

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

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

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

Table of Contents

9	Ecotoxicology (KCP 10).....	6
9.1	Critical GAP and overall conclusions.....	7
9.1.1	Overall conclusions.....	10
9.1.1.1	Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	10
9.1.1.2	Effects on aquatic organisms (KCP 10.2).....	10
9.1.1.3	Effects on bees (KCP 10.3.1).....	11
9.1.1.4	Effects on arthropods other than bees (KCP 10.3.2)	11
9.1.1.5	Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)	11
9.1.1.6	Effects on non-target terrestrial plants (KCP 10.6)	11
9.1.1.7	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	11
9.1.2	Grouping of intended uses for risk assessment.....	11
9.1.3	Consideration of metabolites	12
9.2	Effects on birds (KCP 10.1.1).....	12
9.2.1	Toxicity data	12
9.2.1.1	Justification for new endpoints	12
9.2.2	Risk assessment for spray applications.....	12
9.2.2.1	First-tier assessment (screening/generic focal species)	12
9.2.2.2	Higher-tier risk assessment	12
9.2.2.3	Drinking water exposure.....	12
9.2.2.4	Effects of secondary poisoning.....	13
9.2.2.5	Biomagnification in terrestrial food chains.....	13
9.2.3	Risk assessment for baits, pellets, granules, prills or treated seed.....	13
9.2.4	Overall conclusions.....	13
9.3	Effects on terrestrial vertebrates other than birds (KCP 10.1.2).....	13
9.3.1	Toxicity data	13
9.3.1.1	Justification for new endpoints	14
9.3.2	Risk assessment for spray applications.....	14
9.3.2.1	First-tier assessment (screening/generic focal species)	14
9.3.2.2	Higher-tier risk assessment	14
9.3.2.3	Drinking water exposure.....	14
9.3.2.4	Effects of secondary poisoning.....	14
9.3.2.5	Biomagnification in terrestrial food chains.....	14
9.3.3	Risk assessment for baits, pellets, granules, prills or treated seed.....	15
9.3.4	Overall conclusions.....	15
9.4	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	15
9.5	Effects on aquatic organisms (KCP 10.2).....	15
9.5.1	Toxicity data	15
9.5.1.1	Justification for new endpoints	17
9.5.2	Risk assessment	17
9.5.3	Overall conclusions.....	17
9.6	Effects on bees (KCP 10.3.1).....	17
9.6.1	Toxicity data	17
9.6.1.1	Justification for new endpoints	17

9.6.2	Risk assessment	18
9.6.2.1	Hazard quotients for bees.....	18
9.6.2.2	Higher-tier risk assessment for bees (tunnel test, field studies).....	18
9.6.3	Effects on bumble bees	18
9.6.4	Effects on solitary bees	18
9.6.5	Overall conclusions.....	18
9.7	Effects on arthropods other than bees (KCP 10.3.2)	18
9.7.1	Toxicity data	18
9.7.1.1	Justification for new endpoints	18
9.7.2	Risk assessment	19
9.7.2.1	Risk assessment for in-field exposure.....	19
9.7.2.2	Risk assessment for off-field exposure	19
9.7.2.3	Additional higher-tier risk assessment.....	19
9.7.2.4	Risk mitigation measures	19
9.7.3	Overall conclusions.....	19
9.8	Effects on non-target soil meso- and macrofauna (KCP 10.4)	19
9.8.1	Toxicity data	19
9.8.1.1	Justification for new endpoints	19
9.8.2	Risk assessment	20
9.8.2.1	First-tier risk assessment.....	20
9.8.2.2	Higher-tier risk assessment.....	20
9.8.3	Overall conclusions.....	20
9.9	Effects on soil microbial activity (KCP 10.5).....	20
9.9.1	Toxicity data	20
9.9.1.1	Justification for new endpoints	20
9.9.2	Risk assessment	20
9.9.3	Overall conclusions.....	21
9.10	Effects on non-target terrestrial plants (KCP 10.6)	21
9.10.1	Toxicity data	21
9.10.1.1	Justification for new endpoints	21
9.10.2	Risk assessment	21
9.10.2.1	Tier-1 risk assessment (based screening data)	21
9.10.2.2	Tier-2 risk assessment (based on dose-response data).....	21
9.10.2.3	Higher-tier risk assessment.....	21
9.10.2.4	Risk mitigation measures	22
9.10.3	Overall conclusions.....	22
9.11	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	22
9.12	Monitoring data (KCP 10.8)	22
9.13	Classification and Labelling	22
Appendix 1	Lists of data considered in support of the evaluation	23
Appendix 2	Detailed evaluation of the new studies	28
A 2.1	KCP 10.1 Effects on birds and other terrestrial vertebrates.....	28
A 2.1.1	KCP 10.1.1 Effects on birds	28
A 2.1.2	KCP 10.1.2 Effects on terrestrial vertebrates other than birds	28
A 2.1.3	KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians).....	28
A 2.2	KCP 10.2 Effects on aquatic organisms	28

