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 5b: Estimation of operator exposure towards Glyphosate in orchards, manual hand-held

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,4971852	0,3975215	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0416198	0,0066254	
% of RVNAS	138,73%	22,08%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4,0028901	1,9465742	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0667148	0,0324429	
% of RVAAS	22,24%	10,81%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	17,9484634	0,2991411	*D15*i_AbsorpProduct*
Body	11,7253282	0,1954221	*D16*i_AbsorpProduct*
Head	0,2868955	0,0047816	*D17*i_AbsorpProduct*
Inhalation	6,2330661	0,1038844	*D21*i_AbsorpInhalation*
Sum	36,1937532	0,6032292	
With RPE/PPE (as selected above)			
Hands	17,9484634	0,2991411	*D18*i_AbsorpProduct*
Body	0,1077152	0,0017953	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,2868955	0,0047816	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	6,2330661	0,1038844	*D21*i_AbsorpInhalation*G25*
Sum	24,5761401	0,4096023	
Water soluble bag	24,5761401	0,4096023	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	40,3169280	0,6719488	*D30*i_AbsorpInuse*
Body	2320,5212160	38,6753536	*D31*i_AbsorpInuse*
Head	0,3133440	0,0052224	*D32*i_AbsorpInuse*
Inhalation	99,8400000	1,6640000	*D35*i_AbsorpInhalation*
Sum	2460,9914880	41,0165248	
With RPE/PPE (as selected above)			
Hands	40,3169280	0,6719488	*D33*i_AbsorpInuse*
Body	232,4751360	3,8745856	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	0,3133440	0,0052224	*D32*i_AbsorpInuse*F39*
Inhalation	99,8400000	1,6640000	*D35*i_AbsorpInuse*G39*
Sum	372,9454080	6,2157568	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	66,7900554	1,1131676	*E15*i_AbsorpProduct*
Body	114,9924092	1,9165402	*E16*i_AbsorpProduct*
Head	1,5734890	0,0262248	*E17*i_AbsorpProduct*
Inhalation	29,9380331	0,4989672	*E21*i_AbsorpInhalation*
Sum	213,2939867	3,5548998	
With RPE/PPE (as selected above)			
Hands	66,7900554	1,1131676	*E18*i_AbsorpProduct*
Body	0,8087117	0,0134785	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	1,5734890	0,0262248	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	29,9380331	0,4989672	*E21*i_AbsorpInhalation*G25*
Sum	99,1102892	1,6518382	
Water soluble bag	99,1102892	1,6518382	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	110,0098560	1,8334976	*E30*i_Absorpinuse*
Body	3577,5267840	59,6254464	*E31*i_Absorpinuse*
Head	2,2195200	0,0369920	*E32*i_Absorpinuse*
Inhalation	99,8400000	1,6640000	*E35*i_AbsorpInhalation*
Sum	3789,5961600	63,1599360	
With RPE/PPE (as selected above)			
Hands	110,0098560	1,8334976	*E33*i_Absorpinuse*
Body	1635,3945600	27,2565760	*E34*i_Absorpinuse or E31*i_Absorpinuse*F38*
Head	2,2195200	0,0369920	*E32*i_Absorpinuse*F39*
Inhalation	99,8400000	1,6640000	*E35*i_AbsorpInhalation*G39*
Sum	1847,4639360	30,7910656	

Table 6a: Input parameters considered for the estimation of operator exposure in orchards, manual knapsack

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	1,44 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Outdoor|soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Manual-Knapsack

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	1544	4213	AOEM	
	Body	88868	137007	AOEM	
	Head	12	85	AOEM	
	Protected hands (gloves)	5	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
	Inhalation	26	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 6b: Estimation of operator exposure towards Glyphosate in orchards, manual knapsack

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,6757741	0,1312652	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0112629	0,0021878	
% of RVNAS	37,54%	7,29%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,0400228	0,5316826	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0173337	0,0088614	
% of RVAAS	5,78%	2,95%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	9,1152000	0,1519200	*D15*i_AbsorpProduct*
Body	0,7708800	0,0128480	*D16*i_AbsorpProduct*
Head	0,0048000	0,0000800	*D17*i_AbsorpProduct*
Inhalation	25,0000000	0,4166667	*D21*i_Absorpinhalation*
Sum	34,8908800	0,5815147	
With RPE/PPE (as selected above)			
Hands	9,1152000	0,1519200	*D18*i_AbsorpProduct*
Body	0,0240000	0,0004000	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,0048000	0,0000800	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	25,0000000	0,4166667	*D21*i_Absorpinhalation*G25*
Sum	34,1440000	0,5690667	
Water soluble bag	34,1440000	0,5690667	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	10,4992000	0,1749867	*D30*i_Absorpinuse*
Body	604,3024000	10,0717067	*D31*i_Absorpinuse*
Head	0,0816000	0,0013600	*D32*i_Absorpinuse*
Inhalation	26,0000000	0,4333333	*D35*i_Absorpinhalation*
Sum	640,8832000	10,6813867	
With RPE/PPE (as selected above)			
Hands	10,4992000	0,1749867	*D33*i_Absorpinuse*
Body	60,5404000	1,0090067	*D34*i_Absorpinuse or D31*i_Absorpinuse*F38*
Head	0,0816000	0,0013600	*D32*i_Absorpinuse*F39*
Inhalation	26,0000000	0,4333333	*D35*i_Absorpinuse*G39*
Sum	97,1212000	1,6186867	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	24,4627200	0,4077120	*E15*i_AbsorpProduct*
Body	2,6755200	0,0445920	*E16*i_AbsorpProduct*
Head	0,0105600	0,0001760	*E17*i_AbsorpProduct*
Inhalation	26,0000000	0,4333333	*E21*i_AbsorpInhalation*
Sum	53,1488000	0,8858133	
With RPE/PPE (as selected above)			
Hands	24,4627200	0,4077120	*E18*i_AbsorpProduct*
Body	0,0988800	0,0016480	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	0,0105600	0,0001760	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	26,0000000	0,4333333	*E21*i_AbsorpInhalation*G25*
Sum	50,5721600	0,8428693	
Water soluble bag	50,5721600	0,8428693	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	28,6484000	0,4774733	*E30*i_AbsorpInuse*
Body	931,6476000	15,5274600	*E31*i_AbsorpInuse*
Head	0,5780000	0,0096333	*E32*i_AbsorpInuse*
Inhalation	26,0000000	0,4333333	*E35*i_AbsorpInhalation*
Sum	986,8740000	16,4479000	
With RPE/PPE (as selected above)			
Hands	28,6484000	0,4774733	*E33*i_AbsorpInuse*
Body	425,8840000	7,0980667	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	0,5780000	0,0096333	*E32*i_AbsorpInuse*F39*
Inhalation	26,0000000	0,4333333	*E35*i_AbsorpInhalation*G39*
Sum	481,1104000	8,0185067	

