

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: **ORKAN 350 SL**

Product names: **ORKAN 350 SL, SPRINTER 350 SL**

Chemical active substance(s):

MCPA, 90 g/L

Glyphosate, 260 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(renewal of authorisation)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: **04.2020**

MS Finalisation date: **09.2020; 11.2021**

Version history

When	What
09/2020	RMS finalised dRR assessment
11/2021	Evaluation after commenting period - RR

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1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Synthos Agro Sp. z o.o
Address: ul. Chemików 1
32-600 Oświęcim

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Glyphosate

Glyphosate	min. 950 g/kg
Formaldehyde	max. 1.3 g/kg
N-Nitrosoglyphosate	max. 1 mg/kg

1.2.3.2 MCPA

MCPA	min. 930 g/kg
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1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)
Trade name: Orkan 350 SL, Sprinter 350 SL
Company code number: Orkan 350 SL

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Glyphosate	260 g/L	247.0 – 273.0 g/L	273,7 g/L	23,9 % w/w
MCPA	90 g/L	86.4 – 93.6 g/L	96,8 g/L	8,5 % w/w

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.143 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Formaldehyde	1.3 g/kg
N-Nitrosoglyphosate	1 mg/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Glyphosate

Type	Name/Code Number
ISO common name	Glyphosate
CAS No.	1071-83-6
EC No.	213-997-4
CIPAC No.	0284

Table 1.4-4: Information on MCPA

Type	Name/Code Number
ISO common name	MCPA
CAS No.	94-74-6
EC No.	202-360-6
CIPAC No.	2

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: SL (Soluble concentrate)

[Code: SL]

1.6 Function (KCP 1.6)

Herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of clear straw homogenous liquid, with a slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 5.07 at 20 °C. 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 nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a *Soluble concentrate* formulation.

The intended concentration of use is 1.66% to 2.66%.

According to article 43 of the regulation 1107/2009 during this assessment only additional studies were assessed:

- surface tension determined at the highest in-use spray concentration (2.66%)
- persistence of foaming determined at the highest in-use spray concentration (2.66%)
- degree of dissolution and dilution stability determined at the highest in-use spray concentration (2.66%)
- the content of the relevant impurities in the initial formulation, in the formulation after accelerated storage and 1 year storage at ambient temperature

which were all accepted.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Classification

Eye Irrit. 2 ————— H319: Causes serious eye irritation
Aquatic Chronic 1 ————— H410: Very toxic to aquatic life with long lasting effects

Labelling

Pictograms:
GHS 07 — Exclamation mark
GHS 09 — Environment

Signal words:
Warning

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Hazard Statements:

H319: Causes serious eye irritation
H410: Very toxic to aquatic life with long lasting effects
EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary Statements:

Prevention:

P264 — Wash hands thoroughly after handling.
P273 — Avoid release to the environment.
P280 — Wear protective gloves/protective clothing/eye protection/face protection.

Response:

~~P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.~~
~~P337 + P313 – If eye irritation persists: Get medical advice/attention.~~
~~P391 – Collect spillage.~~

Disposal:

~~P501 – Dispose of contents/container to an approved waste disposal plant.~~

Compliance with FAO specifications:

