

FINAL REGISTRATION REPORT

Part A

Risk Management

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

NATIONAL ASSESSMENT - Poland

(authorization, renewal of authorisation)

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

Submission date: 27/11/2019, 17/07/2024

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

Repentol 6 PA / Repentol 6 PA Bis
Part A - National Assessment
Applicant version

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
01/2026	Updated by ZRMS

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This dRR is prepared for renewal of authorization of Repentol 6 PA and Repentol 6 PA Bis is submitted according to Art. 43 of Reg. 1107/2009. The 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. The proposed zRMS is Poland. No cMS were allocated since registration is only in Poland.

1.2 Letters of Access

Not relevant. No Letters of Access are provided.

1.3 Justification for submission of tests and studies

All conducted studies are necessary for renewal of authorisation of the product. No vertebrate studies were conducted due to animal welfare reason.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	not relevant
Product name in MS	Repentol 6 PA / Repentol 6 PA Bis
Authorization number	R-176/2017 / R-18/2019
Function	repellent
Applicant	DCR Sp. z o.o. S.A.
Active substance(s) (incl. content)	quartz sand; 300 g/kg
Formulation type	paste [Code: PA]

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Packaging	<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
Coformulants of concern for national authorizations	not applicable
Restrictions related to identity	not applicable
Mandatory tank mixtures	not applicable
Recommended tank mixtures	not applicable

2.2 Conclusion

Physical-chemical properties: No data gaps.

For non-professional users, the maximum acceptable volume of packaging should not exceed 2 kg. According to GAP table, this amount will be sufficient for use in maximum recommended rate for two seasons for ca. 100 trees.

Efficacy section:

ZRMs positively assessed the possibility of renewal authorization. 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:

The evaluation of the application for Repentol 6 PA resulted in the decision to grant the authorization.

Fate and behaviour and ecotoxicology: The evaluation of the application for Repentol 6 PA resulted in the decision to grant the authorization.

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 RR Part C of this submission (section 1.2.2).

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2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sens. 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07
Signal word:	Warning
Hazard statement(s):	H317 May cause an allergic skin reaction.
Precautionary statement(s):	P280 Wear protective gloves and work working clothing. 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.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	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).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Professional user: protective gloves and work wear during application Non-professional user: protective gloves
Worker protection:	
-	Protective gloves during post-application activities.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

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2.6 Intended uses

PPP (product name/code): Repentol 6 PA
 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

GAP, date: November 2019
 Formulation type: PA ^(a, b)
 Conc. of as 1: 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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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		

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Zonal uses (new use and amendment use i.e. reduced application rate)													
1	PL	deciduous and coniferous trees in forestry	F Fn	games browsing damage	painting with rubber or gloves: terminal shoots of individual plants	autumn - winter (end of vegetation period and before start of browsing)	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)	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, Christmas trees grown on plantations	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	-
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	-

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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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of grey-green paste of specific odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 8.2 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C and 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PP and HDPE packages. Its technical characteristics are acceptable for a paste formulation.

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

Justified Proposals for Classification and Labelling for physical chemical properties

Not relevant.

3.2 Efficacy (Part B, Section 3)

A total of 12 trials were carried out to evaluate the efficacy of Repentol 6 PA. The application rates used in trials were in range 2-4 kg/1000 trees for controlling of browsing damage and 6-10 kg/1000 trees for controlling of bark stripping. All trials confirmed the efficacy of Repentol 6 PA applied on deciduous and coniferous trees in forestry. No phytotoxicity effects on protected trees were observed in efficacy trials.

In case of minor uses authorized in accordance with Art. 51 Reg. 1107/2009, neither efficacy nor phytotoxicity studies have been submitted.

3.3 Efficacy data

No preliminary tests and minimum effective dose tests were performed. Repentol 6 PA used to be registered and widely used in Poland for many years. The proposed application rates are known of effectiveness. Effectiveness of the product depends on concentration of the active ingredient in the formulation and the thoroughness of application. Application rate expressed in amount per ha depends on density of trees.

