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.4 (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.4. FURTHER INFORMATION

B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

Not relevant.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

HANDLING AND STORAGE

Good industrial practice in housekeeping and personal hygiene should be followed.

Precautions for safe handling	When using do not eat, drink or smoke. Wash hands thoroughly after handling or contact. Wash contaminated clothing before re-use. Thoroughly clean equipment after use. Do not contaminate drains, sewers and water ways when disposing of equipment rinse water. Emptied containers retain vapour and product residue. FOLLOW LABELLED WARNINGS EVEN AFTER CONTAINER IS EMPTIED.
Conditions for safe storage provided by the applicant	Minimum storage temperature: -15 °C Maximum storage temperature: 50 °C Keep out of reach of children. Keep away from food, drink and animal feed. Keep only in the original container. Partial crystallization may occur on prolonged storage below the minimum storage temperature. If frozen, place in warm room and shake frequently to put back into solution. Minimum shelf life: 5 years. This formulation can be stored for 2 to 3 weeks at temperatures colder than -20°C without impact. If the temperature remains below -20°C for longer, the water phase of the formulation may freeze. Should this occur allow the product to warm and it will return to its original homogeneous state. We recommend that customers follow the typical use instructions which state that the container should be agitated (shaken) prior to pouring.
Conditions for safe storage resulting from the assessment	Shelf life: 5 years Minimum storage temperature: 0 °C Maximum storage temperature: 54 °C

TRANSPORT

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

ADR/RID	
UN No.:	Not applicable.
Proper Shipping Name (Technical Name if required):	Not regulated for transport under ADR/RID Regulations.
Transport hazard class:	Not applicable.
Packing Group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for the user:	Not applicable.

IMO

UN No.:	Not applicable.
Proper Shipping Name (Technical Name if required):	Not regulated for transport under IMO Regulations.
Transport hazard class:	Not applicable.
Packing Group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for the user:	Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

IATA/ICAO

UN No.:	Not applicable.
Proper Shipping Name (Technical Name if required):	Not regulated for transport under IATA/ICAO Regulations.
Transport hazard class:	Not applicable.
Packing Group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for the user:	Not applicable.

FIRE-FIGHTING MEASURES

Recommended extinguishing media	Water, foam, dry chemical, carbon dioxide (CO_2)
Special hazards:	
Unusual fire and explosion hazards	Minimise use of water to prevent environmental contamination.
Hazardous products of combustion	Carbon monoxide (CO), phosphorus oxides (P_xO_y), nitrogen oxides (NO_x)
Advice for firefighters	Self-contained breathing apparatus. Equipment should be thoroughly decontaminated after use.
Flash point	Does not flash.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls	No special requirement when used as recommended.
Recommendations for personal protective equipment	
Eye protection:	No special requirement when used as recommended.
Skin protection:	If repeated or prolonged contact: Wear chemical resistant gloves. Chemical resistant gloves include those made of waterproof materials such as nitrile, butyl, neoprene, polyvinyl chloride (PVC), natural rubber and/or barrier laminate.
Respiratory protection:	No special requirement when used as recommended.

When recommended, consult manufacturer of personal protective equipment for the appropriate type of equipment for a given application.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

a) Personal precautions

Use personal protection as recommended in CP 4.2.

b) Methods for cleaning up

SMALL QUANTITIES: Flush spill area with water.

LARGE QUANTITIES: Absorb in earth, sand or absorbent material. Dig up heavily contaminated soil. Collect in containers for disposal. Flush residues with small quantities of water. Minimise use of water to prevent environmental contamination.

c) Methods for cleaning up

Place leaking containers in oversize leakproof drums for transport.
SMALL QUANTITIES: Flush spill area with water.
LARGE QUANTITIES: Absorb in earth, sand or absorbent material. Dig up heavily contaminated soil. Collect in containers for disposal. Flush residues with small quantities of water. Minimise use of water to prevent environmental contamination.

d) Protection of emergency workers and residents, including bystanders

For details on protective equipment please refer to CP 4.2.

e) First aid measures

Description of first aid measures

Eye contact	Immediately flush with plenty of water. Continue for at least 15 minutes. If easy to do, remove contact lenses.
Skin contact	Take off contaminated clothing, wristwatch, and jewellery. Wash affected skin with plenty of water. Wash clothes and clean shoes before re-use.
Inhalation	Remove to fresh air.
Ingestion	Immediately offer water to drink. Never give anything by mouth to an unconscious person. Do NOT induce vomiting unless directed by medical personnel. If symptoms occur, get medical attention.

Most important symptoms and effects, both acute and delayed

Potential health effects	Likely routes of exposure: Skin contact, eye contact Eye contact, short term: Not expected to produce significant adverse effects when recommended use instructions are followed. Skin contact, short term: Not expected to produce significant adverse effects when recommended use instructions are followed. Inhalation, short term: Not expected to produce significant adverse effects when recommended use instructions are followed.