A 2.2.1	KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	28
A 2.2.2	KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms.....	31
A 2.2.3	KCP 10.2.3 Further testing on aquatic organisms	32
A 2.3	KCP 10.3 Effects on arthropods	32
A 2.3.1	KCP 10.3.1 Effects on bees	32
A 2.4	KCP 10.4 Effects on non-target soil meso- and macrofauna.....	32
A 2.4.1	KCP 10.4.1 Earthworms	32
A 2.4.2	KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)	33
A 2.5	KCP 10.5 Effects on soil nitrogen transformation.....	33
A 2.6	KCP 10.6 Effects on terrestrial non-target higher plants.....	33
A 2.6.1	KCP 10.6.1 Summary of screening data	33
A 2.6.2	KCP 10.6.2 Testing on non-target plants.....	33
A 2.6.3	KCP 10.6.3 Extended laboratory studies on non-target plants	33
A 2.7	KCP 10.7 Effects on other terrestrial organisms (flora and fauna).....	34
A 2.8	KCP 10.8 Monitoring data.....	34

9 Ecotoxicology (KCP 10)

This document reviews the eco-toxicological studies 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).

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs / all intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses																				
1	PL	Deciduous and coniferous trees in forestry	F Fn	games and lagomorphs browsing damage	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) 2.5-4.0 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 vegetation 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,	F Fn	games, lagomorphs, squirrel family beaver family	painting with rubber or gloves:	autumn - winter (end of	a) 1 b) 1	not relevant	a) 2.0-4.0 kg/1000 trees	a) 0.6-1.2 kg/1000 trees	not relevant	not relevant	-							

[illegible]

- * 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 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

- Remarks table:**
- (1) Numeration necessary to allow references
 - (2) Use official codes/nomenclatures of EU
 - (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (4) 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
 - (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
 - (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 - (8) The maximum number of application possible under practical conditions of use must be provided
 - (9) Minimum interval (in days) between applications of the same product.
 - (10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
 - (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 - (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
 - (13) PHI - minimum pre-harvest interval
 - (14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

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

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Birds

Effects on birds for quartz sand and Repentol 6 PA were evaluated as part of the EU renewal of quartz sand. The further data on Repentol 6 PA is not relevant as toxicity data for quartz sand were submitted for mammals and demonstrated the low toxicity. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on birds was carried since it was assessed that exposure is negligible and there is no unacceptable risk to birds from the proposed use.

Terrestrial vertebrates (other than birds)

Effects on terrestrial vertebrates other than birds for Repentol 6 PA were evaluated as part of the EU renewal of quartz sand. The existing data on toxicity to terrestrial vertebrates other than birds is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on terrestrial vertebrates other than birds was carried since it was assessed that exposure is negligible and there is no unacceptable risk to terrestrial vertebrates other than birds from the proposed use.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Effects on aquatic organisms for Repentol 6 PA were evaluated as part of the EU renewal of quartz sand. Acute toxicity studies for Repentol 6 PA were submitted and evaluated in appendix 2 of this dRR and results were used for classification. Repentol 6 PA is not classified as dangerous for aquatic organisms. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on aquatic organisms was carried since it was assessed that exposure is negligible and there is no unacceptable risk to aquatic organisms from the proposed use.

