European Commission

Combined Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008

Glyphosate

Volume 3 – B.2 (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.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT MON 52276

The table below summarizes the results from studies which were conducted with the product MON 52276 (containing 360 g/L glyphosate, SL). MON 52276 was also the preparation of the RAR 2015. The studies which had been evaluated and relied upon during AIR2 process are presented in the below table in a grey font. The new studies for first submission of AIR5 process are summarised in a black font.

The appearance of the product is a clear yellow homogeneous liquid free from visible suspended matter and sediment, with amine odour. It is not explosive, has no oxidising properties. The product has no flash point up to boiling point. It has a self-ignition temperature of 440 ± 5 °C. In aqueous solution, it has a pH value 4.83 at room temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content and relevant impurities formaldehyde and NNG, nor the physical properties changed. The ambient temperature shelf-life studies (two years and five years at 20 °C) show no significant changes in physical properties and on the content of active ingredient and relevant impurities formaldehyde and NNG. Therefore, a shelf life of up to five years at ambient temperature can be considered for the product MON 52276. Its physical characteristics are acceptable for a soluble concentrate formulation.

Two new relevant impurities (formic acid and trimethylamine) have been identified following the assessment of the renewal of active substance. The revised EU reference specifications for these impurities are:
Formic acid < 4 g/kg
Triethylamine < 2 g/kg

The potential presence of these two impurities has not been assessed in the different stability studies, as they are not formed during the storage of the formulation.

According to the representative use GAP table, the concentrations of use are 0,375% to 100 % v/v. (Apart from 100%v/v, the highest concentration of use is 5%).

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour B.2.1/01	Visual assessment	MON 52276 360 g/L Batch no.: A8L.10.05.304	Clear yellow homogeneous liquid free from visible suspended matter and sediment with an odour of amine	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.1/01
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties	Theoretical assessment and	MON 52276 360 g/L	The Koenen Tube test was carried out using the standard two-stage dry run packing procedure and	Acceptable	Y	[redacted] 1992.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2/01	EEC A.14 with modification according to series 1 of UN test	Batch no.: LLN260491B	**calibrated heating rate.** **Using the criteria given in test A14, the sample tested did not give a positive result in any of the tests performed ie the sample tested was not explosive.** MON 52276 has no explosive properties.	The PPP should not be classified according to Reg. (EC) 1272/2008.		Report no.: 8383 KCP 2.2/01
Oxidizing properties **B.2.2/02**	Statement	MON 52276 360 g/L	The components of MON 52276 do not contain groups that act as an oxidizing agent. The oxygen atoms that are present in the molecular structures are chemically bonded to carbon, phosphorous or hydrogen. Therefore, MON 52276 is considered to have no oxidising properties.	Acceptable The PPP should not be classified according to Reg. (EC) 1272/2008.	N	Please refer to confidential section: [redacted] 2012. Report no.: MSL0024643 KCP 2.2/02
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations **B.2.3/01**	EEC A 9	MON 52276 360 g/L Batch no.: LLN260491B	The flash point test was found to be unsuitable for MON 52276, as the formulation boils at 105.3 C. Not flammable	Acceptable The PPP should not be classified according to Reg. (EC) 1272/2008.	Y	[redacted] 1992. Report no.: 8383 KCP 2.3/01
Flammability of solid formulations **B.2.3/02**	-	-	**The preparation is a liquid.**	-	-	-
Self-heating of formulation **B.2.3/03**	EEC A 15	MON 52276 360 g/L Batch no.: LLN260491B	Auto-ignition temperature: 440 ± 5 C	Acceptable The PPP should not be classified according to Reg. (EC) 1272/2008.	Y	[redacted] 1992. Report no.: 8383 KCP 2.3/01
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation **B.2.4/01**	CIPAC MT 75.1	-	pH (undiluted): 4.90	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.4/01
pH of a 1 % dilution of the solid or non aqueous formulation **B.2.4/02**	CIPAC MT 75.2	MON 52276 360 g/L Batch no.: A8L.10.05.304	pH 1.0 % in double distilled water (pH 5.8): 4.83 at room temperature	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.4/01
Acidity / Alkalinity **B.2.4/03**	-	-	Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).	Acceptable	-	-