In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. However, Repentol 6 PA was registered few years ago. Also, we should remember that its efficacy depends on accuracy of tree coating not on application rate expressed in amount per hectare. Application rate per hectare depends on trees density and height but has no effect on efficacy. Therefore, the data of minimum effective dose were not required. Also in the literature we can find information's about efficacy of the plant protection products containing quartz sand. Therefore the lack of minimum effective dose tests can be observed as acceptable in the opinion of Evaluator.

The field trials were performed in accordance with EPPO guidelines and in all trials GEP rules were recognized. The field experiments of the repellent – Repentol 6 PA were carried out by the recognised institutes. The testing unit has been mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognised.

The number of efficacy of the product presented in this dossier is sufficient for registration the tested product in Poland and in accordance with EPPO PP/226 (6–15 trials). Applicant presented 6 trials against browsing damage of deciduous (1 trial) and coniferous trees (5 trials) and against bark stripping of deciduous (1 trial) and coniferous trees (5 trials) carried out in one growing season (2018/2019). Only one growing season is seemed to be acceptable since Repentol 6 PA is already registered on the Polish market (with higher dose) and sand quartz is a low risk substance, so Applicant submit more efficacy trials (6 for each use) than is required (2-3).

Efficacy trials were correctly presented and assessed by Applicant. So, ZRMs agree with summary and conclusion presented by Applicant:

- Results of efficacy trials for controlling of browsing damage performed indicate high efficacy of Repentol 6 PA applied in application rates 2.5-4 kg/1000 trees. Efficacy of Repentol 6 PA applied in rates 2.5-4 kg/1000 trees (0.75-1.2 kg as/1000 trees) was above 78%. Regarding above results of Repentol 6 PA, results included in Core Assessment and current authorisation of Repentol 6 PA in Poland, it can be concluded that efficient application rates of Repentol 6 PA may be changed for 2.5-4 kg/1000 trees.
- Results of efficacy trials for controlling of bark stripping performed indicate high efficacy of Repentol 6 PA applied in application rates 8-10 kg/1000 trees. Efficacy of Repentol 6 PA applied in rates 8-10 kg/1000 trees (2.4-3.0 kg as/1000 trees) was above 78%.
- Regarding above results recommended application rates of Repentol 6 PA for controlling of browsing damage can be reduced till 2.5-4 kg/1000 trees. Additionally, new studies of Repentol 6 PA for controlling of bark stripping allows to conclude that product is efficient in rates of 8-10 kg/1000 trees.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The development of resistance to sand quartz repellents used against games and lagomorphs is a complex topic. The concept of resistance is more commonly associated with chemical repellents or pesticides.

Sand quartz, being a natural material, is less likely to lead to resistance compared to synthetic chemical repellents. Animals usually respond to behavioural cues rather than developing a physiological resistance. While resistance in the traditional sense may not occur, animals may adapt their feeding behaviours over time. For example, if a specific texture or barrier is consistently present, animals may learn to navigate or bypass it, though this is not true resistance.

Variability in environmental conditions, such as moisture levels and availability of alternative food sources, can affect how effective sand quartz repellents remain over time. Animals may be less inclined to resist barriers if food scarcity drives them to explore all options.

To mitigate potential behavioural adaptation, it can be effective to combine sand quartz products with other deterrence strategies, such as motion-activated devices or scent repellents.

Regularly checking and maintaining the protective elements can help ensure that they remain effective. As wear occurs, reapplication of the material may be necessary.

Ongoing research and monitoring of animal behaviour can help identify if adaptations are occurring, allowing for adjustments to management strategies.

In summary, while true resistance to sand quartz repellents is unlikely, adaptive behaviours in lagomorphs and game animals may occur. Implementing diverse strategies and maintaining effectiveness is key to successful deterrence.

While sand quartz can serve as a deterrent, it may not entirely effective on its own. The use of combination strategies, such as physical barriers (fencing), other repellents or habitat management, might be necessary for more robust protection. Considering the varying persistence and adaptability of games and lagomorphs, relying solely on sand quartz result in inconsistent protection. Resistance in the form of behavioural adaptation by the animals is possible but not guaranteed.