Table 7a: Input parameters considered for the estimation of operator exposure in vines vehicle-mounted

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha	*i_AppRate*
Assumed area treated	10 ha/day	*d_AreaTreated*
Amount of active substance applied	14,4 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	37853	142003	AOEM	
	Body	23258	156319	AOEM	
	Head	747	4098	AOEM	
	Protected hands (gloves)	195	2852	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	253	2106	AOEM	
	Protected head (hood and face shield)	12	232	AOEM	
	Inhalation	8	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	23333	26437	AOEM	This scenario assumes that small area equipment is used
	Body	32013	40565	AOEM	
	Head	192	2250	AOEM	
	Protected hands (gloves)	93	29	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	400	473	AOEM	
	Inhalation	20	188	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 7b: Estimation of operator exposure towards Glyphosate in vines vehicle-mounted

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4654531	0,2284004	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0077576	0,0038067	
% of RVNAS	25,86%	12,69%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,9793463	0,5586767	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0163224	0,0093113	
% of RVAAS	5,44%	3,10%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	36,3390384	0,6056506	*D15*i_AbsorpProduct*
Body	22,3279566	0,3721326	*D16*i_AbsorpProduct*
Head	0,7172387	0,0119540	*D17*i_AbsorpProduct*
Inhalation	8,1870733	0,1364512	*D21*i_AbsorpInhalation*
Sum	67,5713070	1,1261884	
With RPE/PPE (as selected above)			
Hands	36,3390384	0,6056506	*D18*i_AbsorpProduct*
Body	0,2426604	0,0040443	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,7172387	0,0119540	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	8,1870733	0,1364512	*D21*i_AbsorpInhalation*G25*
Sum	45,4860108	0,7581002	
Water soluble bag	45,4860108	0,7581002	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	158,6623907	2,6443732	*D30*i_AbsorpInuse*
Body	217,6897984	3,6281633	*D31*i_AbsorpInuse*
Head	1,3033579	0,0217226	*D32*i_AbsorpInuse*
Inhalation	20,2262733	0,3371046	*D35*i_AbsorpInhalation*
Sum	397,8818203	6,6313637	
With RPE/PPE (as selected above)			
Hands	158,6623907	2,6443732	*D33*i_AbsorpInuse*
Body	2,7223598	0,0453727	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	1,3033579	0,0217226	*D32*i_AbsorpInuse*F39*
Inhalation	20,2262733	0,3371046	*D35*i_AbsorpInuse*G39*
Sum	182,9143816	3,0485730	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	136,3225593	2,2720427	*E15*i_AbsorpProduct*
Body	150,0659945	2,5010999	*E16*i_AbsorpProduct*
Head	3,9337225	0,0655620	*E17*i_AbsorpProduct*
Inhalation	30,5984548	0,5099742	*E21*i_AbsorpInhalation*
Sum	320,9207311	5,3486789	
With RPE/PPE (as selected above)			
Hands	136,3225593	2,2720427	*E18*i_AbsorpProduct*
Body	2,0217792	0,0336963	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	3,9337225	0,0655620	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	30,5984548	0,5099742	*E21*i_AbsorpInhalation*G25*
Sum	172,8765159	2,8812753	
Water soluble bag	172,8765159	2,8812753	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	179,7749145	2,9962486	*E30*i_AbsorpInuse*
Body	275,8425388	4,5973756	*E31*i_AbsorpInuse*
Head	15,2999155	0,2549986	*E32*i_AbsorpInuse*
Inhalation	187,5081592	3,1251360	*E35*i_AbsorpInhalation*
Sum	658,4255279	10,9737588	
With RPE/PPE (as selected above)			
Hands	179,7749145	2,9962486	*E33*i_AbsorpInuse*
Body	3,2171451	0,0536191	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	15,2999155	0,2549986	*E32*i_AbsorpInuse*F39*
Inhalation	187,5081592	3,1251360	*E35*i_AbsorpInhalation*G39*
Sum	385,8001342	6,4300022	

Table 8a: Input parameters considered for the estimation of operator exposure in vines manual hand-held

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha		*i_AppRate*
Assumed area treated	4 ha/day		*d_AreaTreated*
Amount of active substance applied	5,76 kg a.s./day		*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Manual-Hand held

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	18696	69573	AOEM	
	Body	12214	119784	AOEM	
	Head	299	1639	AOEM	
	Protected hands (gloves)	108	1141	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	112	842	AOEM	
	Protected head (hood and face shield)	5	93	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	5929	16178	AOEM	
	Body	341253	526107	AOEM	
	Head	46	326	AOEM	
	Protected hands (gloves)	19	84	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	34188	240499	AOEM	
	Inhalation	100	100	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 8b: Estimation of operator exposure towards Glyphosate in vines manual hand-held

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,4971852	0,3975215	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0416198	0,0066254	
% of RVNAS	138,73%	22,08%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4,0028901	1,9465742	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0667148	0,0324429	
% of RVAAS	22,24%	10,81%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	17,9484634	0,2991411	*D15*i_AbsorpProduct*
Body	11,7253282	0,1954221	*D16*i_AbsorpProduct*
Head	0,2868955	0,0047816	*D17*i_AbsorpProduct*
Inhalation	6,2330661	0,1038844	*D21*i_AbsorpInhalation*
Sum	36,1937532	0,6032292	
With RPE/PPE (as selected above)			
Hands	17,9484634	0,2991411	*D18*i_AbsorpProduct*
Body	0,1077152	0,0017953	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,2868955	0,0047816	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	6,2330661	0,1038844	*D21*i_AbsorpInhalation*G25*
Sum	24,5761401	0,4096023	
Water soluble bag	24,5761401	0,4096023	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	40,3169280	0,6719488	*D30*i_AbsorpInuse*
Body	2320,5212160	38,6753536	*D31*i_AbsorpInuse*
Head	0,3133440	0,0052224	*D32*i_AbsorpInuse*
Inhalation	99,8400000	1,6640000	*D35*i_AbsorpInhalation*
Sum	2460,9914880	41,0165248	
With RPE/PPE (as selected above)			
Hands	40,3169280	0,6719488	*D33*i_AbsorpInuse*
Body	232,4751360	3,8745856	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	0,3133440	0,0052224	*D32*i_AbsorpInuse*F39*
Inhalation	99,8400000	1,6640000	*D35*i_AbsorpInuse*G39*
Sum	372,9454080	6,2157568	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	66,7900554	1,1131676	*E15*i_AbsorpProduct*
Body	114,9924092	1,9165402	*E16*i_AbsorpProduct*
Head	1,5734890	0,0262248	*E17*i_AbsorpProduct*
Inhalation	29,9380331	0,4989672	*E21*i_Absorpinhalation*
Sum	213,2939867	3,5548998	
With RPE/PPE (as selected above)			
Hands	66,7900554	1,1131676	*E18*i_AbsorpProduct*
Body	0,8087117	0,0134785	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	1,5734890	0,0262248	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	29,9380331	0,4989672	*E21*i_Absorpinhalation*G25*
Sum	99,1102892	1,6518382	
Water soluble bag	99,1102892	1,6518382	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	110,0098560	1,8334976	*E30*i_Absorpinuse*
Body	3577,5267840	59,6254464	*E31*i_Absorpinuse*
Head	2,2195200	0,0369920	*E32*i_Absorpinuse*
Inhalation	99,8400000	1,6640000	*E35*i_Absorpinhalation*
Sum	3789,5961600	63,1599360	
With RPE/PPE (as selected above)			
Hands	110,0098560	1,8334976	*E33*i_Absorpinuse*
Body	1635,3945600	27,2565760	*E34*i_Absorpinuse or E31*i_Absorpinuse*F38*
Head	2,2195200	0,0369920	*E32*i_Absorpinuse*F39*
Inhalation	99,8400000	1,6640000	*E35*i_Absorpinhalation*G39*
Sum	1847,4639360	30,7910656	

