

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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, 14/07/2024

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 assessed dRR for renewal of authorisation
09/2025	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling 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).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product / all intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses														
1	PL	deciduous and coniferous trees in forestry	F Fn	games and lagomorphs browsing damage	painting with rubber or gloves: termi- nal shoots of individual plants	autumn - winter (end of vegeta- tion period and before start of browsing, 2- 5 years old trees)	a) 1 b) 1	not relevant	a) 2.5-4.0 kg/1000 trees b) 2.5-4.0 kg/1000 trees	a) 0.75-1.2 kg/1000 trees b) 0.75-1.2 kg/1000 trees	not relevant	not relevant	-	
2	PL	deciduous and coniferous trees in forestry	F Fn	games bark stripping	painting with rubber or gloves: trees’ bark	autumn - winter (end of vegeta- tion period and before start of bark stripping, 2- 5 years old trees)	a) 1 b) 1	not relevant	a) 8.0-10.0 kg/1000 trees b) 8.0-10.0 kg/1000 trees	a) 2.4-3.0 kg/1000 trees b) 2.4-3.0 kg/1000 trees	not relevant	not relevant	-	
Minor uses according to Article 51 (zonal uses)														
3	PL	Forest nursery plants, renewals, afforestation and seed plantations of forest trees, ornamental shrubs and trees,	F Fn	games, lagomorphs, squirrel family beaver family	painting with rubber or gloves: termi- nal shoots of individual plants	autumn - winter (end of vegeta- tion period and before start of browsing, 2-	a) 1 b) 1	not relevant	a) 2.0-4.0 kg/1000 trees b) 2.0-4.0 kg/1000 trees	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	-	

		Christmas trees grown on plantations				5 years old trees)								
4	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	F Fn	games, lagomorphs, squirrel family beaver family	painting with rubber or gloves: terminal shoots of individual plants	autumn - winter (end of vegetation period and before start of browsing, 2-5 years old trees)	a) 1 b) 1	not relevant	a) 2.0-4.0 kg/1000 trees b) 2.0-4.0 kg/1000 trees	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	-	
5	PL	Gooseberry, choke berry, highbush blueberry, vines	F Fn	games, lagomorphs, squirrel family beaver family	painting with rubber or gloves: terminal shoots of individual plants	autumn - winter (end of vegetation period and before start of browsing, 2-5 years old trees)	a) 1 b) 1	not relevant	a) 2.0-4.0 kg/1000 trees b) 2.0-4.0 kg/1000 trees	a) 0.6-1.2 kg/1000 trees b) 0.6-1.2 kg/1000 trees	not relevant	not relevant	-	
6	PL	Ornamental trees, Christmas trees grown on plantations	F Fn	games bark stripping	painting with rubber or gloves: trees' bark	autumn - winter (end of vegetation period and before start of bark stripping)	a) 1 b) 1	not relevant	a) 8.0-11.0 kg/1000 trees b) 8.0-11.0 kg/1000 trees	a) 2.4-3.3 kg/1000 trees b) 2.4-3.3 kg/1000 trees	not relevant	not relevant	-	
7	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut	F Fn	games bark stripping	painting with rubber or gloves: trees' bark	autumn - winter (end of vegetation period and before start of bark stripping)	a) 1 b) 1	not relevant	a) 8.0-11.0 kg/1000 trees b) 8.0-11.0 kg/1000 trees	a) 2.4-3.3 kg/1000 trees b) 2.4-3.3 kg/1000 trees	not relevant	not relevant	-	

* 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

Explanation for column 15 "Conclusion"

A	Safe use
R	Further refinement and/or risk mitigation measures required

C	To be confirmed by cMS
N	No safe use

- * 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

ZRMS conclusion: Information from previous assessments is still valid for renewal registration of Repentol 6 PA / Repentol 6 PA Bis in line to article 43. In the opinion of ZRMs, Repentol 6 PA / Repentol 6 PA Bis can be renewed for professional and unprofessional uses and minor uses according to acceptable GAP table and label project

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of quartz sand potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Not relevant.	Not relevant.	Not relevant.	Not relevant.	Not relevant.

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, aerobic degradation studies are not required.

ZRMS comment:
Agreed.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, anaerobic degradation studies are not required.

ZRMS comment:
Agreed.

8.4 Field studies (KCP 9.1.1.2)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, field degradation studies are not required.

ZRMS comment:
Agreed.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, soil dissipation studies are not required.

ZRMS comment:
Agreed.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, soil accumulation studies are not required.

ZRMS comment:
Agreed.

8.5 Mobility in soil (KCP 9.1.2)

8.5.1 Column leaching (KCP 9.1.2.1)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, column leaching studies are not required.

ZRMS comment:
Agreed.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, lysimeter studies are not required.

ZRMS comment:
Agreed.

8.5.3 Field leaching studies (KCP 9.1.2.3)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, field leaching studies are not required.

ZRMS comment:
Agreed.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

According to RAR and EFSA Journal 2022;20(9):7552 for quartz sand, due to the naturally occurrence of quartz sand and silicon dioxide in the environment, degradation in the water/sediment system studies are not required.

ZRMS comment:
Agreed.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.7.2 Active substance(s) and relevant metabolite(s)

Not relevant for the environmental exposure assessment. Silicon dioxide and quartz sand naturally occurs in the environment. Owing to the manually application by coating trees with gloves or brush no entry of the active substance into soil is expected. PECs calculation is not considered necessary.

ZRMS comment:

Agreed.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Not relevant for the environmental exposure assessment. Silicon dioxide and quartz sand naturally occurs in the environment. Owing to the manually application by coating trees with gloves or brush no entry of the active substance into ground water is expected. PEC_{gw} calculation is not considered necessary.

ZRMS comment:

Agreed.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Not relevant for the environmental exposure assessment. Silicon dioxide and quartz sand naturally occurs in the environment. Owing to the manually application by coating trees with gloves or brush no entry of the active substance into surface water is expected. PEC_{sw} calculation is not considered necessary.

ZRMS comment:

Agreed.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Quartz sand is not a volatile compound so PEC_{air} calculation is not considered necessary.

ZRMS comment:

Agreed.

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 new Annex II studies

No new studies are submitted.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

No additional information is submitted.