9.1.1.3 Effects on bees (KCP 10.3.1)

Effects on bees for quartz sand and Repentol 6 PA were evaluated as part of the EU renewal of quartz sand. The further data on quartz sand and Repentol 6 PA is not relevant. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to bees from the proposed use.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Effects on arthropods other than bees for quartz sand and Repentol 6 PA were evaluated as part of the EU review of quartz sand. The further data on quartz sand and Repentol 6 PA is not relevant. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on arthropods other than bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to arthropods other than bees from the proposed use.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

Effects on non-target soil meso- and macrofauna as well as soil microbial activity for quartz sand and Repentol 6 PA were evaluated as part of the EU review of quartz sand. The further data on quartz sand and Repentol 6 PA is not relevant. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for non-target soil meso- and macrofauna as well as soil microbial activity was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-target soil meso- and macrofauna as well as soil microbial activity from the proposed use.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

Effects on non-terrestrial plants for quartz sand and Repentol 6 PA were evaluated as part of the EU renewal of quartz sand. The further data on quartz sand and Repentol 6 PA is not relevant. Therefore, all relevant data were assessed in the EU renewal.

No risk assessment for effects on non-terrestrial plants was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-terrestrial plants from the proposed use.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

Not relevant. Since risk assessment for non-target organisms is not required so grouping of uses for risk assessment is not necessary.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of Repentol 6 PA is indicated in the table.

Table 9.1-2 Metabolites of quartz sand

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Not relevant.	Not relevant.	Not relevant.	Not relevant.	Not relevant.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

No avian toxicity studies have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Toxicity data were submitted for mammals (point 9.3.1) and demonstrated the low toxicity. Full details of these studies are provided in the respective EU RAR, EFSA Journal 2022;20(9):7552 and related documents so no further studies on birds were necessary. Further data on the Repentol 6 PA is not considered essential.

9.2.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.2.2 Risk assessment for spray applications

Not relevant. Repentol 6 PA is not to be used if a form of spray. Birds are not assumed to feed on the treated plant material like the bark and the green parts of the treated crops and therefore exposure is negligible. Additionally, Repentol 6 PA is a mechanical repellent, and this mode of action is also assumed to work for birds. Risk assessment for birds is therefore not required.

9.2.2.1 First-tier assessment (screening/generic focal species)

Not relevant, see point 9.2.2.

9.2.2.2 Higher-tier risk assessment

Not relevant, see point 9.2.2.

9.2.2.3 Drinking water exposure

Not relevant, see point 9.2.2.

9.2.2.4 Effects of secondary poisoning

Not relevant, see point 9.2.2.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of mammals is negligible. Repentol 6 PA is a mechanical repellent, so it also repels birds. Quartz sand naturally occurs in several environmental compartments. No further studies with the formulation Repentol 6 PA as well as risk assessment is required.

ZRMS comment:
Agreed.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with quartz sand and lead formulations. Full details of these studies are provided in the respective EU RAR and related documents. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents.

Effects on mammals of Repentol 6 PA were not evaluated as part of the EU renewal assessment of quartz sand since it was concluded those studies are not necessary. However, the provision of further data on the formulation Repentol 6 PA is not considered essential, because it is possible to extrapolate from data for the active substance.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
rat	quartz sand	oral, 1 d, acute	Data available of limited validity, no further data needed. LD ₅₀ = 500 mg/kg bw	EFSA Journal 2022;20(9):7552 & RAR, Arienzo & Bresciano, 1968, Report:-

Species	Substance	Exposure System	Results	Reference
rat	quartz sand (Cervacol)	oral, 1 d, acute	LD ₅₀ > 10 g/kg bw	EFSA Journal 2022;20(9):7552 & RAR, Hackenberg U, 1978a, Report: Report A o479/1527.01
rat	quartz sand (Morsuvin)	oral, 1 d, acute	LD ₅₀ > 2 g/kg bw	EFSA Journal 2022;20(9):7552 & RAR, Novak O, 1998a, Report: 9867

9.3.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.3.2 Risk assessment for spray applications

Not relevant. Repentol 6 PA is not to be used if a form of spray. Mammals are not assumed to feed on the treated plant material like the bark and the green parts of the trees and therefore exposure is negligible. Additionally, Repentol 6 PA is a mechanical repellent and this mode of action is also assumed to work for mammals. Risk assessment for mammals is therefore not required.

9.3.2.1 First-tier assessment (screening/generic focal species)

Not relevant, see point 9.3.1.