3.3.2 Adverse effects on treated crops

No phytotoxicity studies were performed since Repentol 6 PA is neither herbicide not regulator. No phytotoxicity effects were observed in efficacy trials at application rates.

3.3.3 Observations on other undesirable or unintended side-effects

Repentol 6 PA is to be used on trees and bushes and the proposed application manner is annual coating so no impact on succeeding and adjacent crops is expected. The active substance quartz sand naturally occurs in the environment and hence exposure of non-target organisms is also considered negligible.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Two analytical methods have been presented.

The first method for determination of quartz sand in formulation Repentol 6 PA involves determination of the content of silicon in the form of silicic acid anhydride after isolation of it with an acid solution prepared alloy samples from carbonates of alkali metals using the process of dehydration by evaporation with hydrochloric acid. The silica content is determined gravimetrically as the loss of weight of the solid on treatment with hydrofluoric acid. The specificity of the method was demonstrated on the basis of a parallel analysis of the test material and placebo. Silica is not detected in the placebo. It confirms the ability of the method to the determination of an analyte in a formulation without interference from other components. The validation parameters (linearity, precision and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.4.

The second method for determination of quartz sand in formulation Repentol 6 PA is based on spectrophotometrical determination with molybdenum blue complex obtained from a solution prepared by fusion of the quartz sample with sodium hydroxide. The yellow silico-molybdate complex is reduced to molybdenum blue and absorbance read at 816 ± 2 nm. The analytical method was validated with respect to specificity, linearity of detector response, accuracy and precision. Square correlation coefficient (r^2), recovery determination and modified Horwitz values (Horrat) fulfilled the requirements of SANCO/3030/99 rev. 5.

3.4.2 Analytical methods for residues

The active substance quartz sand naturally occurs in the environment. The proposed manner of use of Repentol 6 PA is on trees and bushes so it is not expected that any residues in/on food or feed may occur. Thus no analytical method for the determination of the residues of quartz sand in treated plant material, foodstuff of plant and animal origin as well as feedingstuff is required. Additionally, residues from plant protection product Repentol 6 PA would be indistinguishable from naturally occurring residues in any plant. Repentol 6 PA is a repellent so it will not be taken up by animals nor does it enter into fodder. Product Repentol 6 PA applied on trees will not translocate, it acts mechanically forming layer on the treated area. Regarding above analytical method for determination of quartz sand in soil, water and air is also not required.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed with Repentol 6 PA. Repentol 6 PA was classified using alternative approach according to Regulation No. 1272/2008. See Part C. Repentol 6 PA does not contain formulates classifies as toxic orally or dermally as well as irritating to skin or eye, so it was assumed that the product is also not toxic. Repentol 6 PA contains co-formulats that **is are** classified as sensitizing it will also be classified as sensitizing **Skin Sens.1/H317**.

3.5.2 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 professional and non-professional operator can be identified. A study to provide measurements of operator exposure is also not necessary and was therefore not performed.

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 **working** wear during application”

Non-professional user:

„Wear protective gloves”

3.5.3 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. A study to provide measurements of worker exposure is also not necessary and was therefore not performed.

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.

3.5.4 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. A study to provide measurements of bystander and resident exposure is also not necessary and was therefore not performed.

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

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

No data available in [RAR and EFSA Journal 2022;20\(9\):7552](#). No new data submitted in the framework of this application. Repentol 6 PA is to be applied on bushes, trees and tree trunk and will not be used on edible parts of crops hence no studies on residues are required. Additionally, no MRLs are considered necessary to be fixed. Quartz sand is listed in Annex IV of Regulation 396/2005.

3.6.2 Consumer exposure

No consumer risk assessment is available in [RAR and EFSA Journal 2022;20\(9\):7552](#). No new data were submitted in the framework of this application. Repentol 6 PA is to be applied on bushes, trees and tree trunk and will not be used on edible parts of crops hence no risk assessment for consumers is required. Additionally, no MRLs are considered necessary to be fixed. Quartz sand is listed in Annex IV of Regulation 396/2005.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Calculation of PECs is not relevant for the environmental exposure assessment. Silicon dioxide naturally occurs in the environment. Owing to the manual application by coating bushes, trees and tree trunk with gloves or brush no entry of the active substance into soil is expected. PECs calculation is not considered necessary.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

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

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

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

3.7.4 Predicted environmental concentrations in air (PEC_{air})

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

3.8 Ecotoxicology (Part B, Section 9)

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

3.8.1 Effects on terrestrial vertebrates

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.

