

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: -

Product name: Repentol 6 PA/ Repentol 6 PA Bis

Chemical active substance:

quartz sand, 300 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization, renewal of authorisation)

Applicant: DCR ~~Sp. z o.o.~~ S.A.

Submission date: 27/11/2023, 17/07/2024

MS Finalisation date: 05/2025; 09/2025

Version history

When	What
27/11/2023	Update of dRR/RR including name of applicant, classification, extension of authorisation for non-professional uses, minor uses extension, dose reduction and label extension, change of packaging. Details in Part B0 point 0.1.
27/11/2023	Update of dRR/RR for renewal of PPP authorisation acc. to Art. 43 Reg. 1107/2023.
17/07/2024	Update of renewal dRR/RR after applicant's name change.
05/2025	zRMS assessment of dRR
09/2025	The final Registration Report

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1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: DCR **Sp. z o.o. S.A.**
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Poland
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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

According to Reg. 540/2011:

Purity of quartz sand min. 915 g/kg (acc. to Reg. 540/2011)

According to EFSA, 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. EFSA Journal 2022;20(9):7552, the impurity crystalline silica with a particle diameter $\leq 10 \mu\text{m}$ is of toxicological concern and shall not exceed a level of 0.1 % of particles in the technical material.

Information of quartz sand produced by DCR **Sp. z o.o. S.A.** is confidential information and is provided separately (Part C).

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Repentol 6 PA/ Repentol 6 PA Bis
Company code number: -

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 (g/kg)	FAO Limits (min – max)	Technical content* (g/kg)	Technical content* (%w/w)
quartz sand	300	Not relevant. 285.00 – 315.00	303	30.3

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

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content* (%w/w)
Not relevant.	Not relevant.	Not relevant.	Not relevant.	Not relevant.

* Based on the minimum purity of the safener/synergist declared for registration

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not relevant. crystalline silica with a particle diameter $\leq 10 \mu\text{m}$	Not relevant. Max. 0.1% w/w in technical material Max. 0.3 g/kg in formulation

In accordance with EFSA Journal 2022;20(9):7552 The requirement for methods of analysis for monitoring the respirable crystalline silica with a particle diameter $\leq 10 \mu\text{m}$ in formulations has been waived due to negligible inhalation exposure predicted for the proposed uses.

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

Table 1.4-4: Information on quartz sand

Type	Name/Code Number
ISO common name	Quartz sand (no ISO name)
CAS No.	14808-60-7
EC No.	238-878-4
CIPAC No.	855

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

Table 1.4-5: Information on safeners/ synergists / co-formulants

Type	Name/Code Number
Safeners and synergists	
Safener /synergist	Not relevant.
ISO common name	Not relevant.
CAS No.	Not relevant.
EC No.	Not relevant.
Co-formulants	
Safener /synergist	CONFIDENTIAL information is provided separately (Part C).
ISO common name	CONFIDENTIAL information is provided separately (Part C).
CAS No.	CONFIDENTIAL information is provided separately (Part C).
EC No.	CONFIDENTIAL information is provided separately (Part C).

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

Type: Paste

[Code: PA]

1.6 Function (KCP 1.6)

Repellent.

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 grey-green paste of specific odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 8.2 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 and 18 weeks at 30°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 PP and HDPE packages. Its technical characteristics are acceptable for a paste formulation.

The intended concentration of the active substance in the product is 300 g/kg. The recommended application rate is from 2.0 to 11.00 kg of product/1000 trees.

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

Not relevant. No classification is proposed.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant. No labelling is proposed.

Compliance with FAO specifications:

Not relevant. No FAO specification available.