Table 9a: Input parameters considered for the estimation of operator exposure in vines manual knapsack

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,44 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	1,44 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Knapsack

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	1544	4213	AOEM	
	Body	88868	137007	AOEM	
	Head	12	85	AOEM	
	Protected hands (gloves)	5	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
	Inhalation	26	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 9b: Estimation of operator exposure towards Glyphosate in vines manual knapsack

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,6757741	0,1312652	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0112629	0,0021878	
% of RVNAS	37,54%	7,29%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,0400228	0,5316826	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0173337	0,0088614	
% of RVAAS	5,78%	2,95%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	9,1152000	0,1519200	*D15*i_AbsorpProduct*
Body	0,7708800	0,0128480	*D16*i_AbsorpProduct*
Head	0,0048000	0,0000800	*D17*i_AbsorpProduct*
Inhalation	25,0000000	0,4166667	*D21*i_AbsorpInhalation*
Sum	34,8908800	0,5815147	
With RPE/PPE (as selected above)			
Hands	9,1152000	0,1519200	*D18*i_AbsorpProduct*
Body	0,0240000	0,0004000	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,0048000	0,0000800	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	25,0000000	0,4166667	*D21*i_AbsorpInhalation*G25*
Sum	34,1440000	0,5690667	
Water soluble bag	34,1440000	0,5690667	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	10,4992000	0,1749867	*D30*i_AbsorpInuse*
Body	604,3024000	10,0717067	*D31*i_AbsorpInuse*
Head	0,0816000	0,0013600	*D32*i_AbsorpInuse*
Inhalation	26,0000000	0,4333333	*D35*i_AbsorpInhalation*
Sum	640,8832000	10,6813867	
With RPE/PPE (as selected above)			
Hands	10,4992000	0,1749867	*D33*i_AbsorpInuse*
Body	60,5404000	1,0090067	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	0,0816000	0,0013600	*D32*i_AbsorpInuse*F39*
Inhalation	26,0000000	0,4333333	*D35*i_AbsorpInuse*G39*
Sum	97,1212000	1,6186867	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	24,4627200	0,4077120	*E15*i_AbsorpProduct*
Body	2,6755200	0,0445920	*E16*i_AbsorpProduct*
Head	0,0105600	0,0001760	*E17*i_AbsorpProduct*
Inhalation	26,0000000	0,4333333	*E21*i_AbsorpInhalation*
Sum	53,1488000	0,8858133	
With RPE/PPE (as selected above)			
Hands	24,4627200	0,4077120	*E18*i_AbsorpProduct*
Body	0,0988800	0,0016480	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	0,0105600	0,0001760	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	26,0000000	0,4333333	*E21*i_AbsorpInhalation*G25*
Sum	50,5721600	0,8428693	
Water soluble bag	50,5721600	0,8428693	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	28,6484000	0,4774733	*E30*i_AbsorpInuse*
Body	931,6476000	15,5274600	*E31*i_AbsorpInuse*
Head	0,5780000	0,0096333	*E32*i_AbsorpInuse*
Inhalation	26,0000000	0,4333333	*E35*i_AbsorpInhalation*
Sum	986,8740000	16,4479000	
With RPE/PPE (as selected above)			
Hands	28,6484000	0,4774733	*E33*i_AbsorpInuse*
Body	425,8840000	7,0980667	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	0,5780000	0,0096333	*E32*i_AbsorpInuse*F39*
Inhalation	26,0000000	0,4333333	*E35*i_AbsorpInhalation*G39*
Sum	481,1104000	8,0185067	

Table 10a: Input parameters considered for the estimation of operator exposure in railroad tracks

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,8	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	90	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	155165	591584	AOEM	
	Body	84338	266215	AOEM	
	Head	4670	25610	AOEM	
	Protected hands (gloves)	644	17826	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1283	13163	AOEM	
	Protected head (hood and face shield)	75	1450	AOEM	
	Inhalation	14	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	13349	61869	AOEM	
	Body	7464	38476	AOEM	
	Head	353	1064	AOEM	
	Protected hands (gloves)	488	5633	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	205	502	AOEM	
	Inhalation	10	39	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 10b: Estimation of operator exposure towards Glyphosate in railroad tracks

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4023275	0,2732316	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0067055	0,0045539	
% of RVNAS	22,35%	15,18%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,6083363	1,1071812	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0268056	0,0184530	
% of RVAAS	8,94%	6,15%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	148,9586556	2,4826443	*D15*i_AbsorpProduct*
Body	80,9649254	1,3494154	*D16*i_AbsorpProduct*
Head	4,4827420	0,0747124	*D17*i_AbsorpProduct*
Inhalation	14,1248086	0,2354135	*D21*i_Absorpinhalation*
Sum	248,5311316	4,1421855	
With RPE/PPE (as selected above)			
Hands	148,9586556	2,4826443	*D18*i_AbsorpProduct*
Body	1,2315248	0,0205254	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	4,4827420	0,0747124	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	14,1248086	0,2354135	*D21*i_Absorpinhalation*G25*
Sum	168,7977310	2,8132955	
Water soluble bag	168,7977310	2,8132955	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	90,7739085	1,5128985	*D30*i_Absorpinuse*
Body	50,7547949	0,8459132	*D31*i_Absorpinuse*
Head	2,3988455	0,0399808	*D32*i_Absorpinuse*
Inhalation	9,8688575	0,1644810	*D35*i_Absorpinhalation*
Sum	153,7964064	2,5632734	
With RPE/PPE (as selected above)			
Hands	90,7739085	1,5128985	*D33*i_Absorpinuse*
Body	1,3922897	0,0232048	*D34*i_Absorpinuse or D31*i_Absorpinuse*F38*
Head	2,3988455	0,0399808	*D32*i_Absorpinuse*F39*
Inhalation	9,8688575	0,1644810	*D35*i_Absorpinuse*G39*
Sum	104,4339012	1,7405650	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	567,9208332	9,4653472	*E15*i_AbsorpProduct*
Body	255,5666924	4,2594449	*E16*i_AbsorpProduct*
Head	24,5857659	0,4097628	*E17*i_AbsorpProduct*
Inhalation	31,9638571	0,5327310	*E21*i_AbsorpInhalation*
Sum	880,0371486	14,6672858	
With RPE/PPE (as selected above)			
Hands	567,9208332	9,4653472	*E18*i_AbsorpProduct*
Body	12,6361200	0,2106020	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	24,5857659	0,4097628	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,9638571	0,5327310	*E21*i_AbsorpInhalation*G25*
Sum	637,1065762	10,6184429	
Water soluble bag	637,1065762	10,6184429	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	420,7098154	7,0118303	*E30*i_AbsorpInuse*
Body	261,6393004	4,3606550	*E31*i_AbsorpInuse*
Head	7,2340026	0,1205667	*E32*i_AbsorpInuse*
Inhalation	38,7160596	0,6452677	*E35*i_AbsorpInhalation*
Sum	728,2991780	12,1383196	
With RPE/PPE (as selected above)			
Hands	420,7098154	7,0118303	*E33*i_AbsorpInuse*
Body	3,4147434	0,0569124	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	7,2340026	0,1205667	*E32*i_AbsorpInuse*F39*
Inhalation	38,7160596	0,6452677	*E35*i_AbsorpInhalation*G39*
Sum	470,0746210	7,8345770	

