

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

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.

Submission date: 27/11/2023

MS Finalisation date: 05/2025; 09/2025; 01/2026

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.
05/2025	ZRMS assessment
09/2025	The final Registration Report
01/2026	Updated by ZRMS

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6 Mammalian Toxicology (KCP 7)

This document reviews the mammalian toxicology for the product Repentol 6 PA / Repentol 6 PA Bis containing 300 g/kg quartz sand. Quartz sand was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/127/EC of 18 December 2008 and renewed as a low risk active substance in 2023 by Commission Implementing Regulation (EU) 2023/1488 of 6 July 2023 renewing the approval of the low-risk active substance quartz sand in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011.

The EFSA Scientific report for quartz sand (EFSA Journal 2022;20(9):7552) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.

Information on the detailed composition of Repentol 6 PA / Repentol 6 PA Bis can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Summary

Table 6.1-1: Information on Repentol 6 PA *

Product name and code	Repentol 6 PA / Repentol 6 PA Bis
Formulation type	paste [Code: e.g. PA]
Active substance (incl. content)	quartz sand; 300 g/kg
Function	repellent
Product already evaluated as the 'representative formulation' during the approval of the active substances	no
Product previously evaluated in another MS according to Uniform Principles	no

* Information on the detailed composition of Repentol 6 PA can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for Repentol 6 PA according to Regulation (EC) No 1272/2008 with regard to toxicological data

Hazard class(es), categories:	Skin Sens. 1
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07
Signal word:	Warning
Hazard statement(s):	Skin Sens.1 /H317 May cause an allergic skin reaction.
Precautionary statement(s):	P280 Wear protective gloves and protective clothing . work wear P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
Additional labelling phrases:	EUH401 To avoid risks to man and the environment, comply with the instructions for use. P208 Contains colophony. May produce an allergic reaction.

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Repentol 6 PA

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Professional and non-professional users: Gloves during application.
Workers	Acceptable	Gloves during post-application activities.
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied i.e. gloves during application.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

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Table 6.1-4 Critical uses (all intended uses) and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Bystander	Residents
1	Deciduous and coniferous trees in forestry	F Fn	painting with rubber or gloves: terminal shoots of individual plants	a) 1 b) 1	a) 0.75-1.2 kg/1000 trees b) 0.75-1.2 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)			-	-
2	Deciduous and coniferous trees in forestry	F Fn	painting with rubber or gloves: trees' bark	a) 1 b) 1	a) 2.4-3.0 kg/1000 trees b) 2.4-3.0 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)			-	
3	Forest nursery plants, renewals, afforestation and seed plantations of forest trees, ornamental shrubs and trees, Christmas trees grown on plantations	F Fn	games, lagomorphs, squirrel family beaver family	a) 1 b) 1	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)				
4	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	F Fn	games, lagomorphs, squirrel family beaver family	a) 1 b) 1	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)				
5	Gooseberry, choke berry, highbush blueberry, vines	F Fn	games, lagomorphs, squirrel family beaver family	a) 1 b) 1	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)				
6	Ornamental trees, Christmas trees grown on plantations	F Fn	games bark stripping	a) 1 b) 1	a) 2.4-3.3 kg/1000 trees b) 2.4-3.3 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)				

1	2	3	4	5	6	7	8	9	10
7	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut	F Fn	games bark stripping	a) 1 b) 1	a) 2.4-3.3 kg/1000 trees b) 2.4-3.3 kg/1000 trees	not relevant	not relevant	Operators, workers, bystanders and residents (models: not applicable)	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- data gap 1

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	quartz sand
Common Name	quartz sand
CAS-No.	14808-60-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	not relevant
Additional C&L proposal	not relevant
Agreed EU endpoints	
AOEL systemic	not relevant
Reference	EFSA Journal 2022;20(9):7552
Conditions to take into account/critical areas of concern with regard to toxicology	
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.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Repentol 6 PA is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Repentol 6 PA

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Not classified	-
LD ₅₀ dermal, rat	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Not classified	-
LC ₅₀ inhalation, rat	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Not classified	-
Skin irritation	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Not classified	-
Eye irritation	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Not classified	-
Skin sensitisation	Not submitted, not necessary. Justification presented in Appendix 2	Yes	Skin Sens. 1, H317 See Part C	-
Supplementary studies for combinations of plant protection products	No data – not relevant.			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of Repentol 6 PA

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Quartz sand (30 % (w/w))	-	-	-
Toxicological properties of non-active substance(s) (relevant for classification of product)	Confidential information, see Part C, two substances in formulation in amount of ≥ 1	Skin Sens. 1, H317 criteria ≥ 1 %	Regulation 1272/2008	Skin Sens. 1, H317

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
	% (w/w)*			
Further toxicological information	-	-	-	-

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

No metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L so assessment of the relevance of groundwater metabolites is therefore not required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Repentol 6 PA are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Repentol 6 PA

	quartz sand	
	Value	Reference
Concentrate	negligible	EFSA Journal 2022;20(9):7552
Dilution	negligible	EFSA Journal 2022;20(9):7552

6.5.1 Justification for proposed values – quartz sand

No data on dermal absorption for quartz sand in Repentol 6 PA is available. However no further data are required. It was assessed that dermal absorption of quartz sand is negligible.