The are no FAO specification for mixture of Glyphosate and MCPA in the SL form.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	According to Pharmacopoea Polish Edition, VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6302 to 04	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	Clear straw homogenous liquid, with a slight characteristic odour.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Explosive properties (KCP 2.2.1)	Not applicable. Orkan 350 SL is a product which contains about 45% of water. Ingredients included in the product do not have explosives properties. Furthermore, based on the thermodynamic properties of the product there is no concern of exothermic reactions. According to above there is no necessity to conduct such analysis.					The study was assessed during first authorisation.
Oxidizing properties (KCP 2.2.2)	Not applicable. Orkan 350 SL is a product which contains about 45% of water. Ingredients included in the product do not have explosives properties. Furthermore, based on the thermodynamic properties of the product there is no concern of exothermic reactions with flammable materials. According to above there is no necessity to conduct such analysis.					The study was assessed during first authorisation.
Flash point (KCP 2.3.1)	Not applicable. Orkan 350 SL is a product which contains about 45% of water. The product doesn't contain flammable solvents thus there is no necessity to conduct such analysis.					The study was assessed during first authorisation.
Flammability (KCP 2.3.2)	Not applicable. This analysis is conducted for solid or gas stage products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis. Furthermore, ingredients in this product are not flammable.					The study was assessed during first authorisation.
Self-heating (KCP 2.3.3)	Not applicable. Orkan 350 SL is a product which contains about 45% of water. The product doesn't contain flammable ingredients thus there is no necessity to conduct such analysis.					The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)	Not applicable. This analysis is conducted for plant protection products which are acidic (pH < 4) or alkaline (pH > 10). pH of Orkan 350 SL is between 4 to 10 thus there is no necessity to conduct such analysis.					
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	5.07	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Viscosity (KCP 2.5.1)	OECD 114	Orkan 350 SL; Batch No.: 4/2016 Production date: 05.2016	The kinetic viscosity at 20°C equals 70.9 mm ² /s The kinetic viscosity at 40°C equals 28.1 mm ² /s		Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-63/16; Warsaw; 2016	The study was assessed during first authorisation.
Surface tension (KCP 2.5.2)	EEC A5	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date:	34,1 mN/m in 25°C	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		08.2009				
Surface tension of 2.66% solution (KCP 2.5.2)	EEC A5	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 07N Production date: 04.2018	35,14 mN/m in 20°C	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-63/18, Warsaw, 2018	The surface tension was determined at the highest in-use spray concentration (2.66%). Accepted.
Relative density (KCP 2.6.1)	EEC A3	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	1,143 in 20°C	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Bulk density (KCP 2.6.2)	Not applicable. This analysis is conducted for solid state and granule plant protection products. Orkan 350 SL is a liquid form thus there is no necessity to conduct such analysis.					
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Orkan 350 SL; 91,5 g/l MCPA and 260,8	Orkan 350 SL is stable during storage for 2 weeks in 54°C. The product separated into two layers: the upper layer 80% and lower 20% but after mixing the liquid was clear straw homogenous liquid, with a slight	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		g/l Glyphosate Batch No.: 4 Production date: 08.2009	characteristic odour. Determined parameters as active substance content, pH, density, stability of solution in water CIPAC C were in acceptable range.			
	HPLC	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 07N Production date: 04.2018	<u>Initial sample:</u> Relevant impurities in the formulation: Formaldehyde: <LOQ NNG: <LOQ <u>After the accelerate storage:</u> Relevant impurities in the formulation: Formaldehyde: <LOQ NNG: 0.000008 mg/ml %	Y	Ewa Jolanta Gwoźdź, Eng., Institute of Industrial Organic Chemistry; BA-82/18; 2018	The relevant impurities content in the formulation should be lower than ~0.026% for formaldehyde and lower than ~0.00002% for NNG. LOQ for formaldehyde =0.0008% LOQ for NNG =0.000004% Accepted.
Storage Stability after one year at 20° C (KCP 2.7.2)	Procedure SPO/BF/07/b, based on CropLife International Technical Monograph No 17	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 07N Production date: 04.2018	Orkan 350 SL is stable during storage for one year. The storage temperature varied between 18.1 ° C and 21.8 ° C. The relevant impurities content in the formulation after 1 year of storage: Formaldehyde: <LOQ NNG: <LOQ	Y	Enzo Arevalo, Ph.D., Institute of Industrial Organic Chemistry; BF-63-18; Warsaw; 2019	The study evaluated only the content of relevant impurities after 1 year of storage. Accepted.
Stability after storage for other periods and/or temperatures	Not applicable. Orkan 350 SL is stable during storage for 2 weeks in 54°C thus there is no need to conduct analysis in other period of time or temperature.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46.3	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	The initial content of active substances is 7.96% of MCPA and 22.66% of glyphosate. The content of active substances after storage for 2 weeks in 54°C were: 7.98% of MCPA and 22.47% of glyphosate. The content of active substances were in acceptable range.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	Orkan 350 SL is stable during storage for 7 days in 0 °C. No changes in appearance of product were noticed.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Ambient temperature shelf life (KCP 2.7.5)	Visual inspection	Orkan 350 SL; Batch No.: 07N Production date: 04.2018	After the first year: homogenous straw-colored liquid of characteristic odour of characteristic odour After the second year: homogenous straw-colored liquid of characteristic odour of characteristic odour	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009 and	The study was assessed during first authorisation.
	HPLC		<u>After the first year:</u> Active substances content:			The content of relevant impurities after 1 year

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		And Batch No.: 4 Production date: 15.06.2009	<p>Glyphosate 22.86% (261.29 g/l) MCPA 7.95% (90.87 g/l)</p> <p>Relevant impurities in the preparation : NNG: <LOQ Formaldehyde: 0.00027 mg/ml <LOQ</p> <p><u>After the second year:</u> Active substances content: Glyphosate 22.27% (254.55 g/l) MCPA 7.72% (88.24 g/l)</p> <p>Relevant impurities: NNG: study ongoing Formaldehyde: study ongoing</p>		Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-63/18; Warsaw; 2019	of storage did not change. Accepted.
	CIPAC MT 75.2		<p><u>After the first year:</u> pH Determination of 1%: 5.14</p> <p><u>After the second year:</u> pH Determination of 1%: 5.28</p>			The study was assessed during first authorisation.
	CIPAC MT 39.3		<p>Stability at 0°C <u>After the first year:</u> Homogenous liquid</p> <p><u>After the second year:</u> pH Determination of 1%: Homogenous liquid</p>			The study was assessed during first authorisation.
	GIFAP No.17		<p><u>After the first year:</u> Package evaluation: Stable, white cylindrical HDPE</p>			The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			bottles <u>After the first year:</u> Package evaluation: Stable, white cylindrical HDPE bottles			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. Proposed expiration date is two years.					
Wettability (KCP 2.8.1)	Not applicable. This analysis is conducted for plant protection products which are diluted for use. Orkan 350 SL Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	Foam stability of 1% water solution of Orkan 350 SL (in CIPAC C water) are as follows: After 10 sec. – 29 ml of foam After 1 min. – 26 ml of foam After 3 min. – 22 ml of foam After 12 min. – 12 ml of foam	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Persistence of foaming of 2,66% solution (KCP 2.8.2)	CIPAC MT 47.3	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 07N	2,66% CIPAC D water solution of the preparation formed the following foam volumes: After 1 min – 40 45 ml of foam After 12 min – 3 ml of foam	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-63/18, Warsaw, 2018	The persistence of foaming was determined at the highest in-use spray concentration (2.66%). The MT 47.3 recommends CIPAC C water. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Production date: 04.2018				
Suspensibility (KCP 2.8.3.1)	Not applicable. This analysis is conducted for water dispersible plant protection products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable. This analysis is conducted for water dispersible plant protection products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Dispersion stability (KCP 2.8.3.3)	Not applicable. This analysis is conducted for water dispersible plant protection products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 4 Production date: 08.2009	Directly after preparation and after 18 hours the 5 % water solution was completely clear and homogenous liquid.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2009	The study was assessed during first authorisation.
Degree of dissolution and dilution stability of 2,66% solution (KCP 2.8.4)	CIPAC MT 41.1	Orkan 350 SL; 91,5 g/l MCPA and 260,8 g/l Glyphosate Batch No.: 07N	Immediately after preparation the solution and after storage of 24 hours at 30 °C the 2,66% solution was transparent and homogenous liquid.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-63/18, Warsaw, 2018	The degree of dissolution and dilution stability was determined at the highest in-use spray concentration (2.66%). CIPAC Water D was used. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Production date: 04.2018				
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not applicable. This analysis is conducted for powdery plant protection products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Wet sieve test (KCP 2.8.5.1.2)	Not applicable. This analysis is conducted for water dispersible plant protection products. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Dust content (KCP 2.8.5.2.1)	Not applicable. Orkan 350 SL is not in the form of granules. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Particle size of dust (KCP 2.8.5.2.2)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Attrition (KCP 2.8.5.3)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Hardness and integrity (KCP 2.8.5.4)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Emulsifiability (KCP 2.8.6.1)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) which is not an emulsion thus there is no necessity to conduct such analysis.					
Emulsion stability (KCP 2.8.6.2)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) which is not an emulsion thus there is no necessity to conduct such analysis.					
Re-emulsifiability (KCP 2.8.6.3)	Not applicable. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) which is not an emulsion thus there is no necessity to conduct such analysis.					
Flowability (KCP 2.8.7.1)	Not applicable. This analysis is conducted for plant protection products in the form of granules. Orkan 350 SL is a liquid concentrate intended to					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Pourability (KCP 2.8.7.2)	Not applicable. This analysis is conducted for plant protection products in the form of suspensions. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis.					
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable. This analysis is conducted for plant protection products in powder form. Orkan 350 SL is a liquid concentrate intended to prepare water solution (SL) thus there is no necessity to conduct such analysis					
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. Orkan 350 SL is not recommended to use together with other products.					
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. Orkan 350 SL is not recommended to use together with other products.					
Adhesion to seeds (KCP 2.10.1)	Not applicable. This analysis is conducted for preparations intended for seed treatment. Orkan 350 SL is not a product for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not applicable. This analysis is conducted for preparations intended for seed treatment. Orkan 350 SL is not a product for seed treatment.					
Other/special studies (KCP 2.11)	According to brochure “Dobra praktyka postępowania przy stosowaniu środków ochrony roślin” issued by Research Institute of Horticulture (Instytut Ogrodnictwa, Skierniewice 2014, ISBN 978-83-89800-63-3)	Orkan 350 SL Batch No.: 15N	Residues of active substances in the tank after the cleaning procedure corresponded to <0.3% of the initial concentration in spray liquid. Considering the results, cleaning of the spray equipment with water is considered adequate and no adverse effect would be expected.	N	Piotr Paleń; Synthos Agro Sp. z o.o.; AGRO/20/18; Oświęcim; October 2018	Accepted.

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

All detailed specifications of below packaging have already been submitted.

The product is packed as follows:

50 ml HDPE container

75, 100, 150, 250, 300, 500, 1000 ml HDPE bottles

5, 10,20, 30 l HDPE canisters

220 l drums

75/6 ml double chamber HDPE container

250/10 ml double chamber HDPE container

1000/25 ml double chamber HDPE container

Table 4.1-1: Packaging information for 50 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 37,5 mm diameter x 85 mm
Opening:	13 mm inner diameter
Closure:	polyethylene screw cap with tamper evident band
Seal:	PE liner
Manner of construction	Extruded

Table 4.1-2: Packaging information for 75 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 51,5 mm \pm 0,6 mm diameter x 75,4 mm \pm 0,6 mm
Opening:	30,6 mm \pm 0,6 mm inner diameter
Closure:	polyethylene screw cap with tamper evident band
Seal:	PE liner
Manner of construction	Extruded with blow molding

Table 4.1-3: Packaging information for double neck 75/6 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	approx. 78,8 mm diameter x 87,5 mm
Opening:	18 mm inner diameter
Closure:	polyethylene screw cap
Seal:	PE liner
Manner of construction	Extruded

Table 4.1-4: Packaging information for 100 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 45 mm \pm 0,5 mm diameter x 88 mm \pm 0,5 mm
Opening:	30,5 mm \pm 0,2 mm inner diameter
Closure:	polyethylene “child proof” screw cap
Seal:	Induction sealing
Manner of construction	Extruded with blow molding

Table 4.1-5: Packaging information for 150 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 56 mm \pm 0.6 mm diameter x 108 mm \pm 0.6 mm
Opening:	30.6 mm \pm 0.6 mm inner diameter
Closure:	polyethylene screw cap with tamper evident band
Seal:	PE liner
Manner of construction	Extruded with blow molding

Table 4.1-6: Packaging information for 250 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	1) cylindrical / approx. 63 mm \pm 1 mm diameter x 110.7 mm \pm 1 mm 2) cylindrical / approx. 63.6 mm \pm 0.6 mm diameter x 121.8 mm \pm 0.6 mm
Opening:	1) 30.5 mm \pm 0.2 mm inner diameter 2) 30.6 mm inner diameter
Closure:	1) polyethylene “child proof” screw cap 2) polyethylene screw cap with tamper evident band
Seal:	1) Induction sealing 2) PE liner
Manner of construction	Extruded with blow molding

Table 4.1-7: Packaging information for double neck 250/10 ml bottle

Type	Description
Material:	PE-HD
Opening:	18,5 mm inner diameter
Closure:	Thermosetting polymer screw cap
Seal:	With liner
Manner of construction	extruded

Table 4.1-8: Packaging information for 300 ml bottle

Type	Description
Material:	PE-HD

Type	Description
Shape/size:	cylindrical / approx. 63 mm \pm 1.5% diameter x 142.1 mm \pm 0.5 %
Opening:	32.5 mm inner diameter
Closure:	polyethylene “child proof” screw cap

Table 4.1-9: Packaging information for 500 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 65 mm \pm 1.5% diameter x 221 mm \pm 0.5%
Opening:	32 mm inner diameter
Closure:	polyethylene “child proof” screw cap

Table 4.1-10: Packaging information for 1 l bottle

Type	Description
Material:	PE-HD
Shape/size:	1) cylindrical / approx. 88.5 mm diameter x 234 mm 2) cylindrical / approx. 88.5 mm \pm 1 mm diameter x 231 mm \pm 2 mm
Opening:	1) 40 mm inner diameter 2) 40 mm \pm 1 mm inner diameter
Closure:	polyethylene screw cap
Seal:	1) Induction sealing 2) With liner
Manner of construction	Extruded with blow molding

Table 4.1-11: Packaging information for double neck 1 l/ 25 ml bottle

Type	Description
Material:	PE-HD
Shape/size:	approx. 136 mm diameter x 257 mm
Opening:	22 mm inner diameter
Closure:	Thermosetting polymer screw cap with tamper evident band
Seal:	With liner
Manner of construction	extruded

Table 4.1-12: Packaging information for 5 liter canister

Type	Description
Material:	PE-HD or PE-HD + PE-LD
Shape/size:	canister / approx. 186 mm \pm 1.5 mm diameter x 329 mm \pm 2.5 mm
Opening:	54 mm \pm 0.3 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction sealing
Manner of construction	Extruded with blow molding

Table 4.1-13: Packaging information for 10 liter canister

Type	Description
Material:	PE-HD or PE-HD + PE-LD
Shape/size:	canister / approx. 230 mm ± 3 mm diameter x 375 mm ± 3 mm
Opening:	54 mm ± 0.3 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction sealing
Manner of construction	Extruded with blow molding

Table 4.1-14: Packaging information for 20 liter canister

Type	Description
Material:	PE-HD
Shape/size:	canister / approx. 300 mm ± 3 mm diameter x 400 mm ± 4 mm
Opening:	47.5 mm ± 0.3 mm inner diameter
Closure:	polyethylene screw cap
Manner of construction	extruded

Table 4.1-15: Packaging information for 30 liter canister

Type	Description
Material:	PE-HD
Shape/size:	canister / approx. 382 mm ± 3 mm diameter x 383 mm ± 4 mm
Opening:	47.5 mm ± 0.3 mm inner diameter
Closure:	polyethylene screw cap
Manner of construction	extruded

Table 4.1-16: Packaging information for 200 liter drum with cover

Type	Description
Material:	Steel
Shape/size:	cylindrical / approx. 585 mm diameter x 877 mm ± 3 mm

Table 4.1-17: Packaging information for 200 liter drum with unremoved cover

Type	Description
Material:	Steel
Shape/size:	cylindrical / approx. 585 mm diameter x 880 mm ± 3 mm

Table 4.1-18: Packaging information for 200 liter drum with cork

Type	Description
Material:	PE-HD
Shape/size:	cylindrical / approx. 581 mm diameter x 935 mm

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.4.2	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.1	Idris Al Amin, Ph.D.	2016	Orkan 350 SL Determination of viscosity Institute of Industrial Organic Chemistry; BF-63/16; Warsaw; 2016 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.2	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.5.2	Idris Al Amin, Ph.D.	2018	Orkan 350 SL – Part I: Determination physicochemical properties of the initial preparation. Institute of Industrial Organic Chemistry; Study No.: BF-63/18 Warsaw; 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.6.1	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.1	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.1	Ewa Jolanta Gwoźdź, Eng.	2018	Orkan 350 SL- Development and validation of the methods for determination of the relevant impurities (formaldehyde and N-nitrosoglyphosate) content in the formulation and after accelerated storage. Institute of Industrial Organic Chemistry; Study No.: BA-82/18; Warsaw; 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.2.	Enzo Arevalo, Ph.D.	2019	Orkan 350 SL – Part II: Determination of relevant impurities content after one year of storage. Institute of Industrial Organic Chemistry; Study No.: BF-63/18; Warsaw; 2019 GLP	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 2.7.3	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.4	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Idris Al Amin, Ph.D.	2011	Orkan 350 SL Etap III: Oznaczanie właściwości fizykochemicznych po drugim roku składowania Institute of Industrial Organic Chemistry; BF-08/09; Warsaw; 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.2	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.2	Idris Al Amin, Ph.D.	2018	Orkan 350 SL – Part I: Determination physicochemical properties of the initial preparation. Institute of Industrial Organic Chemistry; Study No.: BF-63/18 Warsaw; 2018 GLP	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 2.8.4	Idris Al Amin, Ph.D.	2009	Orkan 350 SL – Stage I: Determination of physicochemical properties of the initial preparation Institute of Industrial Organic Chemistry; Study No.: BF-08/09; Warsaw; 2009 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.4	Idris Al Amin, Ph.D.	2018	Orkan 350 SL – Part I: Determination physicochemical properties of the initial preparation. Institute of Industrial Organic Chemistry; Study No.: BF-63/18 Warsaw; 2018 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.11	Piotr Paleń, M. Sc.	2018	Orkan 350 SL Effectiveness of the equipment cleaning procedure Piotr Paleń Synthos Agro Sp. z o.o.; AGRO/20/18; Oświęcim; October 2018 Non GLP Unpublished	N	Synthos Agro Sp. z o.o.

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Glyphosate

No new or additional data. Glyphosate

A 2.2 MCPA

No new or additional data.