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td colspan="7">B.2.5. VISCOSITY AND SURFACE TENSION</td></tr>
<tr><td rowspan="3">Viscosity of the liquid formulation
B.2.5/01</td><td>OECD 114 (rotation viscometer)</td><td>MON 52276
360 g/L
Batch no.:
LLN260491B</td><td>Dynamic viscosity:
65 mPa·s at 21 C</td><td>Acceptable</td><td>Y</td><td>[redacted] 1992.
Report no.: 8383
KCP 2.5/01</td></tr>
<tr><td>OECD 114 (Ubbelohde tube viscosimeter)</td><td>MON 52276
360 g/L
Batch no.:
A1D2108105</td><td>Kinematic viscosity:
63.77 mm²/s at 20 C
25.28 mm²/s at 40 C</td><td>Acceptable</td><td>Y</td><td>[redacted] 2011.
Report no.:
MSL0023798
KCP 2.5/02</td></tr>
<tr><td>CIPAC MT 192 (based on OECD 114)</td><td>MON 52276
360 g/L
Batch no.:
AND030720A</td><td>Kinematic viscosity calculated from dynamic viscosity measurements at three shear rates:

At 20 ± 0 5 C
<table>
<tr><th colspan="2">Dynamic viscosity</th><th>Kinematic viscosity (mm²/s)</th></tr>
<tr><th>Shear rate (1/s)</th><th>Viscosity (mPa·s)</th><th></th></tr>
<tr><td>52.80</td><td>64.94</td><td>55.63</td></tr>
<tr><td>39.60</td><td>64.49</td><td>55.25</td></tr>
<tr><td>26.40</td><td>64.49</td><td>55.25</td></tr>
</table>
At 40 ± 0 5 C
<table>
<tr><th colspan="2">Dynamic viscosity</th><th>Kinematic viscosity (mm²/s)</th></tr>
<tr><th>Shear rate (1/s)</th><th>Viscosity (mPa·s)</th><th></th></tr>
<tr><td>66.00</td><td>26.42</td><td>22.87</td></tr>
<tr><td>52.80</td><td>25.91</td><td>22.42</td></tr>
<tr><td>39.60</td><td>25.94</td><td>22.45</td></tr>
</table></td><td>Acceptable</td><td>Y</td><td>[redacted] 2016a.
Report no.:
MSL0027896
KCP 2.5/03</td></tr>
<tr><td rowspan="2">Surface tension of the formulation
B.2.5/02</td><td>OECD 115 (Ring Tensiometer method)</td><td>MON 52276
360 g/L
Batch no.:
LLN260491B</td><td>2.0 % v/v: 40.8 mN/m
5.0 % v/v: 39.8 mN/m
The test item is surface active.

Apart from 100 % v/v, the highest tank concentration is 5 %.</td><td>Acceptable</td><td>Y</td><td>[redacted] 1992.
Report no.: 8383
KCP 2.5/01</td></tr>
<tr><td>PA-U10-METTENS (equivalent to EEC A.5)</td><td>MON 52276
360 g/L
Batch no.:
AND030720A</td><td>33 % v/v: 31.4 mN/m
The test item is surface active.

Considering the slight difference between the surface tension at 2 %, 5 % v/v and 33 % v/v, no more data is required at 100 v/v.
The results are acceptable for the whole in-use</td><td>Acceptable</td><td>Y</td><td>[redacted] 2016a.
Report no.:
MSL0027896
KCP 2.5/03</td></tr>
</table>