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Repentol 6 PA / Repentol 6 PA Bis
Formulation type	PA
Category	repellent
Container size(s), short description	<u>professional users :</u> 2 kg, 7 kg, 25 kg, PP <u>non-professional users:</u> 2 kg, 7 kg, PP 0.3 L, 0.5 L, 1L PP 0.25 L, 0.5 L, 1L HDPE

Active substance(s) (incl. content)	quartz sand 300 g/kg
AOEL systemic	not allocated
Inhalation absorption	negligible
Oral absorption	negligible
Dermal absorption	concentrate: negligible dilution: negligible

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

Not relevant since only one intended use is proposed.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

As quartz sand in Repentol 6 PA is immobilised in the paste it is unlikely that exposure to the aerosolic form can occur. Paintbrush and gloves application of quartz sand formulated as a paste is not considered to be a source of significant exposure. Furthermore, dermal and inhalation absorption is assumed to be negligible; therefore no systemic exposure of the active substance occurs and no possible risk for the operator can be identified.

No further risk assessment for professional and non-professional operator regarding already registered uses and minor uses included in GAP is required.

Taking into account the classification of the Repentol 6 PA (i.e. Skin Sens 1, H317), any activities resulting in dermal contact with the product require the following protection:

Professional user:

„Wear protective gloves and work wear during application”

Non-professional user:

„Wear protective gloves”

ACCEPTED

Professional user: wear protective gloves and work wear during application”

Non-professional user: Wear protective gloves”

6.6.3 Measurement of operator exposure

Since no possible risk for the operator can be identified, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

As quartz sand in Repentol 6 PA is immobilised in the paste it is unlikely that exposure to the aerosolic form can occur. Paintbrush and gloves application of quartz sand formulated as a paste is not considered to be a source of significant exposure. Furthermore, dermal and inhalation absorption is assumed to be negligible; therefore no systemic exposure of the active substance occurs and no possible risk for the worker can be identified.

No further risk assessment for workers regarding already registered uses and minor uses included in GAP is required.

Taking into account the classification of the Repentol 6 PA (Skin Sens 1, H317), any activities resulting in dermal contact with the product, including post-application activities, require the use of **protective gloves**.

ACCEPTED

Require the use of **protective gloves**.

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not relevant.

6.6.4.3 Measurement of worker exposure

Since no possible risk for the worker can be identified, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

As quartz sand in Repentol 6 PA is immobilised in the paste it is unlikely that exposure to the aerosolic form can occur. Quartz sand is also not volatile. Paintbrush and gloves application of quartz sand formulated as a paste is not considered to be a source of significant exposure. Furthermore, dermal and inhalation absorption is assumed to be negligible; therefore, no systemic exposure of the active substance occurs and no possible risk for the bystander and resident can be identified.

No further risk assessment for bystanders and residents regarding already registered major and minor uses included in GAP is required.

ACCEPTED

Measurement of bystander and/or resident exposure

Since no possible risk for the bystander and resident can be identified, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
-	-	-	-	-	-

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
-	-	-	-	-	-

The following tables are to be completed by MS

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 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 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not relevant. No bridging possibilities were proposed.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Evaluator's comments:	Not relevant
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Not relevant. No new studies were provided. Repentol 6 PA does not contain formulates classifies as toxic so it was assumed that the product is also not toxic. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Evaluator's comments:	Not relevant
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Not relevant. No new studies were provided. Repentol 6 PA does not contain formulates classifies as toxic so it was assumed that the product is also not toxic. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Evaluator's comments:	Not relevant
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Not relevant. No acute inhalation study required. The proposed pattern of use excludes the possibility of inhalation exposure. Additionally, the active substance quartz sand is not volatile. Repentol 6 PA does not contain formulates classifies as toxic so it was assumed that the product is also not toxic. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.5 Skin irritation (KCP 7.1.4)

Evaluator's comments:	Not relevant
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Not relevant. No new studies were provided. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.6 Eye irritation (KCP 7.1.5)

Evaluator's comments:	Not relevant
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Not relevant. No new studies were provided. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.7 Skin sensitisation (KCP 7.1.6)

Evaluator's comments:	Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008 as Skin Sens.1/H317
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Not relevant. No new studies were provided. Repentol 6 PA contains **one** **two** **formulants** that **is** **are** classified as sensitizing so it was assumed that the product is also sensitizing. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant. No additional studies were provided.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Evaluator's comments:	Not relevant
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Not relevant. No new studies were provided.

A 2.11 Other/Special Studies

Not relevant. No other/special studies are provided.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for quartz sand

Not relevant. No calculation is provided.

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for quartz sand

Not relevant. No calculation is provided.

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for quartz sand

Not relevant. No calculation is provided.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant. No new information is provided.