3.8.2 Effects on aquatic species

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.

3.8.3 Effects on bees

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.

3.8.4 Effects on other arthropod species other than bees

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.

3.8.5 Effects on soil organisms

Effects on soil organisms 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.

3.8.6 Effects on non-target terrestrial plants

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.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant. 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.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. Product Repent 6 PA contains quartz sand as an active substance which is not candidate for substitution. No comparative assessment is necessary.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Not relevant.

Repentol 6 PA / Repentol 6 PA Bis
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Appendix 1 Copy of the product authorization

Not relevant.

Appendix 2 Copy of the product label

Sekcja fizyko-chemia: W etykiecie powinien znaleźć się zapis „Po przechowywaniu przed użyciem dokładnie wymieszać”.

Sekcja skuteczność: brak uwag do etykiety śor Repentol 6 PA / Repentol 6 PA Bis.

Sekcja toksykologii: Dodano zapis „Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowania oraz w trakcie wykonywania zabiegu”.

Sekcja Metabolizm i Pozostałości:
Brak uwag

Sekcja losu i ekotoksykologii:
Brak uwag

Posiadacz zezwolenia:

DCR Sp. z o.o. S.A., ul. Fabryczna 1, 97-371 Wola Krzysztoporska, tel.: +48 44 616 30 83; fax: +48 44 616 30 70, e-mail: dcr@dcr.com.pl

Podmiot wprowadzający środek ochrony roślin do obrotu na terytorium Rzeczypospolitej Polskiej:

Score Sp. z o.o., ul. Klonowa 12, Bartąg, 10-687 Olsztyn, tel./fax: +48 89 532 57 21, email: score.olsztyn@gmail.com

Repentol 6 PA / Repentol 6 PA Bis

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

piasek kwarcowy (związek z grupy tlenków nieorganicznych) - 300 g/kg (30%)

Zezwolenie MRiRW nr R - 176/2017 z dnia 01.09.2017 r.
Odnowione decyzją MRiRW nr R - /d z dnia

	
Uwaga	
H317	Może powodować reakcję alergiczną skóry
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P280	Stosować rękawice ochronne/odzież ochronną roboczą

Repentol 6 PA / Repentol 6 PA Bis
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P302+P352 P333+P313	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody/mydłem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
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OPIS DZIAŁANIA

Repentol 6 PA / Repentol 6 PA Bis jest środkiem o działaniu odstraszającym ssaki roślinożerne, w formie pasty do bezpośredniego użycia.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu pędzla lub rękawicy.

ZAPOBIEGANIE ZGRYZANIU

Drzewa iglaste i liściaste

Zapobieganie zgryzaniu przez jeleniowate i zajęcowate.

Maksymalna dawka dla jednorazowego zastosowania: 4 kg/1000 sztuk 2-5 letnich drzewek.
Zalecana dawka dla jednorazowego zastosowania: 2,5 - 4 kg/1000 sztuk 2-5 letnich drzewek.
Termin stosowania środka: jesienią.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ZAPOBIEGANIE SPAŁOWANIU

Drzewa iglaste i liściaste

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 10 kg/1000 sztuk 2-5 letnich drzewek.
Zalecana dawka dla jednorazowego zastosowania: 8 - 10 kg/1000 sztuk 2-5 letnich drzewek.
Termin stosowania środka: jesienią.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

ZAPOBIEGANIE ZGRYZANIU

Rośliny szkółkarskie leśne, odnowienia, zalesienia oraz plantacje nasienne drzew leśnych, krzewy i drzewa ozdobne, drzewka bożonarodzeniowe uprawiane na plantacjach

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zajęcowate, wiewiórki pospolite i bobry.