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			concentration range via extrapolation.			
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation **B.2.6/01**	OECD 109 (pycnometer method)	MON 52276 360 g/L Batch no.: LLN260491B	1.1694 g/cm^3 at 20 C	Acceptable	Y	[redacted] 1992. Report no.: 8383 KCP 2.6/01
	OECD 109 (method of Monsanto: LLN-FOR-MET-O 11 equivalent to EEC A.3)	MON 52276 360 g/L Batch no.: A8L.10.05.304	1.166 g/cm^3 at 20 C	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.6/02
	EEC method A.3	MON 52276 360 g/L Batch no.: AND030720A	1.1673 g/cm^3 at 20 C 1.1553 g/cm^3 at 40 C	Acceptable	Y	[redacted] 2016a. Report no.: MSL0027896 KCP 2.5/03
Bulk density (pour and tap) of powder or granules **B.2.6/02**	-	-	The preparation is a liquid.	-	-	-
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) **B.2.7/01**	CIPAC MT 46.1.2 HPLC method (method described in reports MLL31063 and MLL31312 which were not provided)	MON 52276 360 g/L Batch no.: LLN260491B	Accelerated storage stability: 14 days at 54 C Packaging: 1 L HDPE bottle Active substance content: Before storage: 30.4 % w/w After storage: 30.6 % w/w The appearance, pH value, dilution stability and packaing stability were measured before and after storage at 54 C for 14 days. Results for these tests were considered acceptable before and after storage. Please refer to the table below for detailed results.	Results of tested properties are acceptable. However, the determination of the content of two relevant impurities (formaldehyde and NNG) has not been performed. Moreover, the validation of the analytical method for the determination of the active substance is missing. This is considered as a data gap.	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.7/01
	CIPAC MT 46.1.2 HPLC method: Method ME-	MON 52276 360 g/L, Batch no.: 11427995	A sample of MON 52276 was stored for 14 days at 54 C in a closed commercial packaging (a 1L HDPE bottle).	The contents of formaldehyde and NNG found in this study are well below EU specification.	Y	[redacted] 2016. Report no.: MSL0027539 KCP 2.7/02

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td></td><td>1137-01 for formalhehyde and method ME-0766-01 for N-Nitrosoglyphosate (validation of the methods reported in Vol. 3, B.5)</td><td></td><td>After storage, the sample was evaluated for relevant impurities; formaldehyde and N-nitrosoglyphosate concentration.

<table><tr><th></th><th>Initial</th><th>2 weeks</th></tr><tr><td>Content of Formaldehyde</td><td>< LOQ</td><td>< LOQ</td></tr><tr><td>Content of NNG</td><td>< LOQ (0.042 ppm)</td><td>< LOQ (0.037 ppm)</td></tr><tr><td>Weight (g)</td><td>1270.25</td><td>1269.94 (-0.02%)</td></tr></table>
LOQ according to the method validation (please refer to B.5)
Formaldehyde LOQ = 70 ppm
NNG LOQ = 0.202 ppm</td><td>Although only contents of relevant impurities and weight of the sample were assessed, this accelerated storage study is acceptable, considering the results of the previous one ([redacted] 2001).

Acceptable</td><td></td><td></td></tr>
<tr><td></td><td>CIPAC method 47.2</td><td>MON 52276
360 g/L
Batch no.:
A1D2108105</td><td><u>Persistent foaming:</u>

<table><tr><td>Before storage</td><td>After storage for 14 days at 54 C</td></tr><tr><td colspan="2">2 % v/v in CIPAC water D</td></tr><tr><td>after 10 sec: 46 mL
after 1 min: 0 mL
after 3 min: 0 mL
after 12 min: 0 mL</td><td>after 10 sec: 51 mL
after 1 min: 3 mL
after 3 min: 0 mL
after 12 min: 0 mL</td></tr></table>
<table><tr><td>Before storage</td><td>After storage for 14 days at 54 C</td></tr><tr><td colspan="2">5 % v/v in CIPAC water D</td></tr><tr><td>after 10 sec: 35 mL
after 1 min: 0 mL
after 3 min: 0 mL
after 12 min: 0 mL</td><td>after 10 sec: 48 mL
after 1 min: 0 mL
after 3 min: 0 mL
after 12 min: 0 mL</td></tr></table>
<table><tr><td>Before storage</td><td>After storage for 14 days at 54 C</td></tr><tr><td colspan="2">8 % v/v in CIPAC water D</td></tr></table></td><td>Acceptable</td><td>Y</td><td>[redacted], 2011.
Report no.:
MSL0023798
KCP 2.7/03
&
[redacted] 2013.
Report no.:
MSL0025280
KCP 2.7/04</td></tr>
</table>