Table 11a: Input parameters considered for the estimation of operator exposure for invasive species in non-agricultural areas

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,8 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	1,8 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Knapsack

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	11394	30578	AOEM	
	Body	964	3344	AOEM	
	Head	6	13	AOEM	
	Protected hands (gloves)	22	197	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	30	124	AOEM	
	Protected head (hood and face shield)	6	13	AOEM	
	Inhalation	30	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	1853	5056	AOEM	
	Body	106642	164408	AOEM	
	Head	14	102	AOEM	
	Protected hands (gloves)	6	26	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10684	75156	AOEM	
	Inhalation	31	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 11b: Estimation of operator exposure for invasive species in non-agricultural areas

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,8109289	0,1575182	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0135155	0,0026253	
% of RVNAS	45,05%	8,75%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,2480274	0,6380191	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0208005	0,0106337	
% of RVAAS	6,93%	3,54%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	10,9382400	0,1823040	*D15*i_AbsorpProduct*
Body	0,9250560	0,0154176	*D16*i_AbsorpProduct*
Head	0,0057600	0,0000960	*D17*i_AbsorpProduct*
Inhalation	30,0000000	0,5000000	*D21*i_AbsorpInhalation*
Sum	41,8690560	0,6978176	
With RPE/PPE (as selected above)			
Hands	10,9382400	0,1823040	*D18*i_AbsorpProduct*
Body	0,0288000	0,0004800	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,0057600	0,0000960	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	30,0000000	0,5000000	*D21*i_AbsorpInhalation*G25*
Sum	40,9728000	0,6828800	
Water soluble bag	40,9728000	0,6828800	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	12,5990400	0,2099840	*D30*i_AbsorpInuse*
Body	725,1628800	12,0860480	*D31*i_AbsorpInuse*
Head	0,0979200	0,0016320	*D32*i_AbsorpInuse*
Inhalation	31,2000000	0,5200000	*D35*i_AbsorpInhalation*
Sum	769,0598400	12,8176640	
With RPE/PPE (as selected above)			
Hands	12,5990400	0,2099840	*D33*i_AbsorpInuse*
Body	72,6484800	1,2108080	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	0,0979200	0,0016320	*D32*i_AbsorpInuse*F39*
Inhalation	31,2000000	0,5200000	*D35*i_AbsorpInuse*G39*
Sum	116,5454400	1,9424240	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	29,3552640	0,4892544	*E15*i_AbsorpProduct*
Body	3,2106240	0,0535104	*E16*i_AbsorpProduct*
Head	0,0126720	0,0002112	*E17*i_AbsorpProduct*
Inhalation	31,2000000	0,5200000	*E21*i_AbsorpInhalation*
Sum	63,7785600	1,0629760	
With RPE/PPE (as selected above)			
Hands	29,3552640	0,4892544	*E18*i_AbsorpProduct*
Body	0,1186560	0,0019776	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	0,0126720	0,0002112	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,2000000	0,5200000	*E21*i_AbsorpInhalation*G25*
Sum	60,6865920	1,0114432	
Water soluble bag	60,6865920	1,0114432	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	34,3780800	0,5729680	*E30*i_AbsorpInuse*
Body	1117,9771200	18,6329520	*E31*i_AbsorpInuse*
Head	0,6936000	0,0115600	*E32*i_AbsorpInuse*
Inhalation	31,2000000	0,5200000	*E35*i_AbsorpInhalation*
Sum	1184,2488000	19,7374800	
With RPE/PPE (as selected above)			
Hands	34,3780800	0,5729680	*E33*i_AbsorpInuse*
Body	511,0608000	8,5176800	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	0,6936000	0,0115600	*E32*i_AbsorpInuse*F39*
Inhalation	31,2000000	0,5200000	*E35*i_AbsorpInhalation*G39*
Sum	577,3324800	9,6222080	

Table 12a: Input parameters considered for the estimation of operator exposure for invasive species in agricultural areas

Operator exposure for MON 52276 outdoor spray applications

Application rate of active substance	1,8 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	1,8 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0,10%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%	*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Outdoorsoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Knapsack

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	11394	30578	AOEM	
	Body	964	3344	AOEM	
	Head	6	13	AOEM	
	Protected hands (gloves)	22	197	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	30	124	AOEM	
	Protected head (hood and face shield)	6	13	AOEM	
	Inhalation	30	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	1853	5056	AOEM	
	Body	106642	164408	AOEM	
	Head	14	102	AOEM	
	Protected hands (gloves)	6	26	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10684	75156	AOEM	
	Inhalation	31	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table 12b: Estimation of operator exposure for invasive species in agricultural areas

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,8109289	0,1575182	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0135155	0,0026253	
% of RVNAS	45,05%	8,75%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,2480274	0,6380191	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0208005	0,0106337	
% of RVAAS	6,93%	3,54%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	10,9382400	0,1823040	*D15*i_AbsorpProduct*
Body	0,9250560	0,0154176	*D16*i_AbsorpProduct*
Head	0,0057600	0,0000960	*D17*i_AbsorpProduct*
Inhalation	30,0000000	0,5000000	*D21*i_AbsorpInhalation*
Sum	41,8690560	0,6978176	
With RPE/PPE (as selected above)			
Hands	10,9382400	0,1823040	*D18*i_AbsorpProduct*
Body	0,0288000	0,0004800	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	0,0057600	0,0000960	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	30,0000000	0,5000000	*D21*i_AbsorpInhalation*G25*
Sum	40,9728000	0,6828800	
Water soluble bag	40,9728000	0,6828800	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	12,5990400	0,2099840	*D30*i_AbsorpInuse*
Body	725,1628800	12,0860480	*D31*i_AbsorpInuse*
Head	0,0979200	0,0016320	*D32*i_AbsorpInuse*
Inhalation	31,2000000	0,5200000	*D35*i_AbsorpInhalation*
Sum	769,0598400	12,8176640	
With RPE/PPE (as selected above)			
Hands	12,5990400	0,2099840	*D33*i_AbsorpInuse*
Body	72,6484800	1,2108080	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	0,0979200	0,0016320	*D32*i_AbsorpInuse*F39*
Inhalation	31,2000000	0,5200000	*D35*i_AbsorpInuse*G39*
Sum	116,5454400	1,9424240	

3. Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	29,3552640	0,4892544	*E15*i_AbsorpProduct*
Body	3,2106240	0,0535104	*E16*i_AbsorpProduct*
Head	0,0126720	0,0002112	*E17*i_AbsorpProduct*
Inhalation	31,2000000	0,5200000	*E21*i_Absorpinhalation*
Sum	63,7785600	1,0629760	
With RPE/PPE (as selected above)			
Hands	29,3552640	0,4892544	*E18*i_AbsorpProduct*
Body	0,1186560	0,0019776	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	0,0126720	0,0002112	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	31,2000000	0,5200000	*E21*i_Absorpinhalation*G25*
Sum	60,6865920	1,0114432	
Water soluble bag	60,6865920	1,0114432	*C104*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	34,3780800	0,5729680	*E30*i_Absorpinuse*
Body	1117,9771200	18,6329520	*E31*i_Absorpinuse*
Head	0,6936000	0,0115600	*E32*i_Absorpinuse*
Inhalation	31,2000000	0,5200000	*E35*i_Absorpinhalation*
Sum	1184,2488000	19,7374800	
With RPE/PPE (as selected above)			
Hands	34,3780800	0,5729680	*E33*i_Absorpinuse*
Body	511,0608000	8,5176800	*E34*i_Absorpinuse or E31*i_Absorpinuse*F38*
Head	0,6936000	0,0115600	*E32*i_Absorpinuse*F39*
Inhalation	31,2000000	0,5200000	*E35*i_Absorpinhalation*G39*
Sum	577,3324800	9,6222080	

A 1.2 Resident exposure calculation (Table 13-21)

Table 13a: Input parameters considered for the estimation of resident exposure in bare soil

Resident exposure for MON 52276				
Croptype	Bare soil			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,44	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 13b: Estimation of resident exposure towards Glyphosate in bare soil

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0294243	0,0107000	0,0037643	0,0165240	0,0435321
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0029424	0,0010700	0,0003764	0,0016524	0,0043532
% of RVNAS	9,81%	3,57%	1,25%	5,51%	14,51%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0391784	0,0138000	0,0040030	0,0550800	0,0798640
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006530	0,0002300	0,0000667	0,0009180	0,0013311
% of RVNAS	2,18%	0,77%	0,22%	3,06%	4,44%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0294243	0,0029424	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0014257	0,0001426	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0015322	0,0001532	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0008064	0,0000806	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0165240	0,0016524	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt *d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0391784	0,0006530	*(C15*i_Absorpinuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0040030	0,0000667	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_Absorpinuse*	
Entry into treated crops (dermal)	0,0550800	0,0009180	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0169010	0,0016901	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0010438	0,0001044	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0011218	0,0001122	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0005904	0,0000590	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0131751	0,0013175	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0192161	0,0003203	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0029307	0,0000488	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0439171	0,0007320	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 14a: Input parameters considered for the estimation of resident exposure in vegetables one application

Resident exposure for MON 52276				
Croptype	Fruiting vegetables			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,44	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 14b: Estimation of resident exposure towards Glyphosate in vegetables one application

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0294243	0,0107000	0,0037643	0,0165240	0,0435321
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0029424	0,0010700	0,0003764	0,0016524	0,0043532
% of RVNAS	9,81%	3,57%	1,25%	5,51%	14,51%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0391784	0,0138000	0,0040030	0,0550800	0,0798640
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006530	0,0002300	0,0000667	0,0009180	0,0013311
% of RVNAS	2,18%	0,77%	0,22%	3,06%	4,44%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0294243	0,0029424	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0014257	0,0001426	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0015322	0,0001532	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0008064	0,0000806	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0165240	0,0016524	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0391784	0,0006530	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0040030	0,0000667	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*	
Entry into treated crops (dermal)	0,0550800	0,0009180	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0169010	0,0016901	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0010438	0,0001044	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0011218	0,0001122	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0005904	0,0000590	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0131751	0,0013175	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0192161	0,0003203	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0029307	0,0000488	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0439171	0,0007320	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 15a: Input parameters considered for the estimation of resident exposure in vegetables two application

Resident exposure for MON 52276				
Croptype	Fruiting vegetables			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,08	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	10,8	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,24	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 15b: Estimation of resident exposure towards Glyphosate in vegetables two application

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0220682	0,0107000	0,0043016	0,0188826	0,0415808
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0022068	0,0010700	0,0004302	0,0018883	0,0041581
% of RVNAS	7,36%	3,57%	1,43%	6,29%	13,86%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0293838	0,0138000	0,0045743	0,0629419	0,0817468
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0004897	0,0002300	0,0000762	0,0010490	0,0013624
% of RVNAS	1,63%	0,77%	0,25%	3,50%	4,54%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0220682	0,0022068	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0016292	0,0001629	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0017509	0,0001751	*(i_AppRate/100)*C29*d_Turf*d_SolExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0009215	0,0000922	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0188826	0,0018883	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SolExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0293838	0,0004897	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0045743	0,0000762	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*	
Entry into treated crops (dermal)	0,0629419	0,0010490	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0126757	0,0012676	((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS	
Vapour	0,0107000	0,0010700	d_AirCon*d_BreathRCh*d_BwChild	
Surface deposits				
Dermal	0,0011928	0,0001193	(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))	
Hand to mouth	0,0012819	0,0001282	(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF	
Object to mouth	0,0006747	0,0000675	(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF	
Entry into treated crops				
Dermal	0,0150557	0,0015056	(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))	
Hand to mouth			(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0144121	0,0002402	"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"	
Vapour	0,0138000	0,0002300	d_AirCon*d_BreathRAd*d_BwAdult	
Surface deposits (dermal)	0,0033491	0,0000558	(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)	
Entry into treated crops (dermal)	0,0501856	0,0008364	(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)	

Table 16a: Input parameters considered for the estimation of resident exposure in orchards

Resident exposure for MON 52276				
Croptype	Pome fruit			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,44	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	23,96%			
Drift percentage on surface (mean)	18,96%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 16b: Estimation of resident exposure towards Glyphosate in orchards