Maksymalna dawka dla jednorazowego zastosowania: 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.
Zalecana dawka dla jednorazowego zastosowania: 2 - 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

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Part A - National Assessment
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Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski, pigwa pospolita

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.

Maksymalna dawka dla jednorazowego zastosowania: 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Zalecana dawka dla jednorazowego zastosowania: 2 - 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Agrest, aronia, borówka wysoka, winorośl

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.

Maksymalna dawka dla jednorazowego zastosowania: 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Zalecana dawka dla jednorazowego zastosowania: 2 - 4 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ZAPOBIEGANIE SPAŁOWANIU

Drzewa ozdobne; drzewka bożonarodzeniowe uprawiane na plantacjach

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 11 kg/1000 sztuk drzew.

Zalecana dawka dla jednorazowego zastosowania: 8 - 11 kg/1000 sztuk drzew.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski.

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 11 kg/1000 sztuk drzew.

Zalecana dawka dla jednorazowego zastosowania: 8 - 11 kg/1000 sztuk drzew.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

SPOSÓB STOSOWANIA

Zapobieganie zgryzaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą:

Na drzewa iglaste środek nanosić na tegoroczny przyrost pędu drzew, na drzewa liściaste środek nanosić na cały pęd główny, gdy jego grubość nie przekracza 2 cm, a wysokość 60-80 cm.

Zapobieganie spalowaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą.

Środek nanosić na pnie drzew.

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Applicant version

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WRAUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy.

Środek stosować w dni bezdeszczowe, w temperaturze nie niższej niż 0°C.

Po wyschnięciu środek utrzymuje się na pędach do 7 miesięcy.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Nie jeść, nie pić ani nie palić podczas używania produktu.c

Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowania oraz w trakcie wykonywania zabiegu.

Wyprać zanieczyszczoną odzież przed ponownym użyciem.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C – 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradzić się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą umyć dużą ilością wody/mydłem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Repentol 6 PA / Repentol 6 PA Bis
Part A - National Assessment
Applicant version

Sekcja fizyko-chemia: W etykiecie powinien znaleźć się zapis „Po przechowywaniu przed użyciem dokładnie wymieszać”.

Sekcja skuteczność: brak uwag do etykiety sor Repentol 6 PA / Repentol 6 PA Bis.

Sekcja Metabolizm i Pozostałości:

Brak uwag

Sekcja losu i ekotoksykologii:

Brak uwag

Posiadacz zezwolenia:

DCR Sp. z o.o. S.A., ul. Fabryczna 1, 97-371 Wola Krzysztoporska, tel.: +48 44 616 30 83; fax: +48 44 616 30 70, e-mail: dcr@dcr.com.pl

Repentol 6 PA / Repentol 6 PA Bis

Środek przeznaczony do stosowania przez użytkowników nieprofesjonalnych

Zawartość substancji czynnej:

piasek kwarcowy (związek z grupy tlenków nieorganicznych) - 300 g/kg (30%)

**Zezwolenie MRiRW nr R - 176/2017 z dnia 01.09.2017 r.
odnowione decyzją MRiRW nr R - /d z dnia r.**

	
Uwaga	
H317	Może powodować reakcję alergiczną skóry.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P280	Stosować rękawice ochronne.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody/mydłem.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

OPIS DZIAŁANIA

Repentol 6 PA / Repentol 6 PA Bis jest środkiem o działaniu odstraszającym ssaki roślinożerne, w formie pasty do bezpośredniego użycia.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu pędzla lub rękawicy.

ZAPOBIEGANIE ZGRYZANIU

Repentol 6 PA / Repentol 6 PA Bis
Part A - National Assessment
Applicant version

Drzewa iglaste i liściaste

Zapobieganie zgryzaniu przez jeleniowate i zającowate.

Maksymalna dawka dla jednorazowego zastosowania: 0,04 kg/10 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 0,025 – 0,04 kg/10 sztuk 2-5 letnich drzewek.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ZAPOBIEGANIE SPAŁOWANIU

Drzewa iglaste i liściaste

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 0,10 kg/10 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 0,08 – 0,10 kg/10 sztuk 2-5 letnich drzewek.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

ZAPOBIEGANIE ZGRYZANIU

Krzewy i drzewa ozdobne

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.