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			after 10 sec: 24 mL after 1 min: 0 mL after 3 min: 0 mL after 12 min: 0 mL after 10 sec: 52 mL after 1 min: 4 mL after 3 min: ring after 12 min: 0 mL			
Effect of low temperature on stability of liquid formulation **B.2.7/02**	CIPAC MT 39.2	MON 52276 360 g/L Batch no.: A8L.10.05.304	After the 7 days ± 1 h at 0 ± 2 C, MON 52276 samples showed no sign of instability. The samples were homogeneous and free from foreign matter.	Acceptable The formulation is stable after 7 days at 0 C.	Y	[redacted] 2000. Report no.: MLL31425 KCP 2.7/05
Shelf life following storage at ambient temperature **B.2.7/03**	GIFAP Tech. Monograph 17 Analytical method for the active substance: CIPAC 284/SL/(M)/3 (HPLC) (validation of the method reported in Vol. 3, B.5)	MON 52276 360 g/L Batch no.: A8L.10.05.304	Shelf life: two years at ambient temperature Active substance content: Before: 30.4 % w/w After: 30.1 % w/w The appearance, pH value, dilution stability and packaing stability were measured before and after storage at ambient temperature for 2 years. Results for these tests were considered acceptable before and after storage. Please refer to the table below for detailed results.	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.7/06
	GIFAP Tech. Monograph 17	**MON 77973 technical glyphosate**	**Formaldehyde is formed during glyphosate production. It is not formed during the formulation of finished products or during the storage of finished products. Levels of formaldehyde in finished products cannot exceed the maximum level if the initial formaldehyde concentration in the glyphosate wetcake is within specification.**	**This study has not been taken into account, as the formulation used in the report was not the product MON 52276.**	**N**	**[redacted] 2016a. Report no.: MSL0027770 KCP 2.7/07**
	GIFAP Tech. Monograph 17 HPLC method: Method ME-1137-04 for formalhehyde and method ME-0766-04 for N-Nitrosoglyphosate for ime zero and	**MON 52276 360 g/L Batch no.: 11427995**	**Shelf life: two years at ambient temperature A sample of MON 52276 was stored for 2 years in 1 L commercial HDPE bottles. After storage the sample was evaluated for relevant impurities; formaldehyde and *N*-nitrosoglyphosate concentration. Results were compared with untreated test material.** **Description | Initial | 12 months | 24 months**	**The contents of formaldehyde and NNG found in this study are well below EU specification. Although only contents of relevant impurities and weight of the sample were assessed, this long-term storage study is acceptable, considering the results of the previous one ([redacted] 2001). Acceptable MON 52276 is considered to have an expected**	**Y**	**[redacted] 2018. Report no.: MSL0029475 KCP 2.7/08**

