

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

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

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0 Product background, regulatory context and GAP information

0.1 Introduction

The dRR/RR used for the first authorisation of Repentol 6 PA and Repentol 6 PA Bis has been updated with following information and used for renewal of authorisation acc. to Art. 43 Reg. 1107/2009:

- name of applicant (decision no R-246/2018d on 01.06.2018),
- change of classification (decision no R-714/2019d on 08.10.2019, Registration Report Core Assessment zRMS Poland December 2018),
- extension of authorisation for non-professional uses and minor uses extension acc. to Art. 51 (decision no R-438/2019d on 16.07.2019, Registration Report Core Assessment zRMS Poland January 2019),
- dose reduction and label extension (decision no R-39/2020d on 15.01.2020, Registration Report Core Assessment zRMS Poland November 2019),
- change of packaging (decision no R-395/2020d on 24.06.2020, draft Registration Report Core Assessment zRMS Poland May 2020).

The above amendments have been evaluated and accepted by zRMS PL and have been incorporated without using colour. All new information and studies submitted for renewal of authorisation in accordance with Art. 43 of Reg. 1107/2009 are highlighted in yellow.

0.1.1 Reason for application

This application for registration of Repentol 6 PA / Repentol 6 PA Bis is submitted according to Art. 43 of Reg. 1107/2009. This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	zRMS: Poland Authorization No.: Repentol 6 PA: R-176/2017 – Poland Repentol 6 PA Bis: R-18/2019 – Poland	cMS: not applicable, product is registered only in Poland

0.1.3 Regulatory history of the active(s)

0.1.3.1 Quartz sand

Table 0.1-2: Summary of regulatory history of CAS No: 14808-60-7

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0127 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540 Commission Implementing Regulation (EU) No 369/2012 of 27 April 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances blood meal, calcium carbide, calcium carbonate, limestone, pepper and quartz sand http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R0369 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 https://eur-lex.europa.eu/eli/reg_impl/2023/1488/oj
RMS	Austria (1 st approval) Latvia (renewal of approval)
Date of Approval	01/09/2009
Date of renewal of approval	01/09/2023
Current expiration of approval	31/08/2038
Low risk substance or Candidate for Substitution?	low-risk

Issues that need to be considered as part of the EU approval are listed below.

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.

The EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand (EFSA Journal 2022;20(9):7552) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-3: Information on minimum purity of quartz sand

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity of quartz sand is 915 g/kg	minimum purity of quartz sand 990 g/kg Equivalence report available: ✖ NA (the source was assessed during renewal of approval) RMS: Poland Latvia

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please

refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product Repentol 6 PA

Product code	Product name	MS	Authorization No.	Date of initial registration	Date of the expiration
-	Repentol 6 PA	PL	R-99	4 May 2009	16 March 2010
-	Repentol 6 PA	PL	R-176/2017	1 September 2017	NR
-	Repentol 6 PA Bis	PL	R-18/2019	25 January 2019	NR

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: all
Residues section: all
Environmental Fate section: all
Ecotoxicology section: all

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none
Residues section: none
Environmental Fate section: none
Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS: none

Reviewer's comments:

Identity section: The evaluators verified whether the co-formulants contained in plant protection product REPENTOL 6 PA are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by the applicant on co-formulants, the product REPENTOL 6 PA does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to current knowledge and available information, none of the co-formulants in the plant protection product REPENTOL 6 PA meets the Annex to Regulation (EU) 2023/574 criteria for identifying co-formulants that are unacceptable for inclusion in plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III

of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in dRR Part C of this submission (section 1.2.2).

Physical-chemical properties section: No data gaps.

The maximum acceptable volume of packaging for non-professional users should be assessed at a national level.

Efficacy section:

ZRMs positively assessed the possibility of renewal authorization in line to Article 43. Repentol 6 PA/ Repentol 6 PA Bis can still be on the Polish market.

Mammalian toxicology:

Classification of REPENTOL 6 PA is Skin Sens.1/H317. Risk assessment for operator, worker and resident not relevant but professional user: „Wear protective gloves and work wear during application” Non-professional user: „Wear protective gloves”

Metabolism and Residues:

Uses are accepted

Fate and behaviour:

Uses are accepted

Ecotoxicology:

Uses are accepted.

Appendix 1 ALL intended uses

GAP, date: November 2019

PPP (product name): Repentol 6 PA / Repentol 6 PA Bis
Active substance: quartz sand
Safener: not relevant
Synergist: not relevant
Applicant: DCR Sp. z o.o. S.A.
Zone(s): Central Zone ^(d)
Verified by MS: no

Formulation type: PA ^(a, b)
Conc. of as: 300 g/kg ^(c)
Conc. of safener: not relevant ^(c)
Conc. of synergist: not relevant ^(c)
Professional use: ☒
Non professional use: ☒

Field of use: repellent

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					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		
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 rele- vant	not rele- vant	-
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 rele- vant	not rele- vant	-

Minor uses according to Article 51													
3	PL	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 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) 2.0-4.0 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	-
4	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	F F	games, lagomorphs, squirrel family beaver family 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) 2.0-4.0 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 F	games, lagomorphs, squirrel family beaver family 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) 2.0-4.0 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	-

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when 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