

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand<sup>1</sup>

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#### SUMMARY

Quartz sand is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>3</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>4</sup>.

Quartz sand was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>5</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>7</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>8</sup>, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Austria being the designated rapporteur Member State submitted the DAR on quartz sand in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 12 March 2008. The peer review was initiated on 7 August 2008 by dispatching the DAR to the notifiers: Task force of Stähler Agrochemie GmbH & Co, KG and Avenarius Agro GmbH (Notifier A), Flügel GmbH (Notifier B), Nera Agro spol. s.r.o. (Notifier D), Chema sp.zo.o. (Notifier E), and on 20 October 2010 to the Member States for consultation. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on quartz sand.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of quartz sand as a repellent for use on deciduous and coniferous trees in forestry,

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2009-00288, issued on 30 June 2011.

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<sup>3</sup> OJ L 379, 24.12.2004, p.13

<sup>4</sup> OJ L 246, 21.9.2007, p.19

<sup>5</sup> OJ L 309, 24.11.2009, p.1

<sup>6</sup> OJ L 153, 11.6.2011, p.1

<sup>7</sup> OJ L 153, 11.6.2011, p.187

<sup>8</sup> OJ L 37, 10.2.2010, p.12

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. EFSA Journal 2011;9(7):2300. [37 pp.] doi:10.2903/j.efsa.2011.2300. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

as proposed by the notifiers. Full details of the representative uses can be found in Appendix A to this report.

In the area of physical-chemical properties, identity and methods of analysis two data gaps were identified; one for batch analysis for the notifier Chema and the other for particle size distribution for Chema and the Task force.

Based on the representative uses, no areas of concern or data gaps were identified in the mammalian toxicology section.

There is no consumer exposure as these products are not used on edible crops.

“Quartz sand” is a stable inorganic compound. It is insoluble and known to be inert to most mineral acids and bases. Considering the nature of the substance and the method of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

Due to negligible levels of environmental exposure arising from the representative uses, the risk can be considered low for non-target organisms.

#### **KEY WORDS**

Quartz sand, peer review, risk assessment, pesticide, repellent

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## BACKGROUND

Quartz sand is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>9</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>10</sup>.

Quartz sand was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>11</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>12</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>13</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>14</sup> the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Austria being the designated rapporteur Member State submitted the DAR on quartz sand in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 12 March 2008 (Austria, 2008). The peer review was initiated on 7 August 2008 by dispatching the DAR to the notifiers: Task force of Stähler Agrochemie GmbH & Co, KG and Avenarius Agro GmbH (Notifier A), Flügel GmbH (Notifier B), Nera Agro spol. s.r.o. (Notifier D), Chema sp.zo.o. (Notifier E), and on 20 October 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifiers were invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifiers' response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 15 February 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and additional information to be submitted by the notifiers, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in May – June 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a

<sup>9</sup> OJ L 379, 24.12.2004, p.13

<sup>10</sup> OJ L 246, 21.9.2007, p.19

<sup>11</sup> OJ L 309, 24.11.2009, p.1

<sup>12</sup> OJ L 153, 11.6.2011, p.1

<sup>13</sup> OJ L 153, 11.6.2011, p.187

<sup>14</sup> OJ L 37, 10.2.2010, p.12

repellent for use on deciduous and coniferous trees in forestry, as proposed by the notifiers. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (15 February 2011),
- the Evaluation Table (27 June 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of May 2011 containing all individually submitted addenda (Austria, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Quartz sand is the given name for this active substance; it consists mainly of silicon dioxide (IUPAC). It should be noted that another active substance, diatomaceous earth, also consists mainly of silicon dioxide.

The representative formulated products for the evaluation were 'Cervacol extra', 'Wöbra', 'Morsuvin' and 'Repentol 6PA'; all formulations are described as pastes. The formulations contain between 251 - 480 g/kg quartz sand. It should be noted that these formulations also contain other active substances.

Quartz sand has been notified as a repellent for use on deciduous and coniferous trees by application locally with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings. Full details of the representative uses can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

### 1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

The minimum purity of quartz sand is 915 g/kg; there are no relevant impurities. There is an outstanding data gap for notifier E (Chema) for a batch analysis study supported by analytical methods. There is also a data gap for the Task force and Chema for particle size distribution of their quartz sands to demonstrate compliance that the maximum content of particles with diameter below 50 µm should not exceed 0.1 %.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of quartz sand or the representative formulation. The available data regarding the identity of quartz sand and its physical and chemical properties are given in Appendix A.

The need for methods of analysis for monitoring this compound in food of plant and animal origin and in the environment has been waived due to the nature of the compound.

### 2. Mammalian toxicity

Quartz sand was discussed at the PRAPeR TC 55 Experts' Teleconference on mammalian toxicology.

Silica occurs in either a crystalline or non-crystalline (amorphous) form. Quartz sand is one of the most common forms of naturally occurring crystalline silica.

The risk assessment has been based on published information on different types of silica including risk assessment performed by other institutions for purposes other than the pesticide use. The original studies were not available to the RMS for their own evaluation and also no suitable data are available to establish NOAELs. The limited database indicated that quartz sand may be of low concern by the oral and dermal route of administration; however this could not be confirmed. Considering the inhalation route, during the commenting phase it was raised that for hazard assessment the maximum content of particles with diameter below 50 µm in quartz sand should not exceed 0.1 % due to the association between exposure to respirable silica dust (i.e. particles with diameter lower than 10 µm) and silicosis and increased probability of developing lung cancer (see also section 1). However, during the expert meeting it was agreed that inhalation exposure can be considered negligible and therefore this route of exposure is of low concern for quartz sand considering the type of application and the nature of the formulation (i.e. ready to use paste).

The uncertainties from the limited database did not affect the risk assessment, as the paintbrush and gloves application of a paste was not considered to be a source of significant exposure based on the unlikely dermal absorption of quartz sand and the negligible inhalation exposure. Considering the representative uses it was agreed that there is no need to set an Acceptable Operator Exposure Level (AOEL), or an Acceptable Daily Intake (ADI) or an Acute Reference Dose (ARfD) (see also section 3).

### **3. Residues**

There is no consumer exposure as these products are not used on edible crops.

### **4. Environmental fate and behaviour**

“Quartz sand” is a stable inorganic compound, the main component of which is silicon dioxide. It is practically insoluble and known to be inert to most mineral acids and bases.

After application (by brush or gloves) the formulations dry and form a protective coating. The dried formulations are not water soluble. Quartz sand is a significant component of many mineral soils and aquatic sediments. Because of the method of application leading to negligible levels of environmental exposure and the presence of quartz sand in soils and aquatic sediments, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

### **5. Ecotoxicology**

Because of the method of application leading to negligible levels of environmental exposure, the risk can be considered low for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro- organisms, terrestrial non-target plants and biological methods for sewage treatment plants.

## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Not applicable  Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for quartz sand.	Not applicable	-

### 6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Not applicable  Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for groundwater exposure assessment is deemed to be unnecessary for quartz sand.	Not applicable	Not applicable	-	-	-



### 6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
<p>Not applicable</p> <p>Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for quartz sand.</p>	-

### 6.4. Air

Compound (name and/or code)	Toxicology
<p>Not applicable (the maximum content of particles with diameter below 50 µm in quartz sand should not exceed 0.1 %).</p> <p>Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for quartz sand.</p>	-

## **LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED**

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- 5-batch analysis with supporting validated methods of analysis (Chema) (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Particle size distribution of the quartz sands including the content of particles with diameter below 50 µm (Task force and Chema) (relevant for all representative uses evaluated; submission date proposed by the notifiers: unknown; see section 1).

## **PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED**

- Only uses with application by gloves or brush are covered by the current assessment; other types of manual application have not been evaluated.

## **ISSUES THAT COULD NOT BE FINALISED**

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

- None.

## **CRITICAL AREAS OF CONCERN**

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

- None.

## REFERENCES

- Austria, 2008. Draft Assessment Report (DAR) on the active substance quartz sand prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, March 2008.
- Austria, 2011. Final Addendum to Draft Assessment Report on quartz sand, compiled by EFSA, May 2011.
- EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance quartz sand.
- European Commission, 2008. Review Report for the active substance quartz sand finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of quartz sand in Annex I of Directive 91/414/EEC. SANCO/2628/08 – rev.2, 27 October 2008.
- European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

## APPENDICES

### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

#### Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Quartz sand (there is no ISO common name)
Function ( <i>e.g.</i> fungicide)	Repellent
Rapporteur Member State	Austria
Co-rapporteur Member State	---

#### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	1) Silicon dioxide 2) Quartz
Chemical name (CA) ‡	1) Silicon dioxide 2) Quartz
CIPAC No ‡	855
CAS No ‡	1)7631-86-9 2)14808-60-7
EC No (EINECS or ELINCS) ‡	1)231-545-4 2)238-878-4
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured ‡	<u>Notifier A</u> : 915 g/kg <u>Notifier B</u> : > 990 g/kg <u>Notifier D</u> : 985 g/kg <u>Notifier E</u> : Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	SiO <sub>2</sub>
Molecular mass ‡	60.08 g/mol
Structural formula ‡	$\text{O}=\text{Si}=\text{O}$

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Natural quartz: 1610°C (literature) Crystalline quartz: 1710°C (literature)
Boiling point (state purity) ‡	2230°C (literature)
Temperature of decomposition (state purity)	573 – 870°C (literature)
Appearance (state purity) ‡	Notifier A: white-grey-brown, solid-grained substance Notifier B: solid, diaphanous and completely colourless Notifier D: solid, grain, white-grey Notifier E: solid, grainy, white or light cream
Vapour pressure (state temperature, state purity) ‡	1350 Pa at 1732°C (natural quartz) 1333 Pa at 1732°C (crystalline quartz)
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	Insoluble in water
Solubility in organic solvents ‡ (state temperature, state purity)	Insoluble in organic solvents
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable, solid preparation
Partition co-efficient ‡ (state temperature, pH and purity)	Insoluble in water and n-octanol, hence not applicable
Dissociation constant (state purity) ‡	No dissociation
UV/VIS absorption (max.) incl. $\epsilon$ ‡ (state purity, pH)	No peak was identified in the UV/VIS spectrum.
Flammability ‡ (state purity)	Not highly flammable (literature)
Explosive properties ‡ (state purity)	Not explosive (literature)
Oxidising properties ‡ (state purity)	Not oxidizing (literature)

## Summary of representative uses evaluated (Quartz sand) (Annex IIA 3.4)

**Notifier A** (Task Force: Stähler Agrochemie GmbH &Co, KG; Avenarius Agro GmbH):

Crop and/ or situation  (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment	PHI (days)  (l)	Remarks:  (m)
					Type	Conc. of a.s.	method kind	growth stage & season	number min    max	interval between applicatio ns (min)	kg of product per 1000 plants min                    max		
					(d-f)	(i)	(f-h)	(j)	(k)				
Deciduous and coniferous trees in forestry	Germany	Cervacol® extra	F	Deer and red deer	PA	251 g/kg	Coating of undiluted product preferably with glove*	-	-	-	3 - 4	not signi- ficant	*only application by gloves or brush was assessed

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (eg. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) eg. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at 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

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

**Notifier B** (Flügel GmbH):

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Deciduous and coniferous trees in forestry	Germany	Wöbra®	F	Game repellent: Red deer, sitka deer, fallow deer	PA	480 g/kg	coating with brush, individual plants; tree trunks	all-season	1	n. a.	n. a.	no water	200 – 400 g/bole	n. a.	
Deciduous and coniferous trees in forestry	Germany	Wöbra®	F	Game repellent: beaver	PA	480 g/kg	coating with brush, individual plants; tree trunks	all-season	1	n. a.	n. a.	no water	250 g/bole	n. a.	

n. a. = not applicable

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (eg. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) eg. biting and sucking insects, soil born insects, foliar fungi, weeds
  - (d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at 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
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

**Notifier D** (NeraAgro spol. s.r.o.):

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment  kg of product per 1000 pieces of seedlings min max	PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)			
Seedlings of conifer and deciduous trees	Czech republic, Slovak republic, Germany	Morsuvin	F	Ruminant animals: Deer family ( <i>Cervus Elaphus</i> ) Roe family ( <i>Capreolus Capreolus</i> ) Fallow Deer ( <i>Dama Dama</i> )	PA	> 260 g/kg *)	Coating of individual plants with special brush or rubber glove	Young seedlings up to 5 years Season: August - November	1	1 year	4 – 5 for seedlings up to 2 years of age 5 - 6 for seedlings older than 2 years	n. a.	none

n. a. = not applicable

\*) comment from Notifier D at January 2011 (see Reporting Table point 1(22); EFSA, 2011)