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	ME-2070-01 for time 12 and 24 months (validation of methods reported in Vol. 3, B5)		<table><tr><td>Formaldehyde</td><td>< LOQ (16 ppm)</td><td>< LOQ (4.5 ppm)</td><td>< LOQ (4.8 ppm)</td></tr><tr><td>NNG</td><td>< LOQ (0.08 ppm)</td><td>< LOQ (0.18 ppm)</td><td>< LOQ (0.16 ppm)</td></tr><tr><td>%weight loss</td><td></td><td>-0.11</td><td>-0.04</td></tr></table> LOQ according to the method validation (please refer to B.5) Formaldehyde LOQ = 70 ppm NNG LOQ = 0.202 ppm	shelf life of at least 2 years at ambient temperature.		
	Appearance: visual assessment Density: CIPAC MT 3.3.2 pH: CIPAC MT 75.3 Persistent foaming: CIPAC MT 47.3 Dilution stability: CIPAC MT 41.1 NNG: method 15.05.01 Formaldehyde: PCR method Active substance: HPLC method 15.03.03.13	MON 52276 glyphosate IPA salt 480 g/L (equivalent to 360 g/L glyphosate acid) Batch no.: A3G082310A, A3G040510A, A3G152410A	Shelf-life: five years at ambient temperature <u>Packaging:</u> The packaging of the samples are not reported in the study. Moreover, the appearance of the packaging has been descried neither after 5 years storage. <u>Active substance content (glyphosate IPA salt):</u> Batch no.. A3G082310A Before: 485 g/L After: 486 g/L Batch no.. A3G152410A: Before: 477 g/L After: 478 g/L Relevant impurities contents after 5 years: Formaldehyde: not detected NNG: 0.092 ppm LOQ according to the method validation (please refer to B.5) Formaldehyde LOQ = 70 ppm. NNG LOQ = 0.202 ppm The appearance, pH value, density, persistence of foaming and dilution stability were measured after storage at ambient temperature for 5 years. Please refer to the table below for detailed results.	Acceptable MON 52276 is considered to have an expected shelf life of at least 5 years at ambient temperature. However, every properties should have been determined at T0 (including dilution stability and the appearance of the packaging). Moreover, the validation of the analytical methods for the determination of glyphosate, NNG and formaldehyde are missing. This is considered as a data gap.	N	[redacted] 2018. Report no.: MSL0030308 KCP 2.7/09
	GIFAP	MON 52276	Packaging material: HDPE (1L)	Acceptable	N	[redacted] 2012.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	Monograph No. 17	360 g/L Batch no.: A8L1005304	No permeation through the walls of the 1L bottles after 2 years storage at ambient temperature was observed. No leaking or seepage was observed and no contamination of the outer pack surfaces was observed. No alterations to the interior of the pack were observed. MON 52276 is therefore considered to be fully compatible with the 1-litre HDPE bottles.			Report no.: MPW 1536 KCP 2.7/10
			An issue was raised on the maximum content of impurities in the formulation: whether the content should be recalculated using the actual content of AS in the product, or if the maximum content of impurities should be set in line with the FAO specification. **This is a general point of discussion and is not specifically related to the evaluation of glyphosate. It was concluded that this point needs to be agreed on at EU level as a general matter between physchem experts. In the framework of the renewal of the approval of glyphosate, this does not lead to an open point for the representative formulation, as the content of NNG and formaldehyde were below both maximum levels.** **Therefore, no a final decision was made for this issue.**			
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**	-	-	Not applicable since this is only required for a solid formulation	-	-	-
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.2	MON 52276 360 g/L Batch no.: A1D2108105	Concentration 5 % v/v, in CIPAC water D, 21 C 10 sec 35 mL 1 min 0 mL 3 min 0 mL 12 min 0 mL Concentration 2 % v/v, in CIPAC water D, 21 C 10 sec 46 mL	Acceptable	N	[redacted], 2011. Report no.: MSL0023798 KCP 2.8.2/01

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			1 min 0 mL 3 min 0 mL 12 min 0 mL			
		MON 52276 360 g/L Batch no.: AND030720A	Concentration 33 % v/v, 20 C 10 sec 30 mL 1 min 0 mL 3 min 0 mL 12 min 0 mL	Acceptable	N	[redacted] 2016b. Report no.: MSL 0027646 KCP 2.8.2/02
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**	-	-	Not applicable for SL formulation	-	-	-
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**	-	-	Not applicable for SL formulation	-	-	-
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**	-	-	Not applicable for SL formulation	-	-	-
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution and dilution stability of water soluble formulation **B.2.8.4/01 & B.2.8.4/02**	CIPAC MT 41	MON 52276 360 g/L Batch no.: A8L.10.05.304	5 % v/v dilution in CIPAC water D Stable after 18 hours at 20 ± 2 C Homogeneous liquid, no separated material Apart from 100 % v/v, the highest tank concentration is 5 %.	Acceptable	Y	[redacted] 2001. Report no.: MSL-17439 KCP 2.8.4/01
		MON 52276 360 g/L Batch no.: AND030720A	33 % v/v dilution in CIPAC water D Turbid / clear homogeneous after 24 hours at 30 ± 2 C No signs of sedimentation were observed and no visible particles were observed in the dilution. The test was repeated at 20 C. After 24 hours the solution was clear, homogeneous. MON 52276 is therefore considered to have an acceptable dilution stability, but is observed to have some instability at higher temperatures, which in practical situations will not be encountered when spraying in West-Europe.	Acceptable	N	[redacted] 2016b. Report no.: MSL 0027646 KCP 2.8.4/02