Maksymalna dawka dla jednorazowego zastosowania: 0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.

Zalecana dawka dla jednorazowego zastosowania: 0,02-0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski, pigwa pospolita

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.

Maksymalna dawka dla jednorazowego zastosowania: 0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.

Zalecana dawka dla jednorazowego zastosowania: 0,02-0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Agrest, aronia, borówka wysoka, winorośl

Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.

Repentol 6 PA / Repentol 6 PA Bis
Part A - National Assessment
Applicant version

Maksymalna dawka dla jednorazowego zastosowania: 0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.
Zalecana dawka dla jednorazowego zastosowania: 0,02-0,04 kg/10 sztuk 2-5 letnich drzewek/krzewów.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ZAPOBIEGANIE SPAŁOWANIU

Drzewa ozdobne

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 0,11 kg/10 sztuk drzew.
Zalecana dawka dla jednorazowego zastosowania: 0,08-0,11 kg/10 sztuk drzew.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski

Zapobieganie spalowaniu kory z drzew przez jeleniowate.

Maksymalna dawka dla jednorazowego zastosowania: 0,11 kg/10 sztuk drzew.
Zalecana dawka dla jednorazowego zastosowania: 0,08-0,11 kg/10 sztuk drzew.

Termin stosowania środka: jesienią.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

SPOSÓB STOSOWANIA

Zapobieganie zgryzaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą:

Na drzewa iglaste środek nanosić na tegoroczny przyrost pędu drzew, na drzewa liściaste środek nanosić na cały pęd główny, gdy jego grubość nie przekracza 2 cm, a wysokość 60-80 cm.

Zapobieganie spalowaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą.

Środek nanosić na pnie drzew.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WRAUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy.

Środek stosować w dni bezdeszczowe, w temperaturze nie niższej niż 0°C.

Po wyschnięciu środek utrzymuje się na pędach do 7 miesięcy.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne (nitrylowe) oraz kombinezon.

Wyprać zanieczyszczoną odzież przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu wyschnięcia środka na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C – 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradzić się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą umyć dużą ilością wody/mydłem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not relevant. No LoA was submitted.

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 Part A - National Assessment
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Appendix 4 Lists of data considered for national authorization

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

Repentol 6 PA / Repentol 6 PA Bis
 Part A - National Assessment
 Applicant version

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.5/04	Giorgi S	2020	Determination of Silicon Dioxide in Repentol 6 PA product, Study code: 20046-01C Renolab S.r.l. GLP Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.
KCP 2.7.5/05	Patrzalek M	2021	Determination of physicochemical properties after 12 months shelf-life test at 20±2°C, Study code: ICB/32/2020 ICB Pharma GLP:Yes Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.
KCP 2.7.5/06	Giorgi S	2021	Determination of Silicon Dioxide in Repentol 6 PA product after 1 year storage at ambient temperature, Study code: 21090-01C Renolab S.r.l. GLP Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.
KCP 2.7.5/07	Lebek B	2022	Determination of physicochemical properties after 24 months shelf-life test at 20±2°C, Study code: ICB/33/2020 ICB Pharma GLP:Yes Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.
KCP 2.7.5/08	Giorgi S	2022	Determination of Silicon Dioxide in Repentol 6 PA product after 2 years storage at ambient temperature, Study code: 22120-01C Renolab S.r.l. GLP Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.

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 Part A - National Assessment
 Applicant version