Formulation used for tests

The formulation used for tests and studies 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)	visual inspection, nasal inhalation	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	Grey-green paste of a specific odour.	Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	Assessed in RAR and already accepted.
	OPPTS 830.6302, OPPTS 830.6303 OPPTS 830.6304	Repentol 6 PA, Batch No.: 1/2/20, manufacturing date: 18.02.2020	Beige, viscous paste-like liquid of weak characteristic odour.	Y	Wieczorek A., 2020 ICB/30/2020	Accepted.
Explosive properties (KCP 2.2.1)	- EC A14	- Repentol 6 PA, Batch No.: 1/2016, manufacturing date: -	Study confirmed the product does not have explosive properties.	Y	Physico-chemical tests on REPENTOL 6 PA, Report No: 16-903064-002, Demangel B, 2017 (RAR for quartz sand)	In the thermal sensitivity (flame) test no explosion occurred. In the mechanical sensitivity (shock) test no explosion occurred. The formulation does not have explosive properties. Assessed in RAR and already accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (KCP 2.2.2)	- EC A21	- Repentol 6 PA, Batch No.: 1/2016, manufacturing date: -	Study confirmed the product does not have oxidizing properties.	Y	Physico-chemical tests on REPENTOL 6 PA, Report No: 16-903064-002, Demangel B, 2017 (RAR for quartz sand)	During the test no spontaneous ignition was noted; the mean pressure rise time was higher than the reference substance. The formulation does not have oxidising properties. Assessed in RAR and already accepted.
Flash point (KCP 2.3.1)	- EC A21 EC A9 method and ISO Standard 3679 (March 2015)	- Repentol 6 PA, Batch No.: 1/2016, manufacturing date: -	No flash point was observed up to 120.0°C.	Y	Physico-chemical tests on REPENTOL 6 PA, Report No: 16-903064-002, Demangel B, 2017 (RAR for quartz sand)	The test was performed with the closed-cup apparatus. The formulation is not flammable. Assessed in RAR and already accepted.
Flammability (KCP 2.3.2)	-	-	Not relevant. The product does not contain ingredients that are flammable so it can be assumed that it is not flammable.	-	-	Accepted.
Self-heating (KCP 2.3.3)	- EC A21 EC A16 method	- Repentol 6 PA, Batch No.: 1/2016, manufacturing date: -	No self-ignition temperature was observed up to 400°C.	Y	Physico-chemical tests on REPENTOL 6 PA, Report No: 16-903064-002, Demangel B, 2017 (RAR for quartz sand)	Assessed in RAR and already accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not relevant. The product is not a liquid.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	pH of 1% suspension is 8.2	Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	According to SANCO/10473/2003 – rev.5, CIPAC MT 75.3 method should be used. Assessed in RAR and already accepted.
	CIPAC MT 75.3	Repentol 6 PA, Batch No.: 1/2/20, manufacturing date: 18.02.2020	pH of 1% suspension is 8.29	Y	Wieczorek A., 2020 ICB/30/2020	Accepted.
Viscosity (KCP 2.5.1)	-	-	Not relevant. The product is not a liquid.	-	-	
Surface tension (KCP 2.5.2)	-	-	Not relevant. The product is not a liquid.	-	-	
Relative density (KCP 2.6.1)	CIPAC MT 3	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	Density at 20°C is 1.576.	Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015	The pycnometer method was used. Assessed in RAR and already accepted.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
							J. Zagórny, 2015 (RAR for quartz sand)	
Bulk density (KCP 2.6.2)	-	-	Not relevant. The product is not a powder or granulate.			-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46 (visual inspection, nasal inhalation, gravimetric method, CIPAC MT 75, CIPAC MT 3, CIPAC MT 185, GIFAP 17)	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	Parameter	Initial product	After storage at 54°C for 2 weeks	Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	The formulation was stored in screw-capped laboratory bottles made of PE of 250 ml volume. The registered accelerated storage test temperature varied between 53.3 and 54.7°C. Change in a.s. content 2.5%. No significant change in the product properties after the storage. No change to the container after storage. See KCP 2.8.5.1.2 regarding the wet sieve test. Assessed in RAR and already accepted.
			Colour and odour	Gray-green paste of a specific odour.	Gray-green paste of a specific odour. No separated material and liquids.			
			Content of active substance	30%	29.25%			
			pH of 1% suspension	8.2	8.2			
			Relative density	1.576	1.588			
			Wet sieve test	Residues on 75 µm sieve 29.96 %	Residues on 75 µm sieve 29.48 %			
			Packaging	Packaging is homogeneous throughout and free of visible cracks, holes, or planes of weakness.	Packaging is homogeneous throughout and free of visible cracks, holes, or planes of weakness. The difference in weight after			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					2 weeks storage at 54°C was max. 0.054% of the sample mass.			
	OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304, CIPAC MT 75.3, CIPAC MT 185	Repentol 6 PA, Batch No.: 1/2/20, manufacturing date: 18.02.2020	Parameter	Initial product	After storage at 30°C for 18 weeks	Y	Determination of the Active ingredient Content of Repentol 6 PA Product Before and After High Temperature Storage at 30°±2 °C for 18 weeks, Study code: 20046-03C, Giorgi S, 2020	The formulation was stored in commercial packages, buckets made of polypropylene (PP) material. Change in a.s. content 0.7%. No significant change in the product properties after the storage. No change to the container after storage. The phrase “After storage, mix well before use” should be added to the label. See KCP 2.8.5.1.2 regarding the wet sieve test. Accepted.
			Appearance, colour and odour	Beige opaque paste, thick consistency with small (<0.2 mm) sand granules, characteristic odour	Some beige liquid with light brown speckles on the surface, back to pre-storage appearance if mixed vigorously			
			Content of active substance	29.94 %	29.73 %			
			pH of 1% solution	7.98	8.06			
			Wet sieve test	Residues on 75 µm sieve 57.41%	Residues on 75 µm sieve 59.22%			
			Stability of packaging	Commercial packages, buckets made of polypropylene (PP) material, intact, no leaks	Unchanged			
Stability after storage	-	-	Not relevant. The product was stable at 54°C for 2			-	-	