<b>Remarks:</b>	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (eg. fumigation of a structure)	(i)	g/kg or g/l
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at 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
	(c)	eg. biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	All abbreviations used must be explained	(l)	PHI - minimum pre-harvest interval
	(g)	Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench	(m)	Remarks may include: Extent of use/economic importance/restrictions
	(h)	Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated		



**Notifier E** (Chema sp.zo.o.):

Crop and/ or situation  (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment		PHI (days)  (l)	Remarks:  (m)
					Type	Conc. of a.s.	method kind	growth stage & season	number min    max	interval between applications (min)	kg of product per 1000 plants min                    max			
					(d-f)	(i)	(f-h)	(j)	(k)					
Deciduous and coniferous trees in forestry	Poland	Repentol® 6 PA	F	Deer and red deer	PA	300 g/kg	Manually on each tree*	young shoots; autumn (September- November)	Once per year	approx. one year	2                    15	not signific ant	The preparation prevents winter browsing by game (deer family and hare family). The preparation must not be applied in water protection areas and game reserves.  *only application by gloves or brush was assessed	

<b>Remarks:</b>	<p>(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>eg.</i> fumigation of a structure)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) <i>eg.</i> biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) <i>eg.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, <i>eg.</i> high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, <i>eg.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p>	<p>(i) g/kg or g/l</p> <p>(j) Growth stage at 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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p>
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## Methods of Analysis

### Analytical methods for the active substance (Annex IIA, point 4.1)

**Notifier A** (Task Force: Stähler Agrochemie GmbH & Co, KG; Avenarius Agro GmbH):

Technical a.s. (analytical technique)	SiO <sub>2</sub> : Energy Dispersive X-ray analysis; sieve analysis
Impurities in technical a.s. (analytical technique)	None
Plant protection product (analytical technique)	SiO <sub>2</sub> : gravimetry, Fourier Transform InfraRed

**Notifier B** (Flügel GmbH):

Technical a.s. (analytical technique)	SiO <sub>2</sub> : gravimetry (evaporation as silicon tetrafluoride); sieve analysis
Impurities in technical a.s. (analytical technique)	complexometric back-titration
Plant protection product (analytical technique)	SiO <sub>2</sub> : gravimetry (residue after incineration)

**Notifier D** (NeraAgro spol. s.r.o.):

Technical a.s. (analytical technique)	SiO <sub>2</sub> : gravimetry + spectrophotometry; sieve analysis
Impurities in technical a.s. (analytical technique)	Atomic absorption spectroscopy spectrophotometry
Plant protection product (analytical technique)	SiO <sub>2</sub> : gravimetry

**Notifier E** (Chema sp.zo.o.):

Technical a.s. (analytical technique)	No study submitted. Open.
Impurities in technical a.s. (analytical technique)	No study submitted. Open.
Plant protection product (analytical technique)	No study submitted. Open.

### Analytical methods for residues (Annex IIA, point 4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	No residue definition.  Quartz sand has been notified as a repellent for use on trees by application with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings.  Since coating of trees is the only use of quartz sand, no crops are treated directly and therefore no residues on food and/or feed may occur.
Food of animal origin	No residue definition. See statement above.

Soil	<p>No residue definition.</p> <p>Quartz sand is a ubiquitous substance. It consists mainly of SiO<sub>2</sub>, which is a highly abundant element in the earth's crust.</p> <p>It is impossible to differentiate analytically between applied quartz sand and naturally present quartz sand.</p>
Water surface	<p>No residue definition.</p> <p>See statement above.</p>
drinking/ground	<p>No residue definition.</p> <p>See statement above.</p>
Air	<p>No residue definition.</p> <p>See statement above.</p>

### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<p>No residue definition.</p> <p>Quartz sand has been notified as a repellent for use on trees by application with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings.</p> <p>Since coating of trees is the only use of quartz sand, no crops are treated directly and therefore no residues on food and/or feed may occur.</p>
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No relevant. See statement above.
Soil (analytical technique and LOQ)	Not relevant. See statement above.
Water (analytical technique and LOQ)	Not relevant. See statement above.
Air (analytical technique and LOQ)	Not relevant. See statement above.
Body fluids and tissues (analytical technique and LOQ)	No method required since the active substance is not classified as toxic or highly toxic.

### Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

Active substance	<p>RMS/peer review proposal</p> <p>Quartz sand will not be classified from a physical/chemical point of view.</p>
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## Impact on Human and Animal Health

### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Data available of limited validity, no further data needed.
Distribution ‡	Data available of limited validity, no further data needed.
Potential for accumulation ‡	Data available of limited validity, no further data needed.
Rate and extent of excretion ‡	Data available of limited validity, no further data needed.
Metabolism in animals ‡	Data available of limited validity, no further data needed.
Toxicologically relevant compounds ‡ (animals and plants)	Data available of limited validity, no further data needed.
Toxicologically relevant compounds ‡ (environment)	-

### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral ‡	Data available of limited validity, no further data needed.	-
Rabbit LD <sub>50</sub> dermal ‡	Data available of limited validity, no further data needed.	-
Rat LC <sub>50</sub> inhalation ‡	Data available of limited validity, no further data needed.	-
Skin irritation ‡	Data available of limited validity, no further data needed.	-
Eye irritation ‡	Data available of limited validity, no further data needed.	-
Skin sensitisation ‡	Data available of limited validity, no further data needed.	-

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Data available of limited validity, no further data needed.
Relevant oral NOAEL ‡	-

Relevant dermal NOAEL ‡	-
Relevant inhalation NOAEL ‡	-

#### Genotoxicity ‡ (Annex IIA, point 5.4)

Data available of limited validity, no further data needed.	
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#### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Maximum content of particles with diameter below 50 µm in quartz sand should not exceed 0.1 % due to the association between exposure to respirable silica dust (with diameter lower than 10 µm) and silicosis and increased probability of developing lung cancer.
Relevant NOAEL ‡	
Carcinogenicity ‡	

#### Reproductive toxicity (Annex IIA, point 5.6)

##### Reproduction toxicity

Reproduction target / critical effect ‡	Data available of limited validity, no further data needed.	-
Relevant parental NOAEL ‡		-
Relevant reproductive NOAEL ‡		-
Relevant offspring NOAEL ‡		-

##### Developmental toxicity

Developmental target / critical effect ‡	Data available of limited validity, no further data needed.	-
Relevant maternal NOAEL ‡		-
Relevant developmental NOAEL ‡		-

#### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available, not needed.	-
Repeated neurotoxicity ‡	No data available, not needed.	-

Delayed neurotoxicity ‡

No data available, not needed.	-

### Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡

Data available of limited validity, no further data needed.

Studies performed on metabolites or impurities ‡

No data available, not needed.

### Medical data ‡ (Annex IIA, point 5.9)

Data available of limited validity, no further data needed.

### Summary (Annex IIA, point 5.10)

ADI ‡

No data available  
not required.

Study

Safety factor

AOEL ‡

No data available  
not required.

ARfD ‡

No data available,  
not required.

### Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation

negligible

### Exposure scenarios (Annex IIIA, point 7.2)

Operator

Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Workers

Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Bystanders

Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

### Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Quartz sand (0.1% maximum of particles with diameter below 50 µm)

peer review proposal

No classification proposal for carcinogenic properties.  
For other endpoints: data available of limited validity to conclude, no further data needed.



## Residues

### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered

Rotational crops

Metabolism in rotational crops similar to metabolism in primary crops?

Processed commodities

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Plant residue definition for monitoring

Plant residue definition for risk assessment

Conversion factor (monitoring to risk assessment)

Not appropriate. No residue definition.

Quartz sand has been notified as a repellent for use on trees by application with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings.

Since coating of trees is the only use of quartz sand, no crops are treated directly and therefore no residues on food and/or feed may occur.

### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered

Time needed to reach a plateau concentration in milk and eggs

Animal residue definition for monitoring

Animal residue definition for risk assessment

Conversion factor (monitoring to risk assessment)

Metabolism in rat and ruminant similar (yes/no)

Fat soluble residue: (yes/no)

Not appropriate. No residue definition.

See general statement under metabolism in plants.

### Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not appropriate.

See general statement under metabolism in plants.

### Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Not appropriate.

See general statement under metabolism in plants.

### Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Expected intakes by livestock  $\geq 0.1$  mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues  $\geq 0.01$  mg/kg in edible tissues (yes/no)

Ruminant:

Poultry:

Pig:

Conditions of requirement of feeding studies

Not appropriate.

See general statement under metabolism in plants.

Muscle

Liver

Kidney

Fat

Milk

Eggs

Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)

Residue levels in matrices : Mean (max) mg/kg

Not appropriate.

See general statement under metabolism in plants.

**Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)**

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Not appropriate. See general statement under metabolism in plants.						

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

## Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not relevant, see section on mammalian toxicology
TMDI (% ADI) according to WHO European diet	
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	Not relevant, see section on mammalian toxicology
IENTI (% ARfD)	
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	

## Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not appropriate. See general statement under metabolism in plants.				

## Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

.....	Not appropriate. See general statement under metabolism in plants.
.....	
.....	

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

## Environmental fate and behaviour

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

None available, not required.

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.

### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.

### PEC (soil) (Annex IIIA, point 9.1.3)

Not relevant for the environmental exposure assessment. Owing to the manual application by coating forest trees with gloves or brush no entry of the active substance into soil is expected. Therefore the calculation of  $PEC_{soil}$  is not considered necessary.

### Route and rate of degradation in water (Annex IIA, point 7.2.1)

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.

### PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Not relevant for the environmental exposure assessment. Owing to the manual application by coating trees with gloves or brush no entry of the active substance into soil and water will be expected. Therefore the calculation of  $PEC_{SW}$  and  $PEC_{SED}$  is not considered necessary.

### PEC (ground water) (Annex IIIA, point 9.2.1)

Not relevant for the environmental exposure assessment.  
Owing to the manual application by coating trees with gloves or brush no entry of the active substance into soil and ground water will be expected.

### Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Silicon dioxide is not a volatile compound.

### PEC (air)

Silicon dioxide is not a volatile compound.

### Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology), and or requiring consideration for groundwater exposure.

Not necessary. Silicon dioxide is naturally occurring in the environment.

### Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

Surface water (indicate location and type of study)

Ground water (indicate location and type of study)

Air (indicate location and type of study)

Not applicable. Silicon dioxide is naturally occurring in the environment.

### Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Biodegradability assessment not applicable for a mineral. No classification proposed.

## Ecotoxicology

### Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/(day))	End point (mg/kg feed)
Birds ‡				
No data				
Mammals ‡				
<i>rat</i>	a.s.	Acute	Data available of limited validity, no further data needed.	
<i>rat</i>	Preparation Cervacol (Notifier A)	Acute	LD <sub>50</sub> > 10 g/kg bw	
<i>rat</i>	Preparation Morsuvin (Notifier D)	Acute	LD <sub>50</sub> > 2 g/kg bw	
Additional higher tier studies ‡ No data				

### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
	As the treated plant material generally does not constitute an attractive food item for birds and as it is likely that the product also has a slight repellent effect against birds, the risk for birds after application of quartz sand according to the representative uses is considered to be low.			
Tier 1 (Mammals)				
	The lead formulations are used as a coating of trees (manually applied) and hence exposure of mammals is considered negligible. Moreover, the available data on mammalian toxicity for the formulations ‘Cervacol ‘and ‘Morsuvin’ indicate a low risk to mammals via acute exposure.			

**Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)**

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg preparation/L)
Laboratory tests ‡				
Fish				
<i>Oncorhynchus mykiss</i>	Preparation Cervacol (Notifier A)	96 hr (static)	Mortality, LC <sub>50</sub> NOEC	> <b>500</b> (nom) 500 (nom)
<i>Oncorhynchus mykiss</i>	Preparation Wöbra (Notifier B)	96 hr (static)	Mortality, LC <sub>50</sub> NOEC	> <b>100</b> (nom) 100 (nom)
<i>Poecilia reticulata</i>	Preparation Morsuvin (Notifier D)	96 hr (static*)	Mortality, LC <sub>50</sub>	<b>36.9</b> (nom)
Aquatic invertebrate				
<i>Daphnia magna</i>	Preparation Cervacol (Notifier A)	48 h (static)	Mortality, EC <sub>50</sub> NOEC	> <b>500</b> (nom) 500 (nom)
<i>Daphnia magna</i>	Preparation Wöbra (Notifier B)	48 h (static)	Mortality, EC <sub>50</sub> NOEC	> <b>1000</b> (nom) 580 (nom)
<i>Daphnia magna</i>	Preparation Morsuvin (Notifier D)	48 h (static*)	Mortality, EC <sub>50</sub>	<b>92.06</b> (nom)
Sediment dwelling organisms (no data)				
Algae				
<i>Pseudokirchn. subcapitata</i>	Preparation Cervacol (Notifier A)	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	> <b>500</b> (nom) > <b>500</b> (nom)
<i>Scenedesmus subspicatus</i>	Preparation Wöbra (Notifier B)	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	> <b>1000</b> (nom) > <b>1000</b> (nom)
<i>Scenedesmus subspicatus</i>	Preparation Morsuvin (Notifier D)	72 h (static*)	Biomass: E <sub>b</sub> C <sub>50</sub>	<b>13.9</b> (nom)

nom ... test concentration based on nominal (nom) concentration

\* Test conditions were not reported but assumed to be static

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)**

Due to the type of application as coating on trees exposure of aquatic organisms is considered to be low. Therefore a calculation of TER values for aquatic organisms is not considered necessary.

**Bioconcentration**

Quartz sand is a biologically inert substance and therefore no tendency for bioaccumulation is expected.



### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD <sub>50</sub> µg/bee)	Acute contact toxicity (LD <sub>50</sub> µg/bee)
No data, not relevant	The lead formulations are used as a coating on trees (manually applied) and hence exposure of bees is considered to be low.	

### Hazard quotients for honey bees (Annex IIIA, point 10.4)

Test substance	Route	Hazard quotient	Annex VI Trigger
No data, not relevant			

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

#### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR <sub>50</sub> g/ha)
No data, not relevant	Due to the facts that the formulations are used as a coating on trees, which is not a large-area application, and that quartz sand ubiquitously occurs in the environment, no testing is considered necessary.		

#### Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
No data, not relevant						

### Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5, Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
No data, not relevant			
Other soil macro-organisms			
Soil mite			
No data, not relevant			
Collembola			
No data, not relevant			
Soil micro-organisms			
No data, not relevant			

Test organism	Test substance	Time scale	End point

### Toxicity/exposure ratios for soil organisms

Due to the manual application of the formulations by coating trees with gloves or by brush no entry of the active substance/formulation into soil is expected. Therefore exposure of soil organisms is considered to be low.

### Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

#### Preliminary screening data

No data, not relevant. Due to the facts that the formulations are used as a coating on trees, which is not a large-area application, and that quartz sand occurs ubiquitously in the environment, the risk to other non-target plants is considered to be low.

### Effects on biological methods for sewage treatment (Annex IIA 8.7)

No data, not relevant	No inhibitory effects on aerobic waste water microorganisms are expected if the lead formulations are used as a coating on trees (manually applied).
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### Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	None
water	None
sediment	None
groundwater	None

### Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance	RMS/peer review proposal
	No classification proposed (Biodegradability assessment not applicable for a mineral)
Preparation Cervacol extra (Notifier A)	RMS/peer review proposal
Preparation Wöbra (Notifier B)	No classification proposed
Preparation Morsuvin (Notifier D)	No classification proposed
Preparation Repentol 6PA (Notifier E)	No classification was proposed due to the absence of data on aquatic toxicity.

## ABBREVIATIONS

1/n	slope of Freundlich isotherm
$\lambda$	wavelength
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
$\mu\text{g}$	microgram
$\mu\text{m}$	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IENTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K <sub>doc</sub>	organic carbon linear adsorption coefficient
kg	kilogram
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC <sub>50</sub>	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
N/A	not applicable
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PA	paste
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
VIS	visible
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year