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0294243	0,0107000	0,0245394	0,0251767	0,0670938
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0029424	0,0010700	0,0024539	0,0025177	0,0067094
% of RVNAS	9,81%	3,57%	8,18%	8,39%	22,36%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0391784	0,0138000	0,0260955	0,0839225	0,1205801
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006530	0,0002300	0,0004349	0,0013987	0,0020097
% of RVNAS	2,18%	0,77%	1,45%	4,66%	6,70%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0294243	0,0029424	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0092943	0,0009294	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0099882	0,0009988	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0052569	0,0005257	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0251767	0,0025177	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt *d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0391784	0,0006530	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0260955	0,0004349	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*	
Entry into treated crops (dermal)	0,0839225	0,0013987	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0169010	0,0016901	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0073547	0,0007355	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0079039	0,0007904	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0041599	0,0004160	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0200743	0,0020074	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0192161	0,0003203	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0206499	0,0003442	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0669142	0,0011152	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 17a: Input parameters considered for the estimation of resident exposure in vines

Resident exposure for MON 52276				
Croptype	Grapes			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,44	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	6,90%			
Drift percentage on surface (mean)	5,25%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 17b: Estimation of resident exposure towards Glyphosate in vines

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0294243	0,0107000	0,0070669	0,0251767	0,0530522
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0029424	0,0010700	0,0007067	0,0025177	0,0053052
% of RVNAS	9,81%	3,57%	2,36%	8,39%	17,68%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0391784	0,0138000	0,0075150	0,0839225	0,1056482
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006530	0,0002300	0,0001252	0,0013987	0,0017608
% of RVNAS	2,18%	0,77%	0,42%	4,66%	5,87%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0294243	0,0029424	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0026766	0,0002677	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0028764	0,0002876	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0015139	0,0001514	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0251767	0,0025177	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0391784	0,0006530	*(C15*i_Absorpinuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0075150	0,0001252	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_Absorpinuse*	
Entry into treated crops (dermal)	0,0839225	0,0013987	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0169010	0,0016901	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0020365	0,0002037	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0021886	0,0002189	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0011519	0,0001152	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0200743	0,0020074	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0192161	0,0003203	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0057179	0,0000953	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0669142	0,0011152	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 18a: Input parameters considered for the estimation of resident exposure in railroad tracks

Resident exposure for MON 52276				
Croptype	Bare soil			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,8	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	18	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 18b: Estimation of resident exposure towards Glyphosate in railroad tracks

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0367803	0,0107000	0,0052935	0,0232369	0,0542294
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0036780	0,0010700	0,0005294	0,0023237	0,0054229
% of RVNAS	12,26%	3,57%	1,76%	7,75%	18,08%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0489730	0,0138000	0,0056292	0,0774563	0,1036999
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0008162	0,0002300	0,0000938	0,0012909	0,0017283
% of RVNAS	2,72%	0,77%	0,31%	4,30%	5,76%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0367803	0,0036780	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0020049	0,0002005	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0021546	0,0002155	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0011340	0,0001134	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0232369	0,0023237	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0489730	0,0008162	*(C15*i_Absorpinuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0056292	0,0000938	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_Absorpinuse*	
Entry into treated crops (dermal)	0,0774563	0,0012909	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_Absorpinuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0211262	0,0021126	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0014679	0,0001468	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0015775	0,0001577	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0008303	0,0000830	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0185275	0,0018528	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0240201	0,0004003	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0041214	0,0000687	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0617585	0,0010293	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 19a: Input parameters considered for the estimation of resident exposure for invasive species in non-agricultural areas

Resident exposure for MON 52276				
Croptype	Golf course, turf or other sports lawns			
Application method	Downward spraying			
Application equipment	Manual-Knapsack			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,8	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	360	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 19b: Estimation of resident exposure towards Glyphosate for invasive species in non-agricultural areas

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	**Vapour (75th percentile)**	**Surface deposits (75th percentile)**	**Entry into treated crops (75th percentile)**	**All pathways (mean)**
Total systemic exposure (mg a.s./day)	0,7356067	0,0107000	0,0047053	0,0262530	0,4406478
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0735607	0,0010700	0,0004705	0,0026253	0,0440648
% of RVNAS	245,20%	3,57%	1,57%	8,75%	146,88%
1.2 Adult					
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways (mean)**
Total systemic exposure (mg a.s./day)	0,9794592	0,0138000	0,0050037	0,0111690	0,5090350
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0163243	0,0002300	0,0000834	0,0001862	0,0084839
% of RVNAS	54,41%	0,77%	0,28%	0,62%	28,28%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	**Systemic exposure [mg a.s./kg bw/day]**	**Formula**	**Comments**
1-3 year old child				
Spray drift	0,7356067	0,0735607	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0017821	0,0001782	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0019152	0,0001915	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0010080	0,0001008	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0039780	0,0003978	*(i_AppRate/100)*d_MAF*1*d_Turf*d_ReTCCh*d_ExpDurTreatCrop*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth	0,0042750	0,0004275	*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	
Object to mouth	0,0180000	0,0018000	*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Adult				
Spray drift	0,9794592	0,0163243	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0050037	0,0000834	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*	
Entry into treated crops (dermal)	0,0111690	0,0001862	*(i_AppRate/100)*d_MAF*d_Turf*d_ReTCAd*d_ExpDurTreatCrop*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,4225248	0,0422525	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0013048	0,0001305	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0014022	0,0001402	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0007380	0,0000738	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0039780	0,0003978	*(i_AppRate/100)*d_MAF*d_Turf*d_ReTCCh*d_ExpDurTreatCrop*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth	0,0042750	0,0004275	*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	
Object to mouth	0,0180000	0,0018000	*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Adult				
Spray drift	0,4804026	0,0080067	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0036634	0,0000611	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0111690	0,0001862	*(i_AppRate/100)*d_MAF*d_Turf*d_ReTCAd*d_ExpDurTreatCrop*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 20a: Input parameters considered for the estimation of resident exposure for invasive species in agricultural areas

Resident exposure for MON 52276				
Croptype	Cereals			
Application method	Downward spraying			
Application equipment	Manual-Knapsack			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	1,8	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	360	g a.s./l		*d_ConcAS*
Dermal absorption of product	0,10%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%			*i_AbsorpInuse*
Oral absorption	20,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%			
Drift percentage on surface (mean)	4,10%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

Table 20b: Estimation of resident exposure towards Glyphosate for invasive species in agricultural areas

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,7356067	0,0107000	0,0047053	0,0206550	0,4531387
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0735607	0,0010700	0,0004705	0,0020655	0,0453139
% of RVNAS	245,20%	3,57%	1,57%	6,89%	151,05%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,9794592	0,0138000	0,0050037	0,0688500	0,5527624
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0163243	0,0002300	0,0000834	0,0011475	0,0092127
% of RVNAS	54,41%	0,77%	0,28%	3,83%	30,71%