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**	-	-	Not applicable for SL formulation	-	-	-
Size distribution of particles of powder or suspension concentrate formulation **B.2.8.5.1/02**	-	-	Not applicable for SL formulation	-	-	-
Nominal size range of granule **B.2.8.5.1/03**	-	-	Not applicable for SL formulation	-	-	-
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**	-	-	Not applicable for SL formulation	-	-	-
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**	-	-	Not applicable for SL formulation	-	-	-
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**	-	-	Not applicable for SL formulation	-	-	-
Integrity of tablets **B.2.8.5.4/02**	-	-	Not applicable for SL formulation	-	-	-
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**	-	-	Not applicable for SL formulation	-	-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**	-	-	Not applicable for SL formulation	-	-	-
Pourability of suspensions **B.2.8.7/02**	-	-	Not applicable for SL formulation	-	-	-
Dustability of dustable powders after accelerated storage **B.2.8.7/03**	-	-	Not applicable for SL formulation	-	-	-
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures **B.2.9/01**	ASTM E 1518	MON 52276 360 g/L commercial lot	The tank mix compatibility of MON 52276 with a range of commercially available herbicides (14) has been evaluated. Each mix of formulation has been poured through a 150µm sieve and rinsed with cold tap water to check the amount of retained material: - For 9 samples, no apparent material remained on the sieve - For 3 samples, a small but visible amount of retained material was observed - For 2 samples, clearly visible particles of retained material were observed. Visual observation 30 minutes after mixing was recorded: - For 13 samples, the mixture is homogeneous - For 1 sample, the mixture has flocculated. MON 52276 was found to be fully tank mix compatible with 12 of the 14 tested commercial	MON 52276 could be generally considered as a "compatible" mixture partner (12/14 of the tested formulations).	N	[redacted] 2012a. Report no.: MSL 0024054 KCP 2.9/01

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			partners.			
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds **B.2.9.10/01**	-	-	Not applicable for SL formulation	-	-	-
B.2.11. OTHER STUDIES						
	-	-	There is no other study required to be submitted for the test item.	-	-	-

Results referring to the point B.2.7/01: Storage stability of MON 52276 after 14 days at 54 °C ([redacted] 2001)

Test	**Initial**	**14 days at 54 °C**
Content of active (CIPAC 284/SL/(M)/3 modified by method of Monsanto LLN-ES-ASOP-096-2 , HPLC method)	Glyphosate acid : 30.4 % w/w	Glyphosate acid : 30.6 % w/w
Appearance (US EPA Guideline 63.3)	Colour: clear yellow Physical state: homogeneous liquid free from visible suspended matter and sediment Odour: odour of amine	Colour: clear yellow Physical state: homogeneous liquid free from visible suspended matter and sediment Odour: odour of amine
Appearance of packaging material	Well closed, wide neck polyethylene, opaque white bottle of 1 litre without deterioration or special anomaly. No leak during shaking or turning. No observable sign of test item contamination. Internal aspect: no observable alteration of packaging material by the test item.	Well closed, wide neck polyethylene, opaque white bottle of 1 litre. One of the container was a little bit deformed after cooling down at room temperature, but came back to its original shape when opened. No leak during shaking or turning. No observable sign of test item contamination. Internal aspect: no observable alteration of packaging material by the test item.
pH value (CIPAC MT 75.1 and CIPAC MT 75.2)	Undiluted	
	4.9	4.92
	1 % dilution in water	
	4.83	4.84
Dilution stability in water (CIPAC MT 41) Concentration: 5 ± 0.1 % v/v Time: 18 h Temperature: 20 ± 2 °C	Homogeneous liquid, no separated material	Homogeneous liquid, no separated material

Results referring to the point B.2.7/01: Storage stability of MON 52276 after 2 years at room temperature ([redacted] 2001)