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments				
for other periods and/or temperatures (KCP 2.7.2)			weeks.								
Minimum content after heat stability testing (KCP 2.7.3)	gravimetric method	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	29.48%		Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	Assessed in RAR and already accepted.				
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	Preparation homogeneous. No separated material and liquids. The difference in weight after 7 days storage at 0°C was max. 0.239% of the sample mass.		Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	The recorded temperatures during storage varied between -0.4 and 0.7°C. Assessed in RAR and already accepted.				
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 46 (visual inspection, nasal inhalation, gravimetric method, CIPAC MT 75, CIPAC MT 3, CIPAC MT 185,	Repentol 6 PA, Batch No.: 1/2013, manufacturing date: 08.2013	<table><tr><td>Parameter</td><td>After storage at ambient temperature for 2 years</td></tr><tr><td>Colour and odor</td><td>Gray-green paste of a specific odour.</td></tr></table>		Parameter	After storage at ambient temperature for 2 years	Colour and odor	Gray-green paste of a specific odour.	Y	REPENTOL 06PA DETERMINATION OF PHYSICOCHEMICAL PROPERTIES AFTER TWO YEARS STORAGE	The formulation was stored in a bucket of PP with a volume of about 2 kg. Assessed in RAR and already accepted.
Parameter	After storage at ambient temperature for 2 years										
Colour and odor	Gray-green paste of a specific odour.										

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
	GIFAP 17)		Content of active substance	29.94%		Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand) Annex to the study report REPENTOL 6PA DETERMINATION OF PHYSICOCHEMICAL PROPERTIES AFTER TWO YEARS OF STORAGE (008/DPL/2015) Appendix No 2 to SOP/L-10 S. Zając, 2019 (dRR 2020 and decision R-395/2020d)	
			pH of 1% suspension	8.3			
			Relative density	1.529			
			Wet sieve test	Residues on 75 µm sieve 29.68 %			
			Packaging	Packaging is homogeneous throughout and free of visible cracks, holes, or planes of weakness.			
	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 75.3 CIPAC MT 185	Repentol 6 PA, Batch No.: 1/2/20, manufacturing date: 18.02.2020	Stability after 1 and 2 years at ambient temperature in PP buckets.		Y	Determination of physicochemical properties, Study code: ICB/30/2020, Wieczorek A, 2020 Determination of Silicon Dioxide in Repentol 6 PA product, Study code: 20046-01C, Giori S, 2020 Determination of physicochemical properties after 12	The formulation was stored in commercial packages, buckets made of polypropylene (PP) material. Change in a.s. content after storage 0.1%. The content of the a.s. was determined with a method validated according to SANCO/3030/99 rev.5. No significant change in the product properties after the
			Parameter	Time	Description		
			Colour, physical state, odor	Initial	Beige, Colour according to Munsell - 2.5Y 8/4, Viscous paste-like liquid, Weak characteristic odour		
				1 year	Beige, Colour according to Munsell - 2.5Y 8/4, Viscous paste-like liquid, Weak characteristic odour		
				2 years	Beige, Colour according		