2. Resident exposure 75th Percentile

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,7356067	0,0735607	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0017821	0,0001782	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0019152	0,0001915	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0010080	0,0001008	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0206550	0,0020655	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	
Hand to mouth			*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,9794592	0,0163243	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0050037	0,0000834	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*	
Entry into treated crops (dermal)	0,0688500	0,0011475	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

3. Summing of exposure pathways mean

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,4225248	0,0422525	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*	
Vapour	0,0107000	0,0010700	*d_AirCon*d_BreathRCh*d_BwChild*	
Surface deposits				
Dermal	0,0013048	0,0001305	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*	
Hand to mouth	0,0014022	0,0001402	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*	
Object to mouth	0,0007380	0,0000738	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	
Entry into treated crops				
Dermal	0,0164689	0,0016469	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*	
Hand to mouth			*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			*(i_AppRate/100)*1*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,4804026	0,0080067	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*	
Vapour	0,0138000	0,0002300	*d_AirCon*d_BreathRAd*d_BwAdult*	
Surface deposits (dermal)	0,0036634	0,0000611	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*	
Entry into treated crops (dermal)	0,0548964	0,0009149	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*	

Table 21a: Input parameters considered for the estimation of recreational exposure for invasive species in non-agricultural areas

Recreational exposure for MON 52276			
Croptype	Golf course, turf or other sports lawns		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Application rate of the product	1,8	kg a.s./ha	*i_AppRate*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Exposure duration dermal	2	hours	*d_ReExpDur*
Light clothing adjustment factor Adult resident	18,0%		*d_ClothAF*
Drift percentage on surface	100,00%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*

Table 21b: Estimation of recreational exposure for invasive species in non-agricultural areas

2. Details			
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula
1-3 year old child			
Surface deposits			
Dermal	**0,0318240**	**0,0031824**	*(i_AppRate/100)*C13*d_Turf*d_ReTCCh* d_ReExpDur*MAX(i_AbsorpProduct,i_Absorpinuse)*d_MAF)*
Hand to mouth	**0,0342000**	**0,0034200**	*(i_AppRate/100)*C13*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0,0180000**	**0,0018000**	*(i_AppRate/100)*C13*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Total systemic exposure	**0,0840240**	**0,0084024**	
% of RVNAS		**28,01%**	
Adult			
Surface deposits (dermal)	**0,0893520**	**0,0014892**	*(i_AppRate/100)*C13*d_Turf*d_ReTCAd* d_ReExpDur*MAX(i_AbsorpProduct,i_Absorpinuse)*d_MAF*
% of RVNAS		**4,96%**	

A 1.3 Adult bystander exposure calculation (Table 22-29)

Table 22a: Input parameters considered for the estimation of adult bystander exposure in bare soil

Bystander exposure for MON 52276			
Croptype	Bare soil		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,44	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 22b: Estimation of adult bystander exposure towards Glyphosate in bare soil

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,1043562	0,0138000	0,0120686	0,0550800
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0017393	0,0002300	0,0002011	0,0009180
% of RVAAS	0,58%	0,08%	0,07%	0,31%

Table 23a: Input parameters considered for the estimation of bystander exposure in vegetables one application

Bystander exposure for MON 52276			
Croptype	Fruiting vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,44	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 23b: Estimation of adult bystander exposure towards Glyphosate in vegetables one application

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,1043562	0,0138000	0,0120686	0,0550800
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0017393	0,0002300	0,0002011	0,0009180
% of RVAAS	0,58%	0,08%	0,07%	0,31%

Table 24a: Input parameters considered for the estimation of adult bystander exposure in vegetables two applications

Bystander exposure for MON 52276			
Croptype	Fruiting vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,08	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	10,8	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,24	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 24b: Estimation of adult bystander exposure towards Glyphosate in vegetables two applications

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,0782672	0,0138000	0,0137913	0,0629419
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0013045	0,0002300	0,0002299	0,0010490
% of RVAAS	0,43%	0,08%	0,08%	0,35%

Table 25a: Input parameters considered for the estimation of adult bystander exposure in in orchards

Bystander exposure for MON 52276			
Croptype	Pome fruit		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,44	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	29,20%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 25b: Estimation of adult bystander exposure towards Glyphosate in in orchards

1.2 Adult				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,1043562	0,0138000	0,0631694	0,0839225
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0017393	0,0002300	0,0010528	0,0013987
% of RVAAS	0,58%	0,08%	0,35%	0,47%

Table 26a: Input parameters considered for the estimation of adult bystander exposure in vines

Bystander exposure for MON 52276			
Croptype	Grapes		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,44	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	14,4	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,02%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 26b: Estimation of adult bystander exposure towards Glyphosate in vines

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,1043562	0,0138000	0,0173499	0,0839225
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0017393	0,0002300	0,0002892	0,0013987
% of RVAAS	0,58%	0,08%	0,10%	0,47%

Table 27a: Input parameters considered for the estimation of adult bystander exposure for invasive species in non-agricultural areas

Bystander exposure for MON 52276			
Croptype	Golf course, turf or other sports lawns		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,8	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	360	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 27b: Estimation of adult bystander exposure towards Glyphosate for invasive species in non-agricultural areas

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	2,6089056	0,0138000	0,0150858	0,0221850
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0434818	0,0002300	0,0002514	0,0003698
% of RVAAS	14,49%	0,08%	0,08%	0,12%

Table 28a: Input parameters considered for the estimation of adult bystander exposure for invasive species in agricultural areas

Bystander exposure for MON 52276			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,8	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	360	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_Absorpinuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 28b: Estimation of adult bystander exposure towards Glyphosate for invasive species in agricultural areas

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	2,6089056	0,0138000	0,0150858	0,0688500
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0434818	0,0002300	0,0002514	0,0011475
% of RVAAS	14,49%	0,08%	0,08%	0,38%

Table 29a: Input parameters considered for the estimation of adult bystander exposure in railroad tracks

Bystander exposure for MON 52276			
Croptype	Bare soil		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	1,8	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	18	g a.s./l	*d_ConcAS*
Dermal absorption of product	0,10%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0,68%		*i_AbsorpInuse*
Oral absorption	20,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1,21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0,74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0,00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0,00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

Table 29b: Estimation of adult bystander exposure towards Glyphosate in railroad tracks

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,1304453	0,0138000	0,0169715	0,0774563
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0021741	0,0002300	0,0002829	0,0012909
% of RVAAS	0,72%	0,08%	0,09%	0,43%

A1.4 Worker exposure calculations (Table 30-37)

Table 30a: Input parameters considered for the estimation of worker exposure in vegetables one application

Worker exposure from residues on foliage for MON 52276			
Crop type	Fruiting vegetables		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 30b: Estimation of worker exposure towards Glyphosate in vegetables one application

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,3630464	0,5875200	0,1363046	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0227174	0,0097920	0,0022717	
% of RVNAS	75,72%	32,64%	7,57%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,3630464	0,0227174	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,5875200	0,0097920	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	0,1363046	0,0022717	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table 31a: Input parameters considered for the estimation of worker exposure in vegetables two applications