9.3.2.2 Higher-tier risk assessment

Not relevant, see point 9.3.1.

9.3.2.3 Drinking water exposure

Not relevant, see point 9.3.1.

9.3.2.4 Effects of secondary poisoning

Not relevant, see point 9.3.1.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of mammals is negligible. Repentol 6 PA is a mechanical repellent, so it also repels mammals. Quartz sand naturally occurs in several environmental compartments. No further studies with the formulation Repentol 6 PA as well as risk assessment is required.

ZRMS comment:
Agreed.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not relevant. No further data is required.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with quartz sand. Full details of these studies are provided in the respective EU [RAR, EFSA Journal 2022;20\(9\):7552](#) and related documents.

Effects on aquatic organisms of Repentol 6 PA were evaluated as part of the EU renewal assessment of quartz sand. New data submitted with the application for the first approval of Repentol 6 PA as well as in EU quartz sand renewal are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – quartz sand

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	quartz sand (Cervacol)	96 h, s	LC ₅₀ > 500 mg preparation/L _{nom} NOEC = 500 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR , Hernadi D, 2007; Report: 07/493-009H
<i>Oncorhynchus mykiss</i>	quartz sand (Wobra)	96 h, s	LC ₅₀ > 100 mg preparation/L _{nom} NOEC = 100 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR , Scheerbaum D, 1996; Report: FAR49721
<i>Poecilla reticulata</i>	quartz sand	96 h, s	LC ₅₀ = 36.9 mg	EFSA Journal

Species	Substance	Exposure System	Results	Reference
	(Morsuvin)		preparation/L _{nom}	2022;20(9):7552 & RAR, Dolezalova, 1998; Report: 76/L
<i>Daphnia magna</i>	quartz sand (Cervacol)	48 h, s	EC ₅₀ > 500 mg preparation/L _{nom} NOEC = 500 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR; Report: 07/493-023DA
<i>Daphnia magna</i>	quartz sand (Wobra)	48 h, s	EC ₅₀ > 1000 mg preparation/L _{nom} NOEC = 580 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Noack M, 1996; Report: DA149721
<i>Daphnia magna</i>	quartz sand (Morsuvin)	48 h, s	EC ₅₀ = 92.06 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Dolezalova, 1998; Report: 76/L
<i>Pseudokirchneriella subcapitata</i>	quartz sand (Cervacol)	72 h, s	E _b C ₅₀ >500 mg preparation/L _{nom} E _r C ₅₀ >500 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Hernadi D, 2007; Report: 07/493-022AL
<i>Scenedesmus subspicatus</i>	quartz sand (Wobra)	72 h, s	E _b C ₅₀ >1000 mg preparation/L _{nom} E _r C ₅₀ >1000 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Scheerbaum D, 1996; Report: SS049722
<i>Scenedesmus subspicatus</i>	quartz sand (Morsuvin)	72 h, s	E _b C ₅₀ =13.9 mg preparation/L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Dolezalova, 1998; Report: 76/L
Higher-tier studies (micro- or mesocosm studies)				
Not relevant.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Repentol 6 PA

Species	Substance	Exposure System	Results	Reference
<i>Salvelinus fontinalis</i>	Repentol 6 PA	96 h, s	LC ₅₀ > 100 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Kita K/1997/-
<i>Cyprinus carpio</i>	Repentol 6 PA	96 h, s	EC ₅₀ >100 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Kita K/1997/-
<i>Daphnia magna</i>	Repentol 6 PA	48 h, s	EC ₅₀ = 370 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 &

Species	Substance	Exposure System	Results	Reference
				RAR, Kita K/1997/-
<i>Scenedesmus quadricauda</i>	Repentol 6 PA	72 h, s	IC ₅₀ > 100 mg preparation /L _{nom}	EFSA Journal 2022;20(9):7552 & RAR, Kita K/1997/-
Higher-tier studies (micro- or mesocosm studies)				
Not relevant.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.5.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, so the exposure of aquatic organisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for aquatic organisms is therefore not required. Toxicity studies performed for the active substance as well as the formulation is used for classification.

9.5.3 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of aquatic organisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for aquatic organisms is therefore not required. Toxicity studies performed for the active substance as well as the formulation is used for classification.

ZRMS comment:
Agreed.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

No studies on the toxicity to bees have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents. Further data on the Repentol 6 PA is not considered essential since it is to be used manually as a coating onto trees and hence exposure of bees is considered negligible.

9.6.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.6.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, so the exposure of bees is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for bees is therefore not required.

9.6.2.1 Hazard quotients for bees

Not relevant, see point 9.6.2.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant, see point 9.6.2.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of bees is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for bees is therefore not required.

ZRMS comment:
Agreed.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

No studies on the toxicity to non-target arthropods have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto trees which is not a large-area application. Additionally, quartz sand naturally occurs in the environment and hence exposure of bees is considered negligible.

9.7.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.7.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, so the exposure of non-target arthropods is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target arthropods is therefore not required.

9.7.2.1 Risk assessment for in-field exposure

Not relevant, see point 9.7.2.

9.7.2.2 Risk assessment for off-field exposure

Not relevant, see point 9.6.2.

9.7.2.3 Additional higher-tier risk assessment

Not relevant, see point 9.6.2.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of non-target arthropods is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target arthropods is therefore not required.

ZRMS comment:
Agreed.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

No studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of earthworms and other non-target soil organisms is considered negligible.

9.8.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.8.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, so the exposure of earthworms and other non-target soil organisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for earthworms and other non-target soil organisms is therefore not required.

9.8.2.1 First-tier risk assessment

Not relevant, see point 9.8.2.

9.8.2.2 Higher-tier risk assessment

Not relevant, see point 9.8.2.

9.8.3 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of earthworms and other non-target soil organisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for earthworms and other non-target soil organisms is therefore not required.

ZRMS comment:
Agreed.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

No studies on effects soil microorganisms have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of for soil microorganisms is considered negligible.

9.9.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.9.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, so the exposure of soil microorganisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

9.9.3 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, so the exposure of soil microorganisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

ZRMS comment:
Agreed.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

No studies on the toxicity to non-target terrestrial plants have been carried out with quartz sand. For the purpose of renewal of quartz sand approval, no new studies were submitted. Details of justification are included in RAR, EFSA Journal 2022;20(9):7552 and related documents. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of for non-target plants is considered negligible.

9.10.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.10.2 Risk assessment

Not relevant. Repentol 6 PA is to be used as a coating onto trees and bushes, and no drift occurs so the exposure of non-target plants is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target plants is therefore not required.

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant, see point 9.10.2.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not relevant, see point 9.8.2.

9.10.2.3 Higher-tier risk assessment

Not relevant, see point 9.8.2.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Repentol 6 PA is to be applied manually as a coating on trees and bushes, and no drift occurs so the exposure of non-target plants is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

ZRMS comment:
Agreed.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 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 ecotoxicological data is proposed for the preparation:

Table 9.13-1: Justified proposals for classification and labelling for Repentol 6 PA according to Regulation (EC) No 1272/2008 with regard to ecotoxicological data

Hazard class(es), categories:	-
Hazard pictograms or Code(s) for hazard pictogram(s):	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	EUH401 To avoid risks to man and the environment, comply with the instructions for use.
	SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

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
KCP 10.1.2/01	Arienzo & Bresciano	1968	Title: no data, information from IUCLID (2002a) Report No.: no data Source: IUCLID GLP: no data Published: no data	Y	No data.
KCP 10.1.2/02	Hackenberg U	1978a	Bestimmung der LD50 und Erfassung toxischer Symptome von “Cervacol” nach 1-maliger intragastraler Applikation an der männlichen und weiblichen Ratte Report No.: Report A 0479/1527.01 Source: no data	Y	Stähler International GmbH

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
			no GLP Unpublished		
KCP 10.1.2/03	Novak O	1998a	Acute oral toxicity; unpublished report 9867 Report No.: 9867 Source: no data GLP Unpublished	Y	Nera Agro
KCP 10.2/01	■■■■	2007	Fish acute toxicity study with Cervacol Extra on rainbow trout (Oncorhynchus mykiss) ■■■■ GLP Unpublished	Y	Stähler International GmbH & Co. KG, Stade, Germany
KCP 10.2/02	■■■	1996	Fish (Rainbow Trout), Acute Toxicity Test (Limit Test), 96 h ■■■ Source: no data GLP Unpublished	Y	Flügel GmbH
KCP 10.2/03	■■■	1998	Test T37– Acute Toxicity Test in Fish Výzkumný ústav organických syntéz a.s. ■■■■ GLP Published: no data	Y	Nera Agro
KCP 10.2/04	Hernadi D	2007	Acute immobilisation test with Cervacol Extra on Daphnia Magna Report: 07/493-023DA Source: LAB International Research Center Hungary GLP Unpublished	N	Stähler International GmbH & Co. KG, Stade, Germany

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 10.2/05	Noack M	1996	Daphnia magna STRAUS Acute Immobilisation Test, 48 h Report: DA149721 Source: Dr. U. Noack-Laboratorium für Angewandte Biologie, Hildesheim, Germany GLP Unpublished	N	Flügel GmbH
KCP 10.2/06	Dolezalova	1998	Test T38 – Daphnia Acute Immobilization Test Výzkumný ústav organických syntéz a.s. Report No.: 76/L Source: Research Institute for Organic Syntheses GLP Published: no data	N	Nera Agro
KCP 10.2/07	Hernadi D	2007	Cervacol Extra. Growth Inhibition test on Algae Report No.: 07/493-022AL Source: LAB International Research Centre Hungary Ltd. GLP Published: no data	N	Stähler International GmbH & Co. KG, Stade, Germany
KCP 10.2/08	Scheerbaum D	1996	Alga, Growth Inhibition Test Report No.: SS049722 Source: Dr. U. Noack-Laboratorium für Angewandte Biologie, Hildesheim Germany GLP Published: no data	N	Flügel GmbH
KCP 10.2/09	Dolezalova	1998	Test T39 – Algal Growth Inhibition Test Výzkumný ústav organických syntéz a.s. Report No.: 76/L Source: Research Institute for Organic Syntheses GLP	N	Nera Agro

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
			Published: no data		
KCP 10.2.1/01 KCP 10.2.1/02 KCP 10.2.1/03	Kita K	1997	Ocena toksycznego działania preparatu Repentol-6na organizmy wodne Company Report No: - IPO Pszczyna GLP Unpublished	Y	DCR Sp z o.o.

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 studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

Not relevant. No avian toxicity studies have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since the active substance naturally occurs in the environment.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Not relevant. See point 2.1.1.1.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

Not relevant. No mammal toxicity studies have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since the active substance naturally occurs in the environment.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Not relevant. See point 2.1.2.2.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

Not relevant. No vertebrate wildlife toxicity studies have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since the active substance naturally occurs in the environment.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 KCP 10.2.1 Fish

Comments of zRMS:	Noted.
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Reference:	KCP 10.2.1/01
Report	Ocena toksycznego działania preparatu Repentol-6 na organizmy wodne, Kita K, 1997, Report No.: no data
Guideline(s):	Yes, OECD 203
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Acute toxicity test for fish was conducted in order to determine acute toxicity of Repentol 6 PA for two fish species i.e. brook trout (*Salvelinus fontinalis* L.) and carp (*Cyprinus caprio* L.). Tested item was applied in concentration 100 mg/l. For this concentration 7 fishes in case of test with brook trout and 9 in case of test with carp were used. Test duration was 96 hours. Observations were made after 3 and 6 h, and then a every 24 h. On the basis of the results concentration causing 50% of fish mortality was determined (LC₅₀/96h).

Results and discussions

Results of Repentol 6 PA toxicity for fishes are summarised in Table 2.2.1-1.

Table 2.2.1-1: Acute toxicity of Repentol 6 PA for fishes

Concentration (mg/l)	Number of individuals	Mortality (No/%)	LC ₅₀ (mg/l)	LC ₀ (mg/l)	LC ₁₀₀ (mg/l)
Brook trout (<i>Salvelinus fontinalis</i> L.)					
Control	7	0/0			
100	7	0/0	>100	100	>100
Carp (<i>Cyprinus caprio</i> L.)					
Control	9	0/0			
100	9	0/0	>100	100	>100

Conclusion

According to the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December, 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regul

ation (EC) No. 1907/2006, Repentol 6 PA is beyond the classification.

A 2.2.1.2 KCP 10.2.1 Daphnia magna

Comments of zRMS:	Noted.
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Reference:	KCP 10.2.1/03
Report	Ocena toksycznego działania preparatu Repentol-6 na organizmy wodne, Kita K, 1997, Report No.: no data
Guideline(s):	Yes, OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Acute toxicity test for *Daphnia magna* Straus was conducted in order to determine immobilisation of *Daphnia magna* after application of Repentol 6 PA. In the test mortality as well as immobilisation were taken into account. Five concentrations in the range 62.5-1000.0 mg/l of the tested item and a control was used in four replications. Duration of the test was 48 hours. Results were observed after 24 and 48 hours. On the basis of the results EC₅₀ as well as EC₀ EC₁₀₀ after 24 and 48 hours were determined.

Results and discussions

Results of Repentol 6 PA toxicity for *Daphnia magna* are summarised in Table 2.2.1-2.

Table 2.2.1-1: Toxicity of Repentol 6 PA for *Daphnia magna*

Endpoint	after 24 h	after 48 h
EC ₅₀ (mg/l)	950.3	370.4
EC ₀ (mg/l)	125	<62.5
EC ₁₀₀ (mg/l)	>1000	>1000

Conclusion

According to the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December, 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006, Repentol 6 PA is beyond the classification.

A 2.2.1.3 KCP 10.2.1 Algae

Comments of zRMS:	Noted.
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Reference:	KCP 10.2.1/03
Report	Ocena toksycznego działania preparatu Repentol-6 na organizmy wodne, Kita K, 1997, Report No.: no data
Guideline(s):	Yes, OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Acute toxicity test for algae was conducted in order to determine acute toxicity of Repentol 6 PA for algae *Scenedesmus subspicatus*. Test duration was 72 hours. Observations were made after 24, 48 and 72 hours. Test item was applied in 7 concentrations in the range 0.1 to 100 mg/l. Each concentration was in two replications and the controls in four replications were done. On the basis of the results IC₅₀ after 72 hours was determined.

Results and discussions

Results of Repentol 6 PA toxicity for algae are summarised in Table 2.2.1-3. Average concentration causing 50% inhibition of algae growth (IC₅₀/72h) is above 100 mg/L.

Tabela 2.2.1-3: Toxicity of Repentol 6 PA SL for algae

Concentration (mg/l)	N/N ₀ with product in relation to N/N ₀ of control		IC ₅₀ (mg/l) after 72 hours
	N/N ₀ in % control	% of decrease N/N ₀ to the control value	
Control	100		>100
0.1	103.3	0	
0.32	125.0	0	
1.0	112.5	0	
3.2	87.5	12.5	
10	100	0	
32	93.8	6.2	
100	109.5	0	

N – cell concentration after 72 hours after the start of the test
N₀ – the initial cel concentration

Conclusion

According to the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December, 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006, Repentol 6 PA is beyond the classification.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Not relevant. No long term and chronic toxicity studies have been carried out with Repentol 6 PA. Further

data on the Repentol 6 PA is not considered essential since the active substance naturally occurs in the environment.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. No further studies are provided.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

Not relevant. No studies on the toxicity to bees have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since it is to be used manually as a coating onto trees and hence exposure of bees is considered negligible.

A 2.3.1.1 KCP 10.3.1.2. Chronic toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.2 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Not relevant. See point 2.3.1.

A 2.3.1.3 KCP 10.3.1.4 Sub-lethal effects

Not relevant. See point 2.3.1.

A 2.3.1.4 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. See point 2.3.1.

A 2.3.1.5 KCP 10.3.1.6 Field tests with honeybees

Not relevant. See point 2.3.1.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Not relevant. No studies on the toxicity to earthworms have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto

trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of earthworms is considered negligible.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. See point 2.4.1.1.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Not relevant. No studies on the toxicity to non-target soil organisms (meso- and macrofauna) have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is also not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of other non-target soil organisms is considered negligible.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not relevant. See point 2.4.2.1.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

No studies on effects soil microorganisms have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of for soil microorganisms is considered negligible.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Not relevant. No studies on the toxicity to non-target terrestrial plants have been carried out with Repentol 6 PA. Further data on the Repentol 6 PA is not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of for non-target plants is considered negligible.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Not relevant. See point 2.6.1.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. See point 2.6.1.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. No studies on other terrestrial organism were submitted.

A 2.8 KCP 10.8 Monitoring data