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					to Munsell - 2.5Y 8/4, Viscous paste-like liquid, Weak characteristic odour		months shelf-life test at 20±2°C, Study code: ICB/32/2020, Patrzalek M, 2021	storage. No change to the container after storage. See KCP 2.8.5.1.2 regarding the wet sieve test. Accepted. See KCP 2.8.5.1.2 regarding the wet sieve test.
			Active substance content	Initial	29.94%		Amendment No 1 to the FINAL REPORT, Study code: ICB/32/2020, Łebek B, 2025	
				1 year	29.35%			
				2 years	29.92%			
			pH of 1% suspension	Initial	8.29			
				1 year	7.73			
				2 years	7.29			
			Wet sieve test	Initial	48.55% on on 75 µm sieve		Determination of Silicon Dioxide in Repentol 6 PA product after 1 year storage at ambient temperature, Study code: 21090-01C, Giori S, 2021	
				1 year	52.44% on on 75 µm sieve			
				2 years	56.05% on on 75 µm sieve			
			Packaging	1 year	Change in packaging weight 1.15% Change in gross weight: -0.07%		Determination of physicochemical properties after 24 months shelf-life test at 20±2°C, Study code: ICB/33/2020, Łebek B, 2022	
				2 years	Change in packaging weight 1.00% Change in gross weight: -0.15%		Amendment No 1 to the FINAL REPORT, Study code: ICB/33/2020, Łebek B, 2025	
							Determination of Silicon Dioxide in Repentol 6 PA product after 2 years storage at	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					ambient temperature, Study code: 22120-01C, Giori S, 2022	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant. Proposed shelf life is 2 years.	-	-	
Wettability (KCP 2.8.1)	-	-	Not relevant. The product is not to be used as a dilution.	-	-	
Persistence of foaming (KCP 2.8.2)	-	-	Not relevant. The product is not to be used as a dilution.	-	-	
Suspensibility (KCP 2.8.3.1)	-	-	Not relevant. The product is not a water dispersible product.	-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not relevant. The product is not a water dispersible product.	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant. The product is not a water dispersible product.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. The product is not a water soluble product.	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant. The product is not in a form of powder or suspension concentrate.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Repentol 6 PA, Batch No.: 1/2015, manufacturing date: 09.2015	Residue on 75 µm sieve is 29.96%.	Y	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF	As the preparation is a ready-to-use product and is not diluted with water for use, the wet sieve test is not required.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					INITIAL PREPARATION Study code: 008/DPL/2015 J. Zagórny, 2015 (RAR for quartz sand)	Assessed in RAR and already accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. The product is not a granulate.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. The product is not a granulate.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant. The product is not in a form of granules or tablets.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. The product is not in a form of tablets.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant. The product is not in a form that exists as a emulsion in the spray tank.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant. The product is not in a form that exists as a emulsion in the spray tank.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant. The product is not in a form that exists as a emulsion in the spray tank.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not relevant. The product is not in a form of granules.	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not relevant. The product is not in a form of suspension.	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. The product is not in a form of dustable powder.	-	-	
Physical compatibility of tank mixes	-	-	Not relevant. No tank-mix is proposed.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.1)						
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. No tank-mix is proposed.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. Product is not seed treatment.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. Product is not seed treatment.	-	-	
Other/special studies (KCP 2.11)	-	-	Not relevant.	-	-	

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)

zRMS comments:	In the accelerated storage study (J. Zagórny, 2015, no 008/DPL/2015), the formulation was stored in screw-capped laboratory bottles made of PE and the packaging remained stable during the storage. In the accelerated storage study (S. Giorgi, 2020, no: 20046-03C), the formulation was stored in commercial packaging made of PP and the packaging remained stable during the storage. In the shelf-life stability (24 months) study (B. Łebek, 2022, no ICB/33/2020), the formulation was stored in commercial packaging made of PP and the packaging remained stable during the storage. Therefore, the proposed commercial packs made of PP and HDPE are considered acceptable.
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All packaging were evaluated and accepted in Registration Report Core Assessment zRMS Poland December 2016, Registration Report Core Assessment zRMS Poland January 2019 and draft Registration Report Core Assessment zRMS Poland May 2020.