Test	**Initial**	**1 year at room temperature**	**2 years at room temperature**
Content of Glyphosate (Validated HPLC method)	Glyphosate acid : 30.4 % w/w	Glyphosate acid : 30.1 % w/w	Glyphosate acid : 30.1 % w/w
Appearance (US EPA Guideline 63.3)	Colour: clear yellow Physical state: homogeneous liquid free from visible suspended matter and sediment Odour: odour of amine	Colour: clear yellow Physical state: homogeneous liquid free from visible suspended matter and sediment Odour: odour of amine	Colour: clear yellow Physical state: homogeneous liquid free from visible suspended matter and sediment Odour: odour of amine
Appearance of packaging material	Well closed, wide neck polyethylene, opaque white bottle of 1 litre without deterioration or special anomaly. No leak during shaking or turning. No observable sign of test item contamination. Internal aspect: no observable alteration of packaging material by the test item.	Well closed, wide neck polyethylene, opaque white bottle of 1 litre without deterioration or special anomaly. No leak during shaking or turning. No observable sign of test item contamination. Internal aspect: no observable alteration of packaging material by the test item No degradation of the container.	Well closed, wide neck polyethylene, opaque white bottle of 1 litre without deterioration or special anomaly. No leak during shaking or turning. No observable sign of test item contamination. Internal aspect: no observable alteration of packaging material by the test item No degradation of the container.
pH value (CIPAC MT 75.1 and CIPAC MT 75.2)	Undiluted		
	4.9	4.83	4.76
	1 % dilution in water		
	4.83	4.89	4.91
Dilution stability in water (CIPAC MT 41) Concentration: 5 ± 0.1 % v/v Time: 18 h Temperature: 20 ± 2 °C	Homogeneous liquid, no separated material	Homogeneous liquid, no separated material	Homogeneous liquid, no separated material

Results referring to the point B.2.7/01: Storage stability of MON 52276 after 5 years at room temperature ([redacted] 2018)

Test	**Initial**	**5 years at room temperature**
Content of Glyphosate IPA (validated HPLC method) Batch no. A3G082310A Batch no. A3G152410A	 485 g/L 477 g/L	 486 g/L 478 g/L
Glyphosate acid equivalent (g/L) Batch no. A3G082310A Batch no. A3G152410A	 353 g/L 359 g/L	 354 g/L 360 g/L
Appearance (visual assessment)	Yellowish to brown coloured liquid, free from foreign materials	Yellowish to brown coloured liquid, free from foreign materials
Density at 20 °C (CIPAC MT 3.3.2)	1.170 g/cm^3	1.170 g/cm^3
pH value (CIPAC MT 75.3)	Undiluted	
	-	4.81
	1 % aqueous solutions	
		4.67
Persistence of foaming (CIPAC MT 47.3) Batch no. A3G082310A Concentration 10 % v/v in CIPAC water D		After 1 min: 3 mL After 12 min: 0 mL
Batch no. A3G152410A Concentration 50 % v/v in CIPAC water D		After 1 min: 1 mL After 12 min: 0 mL
Dilution stability (CIPAC MT 41.1) Concentration: 0.125 % v/v in CIPAC water D		After 30 min: clear solution After 24 h: clear solution
Concentration: 10 % v/v in CIPAC water D		After 30 min: clear solution After 24 h: clear solution
Concentration: 50 % v/v in CIPAC water D		After 30 min: solution slightly turbid* After 24 h: solution slightly turbid*

*The 50 v/v% dilution of MON52276 became slightly turbid subsequently the dilution was wet sieved.
Wt filter: 2,4112g
Wt filter + residue: 2.4106g
No residue was found visually or by weighing.

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.1-001	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: - Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.1
KCP 2.2-001	[redacted]	1992	Physico-chemical testing of a formulation (MON 52276) Report No.: 352777 Document No.: 8383 Inveresk Research International GLP/GEP: Y Published: N	N	N	-	BCS	Y RAR 2017: IIIA 2.2.1
KCP 2.3-001	[redacted]	1992	Physico-chemical testing of a formulation (MON 52276) Report No.: 352777 Document No.: 8383 Inveresk Research International GLP/GEP: Y Published: N	N	N	-	BCS	Y RAR 2017: IIIA 2.3

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.4-001	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: - Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.4.1 / IIIA 2.4.2
KCP 2.5-001	[redacted]	1992	Physico-chemical testing of a formulation (MON 52276) Report No.: 352777 Document No.: 8383 Inveresk Research International GLP/GEP: Y Published: N	N	N	-	BCS	Y RAR 2017: IIIA 2.5.3
KCP 2.5-002	[redacted]	2011	Kinematic viscosity and persistent foaming properties of MON 52276 Report No.: MSL0023798 Document No.: Monsanto Europe N.V. GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.5.1

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.5-003	[redacted]	2016	Surface tension and kinematic viscosity of several glyphosate formulations. Report No.: MSL0027896 Document No.: Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	BCS	N
KCP 2.6-001	[redacted]r, [redacted]. *et al.*	1992	Physico-chemical testing of a formulation (MON 52276) Report No.: 352777 Document No.: 8383 Inveresk Research International GLP/GEP: Y Published: N	N	N	-	BCS	Y RAR 2017: IIIA 2.6.1
KCP 2.6-002	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.6.1

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.7-001	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: - Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.7.3
KCP 2.7-002	[redacted]	2016	Accelerated Storage Stability to Support the Registration of MON 52276 as an End-Use Herbicide. Report No.: MSL0027539 Document No.: - Monsanto Company GLP/GEP: Y Published: N	N	Y	First submission in EU	BCS	N
KCP 2.7-003	[redacted]	2011	Kinematic viscosity and persistent foaming properties of MON 52276 Report No.: MSL0023798 Document No.: - Monsanto Europe N.V. GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: KIIIA1 2.5.1, KIIIA1 2.8.2 (OECD)

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.7-004	[redacted]	2013	Persistent foaming properties of MON 52276 Report No.: MSL0025280 Document No.: - Monsanto Europe N.V. GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.7.1 / IIIA 2.8.2
KCP 2.7-005	[redacted]	2000	One year storage stability at ambient t°, accelerated storage stability by heating and low temperature stability of MON 52276: a water soluble concentrate (SL) of glyphosate. Report No.: MLL31425 Document No.: F-99-52276-01 Monsanto Services International Formulations Laboratory GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.7.2
KCP 2.7-006	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: - Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.7.3

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.7-007	[redacted]	2016	Statistical analysis of formaldehyde levels in MON 77973, glyphosate wetcake. Report No.: MSL0027770 Document No.: - Monsanto Europe N.V GLP/GEP: N Published: N	N	N	-	BCS	N
KCP 2.7-008	[redacted]	2018	Two Year Storage Stability Study to Support the Registration of MON 52276 as an End-Use Herbicide. Report No.: MSL0029475 Document No.: - Monsanto Company GLP/GEP: Y Published: N	N	Y	First submission in EU	BCS	N
KCP 2.7-009	[redacted]	2018	Shelf-life and stability of MON 52276 after storage for 5 years. Report No.: MSL0030308 Document No.: - Monsanto Europe N.V. GLP/GEP: N Published: N	N	N	-	BCS	N
KCP 2.7-010	[redacted]	2012	Packaging suitability testing of MON 52276 with 1-litre high density polyethylene bottles Report No.: MPW 1536 Document No.: - Monsanto Antwerp GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: KIIIA1 4.1

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.8.2-001	[redacted]	2011	Kinematic viscosity and persistent foaming properties of MON 52276 Report No.: MSL0023798 Document No.: - Monsanto Europe N.V. GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: KIIIA1 2.5.1, KIIIA1 2.8.2 (OECD)
KCP 2.8.2-002	[redacted]	2016	Persistent foam and dilution stability of several glyphosate formulations. Report No.: MSL0027646 Document No.: - Monsanto Antwerp laboratory GLP/GEP: N Published: N	N	N	-	BCS	N
KCP 2.8.4-001	[redacted]	2001	Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature Report No.: MSL-17439 Document No.: - Monsanto Europe S.A. GLP/GEP: Y Published: N	N	N	-	GTF	Y RAR 2017: IIIA 2.7.3

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCP 2.8.4-004	[redacted]	2016	Persistent foam and dilution stability of several glyphosate formulations. Report No.: MSL0027646 Document No.: - Monsanto Antwerp laboratory GLP/GEP: N Published: N	N	N	-	BCS	N
KCP 2.9-001	[redacted]	2012	MON 52276 – Tank Mix Compatibility with Commercially Available Herbicides Report No.: MSL0024054 Document No.: - Monsanto Europe S.A. GLP/GEP: N Published: N	N	N	-	BCS	N

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.
[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013
[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).