Indication of any immediate medical attention and special treatment needed

Advice to doctors	This product is not an inhibitor of cholinesterase.
Antidote	Treatment with atropine and oximes is not indicated.

B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

Table 4.4-1: Packaging information for 500 mL FlexFlo

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 98 x 47 x 207 mm
Nominal volume:	500 mL
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	60 g
Opening:	38 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	4.5 g
UN/ADR	Compliant

Table 4.4-2: Packaging information for 1 L FlexFlo

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 125 x 60 x 248 mm
Nominal volume:	1 L
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	100 g
Opening:	38 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	4.5 g
UN/ADR	Compliant

Table 4.4-3: Packaging information for 1 L RWP

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Round / 90 x 234 mm **(**Ø x H)
Nominal volume:	1 L
Wall thickness:	0.9 – 1.2 mm (variable)
Empty weight:	71 g
Opening:	63 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Blow moulded
Weight of the closure:	17.5 g
UN/ADR	Compliant

Table 4.4-4: Packaging information for 1 L RWPH

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Round / 90 x 234 mm **(**Ø x H)
Nominal volume:	1 L
Wall thickness:	1.3 – 1.8 mm (variable)
Empty weight:	100 g
Opening:	63 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	17.5 g
UN/ADR	Compliant

Table 4.4-5: Packaging information for 2 L AGFLO

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 158 x 91 x 248 mm
Nominal volume:	2 L
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	140 g
Opening:	38 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	4.5 g
UN/ADR	Compliant

Table 4.4-6: Packaging information for 5 L AGFLO

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 221 x 107 x 327 mm
Nominal volume:	5 L
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	260 g
Opening:	63 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	17.5 g
UN/ADR	Compliant

Table 4.4-7: Packaging information for 5 L AGRI

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 193 x 142 x 305 mm
Nominal volume:	5 L
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	240 g
Opening:	63 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	17.5 g
UN/ADR	Compliant

Table 4.4-8: Packaging information for 5 L AGCO

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 221 x 107 x 327 mm
Nominal volume:	5 L
Wall thickness:	1.0 – 1.5 mm (variable)
Empty weight:	230 g
Opening:	63 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(induction) seal
Manner of construction	Injection moulded
Weight of the closure:	17.5 g
UN/ADR	Compliant

Table 4.4-9: Packaging information for 15 L MONAGL

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 291 x 236 x 339 mm
Nominal volume:	15 L
Wall thickness:	1.5 – 3.5 mm (variable)
Empty weight:	1000 g
Opening:	61 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(foam) seal
Manner of construction	Injection moulded
Weight of the closure:	32 g
UN/ADR	Compliant

Table 4.4-10: Packaging information for 20 L MONAGL

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 293 x 236 x 428 mm
Nominal volume:	20 L
Wall thickness:	1.5 – 3.5 mm (variable)
Empty weight:	1120 g
Opening:	61 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(foam) seal
Manner of construction	Injection moulded
Weight of the closure:	32 g
UN/ADR	Compliant

Table 4.4-11: Packaging information for 20 L MONU

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Rectangular / 293 x 236 x 428 mm
Nominal volume:	20 L
Wall thickness:	1.5 – 3.5 mm (variable)
Empty weight:	1120 g
Opening:	61 mm diameter
Closure:	HDPE (tamper evident) screw cap
Seal:	(foam) seal
Manner of construction	Injection moulded
Weight of the closure:	32 g
UN/ADR	Compliant

Table 4.4-12: Packaging information for 220 L WVH

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Round / 581 x 940 mm **(**Ø x H)
Nominal volume:	200 L
Wall thickness:	3.5 – 7 mm (variable)
Empty weight:	8500 g
Opening:	56 mm diameter
Closure:	PP bung
Seal:	PE O-ring
Manner of construction	Injection moulded
Weight of the closure:	29 g
UN/ADR	Compliant

Table 4.4-13: Packaging information for 220 L WV

Type	Description
Material:	HDPE
Manner of construction	Blow moulded
Shape/size:	Round / 581 x 940 mm **(**Ø x H)
Nominal volume:	200 L
Wall thickness:	3.5 – 7 mm (variable)
Empty weight:	8500 g
Opening:	56 mm diameter
Closure:	PP bung
Seal:	PE O-ring
Manner of construction	Injection moulded
Weight of the closure:	29 g
UN/ADR	Compliant

Table 4.4-14: Packaging information for IBC

Type	Description
Material:	HDPE + metal cage + pallet
Manner of construction	Blow moulded
Shape/size:	Rectangular / 1200 x 800 x 1000 mm
Nominal volume:	640 L
Wall thickness:	2 – 6 mm (variable)
Empty weight:	48000 g
Opening:	DN150 mm
Closure:	HDPE screw cap
Seal:	PE O-ring
Manner of construction	Injection moulded
Weight of the closure:	225 g
UN/ADR	Compliant