Worker exposure from residues on foliage for MON 52276			
Crop type	Fruiting vegetables		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,08	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	28	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,5		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,24	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 31b: Estimation of worker exposure towards Glyphosate in vegetables two applications

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,5576012	0,6713798	0,1557601	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0259600	0,0111897	0,0025960	
% of RVNAS	86,53%	37,30%	8,65%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,5576012	0,0259600	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,6713798	0,0111897	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	0,1557601	0,0025960	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table 32a: Input parameters considered for the estimation of worker exposure in orchards, hand harvesting

Worker exposure from residues on foliage for MON 52276			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	28	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,5		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 32b: Estimation of worker exposure towards Glyphosate in orchards, hand harvesting

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	8,0565581	1,6113116	0,8056558	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1342760	0,0268552	0,0134276	
% of RVNAS	447,59%	89,52%	44,76%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	8,0565581	0,1342760	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	1,6113116	0,0268552	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	0,8056558	0,0134276	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table 32c: Estimation of worker exposure towards Glyphosate in orchards, hand harvesting and using the decline calculator

$N_t = N_o \times (0.5)^{\text{number of half-lives}}$					
N_t = amount remaining after specified number of half-lives					
N_o = original amount (3 µg/cm² x kg a.s./ha)					
Number of half-lives = elapsed time ÷ half-life					
Active:				Test Active	
Half-life (days)				30	
Interval between applications				28	Enter your interval between applications in days here
Exclusion period/PHI				7	Enter the PHI for hand harvesting. If you are calculating crop inspection this should be 0 unless you wish to include a worker exclusion period.
					For bystander re entry during a worker exclusion period the exclusion period should be set to 0 days
Application 1					
N_o	Time	Half life	No of half-lives	Nt	
4,32	35	30	1,17	1,92	
Application 2					
N_o	Time	Half life	No of half-lives	Nt	
4,32	7	30	0,23	3,67	
Total Nt	5,60	This adds up the NT values calculated above			
TC	2250	Enter your TC value here			
Duration	8	Enter your activity duration here. 2 hours for crop inspection, 8 hours for hand harvesting, 0.5 hours for bystander reentry during a worker exclusion period			
Dermal exp	100,79	Predicted worker exposure mg/day			
% abs	0,7%	Enter your dermal absorption value in % here			
Body weight	60	Default value 60kg			
Systemic	0,011	Predicted systemic exposure in mg/kg bw/day			
AOEL	0,03	mg/kg bw/day			
% of AOEL	38,07%				

Table 33a: Input parameters considered for the estimation of worker exposure in orchards, inspection

Worker exposure from residues on foliage for MON 52276			
Crop type	Grassland and lawns		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	28	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,5		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_Absorpinuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm²	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm²/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm²/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm²/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 33b: Estimation of worker exposure towards Glyphosate in orchards, inspection

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,1189664	0,1253242	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0186494	0,0020887		
% of RVNAS	62,16%	6,96%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,1189664	0,0186494	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,1253242	0,0020887	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table 34a: Input parameters considered for the estimation of worker exposure in vines, hand harvesting

Worker exposure from residues on foliage for MON 52276			
Crop type	Grapes		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Hand harvesting		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	28	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,5		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 34b: Estimation of worker exposure towards Glyphosate in vines, hand harvesting

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	10,7420775	3,6164994	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1790346	0,0602750		
% of RVNAS	596,78%	200,92%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	10,7420775	0,1790346	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorpinuse*	
Dermal - Work wear - arms, body and legs covered	3,6164994	0,0602750	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse*	
Inhalation				Na for outdoor activities

Table 34c: Estimation of worker exposure towards Glyphosate in vines, hand harvesting and using the decline calculator

$N_t = N_0 \times (0.5)^{\text{number of half-lives}}$
N_t = amount remaining after specified number of half-lives
N_0 = original amount (3 µg/cm² x kg a.s./ha)
Number of half-lives = elapsed time ÷ half-life

Active:	Test Active
Half-life (days)	30
Interval between applications	28
Exclusion period/PHI	7

Enter your interval between applications in days here
Enter the PHI for hand harvesting. If you are calculating crop inspection this should be 0 unless you wish to include a worker exclusion period.
For bystander re entry during a worker exclusion period the exclusion period should be set to 0 days

Application 1				
N_0	Time	Half life	No of half-lives	Nt
4,32	35	30	1,17	1,92

Application 2				
N_0	Time	Half life	No of half-lives	Nt
4,32	7	30	0,23	3,67

Total Nt	5,60	This adds up the NT values calculated above
TC	10100	Enter your TC value here
Duration	8	Enter your activity duration here. 2 hours for crop inspection, 8 hours for hand harvesting, 0.5 hours for bystander reentry during a worker exclusion period
Dermal exp	452,42	Predicted worker exposure mg/day
% abs	0,7%	Enter your dermal absorption value in % here
Body weight	60	Default value 60kg
Systemic	0,051	Predicted systemic exposure in mg/kg bw/day
AOEL	0,03	mg/kg bw/day
% of AOEL	170,91%	

Table 35a: Input parameters considered for the estimation of worker exposure in vines, inspection

Worker exposure from residues on foliage for MON 52276			
Crop type	Grassland and lawns		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,44	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	28	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,5		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,32	µg a.s./cm²	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm²/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm²/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm²/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 35b: Estimation of worker exposure towards Glyphosate in vines, inspection

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,1189664	0,1253242	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0186494	0,0020887		
% of RVNAS	62,16%	6,96%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,1189664	0,0186494	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,1253242	0,0020887	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table 36a: Input parameters considered for the estimation of worker exposure for invasive species in non-agricultural areas

Worker exposure from residues on foliage for MON 52276			
Crop type	Golf course, turf or other sports lawns		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		
Worker's task	Maintenance		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,8	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 36b: Estimation of worker exposure towards Glyphosate for invasive species in non-agricultural areas

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,7038080	0,7344000	0,1703808	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0283968	0,0122400	0,0028397	
% of RVNAS	94,66%	40,80%	9,47%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,7038080	0,0283968	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorpinuse*	
Dermal - Work wear - arms, body and legs covered	0,7344000	0,0122400	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse*	
Dermal - Working wear and gloves	0,1703808	0,0028397	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse*	
Inhalation				Na for outdoor activities

Table 37a: Input parameters considered for the estimation of worker exposure for invasive species in agricultural areas

Worker exposure from residues on foliage for MON 52276			
Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,8	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	0,10%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	0,68%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	5,4	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table 37b: Estimation of worker exposure towards Glyphosate for invasive species in agricultural areas

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0,9180000	0,1028160	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0153000	0,0017136		
% of RVNAS	51,00%	5,71%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	0,9180000	0,0153000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,1028160	0,0017136	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities