

Appendix to:

EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. EFSA Journal 2022;20(9):7552, 37 pp. doi:10.2903/j.efsa.2022.7552

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Appendix B - List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Quartz sand (there is no ISO common name)
Function (e.g. fungicide)	Repellent
Rapporteur Member State	Latvia
Co-rapporteur Member State	Romania

Identity (Regulation (EU) N° 283/2013, Annex Part A, 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	The minimum purity of quartz sand technical is 915 g/kg according to Regulation (EC) No. 540/2011.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Max. 0.1% of particles of crystalline silica with particle diameter $\leq 10 \mu\text{m}$.
Location of the (proposed) reference specification (for significant impurities)	<i>RAR Volume 4, Avenarius-Agro GmbH and Cheminova Deutschland GmbH & Co. KG (May / 2022)*</i> <i>RAR Volume 4, Flügel GmbH (May / 2022)*</i> <i>RAR Volume 4, NeraAgro, spol. s r.o. (May / 2022)*</i> <i>RAR Volume 4, DCR Sp. z o.o. (March / 2022)*</i>

Molecular formula

*Following the Pesticide Peer Review TC 73, it was unanimously agreed to lower - from 50 to 10 μm -the size of the relevant impurity crystalline silica particles that can be present in quartz sand with a maximum limit of 0.1% w/w.

Molar mass

 SiO_2

Structural formula

60.08 g/mol



Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	>410°C (purified, SiO ₂) 1610°C (natural quartz SiO ₂) 1713°C (quartz SiO ₂) 1710°C (silica, crystalline quartz)
Boiling point (state purity)	>410°C (purified, SiO ₂) 2230°C (natural quartz SiO ₂) 2230°C (quartz SiO ₂) 2230°C (silica, crystalline quartz)
Temperature of decomposition (state purity)	Not relevant
Appearance (state purity)	Solid, grainy, white/grey/brown, odourless (quartz sand). Transparent tasteless crystals or amorphous powder (silicon dioxide).
Vapour pressure (state temperature, state purity)	Vapour pressure: 1350 Pa at 1732°C (natural quartz) 1333 Pa at 1732°C (crystalline quartz) Volatility is not required.
Henry's law constant (state temperature)	Not relevant
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 relevant
Partition coefficient (state temperature, pH and purity)	Not applicable. Quartz sand is insoluble in water and organic solvents.
Dissociation constant (state purity)	Not applicable
UV/VIS absorption (max.) incl. ϵ (state purity, pH)	No peaks were identified in the UV/VIS spectrum. No peak was identified in the UV/VIS spectrum above a wavelength of 290 nm.
Flammability (state purity)	Quartz is not flammable and auto-flammable
Explosive properties (state purity)	Not applicable
Oxidising properties (state purity)	Not oxidizing

Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Deciduous and coniferous trees in forestry 3FORC	CEU, NEU, SEU	Repento 16 PA	F	ruminant animals: -deer family 1CERVF (<i>Cervidae</i>) -roe family CAPRCA (<i>Capreolus Capreolus</i>), -fallow deer DAMADA (<i>Dama dama</i>) -lagomorphs 1LAGOO (<i>Lagomorpha</i>)	PA	300	Coating manually with special brush or glove	Young shoots, 2-5 years old, autumn (Sept.-Nov.)	a) 1 b) 1	-	-	-	a) 3 - 4.5 kg/1000 plants b) 3 - 4.5 kg/1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
Deciduous and coniferous trees in forestry 3FORC	EU central	Wöbra	F	Game repellent: CERVSP (<i>Cervus sp.</i>), CERVNI (<i>Cervus nippon</i>), DAMADA (<i>Dama dama</i>)	PA	475:2	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 190.08 kg/ha b) 190.08 kg/ha Here 1000 trees/ha are considered	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
Deciduous and coniferous trees in forestry 3FORC	EU central	Wöbra	F	Game repellent: CASTFI (<i>Castor fiber</i>)	PA	475:2	painting with brush: trunks of individual	all-season	a) 1 b) 1	-	-	-	a) 118.80 kg/ha b) 118.80 kg/ha	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
							ual trees							Here 1000 trees/ha are considered	
Orchard 3FRUC	EU central	Wöbra	F	Game repellent: CERVSP (<i>Cervus sp.</i>), CERVNI (<i>Cervus nippon</i>), DAMADA (<i>Dama dama</i>)	PA	475.2	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 190.08 kg/ha b) 190.08 kg/ha Here 1000 trees/ha are considered	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment. professional and non-professional field use
Orchard 3FRUC	EU central	Wöbra	F	Game repellent: CASTFI (Castor fiber), LEPUEU (<i>Lepus europaeus</i>), ORYTCU (<i>Oryctolagus cuniculus</i>)	PA	475.2	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 118.80 kg/ha b) 118.80 kg/ha Here 1000 trees/ha are considered	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment. professional and non-professional field use
Ornamental shrubs and trees 3ORTC	EU central	Wöbra	F	Game repellent: CASTFI (Castor fiber), LEPUEU (<i>Lepus europaeus</i>), ORYTCU (<i>Oryctolagus cuniculus</i>)	PA	475.2	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 118.80 kg/ha b) 118.80 kg/ha Here 1000 trees/ha are considered	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment. professional and non-professional field use

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Deciduous and coniferous trees in forestry 3FORC	AT, PL, CZ, HU, RO, SK	Cervacol Extra	F	Deer and red deer (against browsing): CERVSP (<i>Cervus sp.</i>), CERVEL (<i>Cervus elaphus</i>)	PA	251	Coating of undiluted product preferably with gloves	all-season	a) 1 b) 1	-	-	-	a) 0.5-1.3 kg /1000 plants b) 0.5-1.3 kg /1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
Deciduous and coniferous trees in forestry 3FORC	PL	Cervacol Extra	F	Deer and red deer (against fraying): CERVSP (<i>Cervus sp.</i>), CERVEL (<i>Cervus elaphus</i>)	PA	251	Coating of undiluted product preferably with gloves	all-season	a) 1 b) 1	-	-	-	a) 3.5 kg /1000 plants b) 3.5 kg /1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
Deciduous and coniferous trees in forestry 3FORC	LV, EE, DE,	Cervacol Extra	F	Deer and red deer (against browsing): CERVSP (<i>Cervus sp.</i>), CERVEL (<i>Cervus elaphus</i>)	PA	251	Coating of undiluted product preferably with gloves	all-season	a) 1 b) 1	-	-	-	a) 0.8-1 kg /1000 plants b) 0.8-1 kg /1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
Deciduous and coniferous trees in forestry 3FORC	LT	Cervacol Extra	F	Deer and red deer (against browsing): CERVSP (<i>Cervus sp.</i>), CERVEL (<i>Cervus elaphus</i>)	PA	251	Coating of undiluted product preferably with gloves	all-season	a) 1 b) 1	-	-	-	a) 0.5-0.8 kg /1000 plants b) 0.5-0.8 kg /1000 plants	Not relevant	Non-professional use 3-4 kg/1000 plants; Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
For up to 2 years old seedlings of conifer and deciduous trees in forestry 3FORC	Czech Republic Slovak Republic Germany	Morsuvin	F	Ruminant animals: Deer family: CERVEL (<i>Cervus Elaphus</i>), Roe family: CAPRCA (<i>Capreolus Capreolus</i>), Fallow Deer DAMADA (<i>Dama dama</i>)	PA	254.8 255 g/kg of quartz sand 40 g/kg of fat distillation residues	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 4-5 kg /1000 plants b) 4-5 kg /1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment
More than 2 years old seedlings of conifer and deciduous trees in forestry 3FORC	Czech Republic Slovak Republic Germany	Morsuvin	F	Ruminant animals: Deer family: CERVEL (<i>Cervus Elaphus</i>) Roe family: CAPRCA (<i>Capreolus Capreolus</i>) Fallow Deer: DAMADA (<i>Dama dama</i>)	PA	254.8 255 g/kg of quartz sand 40 g/kg of fat distillation residues	painting with brush: trunks of individual trees	all-season	a) 1 b) 1	-	-	-	a) 5-6 kg /1000 plants b) 5-6 kg /1000 plants	Not relevant	Undiluted application; the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
 (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
 (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
 (f) All abbreviations used must be explained
 (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).**
 (j) Growth stage range from first to 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) Indicate the minimum and maximum number of applications possible under practical conditions of use
 (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
 (m) PHI - minimum pre-harvest interval

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)
Regulation (EC) N° 1107/2009 Article 8.1(g)

Not relevant

Further information, Efficacy**Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)**

The representative products containing quartz sand are applied manually with special brush or glove on the plant parts in order to protect against damages caused by ruminant animals: deer family, roe family, fallow deer and lagomorphs in winter. The effect is based on an unpleasant abrasive effect which prevents game to damage the plants. A data gap was identified for efficacy data of the formulation 'Morsuvin®'

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

No signs of phytotoxicity of the representative products were visible on coniferous and deciduous trees.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

A paste-like game repellent and will be paint on the trunks of significant trees which shall be protected against game bark stripping. Thus no adjacent plants or non-target organisms will be affected.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

Not relevant

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	<p>UV/Vis</p> <p>X-ray fluorescence</p> <p>Data gaps were identified for a validated method for the analysis of the quartz sand in the technical active substance as manufactured (relevant for NeraAgro, spol. S r.o. and Task force Avenarius and Cheminova.)</p>
Impurities in technical a.s. (analytical technique)	<p>Laser granulometer method</p> <p>Data gaps were identified for a validated analytical method for the determination of the relevant impurity (respirable crystalline silica with particle diameter below 10 µm) in the active substance as manufactured (relevant for DCR Sp. z o.o. and Flügel GmbH) and for validation data for the proposed laser granulometer method for the determination of particle size distribution of the technical quartz sand with a minimum diameter of 10 µm (relevant for NeraAgro, spol. S r.o. and Task force).</p>
Plant protection product (analytical technique)	<p>Repenol 6 PA</p> <p>The method 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.</p> <p>Wöbra</p> <p>Gravimetric method, by weighing the residues after incineration to a temperature of 550 °C.</p> <p>Cercavol Extra</p> <p>CIPAC MT 185 (wet sieve test)</p> <p>‘Morsuvin®’</p> <p>Gravimetric method, by weighing the residues after incineration to a temperature of 600 °C.</p> <p>The requirement for methods of analysis for monitoring the respirable crystalline silica in the representative formulations has been waived due to negligible inhalation exposure predicted for the proposed uses.</p>

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin	None
Food of animal origin	None
Soil	None
Sediment	None
Water surface	None
drinking/ground	None
Air	None
Body fluids and tissues	None

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Not required
Water (analytical technique and LOQ)	Not required
Air (analytical technique and LOQ)	Not required
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Quartz sand
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ¹ :	No classification

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:

No classification

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Negligible due to the intrinsic properties (insoluble and inert) of the active substance.
Toxicokinetics	No data available, not needed.
Distribution	Negligible due to the intrinsic properties (insoluble and inert) of the active substance.
Potential for bioaccumulation	No evidence for accumulation.
Rate and extent of excretion	Ingested silica is eliminated in the faeces; the very limited absorbed fraction (if any) is excreted in urine unmetabolized.
Metabolism in animals	Not occurring.
<i>In vitro</i> metabolism	No data available, not needed.
Toxicologically relevant compounds (animals and plants)	No data available, not needed.
Toxicologically relevant compounds (environment)	Crystalline silica (impurity) with particle size $\leq 10 \mu\text{m}$

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD ₅₀ oral	> 2000 mg/kg bw (supplementary information –studies with amorphous silica).	-
Rat LD ₅₀ dermal	> 2000 mg/kg bw (supplementary information –studies with amorphous silica). (supplementary information –studies with crystalline and amorphous silica).	-
Rat LC ₅₀ inhalation	> 2.2 mg/L air (supplementary information –studies with amorphous silica).	-
Skin irritation	Not irritating (supplementary information –studies with amorphous SiO ₂).	-
Eye irritation	Not irritating (supplementary information –studies with amorphous SiO ₂).	-
Skin sensitisation	Not sensitising (supplementary information –studies with amorphous SiO ₂).	-
Phototoxicity	No data available, not needed.	-

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	No oral or dermal toxicity data available for crystalline SiO ₂ . Inhalation: Rat: lung /inflammatory response, impairment of alveolar macrophage clearance functions, increased incidence of adenocarcinomas and squamous cell carcinomas with crystalline silica. Mouse: silicotic granulomas, and lymphoid cuffing around airways but no malignant tumors.	-
Relevant oral NOAEL	-	-
Relevant dermal NOAEL	-	-
Relevant inhalation NOAEL	Due to the representative uses no exposure by inhalation is expected.	-

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	No data submitted.	-
<i>In vivo</i> studies	According to literature data, conflicting results have been obtained with crystalline silica including quartz, which do not allow to confirm or rule out a direct genotoxic mode of action after inhalation exposure.	-
Photomutagenicity	No data available, not needed.	-
Potential for genotoxicity	Maximum content of particles with diameter below 10 µm in quartz sand should not exceed 0.1 % due to the association between high dose prolonged exposure to respirable silica dust (with diameter lower than 10 µm) and silicosis and increased probability of developing lung cancer. Data not needed, considering the formulation as a paste and the type of application.	-

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	No data submitted, not needed, considering the types of formulations and application. Maximum content of particles with diameter below 10 µm in quartz sand should not exceed 0.1 % due to the association between high dose prolonged exposure to respirable silica dust (with diameter lower than 10 µm) and silicosis and increased probability of developing lung cancer.	-
Relevant long-term NOAEL	-	-
Carcinogenicity (target organ, tumour type)	Orally, negative in rats and mice (supplementary information – feeding studies with silica gel). By inhalation, adenocarcinomas and squamous cell carcinomas in rats.	-
Relevant NOAEL for carcinogenicity	-	-

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)**Reproduction toxicity**

Reproduction target / critical effect	Supplementary information of limited validity with amorphous silica, no further data needed	-
Relevant parental NOAEL	-	-
Relevant reproductive NOAEL	-	-
Relevant offspring NOAEL	-	-

Developmental toxicity

Developmental target / critical effect	None (supplementary information – studies with amorphous silica gels).	-
Relevant maternal NOAEL	-	-
Relevant developmental NOAEL	-	-

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No data available, not needed.	-
Repeated neurotoxicity	No data available, not needed.	-
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data available, not needed.	-

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	No data available, not needed.	
Endocrine disrupting properties	<p>In view of the intrinsic properties (insoluble and inert) of the active substance the assessment does not appear scientifically necessary.</p> <p>Quartz sand does not to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.</p>	
Studies performed on metabolites or impurities	No data available, not needed.	

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

<p>Adverse health effects (silicosis, chronic obstructive pulmonary disease, lung cancer, renal toxicity, increased risk of tuberculosis, and autoimmune diseases) from prolonged/ inhalation of high doses of crystalline silica particles < 10 µm in occupational settings.</p> <p>Considering the types of formulations and applications, no data were submitted and are needed.</p>

Summary² (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	No data available, not required.	-	-
Acute Reference Dose (ARfD)	No data available, not required.	-	-
Acceptable Operator Exposure Level (AOEL)	No data available, not required.	-	-

² If available include also reference values for metabolites

Acute Acceptable Operator Exposure Level (AAOEL)

No data available, not required.	-	-
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* Including correction for limited oral absorption/bioavailability (xx %).

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (*Repentol 6 PA*, *Wöbra*, *Cervacol Extra*, *Morsuvin*)

Dermal absorption is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

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 and residents

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

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Quartz sand (0.1% maximum of particles diameter below 10 µm)

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]³ :

No current harmonized classification

According to the peer review proposal, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:

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

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Residues in or on treated products food and feed

Metabolism studies, methods of analysis and residue definitions in plants

Not required - Due to the inert and insoluble properties of its constituents, quartz sand is not expected to degrade or to form other metabolites relevant for the consumers when used in compliance with the representative uses.

The uses as coating/painting with brush of the individual trees of orchards are relevant for the consumer exposure assessment. It can reasonably be assumed that residues of quartz sand will not be quantified if the application to the orchards trees is conducted in a way that precludes any contamination of the edible parts of the fruits.

Can a general residue definition be proposed for primary crops?	Not relevant	
Rotational crop and primary crop metabolism similar?	Not applicable	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable	
Plant residue definition for monitoring (RD-Mo)	Not relevant	
Plant residue definition for risk assessment (RD-RA)	Not relevant	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Not applicable	

Stability of residues in plants

Not required.

Magnitude of residues in plants

Not required.

Residues in rotational crops**Overall summary**

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Not triggered

Quartz sand is a game repellent and will be used as protection coat on the outer surface of deciduous and coniferous trees in forestry and fruit trees in orchards as well as ornamental shrubs and trees by coating manually with special brush or glove or by painting with brush the trunk of the individual trees.

Residues in rotational and succeeding crops expected based on field rotational crop study?

Processing factors

Not required.

Residues in livestock

Nature of residues and methods of analysis in livestock

Metabolism studies, methods of analysis and residue definitions in livestock

Not required.

Time needed to reach a plateau concentration in milk and eggs (days)	Milk:	not triggered
	Eggs:	not triggered
Metabolism in rat and ruminant similar	not triggered	
Can a general residue definition be proposed for animals?	Not relevant	
Animal residue definition for monitoring (RD-Mo)	Not relevant	
Animal residue definition for risk assessment (RD-RA)	Not relevant	
Fat soluble residues	Yes/No	Not relevant.
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Not applicable	

Stability of residues in livestock

Not required.

Magnitude of residues in livestock

Not required.

Consumer risk assessment

Since data on genotoxicity and general toxicity of this substance were not submitted, the toxicological profile of quartz sand could not be assessed and toxicological reference values (ADI, ARfD) were not derived (see section 2).

However, a negligible exposure for the consumers to residues of quartz sand is expected when the representative uses are considered, and a consumer dietary risk assessment can be waived.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Not relevant

Recommended MRLs

Quartz sand has been notified as a game repellent for the uses on deciduous and coniferous trees in forestry, fruit trees in orchards as well as on ornamental shrubs and trees by coating manually with special brush or glove or by painting with brush the trunk of the individual trees.

Based on these representative uses, a negligible exposure for the consumers to residues of quartz sand is expected and a consumer dietary risk assessment can be waived. No MRLs are therefore proposed for the representative uses.

However, not all the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, were met for quartz sand. Three criteria are considered to be met (III, IV and V) for quartz sand.

The review of existing maximum residue levels (MRLs) under Article 12 of Regulation (EC) No 396/2005 is covered by the assessment of the representative uses on orchards and on deciduous and coniferous trees in forestry since the most critical authorised uses from European Member States consist in a single treatment by coating manually the trunks of the trees with special brush or gloves, at a dose rate covered by the maximum dose rate of application intended in the representative uses.

Environmental fate and behaviour**Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)**

Mineralisation after 100 days	Not relevant
Non-extractable residues after 100 days	Not relevant
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	No metabolites

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	Not relevant
Non-extractable residues after 100 days	Not relevant
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites
Mineralisation at study end	Not relevant
Non-extractable residues at study end	Not relevant

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions						
	Soil type	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
-	-	-	-	-	-	-	-
Geometric mean (if not pH dependent)					-		

pH dependence	-
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Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
-	-	-	-	-	-	-	-
Geometric mean (if not pH dependent)					-		
Arithmetic mean				-			
pH dependence					-		

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Natural background levels of silica in water and soil are a lot higher than the use as a plant protection product might ever cause.

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C	St. (χ^2)	Method of calculation
-	-	-	-	-	-	
Geometric mean (if not pH dependent)				-		

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark anaerobic conditions						
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20°C	St. (χ^2)	Method of calculation
-	-	-	-	-	-	-	-
Geometric mean (if not pH dependent)					-		
Arithmetic mean				-			

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Parent	Soil photolysis				
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	St. (χ^2)	Method of calculation
-	-	-	-	-	-

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent								
Soil Type	OC %	Soil pH	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n	
-	-	-	-	-	-	-	-	-
Geometric mean (if not pH dependent)*						-	-	
Arithmetic mean (if not pH dependent)								-
pH dependence			-					

* Only relevant after implementation of the published EFSA guidance.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Met 1								
Soil Type	OC %	Soil pH	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n	
-	-	-	-	-	-	-	-	-
Geometric mean (if not pH dependent)*						-	-	
Arithmetic mean (if not pH dependent)								-
pH dependence			-					

* Only relevant after implementation of the published EFSA guidance.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not relevant

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

Not relevant

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Quartz is stable in water.

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

Quartz is stable in water.

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

Not relevant

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)

No data submitted, substance considered not readily biodegradable

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole sys.		St. (χ^2)	DT ₅₀ /DT ₉₀ Water		St. (χ^2)	Method of calculation
				At study temp	Norm. to °C		At study temp	Norm. to x °C		
-	-	-	-	-	-	-	-	-	-	-

Met 1										
Max in total system x % after n days										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole sys.		St. (χ^2)	DT ₅₀ /DT ₉₀ Water		St. (χ^2)	Method of calculation
				At study temp	Norm. to x °C		At study temp	Norm. to x °C		
-	-	-	-	-	-	-	-	-	-	-

Mineralisation and non-extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d.	Non-extractable residues. max x % after n d.	Non-extractable residues. max x % after n d
-	-	-	-	-	-

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution <i>max in water x after n d. max. sed x % after n d</i>									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ^2)	DT ₅₀ /DT ₉₀ water	St. (χ^2)	DT ₅₀ /DT ₉₀ sed	St. (χ^2)	Method of calculation
-	-	-	-	-	-	-	-	-	-	-
Geometric mean at 20°C				-		-		-		-

Met 1	Distribution <i>max in water x after n d. max. sed x % after n d. max in total system x % after n days,</i> kinetic formation fraction (k_f/k_{dp}): -									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ^2)	DT ₅₀ /DT ₉₀ water	St. (χ^2)	DT ₅₀ /DT ₉₀ sed	St. (χ^2)	Method of calculation
-	-	-	-	-	-	-	-	-	-	-
Geometric mean at 20°C				-		-		-		-

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
-	-	-	-	-	-

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not relevant
Photochemical oxidative degradation in air	Not relevant
Volatilisation	Quartz is not a volatile compound
Metabolites	No metabolites

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

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

Natural background levels of silica in water and soil are a lot higher than the uses as a plant protection product might ever cause. SiO₂ is chemically inert and does not form any metabolites of environmental concern.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

No residue definitions are proposed for all environmental compartments. SiO₂ is naturally occurring in the environment.

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)	Not relevant
Surface water (indicate location and type of study)	Not relevant
Ground water (indicate location and type of study)	Not relevant
Air (indicate location and type of study)	Not relevant

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Not calculated, not relevant

Met 1 Not calculated, not relevant

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter) Not calculated, not relevant

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent Not calculated, not relevant

Met 1 Not calculated, not relevant

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation Not relevant

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity
Birds				
	Quartz sand (a.s.)	Acute	LD ₅₀	No data.
	Preparations	Acute	LD ₅₀	No data.
	Quartz sand (a.s.)	Long-term	NOAEL	No data.
Mammals				
<i>Rat</i>	Amorphous silica (supplementary information)	Acute	LD ₅₀	>2000
	Preparations	Acute	LD ₅₀	No data.
<i>Rat</i>	Quartz sand (a.s.)	Long-term	NOAEL	No data.
<p>Endocrine disrupting properties (Annex Part A, points 8.1.5)</p> <p>In view of the phys-chem properties (insoluble and inert) and the (eco) toxicological profile of the active substance the assessment does not appear scientifically necessary.</p> <p>Quartz sand does not meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.</p>				
<p>Additional higher tier studies (Annex Part A, points 10.1.1.2):</p> <p>Not required</p>				
<p>Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):</p> <p>No data, not required.</p>				

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

All proposed uses of Quartz sand in forestry

No toxicity from the active substance quartz sand and the formulated products is expected for birds and other terrestrial vertebrates. Quartz sand is a ubiquitous mineral of the earth's crust thus birds and other terrestrial vertebrates are continuously exposed to quartz sand in environment. Quartz sand is used as a coating of trees (manually applied) to prevent game from bark stripping. The risk for birds and terrestrial vertebrates after application of quartz sand is considered low. The calculation of toxicity/exposure ratios is therefore not considered necessary.

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time - scale (Test type)	End point	Toxicity ¹
Laboratory tests				
Fish				
	Quartz sand (a.s.)	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC ₅₀	No data.
Rainbow trout <i>Oncorhynchus mykiss</i>	Preparation Cervacol Extra	Acute 96 hr, (static)	Mortality, LC ₅₀	>500 mg /L _{nom}
Rainbow trout <i>Oncorhynchus mykiss</i>	Preparation Wöbra**	Acute 96 hr, (static)	Mortality, LC ₅₀	>100 mg/L _{nom}
Guppy <i>Poecilla reticulata</i>	Preparation Morsuvin**	Acute 96 hr, (static)*	Mortality, LC ₅₀	>36.9 mg/L _{nom}
Brook trout <i>Salvelinus fontinatis</i>	Preparation Repentol 6 PA**	Acute 96 hr, (static)	Mortality, LC ₅₀	>100 mg/L _{nom}
Carp <i>Cyprinus carpio</i>	Preparation Repentol 6 PA**	Acute 96 hr, (static)	Mortality, LC ₅₀	>100 mg/L _{nom}
	Quartz sand (a.s.)	Chronic (static, or semi-static or flow- through)	Growth, or development, or behaviour, or reproduction NOEC	No data.
Aquatic invertebrates				
	Quartz sand (a.s.)	Acute 48 hr (static, or semi-static or flow-through)	Mortality, EC ₅₀	No data.
<i>Daphnia magna</i>	Preparation Cervacol Extra**	Acute 48 hr, static	Mortality, EC ₅₀	>500 mg/L _{nom}
<i>Daphnia magna</i>	Preparation Wöbra**	Acute 48 hr, static	Mortality, EC ₅₀	>1000 mg/L _{nom}
<i>Daphnia magna</i>	Preparation Morsuvin**	Acute 48 hr, static*	Mortality, EC ₅₀	92.06 mg/L _{nom}
<i>Daphnia magna</i>	Preparation Repentol 6 PA**	Acute 48 hr, static	Mortality, EC ₅₀	370 mg/L _{nom}

Group	Test substance	Time - scale (Test type)	End point	Toxicity ¹
	Quartz sand (a.s.)	Chronic 21 d (static, or semi-static or flow-through)	Reproduction or development, NOEC	No data.
Sediment-dwelling organisms				
	Quartz sand (a.s.)	28 d (static, or semi-static or flow-through)	NOEC	No data.
Algae				
	Quartz sand (a.s.)	72 hr (static, or semi-static or flow-through)	Growth rate: E_rC_{50} Biomass: E_bC_{50} Yield: E_yC_{50}	No data.
Green alga <i>Pseudokirchneriella subcapitata</i>	Preparation Cervacol Extra**	72 h, static	Growth rate: E_rC_{50} Biomass: E_bC_{50} Yield: E_yC_{50}	$E_rC_{50} = >500 \text{ mg/L}_{\text{nom}}$ $E_bC_{50} = >500 \text{ mg/L}_{\text{nom}}$ $E_yC_{50} = >500 \text{ mg/L}_{\text{nom}}$
Green alga <i>Scenedesmus subspicatus</i>	Preparation Wöbra**	72 h, static	Growth rate: E_rC_{50} Biomass: E_bC_{50}	$E_rC_{50} = >1000 \text{ mg/L}_{\text{nom}}$ $E_bC_{50} = >1000 \text{ mg/L}_{\text{nom}}$
Green alga <i>Scenedesmus subspicatus</i>	Preparation Morsuvin**	72 h, static*	Biomass: E_bC_{50}	$E_bC_{50} = 13.9 \text{ mg/L}_{\text{nom}}$
Green alga <i>Scenedesmus subspicatus</i>	Preparation Repentol 6 PA**	72 h, static	Growth: IC_{50}	$E_rC_{50} = >100 \text{ mg/L}_{\text{nom}}$
Higher plant				
No endpoints available, not required				
Further testing on aquatic organisms No additional testing was required.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) In view of the phys-chem properties (insoluble and inert) and the (eco)toxicological profile of the active substance the assessment does not appear scientifically necessary. Quartz sand does not to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.				

¹ (_{nom}) nominal concentration; a.s.: active substance

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

**The studies are not fully reliable

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	No relevant metabolites
logP _{O/w}	No studies on bioconcentration in fish were submitted for Annex I inclusion of quartz sand and no studies are considered necessary for re-evaluation. Quartz sand ubiquitously occurs in the environment. It is chemically inert and insoluble in water/lipids, thus has no potential for bioaccumulation.	
Steady - state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)		
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)		
Annex VI Trigger for the bioconcentration factor		
Clearance time (days) (CT ₅₀)		
(CT ₉₀)		
Level and nature of residues (%) in organisms after the 14-day depuration phase		
Higher tier study		
No data.		

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)**All proposed uses of Quartz sand in forestry**

Quartz sand is commonly found in all environmental compartments (water, soil, sediment, plants and algae) and is not soluble in water. Due to its properties (chemically inert, non-soluble) it can be considered as not bioavailable for aquatic organisms and will be indistinguishable from natural occurring sand particles.

Representative formulations are prepared in a form of a paste and will be manually applied onto tree trunks, so no direct contamination of water is expected and aquatic organisms will not be directly affected. Furthermore, most formulations have been demonstrated not to be toxic to the standard test species of fish, aquatic invertebrates and algae. Due to the assumed lack of exposure and due to the low toxicity of the formulations, the acute risk for aquatic organisms after use of repellents containing quartz sand is considered low. Calculation of Predicted Environmental Concentrations in surface waters (PEC_{sw}) for quartz sand is not considered relevant. The derivation of acute and long-term toxicity regulatory acceptable concentrations (RAC) and comparison with PEC_{sw} is therefore not considered necessary.

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	Toxicity
Honeybees	Preparation Morsuvin	Acute (24h)	Oral (LD ₅₀)	>20 mg/bee
Honeybees	Preparation Morsuvin	Acute (24h)	Contact (LD ₅₀)	>2000 µg/bee
	Quartz sand (a.s.)/ Preparations	Chronic	10 d-LC50	No data, not required.
	Quartz sand (a.s.)/ Preparations	Bee brood development	NOEClarvae	No data, not required.
	Quartz sand (a.s.)/ Preparations	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	No data, not required.

Potential for accumulative toxicity: No data.
Semi-field test (Cage and tunnel test) No data.
Field tests No data.

Risk assessment for all proposed uses of Quartz sand

Quartz sand is a natural ubiquitously occurring substance intended for a manual application onto trees, hence the exposure of bees is considered negligible and thus risk is considered as low. The calculation of Hazard Quotients (HQ) and Exposure/Toxicity Ratios (ETR) are therefore not considered necessary.

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)
Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	Quartz sand (a.s.)/ Preparations	Mortality, LR ₅₀ Reproduction, ER ₅₀	No data, not required.
<i>Aphidius rhopalosiphi</i>	Quartz sand (a.s.)/ Preparations	Mortality, LR ₅₀ Reproduction, ER ₅₀	No data, not required.
Additional species			
No data.			

Extended laboratory tests, aged residue tests

No data.

Risk assessment for all proposed uses of Quartz sand

Due to the facts that the quartz sand is used as a coating onto trees, which is a no large-area application and quartz sand ubiquitously occurs in the environment, exposure to non-target arthropods is considered negligible and thus the risk is considered as low. The calculation of Hazard Quotients (HQ) is therefore not considered necessary.

Semi-field tests
No data.
Field studies
No data.
Additional specific test
No data.

**Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation
 (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013
 Annex Part A, points 10.4, 10.5)**

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Earthworms					
	Quartz sand (a.s.)/ Preparations		Chronic	Growth, reproduction, behaviour	No data, not required.
Other soil macroorganisms					
<i>Folsomia candida</i>	Quartz sand (a.s.)/ Preparations			Mortality, reproduction, behaviour	No data, not required.
<i>Hypoaspis aculeifer</i>	Quartz sand (a.s.)/ Preparations			Mortality, growth, reproduction, behaviour	No data, not required.

¹To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies)

No data.

Nitrogen transformation	No data, not relevant.
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Toxicity/exposure ratios for soil organisms

Risk assessment for all proposed uses of Quartz sand

Quartz sand is a natural ubiquitously occurring substance intended for a manual application onto trees. The applied active substance is expected to be indistinguishable from the natural soil due to its structural similarity. The calculation of Toxicity/Exposure Ratios (TERs) is therefore not considered necessary.

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Quartz sand is a natural ubiquitously occurring substance intended for a manual application onto trees. It is very unlikely that quartz sand harms plants physiologically. Silicon is a plant nutrient, but since quartz is a very stable mineral and not soluble in water, the plant can get no benefit out of the application with quartz sand. Calculations of Predicted Environmental Rates (PER) and estimation of toxicity/exposure ratios (TERs) is not considered necessary.

Laboratory dose response tests

Species	Test substance	ER ₅₀ (g/ha) ² vegetative vigour	ER ₅₀ (g/ha) ² emergence	Exposure ¹ (g/ha) ²	TER	Trigger
	Quartz sand (a.s.)/ Preparations	No data, not required.	No data, not required.			

Extended laboratory studies: No data.

Semi-field and field test: No data

¹ explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

² for preparations indicate whether dose is expressed in units of a.s. or preparation

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	End point
Activated sludge	No data. Quartz sand is practically insoluble in water and chemically relatively inert. No inhibitory effects on aerobic waste water microorganisms are expected if the formulation is correctly used as a coating onto trees (manually applied)
<i>Pseudomonas sp</i>	No data

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.
No data.
Available monitoring data concerning effect of the PPP.
No data.

**Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)
Ecotoxicologically relevant compounds**

Compartment	
soil	A residue definition is not needed ¹
water	A residue definition is not needed ¹
sediment	A residue definition is not needed ¹
groundwater	A residue definition is not needed ¹

¹ Quartz sand is a natural ubiquitously occurring substance. It is not possible to distinguish between the residues arising from the uses of Quartz sand as a plant protection product and its natural presence in environmental compartments.

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance

Quartz sand

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴:

No current harmonised classification

According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:

None

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.