CONCLUSION ON PESTICIDE PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance quartz sand

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Abstract

The conclusions of the EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Latvia, and co-rapporteur Member State, Romania, for the pesticide active substance quartz sand and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative field uses of quartz sand as a game repellent on deciduous and coniferous trees (professional use and non-professional use), orchards, ornamental shrubs and trees in forestry (professional use and non-professional use) and seedlings of conifer and deciduous trees in forestry (professional use). The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. No concerns are identified.

Keywords: quartz sand, peer review, risk assessment, pesticide, repellent, MRL review

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Quartz sand is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Latvia, and co-rapporteur Member State (co-RMS), Romania, received an application from DCR Sp.z.o.o., Flügel GmbH, NeraAgro, spol. S r.o, and Task force including Avenarius Agro GmbH and Cheminova GmbH & Co. KG., for the renewal of approval of the active substance quartz sand. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on quartz sand was provided by the RMS in the renewal assessment report (RAR), and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of quartz sand according to the proposed EU representative field uses as a game repellent on deciduous and coniferous trees (professional use), orchards, ornamental shrubs and trees in forestry (professional and non-professional use) and seedlings of conifer and deciduous trees in forestry (professional use), resulted in a sufficient game repellent efficacy.

Quartz sand is composed largely of the mineral quartz, the major constituent of which is silicon dioxide. The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to **identity, physical and chemical properties and analytical methods**.

In the area of **mammalian toxicology**, there were no issues not finalised or critical areas of concern identified.

In the area of the **residues**, 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. A maximum residue level (MRL) application for inclusion of quartz sand into Annex IV of Regulation (EC) No 396/2005 has also been submitted. With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion of substances in Annex IV of Regulation (EC) No 396/2005, 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.

The information available and its evaluation regarding the **environmental fate and behaviour** of the active substance were considered sufficient to complete the assessments necessary regarding the environmental exposure assessment for the representative uses assessed. Considering the nature of the substance and the use pattern, environmental concentrations of quartz sand being added (except on the treated trees/shrubs) are expected to be too low to measure; consequently, a definition of the residue in the environment for monitoring is considered unnecessary for quartz sand.

In the area of **ecotoxicology**, low risk to all non-target organisms was concluded based on the low exposure in the environment and relevant food items for non-target organisms.

Quartz sand does not meet the criteria for **endocrine disruption** for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

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Background

Commission Implementing Regulation (EU) No 844/2012[1],as amended by Commission Implementing Regulation (EU) No 2018/1659[2] (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, Latvia, and co-RMS, Romania, received an application from DCR Sp.z.o.o., Flügel GmbH, NeraAgro, spol. S r.o and Task force including Avenarius Agro GmbH and Cheminova GmbH & Co. KG for the renewal of approval of the active substance quartz sand. In addition, the applicants submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005[4]. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Romania), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on quartz sand in the RAR, which was received by EFSA on 2 March 2021 (Latvia, 2021). Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 31 May 2021, EFSA invited the Member States and the UK[5] to submit their good agricultural practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, DCR Sp.z.o.o., Flügel GmbH, NeraAgro, spol. S r.o and Task force including Avenarius Agro GmbH and Cheminova GmbH & Co. KG., for consultation and comments on 27 May 2021. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 27 July 2021. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a telephone

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, pp. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine-disrupting properties introduced by Regulation (EU) 2018/605.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, pp. 1–16.

[5] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on Ireland/Nothern Ireland, the EU requirements on data reporting are also applicable to NI.

conference between EFSA and the RMS on 30 September 2021. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology.

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 an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, 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 and on the Article 12 MRL review of Regulation (EC) No 396/2005 took place with Member States via a written procedure in July 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of quartz sand as a game repellent on deciduous and coniferous trees (field), orchards, ornamental shrubs and trees in forestry (professional use and non-professional use) and seedlings of conifer and deciduous trees in forestry (field), as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for quartz sand according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2022), 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 comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (30 September 2021);
- the evaluation table (19 July 2022);
- the report(s) of the scientific consultation with Member State experts;
- the comments received on the assessment of the additional information;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Latvia, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Quartz sand is the given name for this active substance; it consists largely of the mineral quartz, the major constituent of which is silicon dioxide (IUPAC). Silicon dioxide or silica exists in two forms, namely crystalline silica and amorphous silica. According to ATSDR (2019), 'Crystalline silica and amorphous silica are not single entities, each having several forms (polymorphs) with different surface chemistry characteristics. For a single polymorph, surface characteristics may vary due to processing and particle ageing, even for polymorphs within the same silica industry. The most common polymorphs of naturally occurring crystalline silica include quartz, cristobalite and tridymite (NIOSH, 2002).'

The representative formulated products for the evaluation were 'Repentol 6 PA', 'Wöbra', 'Cervacol Extra' and 'Morsuvin®', all of them described as paste formulations. 'Repentol 6 PA' contains 300 g/kg of quartz sand; two ingredients in 'Repentol 6 PA' are approved or have been approved as pesticidal

active substances and the applicant (DCR Sp.z o.o.) should justify that these ingredients do not function as active substances, but as co-formulants (data gap, see section 10). 'Wöbra' contains 475 g/kg quartz sand and 'Cervacol Extra' contains 251 g/kg of quartz sand. 'Morsuvin®' contains 255 g/kg of quartz sand and 40 g/kg of fat distillation residues as a second active substance.

The representative uses evaluated comprise field applications as a game repellent for use on deciduous and coniferous trees in forestry (professional and non-professional use), on orchards, ornamental shrubs and trees (professional and non-professional use) and on seedlings of conifer and deciduous trees in forestry (professional use) by application locally with a brush or gloves. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix B.

Data were submitted to conclude that the representative uses of quartz sand as proposed at EU level result in a sufficient repellent efficacy following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014). A data gap was identified for efficacy data of the formulation 'Morsuvin®' (see Section 10).

A data gap has been identified for applicants (DCR Sp.z.o.o.,[6] NeraAgro, spol. s r.o.[7] and Task Force Avenarius and Cheminova[7]) for the search of the scientific peer-reviewed open literature on the active substance (relevant for Sections 2 and 3), published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). Moreover, a transparent evaluation by the available search by the RMS was missing.

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: European Commission (2000).

The proposed specifications for quartz sand are based on batch data from industrial scale productions. The RMS proposed that the minimum purity of 915 g/kg, as agreed during the first approval of quartz sand, should be kept; however, based on the submitted batch data, a higher minimum purity could have been proposed. A data gap was identified for the Task force Avenarius and Cheminova to provide data on the content of quartz sand in at least five recent representative batches of the technical material (see Section 10). Validation data are required for the analytical method used for the determination of quartz sand in the batches manufactured by the applicant NeraAgro, spol. S r.o. (see Section 10). Respirable crystalline silica (SiO_2) with a diameter $\leq$ 10 μm was considered as a relevant impurity with a maximum amount of 1 g/kg (See Section 2). Data gaps were also identified for five-batch data for the content of the relevant impurity in the technical active substance as manufactured by NeraAgro, spol. S r.o. and Flügel GmbH (see Section 10). It is proposed to update the reference specification as the specification for the first approval did not consider respirable crystalline silica (SiO_2) with a diameter $\leq$ 10 μm as a relevant impurity. The current and proposed specifications are supported by the (eco)toxicological assessment (see Sections 2 and 5). There is no FAO specification available for quartz sand.

The main data regarding the identity of quartz sand and its physical and chemical properties are given in Appendix B.

Data gaps were identified for the applicant Task force Avenarius and Cheminova to provide data on the active substance content in the formulation 'Cervacol Extra' before and after accelerated storage, before and after shelf-life at ambient temperature and the analytical method used for its determination (see Section 10). Data gaps were identified for the representative formulation 'Morsuvin®' for data on shelf-life following storage at ambient temperature and self-heating data (relevant for the applicant NeraAgro, spol. S r.o., see Section 10).

Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations. Data gaps were identified for a validated method for the analysis of the quartz sand in technical active substance as manufactured (relevant for Task force Avenarius and Cheminova, see Section 10). Data gaps were identified for a validated analytical method

[6] See data requirement 2.3 in Evaluation Table section 2
[7] See data requirement 3.1 in the Evaluation Table section 3.

for the determination of the relevant impurity (respirable crystalline silica with particle diameter ≤ 10 μm) in the active substance as manufactured (relevant for DCR Sp. z o.o. and Flügel GmbH, see Section 10) and for validation data for the proposed method for the determination of particle size distribution of the technical quartz sand with a minimum diameter ≤ 10 μm (relevant for NeraAgro, spol. S r.o. and Task force Avenarius and Cheminova, see Section 10). 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 (See Section 2).

Analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions are proposed.

2. Mammalian toxicity

This assessment is based on the following guidance documents: European Commission, 2012 and ECHA, 2017. The toxicological profile of the active substance was discussed at the Pesticides Peer Review Experts' Teleconference 73 in April 2022.

Quartz sand is one of the most common forms of naturally occurring crystalline silica (or silicon dioxide SiO_2). Silica occurs either in a crystalline or non-crystalline (amorphous) form. Regarding impurities, crystalline silica with particle size ≤ 10 μm has been identified as a toxicologically relevant impurity with a maximum acceptable level of 1 g/kg (see Section 1). There is sufficient evidence of carcinogenicity via inhalation for respirable crystalline silica dust (see Directive 2017/2398 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens[8]).

For the formulations 'Morsuvin®' and 'Wöbra', the maximum content of crystalline silica particles below 10 μm was not demonstrated to be below 1 g/kg (see Section 10). This lacking information is not relevant for the representative formulations (paste) and application types; however, this might be an issue for different types of formulations and/or equivalence check of technical materials done by member states.

With regard to the reference specifications (see Section 1), no toxicological studies were submitted. Therefore, the representativeness of the toxicological batches and validated analytical methods could not be assessed. However, the proposed reference specifications are toxicologically acceptable for the representative paste formulations and uses.

The toxicological risk assessment of quartz sand is mainly based on studies on silica from the open literature and on assessments by other assessment bodies and/or under other regulatory frameworks, such as ATSDR (ATSDR, 2019), WHO (WHO, 2000), EFSA (EFSA ANS Panel, 2018) in the context of the Scientific Opinion on amorphous SiO_2 (i.e. synthetic amorphous silica including fumed (pyrogenic) silica and precipitated silica, silica gel and hydrous silica) as a food additive (E 551)[9] by the EFSA Panel on Food Additives and Nutrient Sources added to Food, and OECD Environment, Health and Safety (OECD, 2004).

Silicon dioxide is chemically and biologically inert when ingested in any physical form, such as crystalline quartz, amorphous siliceous earth or colloidal silica gels.

No **ADME** (Absorption, Distribution, Metabolism, Excretion) studies with quartz sand (as a consequence, also *in vitro* comparative metabolism studies) have been submitted by the applicants. Considering the intrinsic physico-chemical properties of quartz sand (poorly soluble in water and organic solvents, and inert), the rate and extension of **oral absorption** is expected to be negligible and no metabolism is expected to occur. For unspecified silica, the non-absorbed fraction is eliminated directly in the faeces, whereas the small fraction of dissolved silica into the blood stream as silicic acid (H_2SiO_3) is excreted through the kidneys without being further metabolised.

Dermal penetration of crystalline silica also seems minimal, whereas according to current knowledge, **inhalation** is the major pathway for silica to enter the human body, with the particle size being the most important aspect regarding clearance and deposition in the lung.

No adverse effects have been reported upon **oral** acute exposure to silica compounds (ECHA, 2014; EFSA ANS, 2018; ATSDR, 2019). Also, low dermal and inhalation acute toxicity has been

[8] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 345, 27.12.2017, pp. 87–95.

[9] The re-evaluation of silicon dioxide (E 551) as a food additive in foods for infants below 16 weeks of age is ongoing (EFSA-Q-2018-00526). A call for data to submit documented information relevant to the evaluation was launched in November 2018 (EFSA, 2018).

reported in studies with silica gels reviewed in the context of other risk assessments (see e.g. ECHA, 2014).

Considering SiO_2 low systemic bioavailability, its physico-chemical properties, the product formulations and application types, the submission of oral toxicological studies was waived for short-term toxicity, genotoxicity, long-term toxicity and carcinogenicity, reproductive and developmental toxicity, neurotoxicity, immunotoxicity studies and studies to assess endocrine-disrupting potential. It is noted that a similar approach has been used for Kieselgur, another silica-based active substance[10] (EFSA, 2020).

Extrapolating information from amorphous SiO_2 neither **skin or eye irritation potential** nor sensitising potential is expected for quartz sand (IUCLID, 2000).

Considering **genotoxicity** data from the literature (WHO, 2000; ATSDR, 2019), 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 (see derivation of reference values below). Nevertheless, for the representative uses, data with the active substance are not considered needed in view of the type of formulation and application.

Short-, long-term or carcinogenicity studies are not available for crystalline SiO_2 via the **oral and/or dermal** route: Nonetheless, based on data with amorphous SiO_2 or other unspecified silica, no toxicity is expected for crystalline SiO_2. Concerning inhalation both short- and long-term exposure of rats to silica (particularly crystalline silica) is associated with adverse effects on the lung, encompassing inflammation, impairment of alveolar macrophage clearance functions, increased incidence of adenocarcinomas and squamous cell carcinomas (ATSDR, 2019). While quartz is clearly carcinogenic in rats, there is less or no malignant tumour response in mice or hamsters. In **humans,** prolonged **inhalation** of high doses of crystalline silica dust ($\leq$ 10 μm) in occupational settings is closely linked to adverse health effects which include silicosis, chronic obstructive pulmonary disease, lung cancer, renal toxicity, increased risk of tuberculosis and autoimmune diseases (ATSDR, 2019).

No data are available on the **reproductive toxicity** of crystalline SiO_2. However, extrapolating the information obtained for amorphous silica, only low reproductive toxicological potential can be expected (EFSA ANS Panel, 2018).

Quartz sand does not possess a structural alert for **neurotoxicity**.

As for **immunotoxicity,** there is no indication of such potential from the available literature data.

The available toxicological data do not support the derivation of any **toxicological reference value** (acceptable daily intake (ADI), acute reference dose (ARfD), acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL) values) for quartz sand. Nonetheless, in this particular case for the representative uses the setting of reference values is not needed, due to the specific nature of the product formulations (ready-to-use paste) and the types of application (paintbrush or glove), which prevent inhalation exposure. Oral and dermal absorption of quartz sand are also considered negligible due to the intrinsic properties of the active substance.

For the representative formulation 'Repentol 6 PA', co-formulants of potential toxicological concern include tall oil crude (CAS 8002-26-4), a pesticide active substance not approved under Regulation (EU) No 1107/2009 (EFSA, 2012; Commission Implementing Regulation (EU) 2017/1186 from 3 July 2017[11]) for which the available data do not allow to conclude on the possible effects on the toxic potential of the formulation (see Section 'The active substance and the formulated product').

For the representative formulation 'Wöbra', a co-formulant of potential concern includes a styrene co-polymer. Styrene as a monomer is classified as Skin Irrit. 2, Eye Irrit. 2, Acute tox 4, STOT RE1 and Repr. 2 according to Regulation (EC) No 1272/2008[12]. Additionally, EFSA has recently re-assessed styrene safety for use as a food contact material (EFSA CEP Panel, 2020) and concluded that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded.

For the representative formulation 'Cervacol Extra', no co-formulants of concern were identified at the proposed level.

In the representative formulation 'Morsuvin®', the presence of a second active substance, i.e. fat distillation residues, is noted. For the latter, a peer review re-evaluation is ongoing (EFSA-Q-2021-00474,

[10] Please refer to Pesticide Peer Review Experts' TC 70 (discussion point 2.2) (EFSA, 2022).

[11] Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil crude, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 171, 4.7.2017, pp. 131–133.

[12] 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, pp. 1–1,355.

data gap Section 10). 'Morsuvin®' also contains a co-formulant of potential toxicological concern, i.e. titanium dioxide (TiO_2) of unknown particle size at a final concentration higher than 1%. Titanium dioxide is classified as a suspected carcinogen (Category 2) by inhalation according to Regulation (EC) No 1272/2008. This classification specifically applies to TiO_2 in powder form containing 1% or more particles with aerodynamic diameter $\leq$ 10 μm. The presence of TiO_2 at a level > 1% might trigger the classification of the product as carcinogen category 2, pending further considerations of the aerodynamic diameter of particles in the product. Additionally, EFSA has recently revised its safety assessment of TiO_2 as a food additive (EFSA FAF Panel, 2021) and has concluded that a genotoxic concern for TiO_2 particles (with unknown relationship to particle size) cannot be ruled out.

Overall, the lack of additional toxicological information on the above co-formulants is not considered relevant for the representative uses and the representative formulations (pastes), given that exposure by inhalation and/or ingestion is not expected (see Section 3). However, this might be an issue for different types of formulations and/or other potential uses triggering inhalation exposure, to which consideration should be given by member states. The same also applies to the possible presence of toxicologically relevant impurities.

3. Residues

3.1. Representative use residues

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.

Since data on genotoxicity and general toxicity of this active 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, as for the uses intended on orchards by painting with brush the trunk of the individual trees, it can reasonably be assumed that residues of quartz sand will not be quantified if the application to the orchard trees is conducted in a way that precludes any contamination of the edible parts of the fruits. A negligible exposure for the consumers to residues of quartz sand is therefore expected when the representative uses are considered, and a consumer dietary risk assessment can be waived.

Quartz sand is not expected to be translocated to plant tissues. It is therefore unlikely that residues may be found in pollen and bee products.

With regard to 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, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V), not all the criteria were met for quartz sand for the following reasons:

- Criterion I is not applicable, and criterion II is not met as the substance is not listed in Annex I of Regulation (EC) No 396/2005.
- Criterion III is met. The hazard assessment of quartz sand could not be carried out in the absence of a (geno)toxicity data package. Nonetheless, considering the representative uses, the setting of toxicological reference values is not needed, due to the nature of the product formulations (ready-to-use paste) and the mode of application (paintbrush or glove) (see Section 2).
- Criterion IV is met. Considering the mode of application of this active substance on the trees (painting the trunk of the individual tree by brush) and the nature of the product formulations (ready-to-use paste), residues of quartz sand on edible commodities following the use of this active substance as a plant protection product are unlikely to occur and it can be reasonably assumed that the consumer exposure resulting from the plant protection uses will not be higher compared to the natural background levels of sand in soils.
- Criterion V is met. Provided quartz sand is applied according to the representative uses, the consumers' exposure to quartz sand residues through dietary intake is expected to be negligible.

It is noted that some of the representative plant protection products contain a co-formulant of potential concern (see Section 2). However, regarding the assessment of potential residues resulting from the co-formulants used in the representative plant protection products, consumer exposure is not

expected for the representative uses on orchards, deciduous and coniferous trees in forestry, ornamental shrubs and trees, seedlings of conifer and deciduous trees in forestry.

3.2. Maximum residue levels

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 the 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.

4. Environmental fate and behaviour

Sand/silicon dioxide is a major component of nearly all mineral soils and many aquatic sediments. In some regions, it is the solid material of groundwater aquifers. After application (by brush or glove), the formulation dries and forms a protective coating. Quartz sand is not water soluble. Because of the method of application, environmental concentrations of the quartz sand being added (except on the treated trees/shrubs) are expected to be too low to measure. Considering the natural presence of quartz sand in soils and aquatic sediments and sand being a groundwater aquifer material, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

5. Ecotoxicology

Valid toxicity data with the active substance were not available for any group of non-target organisms. Therefore, an assessment of the compliance of the material tested with the specifications was not required. Only acute fish and aquatic invertebrates and algae studies were available with each of the representative formulations. However, all the available studies showed deficiencies (e.g. lack of analytical measurements) and, therefore, were only considered supportive. Quartz sand is intended to be used by manually coating deciduous and coniferous trees in forestry, orchards, ornamental shrubs and trees in forestry and seedlings of conifer and deciduous trees in forestry with special brush or glove to act as repellent preventing browsing damage. As reported in Sections 3 and 4, given the type of application and the properties of the active substance, the representative uses are expected to result in exposure levels which are too low to measure in the environment. In addition, it is anticipated that the exposure through food items relevant for non-target organisms would be low, considering the application method and the properties of quartz sand. Therefore, low risk was concluded for all non-target organisms for all the representative uses.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of quartz sand for humans and non-target organisms according to the ECHA/EFSA guidance (ECHA/EFSA, 2018), although no (eco)toxicological data are available to assess the endocrine-disrupting properties, this does not appear scientifically necessary for the following reasons:

1) Quartz sand is poorly soluble in water, and it showed poor absorption; it is not bioavailable after oral, dermal and inhalation exposure.
2) The available information does not show any evidence for endocrine activity or adversity, as in the available short- and long-term toxicity studies including reproductive toxicity studies with amorphous SiO_2, there is no evidence of effects on endocrine organs.
3) There is no evidence on endocrine activity based on the available in vitro high-throughput screening (HTS) data on Oestrogen-, Androgen-, Thyroid- and Steroidogenesis-(EATS) modalities with SiO_2 (i.e. ToxCast) and no alerts in ED QSAR models with silicon dioxide.
4) Amorphous SiO_2 is approved as a food additive (E 551) for which an ADI was not derived (EFSA ANS Panel, 2018).

Based on the available information, it can be concluded that quartz sand does not meet the criteria for endocrine disruption for humans and non-target organisms for the EATS-modalities according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
Not applicable Considering the nature of the substance, it being a constituent of many soils and the limited environmental exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for quartz sand	Not triggered

Table 2: Groundwater[(a)]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[(b)] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
Not applicable Considering the nature of the substance, it being a groundwater aquifer material and the limited environmental exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for quartz sand	Due to quartz sand being inorganic and its function as a repellent, the parametric drinking water limit (0.1 µg/L) for pesticides and their relevant metabolites as defined by the drinking water directive 98/83/EEC[(c)] is not applicable according to the regulatory framework.	Yes	Not triggered	No	Not triggered

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or relevant lysimeter.
(c): Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, pp. 32–54.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable Considering the nature of the substance, it being insoluble, a constituent of most soils and many sediments and the limited environmental exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for quartz sand	Not triggered

Table 4: Air

Compound (name and/or code)	Toxicology
Not applicable Considering the nature of the substance, its lack of volatility, it being a constituent of most soils and the limited environmental exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for quartz sand	2.2 mg/L air (supplementary information – studies with amorphous silica)

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

No particular conditions are proposed for the representative uses evaluated.

9. Concerns and related data gaps

9.1. Concerns and related data gaps for the representative uses evaluated

9.1.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[13] and if 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).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

Issues or assessments that could not be finalised were not identified.

9.1.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

[13] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, pp. 127–175.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concern were not identified.

9.1.3. Overview of the concerns identified for each representative use considered (Table 5)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		Deciduous and coniferous trees (professional use)	Orchards, ornamental shrubs and trees in forestry (professional and non-professional use)	Seedlings of conifer and deciduous trees in forestry (professional use)
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Resident/bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non-target terrestrial vertebrates	Risk identified			
	Assessment not finalised			
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Risk to aquatic organisms	Risk identified			
	Assessment not finalised			
Groundwater exposure to active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure to metabolites	Legal parametric value breached[(a)]			
	Parametric value of 10 µg/L[(b)] breached			
	Assessment not finalised			

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- Applicant DCR Sp. z o.o. should address the issue that some of the ingredients in the formulation 'Repentol 6 PA' are approved or have been approved as pesticidal active substances. The applicant should justify that these ingredients do not function as active substances, but as co-formulants (relevant for the representative uses evaluated for 'Repentol 6 PA'; see Section 1).
- Applicant Task force Avenarius and Cheminova to provide data on the content of the active substance in at least five representative and recent batches of the technical material (relevant for the representative uses evaluated for 'Cervacol Extra'; see Section 1).
- Applicant NeraAgro, spol. S r.o. to provide efficacy data of the formulation 'Morsuvin®' (relevant for the representative uses evaluated for 'Morsuvin®'; see Section 1).
- Applicant Flügel GmbH to provide five-batch data on the content of respirable crystalline silica (SiO_2) with a diameter $\leq$ 10 μm in the technical active substance (see Section 1).
- Applicant NeraAgro, spol. S r.o. to provide five-batch data on the content of respirable crystalline silica (SiO_2) with a diameter $\leq$ 10 μm in the technical active substance (see Section 1).
- Applicant Task force Avenarius and Cheminova to provide data on the active substance content in the formulation 'Cervacol Extra' before and after accelerated storage, before and after shelf-life at ambient temperature and the analytical method used for its determination (relevant for representative uses evaluated for 'Cervacol Extra'; see Section 1).
- Applicant Nera Agro to provide data on the shelf- life following storage at ambient temperature and self-heating data for the representative formulation 'Morsuvin®' (relevant for representative uses evaluated for 'Morsuvin®'; see Section 1).
- Applicant Nera Agro to provide validation data, fulfilling the requirements of SANCO/3030/99 rev.4, for the analytical method used for the determination of quartz sand in the batches provided included in the dossier, manufactured by the applicant NeraAgro, spol. S r.o. (relevant for the representative uses evaluated for 'Morsuvin®'; see Section 1).
- Applicant Task force Avenarius and Cheminova to provide a validated method for the determination of the quartz sand in the active substance as manufactured (relevant for the representative uses evaluated for 'Cervacol Extra'; see Section 1).
- Applicant DCR Sp. z o.o. to provide a validated analytical method for the determination of the relevant impurity (crystalline silica with particle diameter $\leq$ 10 μm) in the active substance as manufactured (see Section 1).
- Applicant Flügel GmbH to provide a validated analytical method for the determination of the relevant impurity (crystalline silica with particle diameter $\leq$ 10 μm) in the active substance as manufactured (see Section 1).
- Applicant NeraAgro to provide validation data for the proposed laser granulometry method for the determination of particle size distribution of the technical active substance. It should be noted that a method that can determine particles with a diameter $\leq$ 10 μm is required. Alternatively, any other validated method that can determine particles with a diameter below 10 μm can be provided (see Section 1).
- Applicant Task force Avenarius and Cheminova to provide validation data for the proposed laser granulometry method for the determination of particle size distribution of the technical active substance. It should be noted that a method that can determine particles with a diameter $\leq$ 10 μm is required. Alternatively, any other validated method that can determine particles with a diameter $\leq$ 10 μm can be provided (see Section 1).

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Abbreviations

1/*n*	slope of Freundlich isotherm
λ	Wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AAOEL	acute acceptable operator exposure level
AChE	Acetylcholinesterase

ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AOP	adverse outcome pathway
AP	alkaline phosphatase
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
ARSTTA	Stably Transfected Human Androgen Receptor Activation Assay
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
CAS	Chemical Abstracts Service
CFU	colony-forming units
CHO	Chinese hamster ovary cells
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
C&L	classification and labelling
CL	confidence limits
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EAS	oestrogen, androgen and steroidogenesis modalities
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals 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_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ERO	ecological recovery option
ERSTTA	Stably Transfected Human Oestrogen Receptor-alpha Transcriptional Activation Assay
ETO	ecological threshold option
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
iv	Intravenous
mm	millimetre (also used for mean measured concentrations)
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake

NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	Pasca
PA	Paste (formulation type)l
PD	proportion of different food types
PEC	predicted environmental concentration
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	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
UF	uncertainty factor
UV	Ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organisation

Appendix A – Consideration of cut-off criteria for quartz sand according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

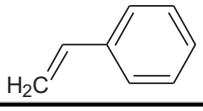
Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Quartz sand is not considered to be mutagenic, carcinogenic or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation (EC) 1,107/2009.
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine-disrupting properties		Quartz sand is not considered to meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Quartz sand is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Quartz sand is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Quartz sand is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

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

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7552

Appendix C – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Styrene	Ethenylbenzene C=Cc1ccccc1 PPBRXRYQALVLMV-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021 Release (File version N15e41, Build 123,232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021 Release (File version C25H41, Build 123,835, 29 August 2021).