Packaging for professional users:

Table 4.1-1: Packaging information for 2 kg bucket

Type	Description
Material:	PP
Shape/size:	cylindrical / approx. 121.2-143.2 mm diameter x 130.3 mm
Opening:	Not relevant.
Closure:	PE
Seal:	Yes.
Manner of construction	Not relevant.
UN/ADR	Not relevant.

Table 4.1-2: Packaging information for 7 kg bucket

Type	Description
Material:	PP
Shape/size:	cylindrical / approx. 193.5-224.2 mm diameter x 185 mm
Opening:	Not relevant.
Closure:	PE
Seal:	Yes.
Manner of construction	Not relevant.
UN/ADR	Not relevant.

Table 4.1-3: Packaging information for 25 kg bucket

Type	Description
Material:	PP
Shape/size:	cylindrical / approx. 282-326 mm diameter x 318.3 mm
Opening:	Not relevant.
Closure:	PE
Seal:	Yes.
Manner of construction	Not relevant.
UN/ADR	Not relevant.

Packaging for non-professional users:

Table 4.1-4: Packaging information for 0.25 liter jar

Type	Description
Material:	HDPE
Shape/size:	cylindrical / approx. 90.5±0.5 mm diameter x 66.0±0.5 mm
Opening:	73.5±0.3 mm inner diameter
Closure:	PEHD screw cap
Seal:	Yes
Manner of construction	extruded
UN/ADR	not relevant

Table 4.1-5: Packaging information for 0.30 liter jar

Type	Description
Material:	PP
Shape/size:	cylindrical / approx. 81 mm diameter x 81.9 mm
Opening:	72 mm diameter
Closure:	PE screw cap
Seal:	Yes
Manner of construction	extruded
UN/ADR	not relevant

Table 4.1-6: Packaging information for 0.50 liter jar

Type	Description	
Material:	PP	HDPE
Shape/size:	cylindrical / approx. 101 mm diameter x 109 mm	cylindrical / approx. 99.3±1 mm diameter x 100.5±1 mm
Opening:	93 mm diameter	84±0.3 mm inner diameter
Closure:	PE screw cap	PEHD screw cap
Seal:	Yes	Yes

Type	Description	
Manner of construction	extruded	extruded
UN/ADR	not relevant	not relevant

Table 4.1-7: Packaging information for 1 liter jar

Type	Description	
Material:	PP	HDPE
Shape/size:	cylindrical / approx. 101 mm diameter x 157.2 mm	cylindrical / approx. 99.5 mm diameter x 199.5 mm
Opening:	93 mm inner diameter	84±0.3 mm inner diameter
Closure:	PE screw cap	PEHD screw cap
Seal:	Yes	Yes
Manner of construction	extruded	extruded
UN/ADR	not relevant	not relevant

Table 4.1-8: Packaging information for 2 kg bucket

Type	Description	
Material:	PP	
Shape/size:	cylindrical / approx. 121.2-143.2 mm diameter x 130.3 mm	
Opening:	121.2-143.2 mm diameter	
Closure:	PE	
Seal:	Yes	
Manner of construction	extruded	
UN/ADR	not relevant	

Table 4.1-9: Packaging information for 7 kg bucket

Type	Description	
Material:	PP	
Shape/size:	cylindrical / approx. 193.5-224.2 mm diameter x 185 mm	
Opening:	193.5-224.2 mm diameter	
Closure:	PE	
Seal:	Yes	
Manner of construction	extruded	
UN/ADR	compliant	

Table 4.1-10: Packaging information for 2 kg bucket

Type	Description	
Material:	PP	
Shape/size:	cylindrical / approx. 121.2-143.2 mm diameter x 130.3 mm	
Opening:	Not relevant.	

Type	Description
Closure:	PE
Seal:	Yes.
Manner of construction	Not relevant.
UN/ADR	Not relevant.

Table 4.1-11: Packaging information for 7 kg bucket

Type	Description
Material:	PP
Shape/size:	cylindrical / approx. 193.5-224.2 mm diameter x 185 mm
Opening:	Not relevant.
Closure:	PE
Seal:	Yes.
Manner of construction	Not relevant.
UN/ADR	Not relevant.

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 2.1/01	Wieczorek A	2020	Determination of physicochemical properties, Study code: ICB/30/2020 ICB Pharma GLP Unpublished	N	DCR S.A.
KCP 2.4.2	Wieczorek A	2020	Determination of physicochemical properties, Study code: ICB/30/2020 ICB Pharma GLP Unpublished	N	DCR S.A.
KCP 2.7.1/02	Giorgi S	2020	Determination of the Active ingredient Content of Repentol 6 PA Product Before and After High Temperature Storage at 30±2 °C for 18 weeks, Study code: 20046-03C Renolab S.r.l. GLP Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/02	Zajac S.	2020 2019	Annex to the study report REPENTOL 6PA DETERMINATION OF PHYSICOCHEMICAL PROPERTIES AFTER TWO YEARS OF STORAGE (008/DPL/2015) Appendix No 2 to SOP/L-10 Pestila II Sp. z o. o. Sp. k., Poland GLP:Yes Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/03	Wieczorek A	2020	Determination of physicochemical properties, Study code: ICB/30/2020	N	DCR Sp. z o.o. S.A.

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
			ICB Pharma GLP:Yes Unpublished		S.A.
KCP 2.7.5/04	Giorgi S	2020	Determination of Silicon Dioxide in Repentol 6 PA product, Study code: 20046-01C Renolab S.r.l. GLP Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/05	Patrzalek M	2021	Determination of physicochemical properties after 12 months shelf-life test at 20±2°C, Study code: ICB/32/2020 ICB Pharma GLP:Yes Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/06	Giorgi S	2021	Determination of Silicon Dioxide in Repentol 6 PA product after 1 year storage at ambient temperature, Study code: 21090-01C Renolab S.r.l. GLP Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/07	Lebek B	2022	Determination of physicochemical properties after 24 months shelf-life test at 20±2°C, Study code: ICB/33/2020 ICB Pharma GLP:Yes Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/08	Giorgi S	2022	Determination of Silicon Dioxide in Repentol 6 PA product after 2 years storage at ambient temperature, Study code: 22120-01C Renolab S.r.l. GLP Unpublished	N	DCR Sp. z o.o. S.A.
KCP 2.7.5/09	Lebek B	2025	Amendment No 1 to the FINAL REPORT Determination of physicochemical properties after 12 months	N	DCR S.A.

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
			shelf-life test at 20±2°C, Study code: ICB/32/2020 ICB Pharma GLP: Yes Unpublished		
KCP 2.7.5/10	Łebek B	2025	Amendment No 1 to the FINAL REPORT Determination of physicochemical properties after 24 months shelf-life test at 20±2°C, Study code: ICB/33/2020 ICB Pharma GLP: Yes Unpublished	N	DCR S.A.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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 2.1/01 KCP 2.4.2/01 KCP 2.6.1/01 KCP 2.7.1/01 KCP 2.7.3/01 KCP 2.7.4/01 KCP 2.7.5/01 KCP 2.8.5.1.2/01	Zagórny J	2015a	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 Pestila Sp. z o. o. GLP Unpublished	N	DCR Sp. z o. o. S.A.
KCP 2.2.1/01	Demangel B	2017	Physico-chemical tests on REPENTOL 6 PA,	N	DCR

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 2.2.2/01 KCP 2.3.1/01 KCP 2.3.3/01			Report No: 16-903064-002 Source: DEFITRACES GLP Unpublished		Sp. z o.o. S.A.
KCP 2.7.5/01	Zagórny J	2015b	REPENTOL 06PA: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES AFTER TWO YEARS STORAGE Study code: 008/DPL/2015 Pestila Sp. z o. o. GLP Unpublished	N	DCR Sp. z o.o. S.A.

List of data submitted by the applicant and not 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
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

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
-	-	-	-	-	-

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

A 2.1 Quartz sand

Not relevant. No additional data on the physical, chemical and technical properties of the active substance quartz sand is provided.