Table 4.4-15: Packaging information for IBC

Type	Description
Material:	HDPE + metal cage + pallet
Manner of construction	Blow moulded
Shape/size:	Rectangular / 1200 x 1000 x 1160 mm
Nominal volume:	1000 L
Wall thickness:	2 – 6 mm (variable)
Empty weight:	67000 g
Opening:	DN150 mm
Closure:	HDPE screw cap
Seal:	PE O-ring
Manner of construction	Injection moulded
Weight of the closure:	225 g
UN/ADR	Compliant

During the evaluation of physical and chemical properties and storage stability ([redacted] 2001, KCP 2.7/001 and KCP 2.7/006), 1-litre HDPE commercial packs were used.
At the start of the test, after 14 days accelerated storage and after 2 years storage, the packaging material showed no deterioration, had not been altered by the test item and there were no signs of contamination on the outer surface or of leakage during shaking or turning. This small pack is constructed of the same material (HDPE) as the larger packs and is considered representative of the complete range.
The data on recorded pack weights and observations presented in [redacted] 2001 relevant to the suitability and resistance of the packaging was summarized in [redacted] 2012 (KCP 4.4/001).

Further studies with MON 52276 in 20-litre HDPE containers have also been conducted to evaluate its rinsing efficiency.
This study confirms that the rinsing of the 20-litre container, when executed according to the recommended cleaning instructions at a working pressure of 4 bar during 30 seconds, meets the requirements of the CIPAC norm, giving a limit of 0.01% for the remaining product. All rinsing experiments, executed by moving the vessel up and down in a leaning position at a working pressure of only 2.0 bar, result in a rinsing efficiency of >99.99% even after 15 seconds. Less rinsing efficiency will be obtained when the vessel is kept in a static position with the opening close to the base of the rinsing device, avoiding optimal draining of the container during the rinsing procedure.
The results are summarized in [redacted] 2001 (see study report KCP 4.4/002).

All the containers listed above are UN approved for substances which are non-classified. MON 52276 is not classified for transport following ADR regulations.

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

Waste treatment methods

Product

Follow all local/regional/national/international regulations on waste disposal. Follow current edition of the General Waste, Landfill, and Burning of Hazardous Waste Directives and the Shipment of Waste Regulation. According to the manufacturer self-classification, following Regulation (EC) No. 1272/2008 [CLP], the product can be disposed as a non-hazardous industrial waste. Disposal in an industrial waste incinerator with energy recovery is recommended. Keep out of drains, sewers, ditches and water ways.

Container
Follow all local/regional/national/international regulations on waste disposal, packaging waste collection/disposal. Follow current edition of the General Waste, Landfill, and Burning of Hazardous Waste Directives and the Shipment of Waste Regulation. Do NOT re-use containers. Pour rinse water into spray tank. Properly rinsed container can be disposed as a non hazardous industrial waste. Store for collection by approved waste disposal service. Recycle if appropriate facilities/equipment available. Recycle the non-hazardous container only when a proper control on the end use of the recycled plastic is possible. Suitable for industrial grade recycling only. Do NOT recycle plastic that could end in any human or food contact application. This package meets the requirements for energy recovery. Disposal in an incinerator with energy recovery is recommended. Triple or pressure rinse empty containers.

B.4.5.1. Neutralisation procedure

Methods for cleaning up:

Place leaking containers in oversize leakproof drums for transport. SMALL QUANTITIES: Flush spill area with water. LARGE QUANTITIES: Absorb in earth, sand or absorbent material. Dig up heavily contaminated soil. Collect in containers for disposal. Flush residues with small quantities of water. Minimise use of water to prevent environmental contamination.

B.4.5.2. Controlled incineration

Follow all local/regional/national/international regulations on waste disposal, packaging waste collection/disposal. Follow current edition of the General Waste, Landfill, and Burning of Hazardous Waste Directives and the Shipment of Waste Regulation. Do NOT re-use containers. Pour rinse water into spray tank. Properly rinsed container can be disposed as a non hazardous industrial waste. Store for collection by approved waste disposal service. Recycle if appropriate facilities/equipment available. Recycle the non-hazardous container only when a proper control on the end use of the recycled plastic is possible. Suitable for industrial grade recycling only. Do NOT recycle plastic that could end in any human or food contact application. This package meets the requirements for energy recovery. Disposal in an incinerator with energy recovery is recommended. Triple or pressure rinse empty containers.

B.4.6. 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 4.4-001	[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: IIIA 4.1
KCP 4.4-002	[redacted]	2001	Pressure rinsing of the 20L MONAGL container according to the CEN directive EN 12761-3:2001 Report No.: MPW 1066 Document No.: - Monsanto Antwerp GLP/GEP: N Published: N	N	N	-	GTF	Y RAR 2017: IIIA 4.2

[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).