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.5/09	Łebek B	2025	Amendment No 1 to the FINAL REPORT Determination of physicochemical properties after 12 months shelf-life test at 20±2°C, Study code: ICB/32/2020 ICB Pharma GLP: Yes Unpublished	N	Y	New study submitted for renewal of application.	DCR S.A.
KCP 2.7.5/10	Łebek B	2025	Amendment No 1 to the FINAL REPORT Determination of physicochemical properties after 24 months shelf-life test at 20±2°C, Study code: ICB/33/2020 ICB Pharma GLP: Yes Unpublished	N	Y	New study submitted for renewal of application.	DCR S.A.
KCP 5.1.1/02	Giorgi S	2020	Determination of Silicon Dioxide in Repentol 6 PA product, Study code: 20046-01C Renolab S.r.l. GLP Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.
KCP 6.2/01 KCP 6.2/02 KCP 6.2/03	Sekrecka M.	2019	Badanie skuteczności działania preparatu Repentol 6 PA (piasek kwarcowy 300 g/kg) w zabezpieczaniu drzew w lasach przed zgryzaniem przez zwierzynę łowną (jeleniowate) Company Report No: ZORPS/15/2018 Source: InHort, Research Institute of Horticulture, Poland GEP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.
KCP 6.2/04	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as repellent against browsing damage in Forest, 3 Sites Poland 2018/2019 Company Report No: S18-07559-01 Source: Eurofins Agroscience Service Sp. z o.o., Poland	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.

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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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2/05	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as repellent against browsing damage in Forest, 3 Sites Poland 2018/2019 Company Report No: S18-07559-02 Source: Eurofins Agroscience Service Sp. z o.o., Poland GEP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.
KCP 6.2/06	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as repellent against browsing damage in Forest, 3 Sites Poland 2018/2019 Company Report No: S18-07559-03 Source: Eurofins Agroscience Service Sp. z o.o., Poland GEP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.
KCP 6.2/07 KCP 6.2/08 KCP 6.2/09	Warabieda W.	2019	Badanie skuteczności działania preparatu Repentol 6 PA (piasek kwarcowy 300 g/kg) w zabezpieczaniu drzew w lasach przed spalowaniem przez zwierzynę łowną (jeleniowate) Company Report No: ZORPS/15/2018 Source: InHort, Research Institute of Horticulture, Poland GEP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.
KCP 6.2/10	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as Repellent against peeling of bark damage in Forest, 3 Site Poland 2018/2019 Company Report No: S18-07558-01 Source: Eurofins Agroscience Service Sp. z o.o., Poland GEP Unpublished	N	Y	New study submitted to register new type of application.	DCR Sp. z o.o. S.A.
KCP 6.2/11	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as Repellent against peeling of bark damage in Forest, 3 Site Poland 2018/2019 Company Report No: S18-07558-02 Source: Eurofins Agroscience Service Sp. z o.o., Poland	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.

Repentol 6 PA / Repentol 6 PA Bis
Part A - National Assessment
Applicant version

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2/12	Różalski K.	2019	Determination of Efficacy of Repentol 6 PA as Repellent against peeling of bark damage in Forest, 3 Site Poland 2018/2019 Company Report No: S18-07558-03 Source: Eurofins Agroscience Service Sp. z o.o., Poland GEP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01 KCP 2.4.2/01 KCP 2.6.1/01 KCP 2.7.1/01 KCP 2.7.3/01 KCP 2.7.4/01 KCP 2.7.5/01 KCP 2.8.5.1.2/01	Zagórny J	2015a	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 Pestila Sp. z o. o. GLP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o.o. S.A.
KCP 2.2.1/01 KCP 2.2.2/01 KCP 2.3.1/01 KCP 2.3.3/01	Demangel B	2017	Physico-chemical tests on REPENTOL 6 PA, Report No: 16-903064-002 Source: DEFITRACES GLP Unpublished	N	Y	New study submitted for renewal of application.	DCR Sp. z o.o. S.A.

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 Part A - National Assessment
 Applicant version

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.5/01	Zagórny J	2015b	REPENTOL 06PA: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES AFTER TWO YEARS STORAGE Study code: 008/DPL/2015 Pestila Sp. z o. o. GLP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o. o. S.A.
KCP 5.1.1/01	Zagórny J	2015a	REPENTOL 06PA STAGE 1: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF INITIAL PREPARATION Study code: 008/DPL/2015 Pestila Sp. z o.o. GLP Unpublished	N	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o. o. S.A.
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	Y	Application for data protection submitted at national level before renewal application.	DCR Sp. z o. o. S.A.

The following tables are to be completed by MS

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 Part A - National Assessment
 Applicant version

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner