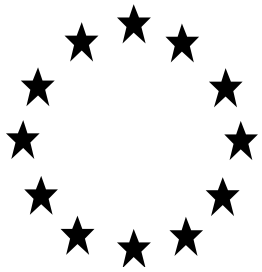
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Synthetic amorphous silicon dioxide (Rentokil Initial) Product-type 18 (Insecticide)

March 2014

RMS: FRANCE

Synthetic amorphous silicon dioxide (PT18)
Assessment report
Finalised in the Standing Committee on Biocidal Products at its meeting on 13 march 2014

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of synthetic amorphous silicon dioxide CAS n° 112926-00-8 as product-type 18 (insecticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 18 containing of synthetic amorphous silicon dioxide that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of synthetic amorphous silicon dioxide for product-type 18, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 18 that contain synthetic amorphous silicon dioxide. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix I). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.
For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of amorphous silicon dioxide for product-type 18, carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market2, with a view to the possible inclusion of this substance into Annex I to the Directive.

Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market, OJ L 123, 24.4.98, p.1

the Council concerning the placing of biocidal products on the market[3] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes amorphous silicon dioxide (CAS No. 7631-86-9).

However, the data submitted by Rentokil Initial plc, hereafter referred to as the applicant, for product type 18 are related to **synthetic amorphous silicon dioxide with CAS No. 112926-00-8, included under the more general CAS 7631-86-9**. The evaluation presented in this report did not allow conclusions to be drawn regarding any other substance complying with the definition of amorphous silicon dioxide in the abovementioned list of active substances in Regulation (EC) No 1451/2007. Therefore, only synthetic amorphous silicon dioxide (CAS No. 112926-00-8) should be approved according to Regulation (EU) No 528/2012 based on the existing evaluation.

Commission Regulation (EC) No 1451/2007 of the 4th of December 2007 lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into the Annex I or IA of the Directive.

In accordance with the provisions of Article 3 paragraph 2 of that Regulation, France was designated Rapporteur Member State to carry out the assessment of the active substance of synthetic amorphous silicon dioxide on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for synthetic amorphous silicon dioxide as an active substance in product type 18 was the 30th of April 2006, in accordance with Article 9 paragraph 2 of Regulation (EC) No 1451/2007.

On the 21st of April 2006, the French Competent Authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation, taking into account the supported uses, and confirmed the acceptance of the dossier on the 24th of October 2006.
Initially, the intended use against “bed bugs” has been submitted by Rentokil Initial plc. On 6th May 2008, the applicant decided to withdraw the application for this intended use and to support only the application for use against cockroaches (professional indoor use only).

On 16 April 2009, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 15th June 2009. The competent authority report included a recommendation for the inclusion of synthetic amorphous silicon dioxide in Annex I to the Directive for PT 18.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on the 23 June 2009. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organized by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

3 OJ L 325, 11.12.2007, p. 3.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalized during its meeting held on 13 March 2014.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties and Methods of Analysis

2.1.1.1. Identity and physico-chemical properties

CAS- No.	112926-00-8
EINECS-No.	231-545-4
Other-No. (CIPAC, ELINCS)	Not known
IUPAC Name	Silicon dioxide
Common name, synonyms	Silica
Molecular formula	SiO_2
Structural formula	O=Si=O
Molecular weight (g/mol)	60.08 g/mol

The active substance silicon dioxide is a synthetic amorphous silica gel obtained by wet-process, with the CAS No 112926-00-8 (which includes both "precipitated silica" and "silica gel"). All the statements and risk assessments in this dossier apply solely to synthetic amorphous silica gel, as marketed by the applicant. Other forms of silica, included under the more general CAS No 7631-86-9 are not covered by the assessment. The active substance as manufactured is defined as Gasil 23D which contains at least 80% of synthetic amorphous silica gel.

With the analytical method (X-ray analysis) provided for quantification of possible crystalline material presents as impurity in the active substance, no limit of quantification (LOQ) for the method of quantification of crystalline silica can be set. Therefore, the RMS considers that crystalline silica is an impurity of concern with a maximum content of 0.1%. In consequence, it must be checked at the product authorisation stage that no more than 0.1 % of crystalline SiO_2 is present in Gasil 23D.

At room temperature, amorphous silicon dioxide is a white powder. Its melting point is ca. 1710°C; its boiling point is ca. 2230˚C. The tap density is 0.13 g/mL.

Silicon dioxide particle is not soluble in water or organic solvents. However, they form stable suspensions.

Partition coefficient - n-octanol/water is not relevant for silicon dioxide.

Silicon dioxide is neither flammable nor auto-flammable nor does it degrade. Silicon dioxide has no oxidizing or explosive properties and shows no re-activity towards its container material (HDPE lined paper bags).

Particle size distribution and specific surface area are not a data requirement for Annex I inclusion for active substances but were submitted at the demand of the RMS for characterisation of the active substance The Gasil 23D particle size distribution (in mass) is: 90% below 4.8 µm; 50% below 3 µm and 1% below 1.9 µm.

Specific surface area of Gasil 23D is in the region of 300-350 m²/g. Taking into account the generic density of bulk silicon dioxide found in literature (2.1 to 2.6) a volume specific surface area of 630 – 900 m^2/cm^3 can be calculated.

Based on primary particle size (< 25 nm) and specific surface area by volume submitted, Gasil 23D is a nanomaterial according to the Commission recommendation on definition of nanomaterial (2011/696/EU) and the Article 3(1)(z) of Regulation EU 528/2012. The data provided by the notifier show that in Gasil 23D, primary particles are aggregated in particles of 1 to 6 µm. Aggregate means a particle comprising of strongly bounds or fused particles. Under conditions of normal handling and use, it is considered that aggregates are the smallest stable particles. In this context, data provided by the notifier and literature tend to show that liberation of primary particles and exposure to nano-object (material with one, two or three external dimensions in the nanoscale) is not expected during and after the intended biocidal application considered in this dossier
Since exposure to nanoscale primary particles was not expected during the specific intended biocidal use, the hazard and risk of the **individual particles** of silicon dioxide with a nanometric size were not evaluated in this dossier (ie. individual particles not aggregated). This position will be updated with the evolution of knowledge and specific regulations about nanomaterials or with complementary data showing that use of Gasil 23D leads to exposure to individual particles of silicon dioxide with nanometric size.

The representative product, RID Insect Powder, contains 40% to 50% of amorphous silicon dioxide. Due to the hygroscopic properties of this silicon dioxide, RID Insect Powder is still a white and odorless powder, with a particle size distribution ranging from 1 to 600 µm. This particle size distribution is composed of 3 maximum peaks: 4 µm, 20 µm and 160 µm. The volumetric particle size distribution reveals that ca. 34.62% of the powder has a particle diameter lower than 10 µm.
It is neither flammable nor auto-flammable, has no oxidising or explosive properties.
An accelerated storage stability study with amorphous silicon dioxide (IIIA3.17) and a 24-month shelf-life with the product (IIIB3.7) show that silicon dioxide remains stable in its commercial container for 2 weeks at 54°C and up to 24 months under ambient conditions, respectively.

In conclusion, the risks associated with physico-chemical properties of both the active substance and the biocidal product such as flammability, explosivity and thermal stability, are low due to the amorphous properties of silicon dioxide, when used as recommended.

2.1.1.2. Methods of analysis

Analysis of active substance in Gasil 23D
Only ICP-AES has been provided by the applicant as analytical method of the substance, which was deemed quantitatively sufficient.
An X-ray analysis provided confirmed that the active substance is effectively amorphous; however, no LOQ for the method can be set.

Analysis of formulation
Amorphous silicon dioxide is analysed in the product, RID Insect Powder, by ICP-AES after fusion of the sample with sodium hydroxide, dissolving in demineralised water and the addition of concentrated nitric acid.
The water content of RID Insect Powder is measured by weighing a sample before and after heating at 550˚C for 24 hours (a subsequent heating at 750˚C for 3 days then takes place to ensure that there is no further weight loss).

2.1.2. Intended Uses and Efficacy

- **Intended use**

RID Insect Powder, as product of PT 18, is intended to be used with other insecticide products as part of an Integrated Pest Management Program, only in indoor area and applied by professional operators for the control of cockroaches such as Oriental cockroaches (*Blatta orientalis*) and German cockroaches (*Blattella germanica*).

RID Insect Powder is an insecticidal powder containing 50% of Gasil 23D (> 80% synthetic amorphous silica gel). It is a ready-to-use powder supplied in a 50 g plastic bottle. Before use, it is decanted into a hand-operated pump or motorised blower (dust gun) for application onto surfaces including those with inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits.
The situation in which it will be applied will vary greatly from place to place as treatment may be required in many places such as hotels, offices, residential homes, etc.

- **Efficacy and resistance**

Although the mechanism of biocidal action of amorphous silicon dioxide is currently not clear (there is actually a wide variety of opinions about how dusts, such as silicon dioxide, bring about the water loss in insects leading to death) "*The Manual of Decisions for Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products*" updated on 10th July 2008 states in its section 2.3.4 that amorphous silica powder "*leads to dehydration of the insects most probably through absorption of the lipid layer covering insects' chitin protection, which then leads to desiccation and death of the target organism*". This acknowledged mechanism allows amorphous silicon dioxide to be covered by the directive 98/8/EC principles.

It is however demonstrated that adults with fully developed cuticles are less susceptible to the action of silicon dioxide. Nymphs, whose cuticles are not fully developed, are in contrast more susceptible. Consequently, amorphous silicon dioxide must be used with adulticide products as part of an Integrated Pest Management Program.
Regarding the available efficacy studies performed with the active substance and the accompanying biocidal product, the results established that the product is effective against the first nymphal instars but has a limited action against medium and late nymphal instars or against adults. As RID insect powder is intended to be used as part of an overall pest control program, the operational application rate at which it will be used is 20 g product/m^2 and it should be applied at least 4 treatments/year. However, no practical trials were performed to exclude some variations according to the protocol designs or, the nature of treated surfaces.

At this level, the active substance has demonstrated its efficacy against German cockroaches *(Blattella germanica)* and Oriental cockroaches *(Blatta orientalis)*. Field trials should be provided at product authorisation stage.

Resistance *per se* i.e. the ability of a given population to withstand a poison that was effectively lethal to earlier generations of the species has not been reported for amorphous silicon dioxide. Furthermore, sorptive dusts like silicon dioxide have been identified in literature reviews as a possible means of controlling insects that are resistant to conventional insecticides.
Nevertheless, this aspect should be reviewed at product authorization stage.

2.1.3. Classification and Labelling

2.1.3.1. Current classification of the active substance

The classification and labelling of the active substance silicon dioxide in accordance with Annex I of Council Directive 67/548/EEC are given in Table 2.1.3.1-1.

Table 2.1.3.1-1: Classification and labelling of the active substance silicon dioxide indicated by the applicant

Classification:	Not included in Annex I
Class of danger:	None
Risk phrases:	None
Safety phrases:	None

2.1.3.2. Proposed classification of the active substance

Classification	Xn; R48/20
Class of danger	Xn: Harmful
R phrases	48/20: danger of serious damage to health by prolonged exposure by inhalation
S phrases	S2, S22

Proposed classification and hazard statement according to GHS:
STOT RE 2 H373: May cause damage to organs through prolonged or repeated exposure.

2.1.3.3. Current classification of the biocidal product

The classification and labelling of the biocidal product, RID Insect Powder, according to Directive 1999/45/EC is given in Table 2.1.3.3-1.

Table 2.1.3.3-1: Classification and labelling of RID Insect Powder

Classification	None
Class of danger	None
R phrases	None
S phrases	None

2.1.3.4. Proposed classification of the biocidal product

Classification	Xn; R48/20
Class of danger	Xn: Harmful
R phrases	48/20: danger of serious damage to health by prolonged exposure by inhalation
S phrases	S2, S22

Proposed classification and hazard statement according to GHS:
STOT RE 2 H373: May cause damage to organs through prolonged or repeated exposure.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

Remarks on the data set used for the human health risk assessment

Due to the nature of the active substance and the limited exposure expected from the intended use, the applicant provided a limited set of data.

The dossier was accepted by the RMS, taking into account the following parameters.
As a foreword, it should be underlined that the following considerations are only focused on wet-process synthetic amorphous silica, especially silica gel (CAS No 112926-00-8), which is discussed in the present report. This does not apply to other silica, in particular crystalline silica, which, contrary to amorphous silica, is inhaled in the form of quartz or cristobalite from occupational sources, and is classified as Group I carcinogen by the IARC. In this dossier, X-ray analysis confirmed that the active substance is effectively amorphous (without any crystalline silica as impurity), however, no LOQ for the method of quantification of crystalline silica is available. Given its classification as carcinogen, crystalline silica must be considered as an impurity of concern with a maximum content < 0.1%.

Silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment:
Silicon dioxide and silicates correspond to about 25% of the earth's crust. Silicon dioxide and silicates are present in practically all plants, animals and in natural waters.
According to the Joint FAO/ WHO Expert Committee on Food Additives, very small amounts of silica are normally present in all body tissues and there is no evidence that they play any physiological role[4].
Although silicon dioxide is obtained from chemical synthesis, the produced substance is chemically equivalent to the natural silicon dioxide.

Synthetic amorphous silica are used in a wide variety of applications, including consumer products:
They are used in ointments and thicken pastes, and are present in cosmetics, pharmaceuticals and food. They are also used in feed[5], rubber and silicones, paints, lacquers and plastics.

Silicon dioxide is an approved food additive:
Silicon dioxide (E551) is used as an anti-caking agent[6] in dry powdered foodstuffs (including sugars) with a maximum level of 10 g/kg. In addition, it is approved for use in plastic material coming into contact with food, without hazard to public health.
The US Food and Drug Administration (FDA) has classified silicon dioxide as Generally Recognised as Safe (GRAS) and has approved its use as a dietary food additive at levels of up to 2% by weight in food. Moreover, UK food supplements contain up to 500 mg silicon[7]. In agreement with the review by the US Environmental Protection Agency (EPA), the FDA considered that exposure to amorphous silicon dioxide in food does not pose any risk for Human. Besides, the Acceptable Daily Intakes (ADI)

[4] Joint FAO/ WHO Expert Committee on Food Additives which met in Geneva, 25 June - 4 July 1973 (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53)

[5] Additive authorised in feed (Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003, Appendixes 3&4, Annex: List of additives, Released 21 October 2008 [Rev. 35]).

[6] European parliament and council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ No L 61, 18.3.1995, p.1)

[7] Expert Group on Vitamins and Minerals of the UK Food Standards Agency: Safe Upper Levels for Vitamins and Minerals: www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf. p.306- 312

for silicon dioxide and certain silicates was qualified as "not specified" by the JECFA during its 29th meeting (1985).

Occupational exposure:
Long-term occupational exposure limits (OELs) for amorphous silica exist in several countries. Most of these workplace exposure limits are based on ACGIH (American Conference of Governmental Industrial Hygienists) conclusions.
In 1984, ACGIH set a limit for amorphous silica at 3 mg/m^3 for respirable dust and at 6 mg/m^3 for inhalable dust. According to the MDHS (Methods for the Determination of Hazardous Substances) 14/3 *General methods for sampling and gravimetric analysis of respirable and inhalable dust,* "***Inhalable dust*** *approximates to the fraction of airborne materials that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract",* whereas *"**respirable dust** approximates to the fraction that penetrates to the gas exchange region in the lung".*
Due to insufficient data, ACGIH withdrew the threshold limit value for amorphous silica in 2006 and since this time, amorphous silica was considered as "*particles (insoluble or poorly soluble) not otherwise specified*" by ACGIH which recommends that airborne concentrations should be kept below 10 mg/m^3 for inhalable dust and 3 mg/m^3 for respirable dust.
Other threshold values are available through the Gestis data base: 2 mg/m^3 in Denmark, 4 mg/m^3 in Germany, Austria and Switzerland and 10 mg/m^3 in Belgium and Spain. In the UK, the 8 h Time Weighted Average for amorphous silica is 2.4 mg/m^3 for respirable dust and 6 mg/m^3 for inhalable dust[8].

During the normal use of silicon dioxide as a biocide, the level of exposure is low compared with exposures from other sources:
In this dossier, the total exposure level by inhalation per day for workers without Personal Protective Equipment (PPE) across all tasks involved in the manipulation of RID Insect Powder is 0.0665 mg/m^3 (corresponding to 0.665 mg/day) 8h TWA. This value decreases with the use of PPE..

Natural intake of silicon via food and water:
The estimated adult silicon intake via diets in the United States is 0.32 mg Si/kg bw/d (corresponding to 0.68 mg SiO_2/kg bw/d) in females and 0.53 mg Si/kg bw/d (corresponding to 1.13 mg SiO_2/kg bw/d) in males[9]. These values can be considered as representative for the intake in the Western world. These figures are in agreement with another publication which demonstrates that the average Si intakes are around 25 mg/day for the same part of the world[10]. Silicon levels appear to be higher in foods derived from plants than in foods from animal sources. Grains, especially oats, barley and some rice fractions are the foods which contain the highest level of silicon[11].

The amount of silica contained in food is up to 50 mg/day[12;13]. Moreover, UK food supplements contain up to 500 mg silicon[14]. Silicon is also found in drinking water as orthosilicic acid. Consumption of 2 L/day drinking water could result in consumption of up to 10 mg silicon[15].

[8] EH40/2005 Workplace Exposure Limits. Table 1: List of approved workplace exposure limits (as consolidated with amendments October 2007)

[9] Pennington, J.A.T. "Silicon in foods and diets", Food Additives and Contaminants, 1991;8, 97-118

[10] Sripanyakorn S. *et al*. "Dietary silicon and bone health", British Nutrition Foundation, Nutrition Bulletin, 2005; 30, 222-230

[11] Human Environmental Risk Assessment (HERA) on Ingredient of European Household Cleaning Products Soluble silicates (Draft), February 2005; 17-28

[12] Bowen, H.J.M. and Peggs, A. "Determination of the silicon content of food", Journal of Science Food and Agriculture, 1984; 35, 1225-1229 + Pennington, J.A.T. "Silicon in foods and diets", Food Additives and Contaminants, 1990;8, 97-118

In conclusion, the estimated maximum intake per day is 50 (food) + 500 (food supplements) + 10 (water) mg = 560 mg/day[15].

For comparative purpose, the applicant provided the following information: one litre of beer contains 131 mg of silicon dioxide and the silicon dioxide content of raw potatoes is reported to be 10.1 mg/kg[16].

The amount of silicon dioxide manufactured each year for use as a biocide is very low in comparison to the other non-biocidal uses of silicon dioxide and natural occurrence.

To conclude, considering the above elements, the RMS accepted the applicant's dossier even if some data were not complete and because there is not any alert knowledge in the literature. In addition, considerations have been given to minimise testing on vertebrate animals or to avoid unnecessary suffering of experimental animals.

[13] Pennington, J.A.T. "Silicon in foods and diets", Food Additives and Contaminants, 1991;8, 97-118

[14] Expert Group on Vitamins and Minerals of the UK Food Standards Agency: Safe Upper Levels for Vitamins and Minerals: www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf. p.306- 312

[15] Pennington, J.A.T. "Silicon in foods and diets", Food Additives and Contaminants, 1990;8, 97-118

[16] Federation of American Societies for Experimental Biology (1979) Evaluation of the Health Aspects of Certain Silicates as Food Ingredients US Department of Commerce, National Technical Information Service / Published Applicant's reference number SILICA 19

2.2.1.1. Hazard assessment (active substance)

As justified above, limited set of data was submitted in the dossier. To assess the toxicity profile of the notified active substance, the applicant submitted in the dossier studies that were carried out with several types of amorphous silica, obtained with wet process (as Gasil 23D) or with thermal process. No studies were performed with the notified silica gel itself. Read-across between data on amorphous silica obtained with wet process and silica obtained with thermal process was accepted on a case-by-case basis and considered by the RMS as explained below:

When data on silica gels were available for an endpoint, the results of the studies were used to evaluate the toxicity profile of the notified substance, as Gasil 23D is a silica gel.

When an endpoint could not be documented with a silica gel, it was accepted to use the results from precipitated silica, as precipitated silica and silica gel are both obtained with wet process by the reaction of sodium silicate with an acid. In the dossier, the endpoints fulfilled with data on precipitated silica are repeated-dose toxicity by inhalation and epidemiological data by inhalation. The relevant physico-chemical parameter influencing the inhalation toxicity is the particle size of the silica: according to the ECETOC report on synthetic amorphous silica, the aggregate size of precipitated silica ranges from 0.1 to 1 µm. In comparison, it is stated the aggregate size of Gasil 23D ranges from 1 to 6 µm. Considering that, data from precipitated silica could be considered as worst case for inhalation toxicity. Therefore, inhalation toxicity on precipitated silica was considered by the RMS to fulfill the data gap for the notified silica gel.

When an endpoint could not be documented neither with data on silica gel nor with data on precipitated silica, other types of silica (such as synthetic amorphous fumed silica, crystalline silica) were exceptionally considered. These data were only used as supportive data or as a worst case, depending on the endpoint considered.

Some toxicological data on surface-treated silica were also submitted. Read-across with this type of silica has not been accepted since it cannot be concluded that the physico-chemical properties of treated and non-treated silica are similar and because of the absence of scientific justifications concerning the relevance of this read-across. Furthermore, considering the lack of reliable data allowing the comparison between these different forms of silica, it cannot be concluded they are similar.

A summary table presenting the different silica met in the dossier is appended at the end of this document (appendix III).

Toxicokinetics
Although no oral absorption study has been performed with amorphous silicon dioxide, it is however known that silica, when ingested, could be absorbed via the human gastro-intestinal tract as silicic acid (after dissolution of silicon dioxide in water) and excreted through urine. As no systemic effects were observed in the different studies submitted, it is not deemed necessary to ask for additional data about oral absorption of silicon dioxide.

As studies by inhalation did not show any systemic effects, it is not deemed necessary to determine a systemic NOAEL.

No study on percutaneous absorption has been provided but as far as toxicity observed during the acute toxicity study by dermal route was not significantly different from the toxicity observed during the acute toxicity study by oral route (both have a LD_{50} > 2000 mg/kg bw), no higher absorption by dermal route was suspected (compared to the oral absorption). Furthermore, due its non solubility in

water and organic solvents, it can be assumed that a dermal penetration of the silica would be very limited.

There are no metabolites of concern which are formed in mammals. On the basis of available kinetic studies, it was not deemed scientifically necessary to request additional data on possible metabolites of concern from silicon dioxide.

Acute toxicity
No study using the silica used by the applicant was provided. Submitted data came from the public domain. Data on silica gels (Silcron G-910 and Syloid 244) showed very low acute toxicity by oral and dermal routes (LD_{50} >2000 mg/kg bw) and after inhalation (LC_{50} > 2 mg/L).

Local effects
With regards to the *irritation* studies, a drying effect on the skin subsequent to skin contact and discomfort and a mild irritation after eye contact are reported. These effects are especially due to dust nature of silica.

No specific data are available concerning the respiratory tract irritation potential of silicon dioxide. However, inflammation observed in the repeated-dose toxicity studies by inhalation could be related to a respiratory irritation.

With regards to the *sensitisation* potential of silicon dioxide, there is no evidence of skin-sensitising properties with the Zeolithe A (cubic microcrystalline structure) tested with the modified Magnusson-Kligman test. It was considered that the test protocol itself and the crystalline structure of the tested substance which is irritating for skin could promote the cutaneous absorption of the substance and tend to maximize the risk. In conclusion, this test was considered as a worst case. Besides, no evidence of a sensitising potential of the silica is noted from the industrial hygiene surveillance data over decades. Furthermore, there is no structural alert which indicates any potential for skin sensitisation.
No data on the potential of silicon dioxide to induce respiratory sensitisation are available.
Eventually, it was concluded that silicon dioxide has no sensitising properties.

Repeated dose toxicity
Concerning the *oral route*, no adequate subchronic study with amorphous silica is available. Nevertheless, the submitted teratogenicity study with a silica aerogel gives some data by oral route in four species (mouse, rat, golden hamster and rabbit) and can compensate for the lack of information on sub-chronic toxicity by oral administration.

An oral chronic/carcinogenicity study in mice and rats fed with Syloid 244 (silica gel) for 93 weeks and 103 weeks, respectively, was submitted. No significant treatment-related effects were observed at the highest tested concentration. Therefore, the NOEL is the highest tested dose, i.e. 5% in food (50 g/kg food), corresponding to 2055 mg/kg bw/d in male rats, 2182 mg/kg bw/d for female rats, 6157 mg/kg bw/d for male mice and 6605 mg/kg bw/d in female mice.

No reliable information was available after repeated exposure *by dermal route*. However, amorphous silicon dioxide is considered to have a low dermal toxicity based on the acute data available and on the low expected dermal absorption.

Three studies *by inhalation* in animals exposed to various forms of silica were submitted.

The first study performed in rats Fisher-344 exposed for 13 weeks to Aerosil 200 (fumed silica) focused on the mutagenicity of silica. Toxic effects in rats were poorly reported. Reversible inflammation characterized by changes in bronchoalveolar fluid parameters and increased macrophages count in the lung was related to the lung load. Fibrosis was detected in alveolar septa of lungs.

A second 13-week study compared inhalation toxicity of three amorphous silica (precipitated silica, surface-treated silica and fumed silica) with crystalline silica (quartz). Only the effects observed with the precipitated silica (Sipernat 22S) was considered in order to evaluate the toxicity of Gasil 23D. When inhaled at 35 mg/m^3, Sipernat 22S adversely affected the respiratory tract such as increases in lung weight and pulmonary lesions (accumulation of alveolar macrophages and intra-alveolar polymorphonuclear leucocytes, slight increased septal cellularity, higher lung collagen content). These changes were generally well marked by the end of the exposure period, but disappeared more or less quickly within one year after end of exposure. Silicon dioxide was completely cleared from the lungs. Treatment-related changes were also found in the nose of all exposed rats at the end of the exposure period only (focal necrosis, rhinitis and slight degeneration of the olfactory epithelium). As only a single concentration of Sipernat 22S was tested, no NOAEC could be derived.

In the third study, rats, guinea-pigs and monkeys were exposed to 15 mg/m^3 (corresponding to 6.9 – 9.9 mg/m^3 respirable dust) of a silica gel during 6 h/d for 12 months in rats and guinea-pigs and 18 months in monkeys. In addition, two other silica (pyrogenic silica and precipitated silica) were tested in this study but they were not further considered by the RMS because of their lower similarity with the applicant's silica. The most significant alterations related to exposures to the silica were confined to the lungs of the monkeys. The lungs of each monkey contained large numbers of macrophages and mononuclear cell aggregates, containing silicon. In several lungs, the numerous large aggregates in the respiratory bronchioles seemed to significantly reduce the size of the bronchiolar lumen. The histopathological examination of the lungs of the rats and guinea pigs revealed far fewer and smaller macrophage aggregates than those seen in the monkeys. Interstitial fibrosis appeared in some rats, nevertheless the presence of this lesion in the control group put in perspective the role of silica in the development of the lesion. There were no statistically significant differences between the treated group and the control concerning the clinico-chemical and haematological parameters. No data was reported on the presence or not of tumours. Moreover, significantly lower lungs volumes were noted compared to controls (Total Lung Capacity and Forced Vital Capacity were decreased). Nevertheless, the author of the study declared that "*because of the paucity of pulmonary function data on monkeys and comparisons with human data, no quantitative extrapolation to the clinical significance of these findings in humans can be made*". Finally, collagen fibers were observed in "*very few lungs*". As only a single dose was tested, no NOAEC could be derived.

The effects observed in these studies have to be taken with precaution because only a very high single dose was tested. Therefore, effects were mainly related to a pulmonary overload and no dose-response relationship could be established. However, these studies are considered as supportive data in order to evaluate the toxicological profile of the amorphous silica gel.

Finally, a five-day inhalation study performed in rat exposed to 1, 5 or 25 mg/m^3 of three types of synthetic amorphous silica, including a silica gel (Syloid 74), was found by the RMS in the public literature[17]. Exposure to Syloid 74 resulted in increases in biomarkers of cytotoxicity and inflammation in bronchoalveolar lavage fluid, increases in lung weights and histopathological lung changes (increased intra-alveolar accumulation of macrophages and bronchial/bronchiolar hypertrophy). A slight increase in hydroxyproline content was observed 3 months after the exposure to 25 mg/m^3 of Syloid 74 and could indicate a treatment-related increase in collagen content in the lungs. All the effects disappeared within 3 months post-exposure. Based on these results, a NOAEC at 5 mg/m^3 was derived from this study.

The comparison of effects observed in this study to those in 90-day studies permits to conclude that short-term (5-day) exposure study would predict toxicity upon long-term (90-day) exposure. Indeed, the results of the 5-day study are similar to those of other published studies (90-day exposure period)

[17] Arts JHE, *et al*. "Five-day inhalation toxicity study of three types of synthetic amorphous silicas in Wistar rats and post-exposure evaluations for up to 3 months*"*. Food and Chemical Toxicology 45 (2007) 1856–1867

and both types of studies indicate that the lack of lung clearance is a key factor in the development of silicosis.
It was therefore chosen to adopt the NOAEC of 5 mg/m^3 as the most relevant dose-descriptor for the risk assessment.

According to the Directive 67/548/EEC, the findings observed in rats and monkeys could meet the following criteria for classification R48: "*major functional changes in other organ systems (for example the lung)*", based on the impairment of the pulmonary function observed in the study in monkeys and "*widespread or severe necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity*", based on the increased collagen content and fibrosis observed in the lungs of rats and monkeys. Similar criteria were set in the CLP regulation for STOT RE 2 H373 (criteria b and e).

Classification for this endpoint is required if effects were observed in a 90-day study in rats at doses below 250 mg/m^3 (Directive 67/548/EEC) or between 20 and 200 mg/m^3 (CLP regulation). In the 90-day study in rats, the effects were observed at 35 mg/m^3. This value meets the above-mentioned criteria for classification.

Considering the 18-month study in monkeys, effects were observed at 15 mg/m^3 (corresponding to 6.9 – 9.9 mg/m^3 respirable dust). According to the guidance on the application of the CLP criteria, "*the Haber's rule is used to adjust the standard guidance values, which are for studies of 90-day duration, for studies of longer or shorter durations*". Considering an 18-month exposure, the equivalent guidance value should be 42 mg/m^3 (Directive 67/548/EEC) or between 3 and 33 mg/m^3 (CLP regulation). If in the absence of specific threshold values in monkeys, rat threshold values are considered, the effect concentration in monkeys also meets the classification criteria.

Finally, even if there is no or little long-term respiratory health effects in the available epidemiological studies in workers, these data are not fully reliable. As there is evidence of possible impairment of pulmonary function in experimental tests, the RMS proposes a classification Xn, R48/20 according to the Directive 67/548/EEC and STOT RE 2 H373 according to the CLP regulation.

Mutagenicity
Genotoxicity tests were taken from the public domain. Silica other than silica supported by the applicant were used. A non-guideline bacterial assay in *Salmonella typhimurium* (Ames test) performed with a silica gel (Silcron G-910), a cell transformation assay in SHE cells with a fumed silica (Aerosil OX50), and a non-guideline *in vivo* HPRT assay in type-II alveolar cells performed with a fumed silica (Aerosil 200) did not reveal any genotoxic effects. Even if some studies were performed with a fumed silica, the results could be extrapolated to Gasil 23D. Considering that the hypothetical mechanism for potential mutagenicity of silica is mainly related to a marked persistent inflammation (IARC monography volume 68) and that fumed silica induced a more severe pulmonary inflammation than wet-process silica in the repeated-dose toxicity studies by inhalation, data from these mutagenicity studies could be considered as a worst-case.

Finally, although these data have their limitations, it was not deemed necessary to require additional genotoxicity studies since:

- negative results were observed in an Ames assay and in an *in vivo* HPRT performed with non-treated silica,
- an *in vitro* cell transformation assay showed that fumed amorphous silica was neither cytotoxic nor transforming in SHE cells,
- no carcinogenic concern was raised in adequate studies.

Carcinogenicity
An oral chronic/carcinogenicity study in mice and rats treated with Syloid 244 (amorphous silica gel) for 93 weeks and 103 weeks, respectively, was submitted. Comparison of the rates of tumors found in the exposed groups with those occurring in the controls indicated that no carcinogenic effects could be

attributed to the exposure to the test substance. The absence of systemic effects up to the maximum tested dose could be attributed to both a limited absorption and/or a limited toxicity of silicon dioxide by oral route.

No carcinogenicity study by inhalation route performed with the applicant's silica was available. Studies for silica-exposed workers were provided for this endpoint. Although they are not fully reliable, they do not support any evidence of incidence of pulmonary diseases or tumors in this population.

Furthermore, according to the IARC, amorphous silica is not classifiable regarding to its carcinogenicity in humans (Group 3).

Toxicity on the reproduction and teratogenicity
The evaluation of this toxicity endpoint relies on a teratogenicity study conducted in four different species (mouse, rat, hamster, and rabbit) with an amorphous silica gel (Syloid). After animal exposure during the organogenesis period, no teratogenic effects were observed up to the highest dose tested (between 1 340 and 1 600 mg/kg bw/d, depending on the species). At the highest dose, skeletal findings were observed in mice fetuses such as incomplete ossifications of sternebrae, of vertebrae, of extremities or the sternebrae missing. This ossification delay is not considered as adverse for development.

Concerning the fertility, no study was submitted. This data gap was accepted given the absence of systemic effects observed, especially effects on reproductive parameters/organs, in the different studies. In addition, because of the level of exposure to the amorphous silicon dioxide used as a biocide is low, a study was not required.

Determination of Acceptable Exposure Level (AEL)
As far as no systemic effects were observed during the hazard assessment, no AELs were derived. The risk assessment will only be focused on the local pulmonary effects.

For exposure by inhalation, the acute AEC was calculated with the NOAEC from the five-day toxicity study by inhalation route in rat (5 mg/m^3) divided by the 25-fold safety factor (2.5 for inter-species variation[18] and 10 for intra-species variation). **An acute AEC of 0.2 mg/m^3 was proposed.**

As the results of the five-day study indicate that short-term exposure test by inhalation already anticipates the toxicity observed in the 90–day study in rats (similar effects characterized by an inflammatory reaction were observed in the 5-day inhalation study and in the 90-day inhalation study), it is not deemed necessary to apply a factor for subacute to subchronic extrapolation and a **medium-term AEC of 0.2 mg/m^3 is proposed.**

As it cannot be ruled out that the effects observed in the 5-day and 90-day studies will be different from those which would be observed after a more prolonged exposure, a factor of 2 for subchronic to chronic extrapolation was used in order to derive the long-term AEC. Therefore the long-term AEC was calculated with the NOAEC (5 mg/m^3) divided by the 50-fold safety factor (2.5 for inter-species variation, 10 for intra-species variation and 2 for the extrapolation from sub-chronic to chronic). **A long-term AEC of 0.1 mg/m^3 was proposed.**

These retained values are considered as conservative as occupational exposure limits for amorphous silica in several countries ranged from 2 to 10 mg/m^3 (depending on countries). However, it was preferred to derive the AECs from a well-conducted study rather than using current occupational

[18] The usual interspecies factor of 10 was reduced to 2.5 due to the absence of systemic toxicity (only local effects were observed) (TNsG on Quantitative Risk Characterisation).

exposure limits (OELs) because the existing values are different depending on countries (from 2 to 10 mg/m^3) and because no scientific basis was found behind the derivation of these OELs.

Considerations have been given to the possibility of local effects by dermal route. Since the notified substance is not classified as irritant to the skin and to the eye, and as no skin sensitising potential is expected, it is suggested that dermal route is at very low risk. Finally, considering the Annex VI of the Directive 98/8/EC point 24 "*In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues",* it is proposed that a dermal AEC would not be derived.
Nevertheless, literature studies show drying effects on workers exposed to various forms of silica by dermal contact or after ocular contact. In the Safety Data Sheet of the Gasil 23D, a discomfort and a mild irritation are described by eye contact. These effects were due to the dust nature of silica and could be expected after a repeated exposure. However, the recommendation of wearing gloves and goggles in the SDS could prevent skin exposure and thus the occurrence of drying effect in professional users.

2.2.1.2. Effects assessment (product)

Considering the composition of RID Insect Powder, the toxicity data submitted for the active substance silicon dioxide were considered applicable to the product. No other data were submitted in the dossier.

2.2.1.3 Exposure assessment

Considering the variability of RID Insect Powder composition in terms of amorphous silicon dioxide concentration (between 40% and 50%), a worst case exposure was determined taking into account a composition of 50 % silicon dioxide.
RID Insect Powder is a professional product, intended for use by Rentokil Service Staff only.
RID Insect Powder is supplied in a 50 g plastic bottle. Before use, it is decanted into a hand-operated pump or motorised blower (dust gun) for application into enclosed / inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits. The application rate of RID Insect Powder is 20 g/m^2.
Both primary exposure to professional users and secondary exposure to general public were assessed.
The exposure assessment is described in detail in Document II-B of this Competent Authority Report.

Table 2.2.1-1: Identification of main paths of human exposure towards silicon dioxide from its use in RID Insect Powder

Exposure path	Industrial use	Professional use	General public	Via the environment
Inhalation	no	yes	yes (indirect)	no
Dermal	no	yes	yes (indirect)	no
Oral	no	no	yes (indirect)	no

Inhalation exposure:
The particle size distribution of RID Insect Powder (containing 50 % of silica gel) is composed of 3 maximum peaks (4 µm, 20 µm and 160 µm) and 34.62% of the powder has a particle diameter lower than 10 µm (respirable fraction). The 4 µm is consistent with the size of aggregates. The 20 µm and 160 µm should be considered as agglomerates of aggregates (agglomerate means a collection of weakly bound particles or aggregates which are particles comprising of strongly bound or fused particles).

The respirable particles of active substance are responsible of pulmonary local effects in the experimental studies. Consequently, only the respirable fraction of active substance in the biocidal product (corresponding to 34.62%) will be taken into account in the calculation of the inhalation intake during loading and application since the professional will be exposed to the product as such.

Due to environmental conditions (e.g humidity, dust concentration, temperature…), there is a possibility that the agglomerates be divided in aggregates or in smaller agglomerates after application of the product. Therefore, as a worst case, it will be considered that 100% of the particles are in aggregated form (1-6 µm according to characterisation of Gasil 23D); thus a respirable fraction of 100% will be taken into account in the calculation of the inhalation intake during post application (removal of old powder) and for secondary exposure.

Dermal exposure:
As there is no systemic effect by oral route or local effect (leading to classification) after acute dermal exposure observed in the submitted studies, this exposure path will not be assessed. Nevertheless, as literature studies show drying effects on workers exposed to various forms of silica by dermal contact or after ocular contact, the RMS supports the recommendation of gloves and goggles as already recommended in the SDS to prevent drying effect in professional users.

Professional exposure

Potential for primary human exposure to RID Insect Powder, under normal conditions of use, was identified for following tasks:

- Loading of the product into the application equipment
- Application of RID Insect Powder
- Removal (vacuuming) and disposal of spilt or old powder

During these tasks, there is a potential for dust to become airborne or deposit on skin. As there is no systemic effect observed in the submitted studies by oral route or local effect (leading to classification) after acute dermal exposure, the dermal exposure path has not been assessed.

Task 1: Loading
RID Insect Powder is a white powder, which is decanted from its 50 g bottle into the open top of a dust gun. This task is normally done before application. As RID Insect Powder is supplied as a ready-to–use product, there is no mixing or dilution prior to loading.

Frequency and duration of task are those used in example for product called "Barnspray" in TNsG part 3 p.72[19]. They have been chosen as the most appropriate ones taking into consideration actual experience. Considering 3 applications per day, needing 100 g (2 bottles), 6 (3x2) loading tasks per day are assumed. Duration of loading task is assumed to be 3 minutes. Specialised operators may use RID Insect Powder each working day.

For the evaluation, the indicated values from '*Mixing and loading Model 5: pouring from container into portable reservoir*' from TNsG for human exposure assessment (TNsG part 2 p.139 and TNsG user guidance[20] p.24) are used.

Task 2: Application

Once decanted into a dust gun, RID Insect Powder is applied into enclosed/inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits. Using a dust gun means that the dust can be applied directly into the desired location, with little exposure to the operator.

For the exposure assessment, an application task is defined as applying 50 g (one bottle) of product. However, to fulfil the application rate of 20 g/m², up to 100g (two bottles) may be used per complete application. Frequency and duration of task are those used in example for product called "Bugdust" for household crack and crevice use in TNsG part 3 p 73. They have been chosen as the most appropriate ones taking into consideration actual experience. Considering 3 applications per day, needing 100 g (2 bottles), 6 application tasks per day are assumed. Specialised operators may use RID Insect Powder each working day.

For the evaluation, the indicative values are taken from *'Consumer spraying and dusting Model 2, hand-held dusting applicator pack for crack and crevice*' in TNsG for human exposure assessment (TNsG part 2 p.200).

Task 3: Removal and disposal of spilt or old powder, after application

In some cases, spilt material or old powder (e.g. if it becomes damp or covered in debris) once laid down may be removed. A hand-held vacuum cleaner is then used. Once removed, waste dust is emptied into a container, which is sealed, and disposed of as controlled waste. As a worst-case scenario, it is proposed that all RID Insect Powder applied is cleared away after use, even if it should happen only occasionally.

For the exposure assessment, a post-application task is defined as removing 50 g of product, for consistency with application task. Frequency and duration of task are those used in example for product called "Bugdust" in TNsG part 3 p 73. They have been chosen as the most appropriate ones taking into consideration actual experience. The frequency is the same than for application. Duration of post-application task is assumed to be 8 minutes: 5 minutes for vacuuming and 3 minutes for disposing the powder. Specialised operators may use RID Insect Powder each working day.

For the evaluation of exposure during vacuuming, indicative values are taken from *'Consumer spraying and dusting Model 2, vacuuming after dusting application, non-cyclone vacuum cleaner*' in TNsG for human exposure assessment (TNsG part 2 p.200). Exposure during disposal was considered to be equal to the one occurring during loading.

For each tasks, exposures were estimated with a tiered approach: tier 1 without any personal protective equipment (PPE), tier 2 with appropriate PPE (respiratory mask). The results are reported in following table.

19 Technical Notes for Guidance on Human Exposure to biocidal products 2002

20 User Guidance version 1 _ TNsG 2002 Human Exposure to biocidal products

Table 2.2.1-2: Exposures by inhalation route

	Respirable Inhalation exposure (mg/day)	
	Tier 1	Tier 2*
Loading of application equipment	0.078	0.0078
Application into inaccessible locations	0.107	0.0107
Removal and disposal of spilt or old powder	0.48	0.048
Total exposure	**0.665**	**0.0665**

* In tier 2, PPE are taken into account (penetration rate into brackets): mask (10%)

Furthermore, considering an inhalation rate of 1.25 m^3/h and a 8-hour daily occupational exposure duration, it is assumed the operator will inhale 8 x 1.25 = 10 m^3/day. The 8h-Time Weighted Average (TWA) concentration leading to an exposure of 0.665 mg/day (tier 1) and 0.0665 mg/day (tier 2) are respectively:

- 0.665 (mg)/ 10 (m^3) = 0.0665 mg/m^3 for tier 1
- 0.0665 (mg)/ 10 (m^3) = 0.00665 mg/m^3 for tier 2

These values are summarised in the table below.

	Respirable inhalation exposure* (mg/m^3)
Tier 1	0.0665
Tier 2	0.00665

* 8h-TWA exposure concentration for 6 applications per day

Indirect exposure

RID Insect Powder is intended for use by professional operators only. During the application of RID Insect powder and until the powder has settled, bystanders are excluded from the application area, and thus will not be exposed to the product. Moreover, according to the instructions, the product is applied in inaccessible places (such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits). Thus, indirect exposure is improbable. Nevertheless, it cannot be excluded and following scenarios have been discussed.

Table 2.2.1-3: Identification of potential indirect exposure scenarios

Scenarios of secondary exposure	**Route of exposure**	**Can secondary exposure occur?**	**Comments**
Bystanders present during application	Inhalation Acute	No	There are no relevant acute exposure phase scenarios for professional applications since bystanders are kept out of the treatment areas during application.
Occupants present in treatment area after application	Inhalation Acute	No	There are no relevant acute exposure phase scenarios for professional applications where bystanders are kept out of the treatment areas until the powder has settled.
Infant: contact with parent's contaminated clothing	Dermal and ingestion Acute	Yes	As only inhalation local effects are observed in toxicological studies, this scenario is not developed in the exposure assessment.
Cleaning up old dust with vacuum cleaner	Inhalation and dermal Acute	Yes	The removal of old powder is usually done by professional operator. Nevertheless, cleaning by occupant would be possible.
Child and infant: contact with overspill dust	Dermal and ingestion Acute	No	Professional operator should remove overspill dust before children come into the treatment area.
Child and infant: contact with powder in inaccessible area	Dermal and ingestion Acute	Yes (transient)	Although RID Insect Powder should be applied in inaccessible places, contact by playing child or infant is still possible. As only inhalation local effects are observed in toxicological studies, this scenario is not developed in the exposure assessment.

Cleaning up old dust with vacuum cleaner

The removal of old powder is usually done by a professional operator, but in some cases, occupants may vacuum it themselves. As a worst-case, exposure would be as the same than for a professional operator not wearing a PPE but restricted to one task instead of six.

Table 2.2.1-4: Results of the exposure doses for indirect scenario

Scenarios of secondary exposure	**Relevant route of exposure**	**Phase**	**Respirable exposure doses**
Cleaning up old dust with vacuum cleaner	Inhalation	Acute	Inhalation (8-hr TWA): 7.9×10^{-3} mg/m^3

2.2.1.4 Risk characterisation

Professional users

Dermal exposure:

As there is no systemic effect by oral route or local effect (leading to classification) after acute dermal exposure observed in the submitted studies, this exposure path has not been considered.

Respiratory exposure:

The results of the Risk Assessment for professional users by inhalation are summarised in Table 2.2.1-5.

Table 2.2.1-5: Summary of Risk Assessment for professional users exposed by inhalation

Exposure Scenario		**Inhalation exposure External concentration (mg/m^3 air)**	**Relevant NOAEC (mg/m^3)**	**AF MOE_{ref}**	**AEC (mg/m^3)**	**MOE**	**Exposure (%AEC)**
Tier 1 (no PPE)	Total tasks duration: 78 min Daily Whole year	0.0665	5	50	0.1	75.2	66.5 %

The exposure to the respirable fraction of silica gel in RID Insect Powder represents 66.5% of the AEC. Thus, the risks are considered as acceptable for professional users. Likewise, the MOE (75.2) is higher than the MOE_{ref} (50). It confirms that the use of RID Insect Powder for the control of cockroaches is not likely to induce any unacceptable risk to professional users[21].
A tier 2 (with PPE) has not been considered as necessary.

Reverse scenario:
As without Respirable Protection Equipement (RPE) 6 applications lead to an estimated exposure of 0.0665 mg/m^3 8h TWA, thus 1 application lead to an estimated exposure of 0.011 mg/m^3 8h TWA. Considering an $AEC_{long\ term}$ of 0.1 mg/m^3, it is calculated that more than 9 applications per day are needed to exceed this AEC and more than 91 are needed if a RPE is considered.

Conclusion of the direct exposure:

[21] As tier 1 did not show any unacceptable risk for users, no PPE is deemed necessary. Nevertheless, the use of coverall, respiratory mask, goggles and gloves is recommended by the applicant in the frame of good working practices.

After dermal exposure, no risks are expected in the absence of systemic (by oral route) and local effects (irritation and sensitisation) as concluded from the hazard assessment.

After inhalation exposure, the result above demonstrates that the use of RID Insect Powder for the control of cockroaches in accordance with the label instruction does not pose any unacceptable risk by inhalation route to the professional users even when not wearing personal protective equipment.

Non-professional users

This product is for use by professional users only. Therefore there is no exposure expected for non-professional users.

Indirect exposure as a result of use of the active substance in biocidal product

Adult cleaning up old dust with vacuum cleaner:

The scenario "*adult cleaning up old dust with vacuum cleaner*" was presented by the applicant. Consequently, the RMS kept this scenario as a very worst-case exposure, although dust is supposed to be removed by the operator.

Dermal exposure: As there is no systemic effect by oral route or local effect after acute dermal exposure observed in the submitted studies, this exposure path has not been considered.

Respiratory exposure: Only local effects are observed by the inhalation route. The AEC and MOE approaches have been used in order to assess the risk. The results are presented in the following table (Table 2.2.1-6).

Table 2.2.1-6: Summary of Risk Assessment by inhalation for the scenario *adult cleaning up old dust with vacuum cleaner*

Exposure Scenario	**Estimated inhalation value (mg/m^3)**	**Relevant NOAEC (mg/m^3)**	**AF MOE_{ref}**	**AEC (mg/m^3)**	**MOE**	**Exposure (%AEL)**
Adult: Cleaning up old dust with vacuum cleaner - Acute	7.9×10^{-3}	5	25	0.2	633	3.9 %

This figure shows that the risk of indirect respiratory exposure to RID Insect Powder is then considered as acceptable for an adult cleaning up old dust with vacuum cleaner. Indeed, the exposure is lower than 100% AEC and the calculated MOE (633) is higher than the MOE_{ref} (25).

Exposure via residues in food

According to Directive 95/2/EC of 20 February 1995, silicon dioxide is considered as a food additive (E551) and no dietary toxicological reference values have been set. Considering the intended use (application into enclosed / inaccessible locations), consumer exposure to silicon dioxide residues in food or feed items via biocidal products will be much lower compared to consumer exposure to silicon dioxide occurring as natural food ingredient and from use as registered food additive and authorised feeding stuff additive.

Conclusion of the secondary exposure:

In case of dermal or oral indirect exposures, no risks are expected in the absence of systemic (by oral route) and local effects (irritation and sensitisation) as concluded from the hazard assessment.
In case of inhalation exposure, the result above demonstrates that the exposure to RID Insect Powder does not pose unacceptable risk for an adult cleaning up old dust with vacuum cleaner.

Combined Exposure

A combined exposure assessment is not deemed relevant: users or general public would unlikely be exposed to RID Insect Powder following more than one of the identified scenarios.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. Based on the physico-chemical nature of this compound (inorganic structure, chemical stability, *i.e.* high stability of the Si-O bond), it was not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds. Due to the limited water solubility of this compound, the transformation in silicic acid from dissolution by water would be negligible. No light-induced transformation is expected.

Due to its limited water solubility in natural conditions and extremely low vapour pressure, silicon dioxide is expected to be distributed mainly into soils/sediments, weakly into water and probably not at all in the air. This compound is expected to combine indistinguishably with the soil layer and sediment due to its chemical identity with inorganic soil matter. Whatever its origin, man-made or natural (mostly as sand or quartz), and whatever its structure, crystalline or amorphous silica, once released and dissolved into the environment, no distinction can be made between the initial forms of silica.

Within the scope of its use as insecticide, amorphous silicon dioxide is not expected to reach the different environmental compartments. The use of this compound as biocidal product (PT18) is restricted to indoors application into enclosed/inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits; old powder is removed by hand-held vacuum cleaner and disposed into sealed containers. A release to environment is therefore considered to be insignificant.

2.2.2.2. Hazard assessment (active substance)

Aquatic compartment

Acute and chronic toxicity to fish
The acute toxicity of amorphous silicon dioxide to rainbow trout (*Oncorhynchus mykiss*) was studied under laboratory conditions during 96 hours of static exposure. The 96-h LC_{50} was defined to be higher than 110 mg a.s./L. As no mortality was observed at the tested concentration, a no observed effect concentration (NOEC) was set at 110 mg/L.

Acute toxicity to invertebrates
The acute toxicity of amorphous silicon dioxide to aquatic invertebrates was tested on freshwater species *Daphnia magna* in a static system during 48 hours at the nominal dose rate of 110 mg/L. The 48-h LC_{50} was defined to be higher than 86 mg a.s./L (measured concentration). As no immobilisation was observed at the tested concentration, a no observed effect concentration (NOEC) was set at 86 mg/L.

Growth inhibition in algae and aquatic plant toxicity

The algastatic activity of amorphous silicon dioxide was measured in a 72-h laboratory study using *Selenastrum capricornutum*. The E_rC_{50} and E_bC_{50} were determined to be higher than highest attainable concentration of 54 mg a.s./L. No inhibition was observed at the tested concentration, however several deficiencies led to consider the study as not reliable. Nevertheless, considering the toxic mode of action of the compound, no toxicity to algae was expected. Moreover, no exposure to the aquatic environment is expected, then the RMS stated that repeating the study is not necessary.

Inhibition to microbiological activity

In test flasks dosed with amorphous silicon dioxide, less than 10 % of inhibition was observed in the single tested concentration of 1000 mg a.i./L. A 3 hour NOEC was therefore defined as 1000 mg a.s./L.

PNEC definition for aquatic compartments

$PNEC_{surfacewater}$ was calculated from the lowest available freshwater LC_{50} (*Daphnia magna*, $EC_{50} \geq 86$ mg a.s./L) with an Assessment Factor (AF) of 1000 as short-term toxicity studies are available for at least three species representing three trophic levels. The calculated PNEC value (0.086 mg/L) is lower than the background levels of dissolved silica found in the natural aquatic compartments (reported to be from 0.4 to 26 mg/L).

The calculation of a $PNEC_{sediment}$ based on partitioning method from $PNEC_{water}$ is not reliable because log Kow for this substance is not reliable. Therefore, as agreed during TMIII10, PNEC sediment is replaced by silica background in sediment, which varies in a range from 2.19 to 16.48 mg Si/kgwwt. The value of 2.19 mg Si/kgwwt will be used in the risk assessment.

According to the TGD for Risk Assessment (2003), and taking into account the available test with aquatic microorganisms, an assessment factor of 10 can be applied to define a **$PNEC_{microorganisms}$** 100 mg/L.

The different PNEC for the aquatic compartments are summarized in Table 2.2.2.2–1

Table 2.2.2.2-1: PNEC for water compartments

Compartment	Test organisms Study type	$L(E)C_{50}$	Assessment factor	PNEC
Surface water [mg a.s./L]	*Daphnia magna* static, 48h	≥ 86	1000	86×10^{-3}
Sediment [Silica background in sediment (mg Si/kgwwt)]	n.a	n.a	n.a	2.19
STP [mg a.s./L]	Activated sludge, respiration inhibition test	1 000	10	100

n.a = not available

Atmosphere

Silicon dioxide is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant.

Notwithstanding the above, the structure of silicon dioxide is O=Si=O means that •OH radicals are unlikely to be generated during degradation in air. When pseudo-first order rate constant for degradation in air was estimated using the QSAR method, the rate constant was zero. This result supports the above statement that •OH radicals are unlikely to be generated during degradation of silicon dioxide in air.
Silicon dioxide will not have an impact on global warming because it does not exist in the gaseous state at ambient temperature and pressure. The presence of absorption bands in the IR spectrum region 800-1200 nm is therefore not applicable. It is also highly unlikely that silicon dioxide will have any impact either on ozone depletion in the stratosphere or ozone formation in the troposphere, because silicon dioxide does not contain chlorine substituents, and •OH radicals are unlikely to be generated during degradation of silicon dioxide in air. The final atmospheric risk indicator is acidification. As silicon dioxide does not contain Cl, F, N or S substituents, acidification is not considered to be at risk to receiving soil or surface water.

Terrestrial compartment

Tests on terrestrial organisms were not deemed necessary, as the risk assessment for this compartment does not indicate a concern (under normal condition of use, the exposure to silicon dioxide as insecticide is considered as limited).

$PNEC_{soil}$ definition

A $PNEC_{soil}$ cannot be calculated with the partitioning method from $PNEC_{water}$ while log Kow value is not reliable for this compound.
Therefore, as agreed during TMIII10, PNEC soil is replaced by silica background which is about 706 $g/kg_{dry\ soil}$

Non compartment specific effects relevant to the food chain (secondary poisoning)

The assessment of the potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through the food chain. Ideally a comparison between concentrations found in top predators should be made with the no effect concentration for that predator. As these data are not available a theoretical assessment is made.

The first step in the assessment is to consider the bioaccumulation potential. Bioaccumulation has been assessed as unlikely to occur. Next the classification on the basis of mammalian toxicity is considered but amorphous silicon dioxide is not classified as toxic. In addition there is no indication of genotoxicity, although not directly relevant for the environment, it may be indicative for top predators.

For all these reasons, it is therefore not necessary to perform an assessment of secondary poisoning (Technical Guidance Document on Risk Assessment Part II Chapter 3 Section 3.8.3.1 (2003).

2.2.2.3. Effects assessment (product)

Considering the composition of RID Insect Powder the ecotoxicological data submitted for silicon dioxide will apply to the product.

2.2.2.4. PBT assessment

According to the PBT assessment in the TGD, criterion for substance to be persistent is fulfilled when:
T 1/2 in freshwater > 40 days or,
T 1/2 in freshwater sediment > 120 days.

As silicon dioxide is not expected to undergo any transformation in the environment, this substance will persist in the environment.

Considering these data, silicon dioxide would theoretically fulfil the P criterion, but this criterion is not set for inorganic compound. This substance is therefore not P.

According to the PBT assessment in the TGD, a substance is considered to fulfill the B criterion when the bioconcentration factor (BCF) exceeds a value of 2 000 L/kg.
Considering the particle size distribution of the silicon dioxide molecule, the practically non-solubility of the molecule in organic solvents, silicon dioxide is not selected according to the screening B criterion.

According to the PBT assessment in the TGD, the toxicity criterion is fulfilled when the chronic NOEC for aquatic organism is less than 0.01 mg/L or when the substance is toxic to mammals and classified as Very Toxic or Toxic after oral dosing.
Based on all the ecotoxicity freshwater data (with the lowest EC_{50} > 54 mg a.s./L), T screening criteria is not fulfilled.

As the B and T criteria are not fulfilled, silicon dioxide is not classified according the PBT assessment.

2.2.2.5. POP & Endocrine disrupting assessment

- ***POP***

Silicon dioxide is inorganic natural compound. Therefore, POP criteria do not fit to natural compound as silicon dioxide.

- ***Endocrine disruption***

Silicon dioxide is not considered to have endocrine disrupting effects and was not listed in any document of the EU Commission on endocrine disrupting chemicals (i.e. Communication from the Commission to the council and the European parliament on the implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706) or the list produced by the Commission contractant BKH (2002): Endocrine disrupters – Study on gathering information on 435 substances with insufficient data). Moreover, it could be added that in the Human Health part, no reprotoxicity or carcinogenicity effect are noticed.
And finally, considering the mode of action of silicon dioxide, desiccation of the insects, the possible endocrine disruptor activity of the compound seems to be improbable.

2.2.2.6. Exposure assessment

The notifier applied for an intended use of RID Insect Powder against cockroaches indoors in domestic and public areas. This use was described to be restricted to application into enclosed/inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits. The product will be applied especially by professional pest-control personnel. Cleaning is made by vacuum cleaner, placed into sealed containers and disposed appropriately.
Due to the localisation of application in enclosed/inaccessible sites, no release to the environment was considered relevant from the use of the RID Insect Powder.
A negligible level of exposure level towards the environmental compartments was acknowledged.

2.2.2.7. Risk characterisation

The substance under consideration is a synthetic amorphous form of silicon dioxide, which is similar to natural forms of silica.

Acute toxicity testing did not allow identifying significant hazard to the environment at least up to 86 mg/L, which was the highest measured tested dose for Daphnids.
A negligible exposure level of the environment is expected from the use of silicon dioxide in the insecticidal product, RID Insect Powder, to be applied against cockroaches in enclosed/inaccessible locations.

On the basis of the Annex VI of the 98/8/EC Directive 'Common principles for the evaluation of the dossiers for biocidal products (point 38), the RMS did agree with the risk assessment proposed by the applicant considering that risk characterisation in relation to the effect of a biocidal product is not necessary if the different studies carried out to identify its hazard have not led to classification of this biocidal product.

The risk for the environment was deemed acceptable due to the lack of identified toxicity to the organisms and considering that exposure of environmental compartments is unlikely.

2.3. Overall summary

Application by professional operators (PCO) for the control of cockroaches into enclosed / inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits (20g product/m^2)							
Human primary exposure	**Human secondary exposure**	**Aquatic compartment (including sediment)**	**STP**	**Terrestrial compartment**	**Groundwater**	**Air**	**Secondary poisoning**
Professional	**Consumer**						
Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

3. PROPOSED DECISION

3.1. Background to the proposed Decision

The active substance synthetic amorphous silicon dioxide has been reviewed for a use in Product Type Insecticides, acaricides and products to control other arthropods (PT18), considering professional uses only.

Based on primary particle size and specific surface area by volume submitted, the active substance synthetic amorphous silicon dioxide is a nanomaterial according to the Commission recommendation on definition of nanomaterial (2011/696/EU) and Article 3(1)(z) of Regulation EU 528/2012 (BPR).

Under conditions of normal handling and use, it is considered that aggregates (1-6 µm for active substance) are the smallest stable particles. In this context, data provided by the notifier and literature tend to show that liberation of primary particles and exposure to nano-object (material with one, two or three external dimensions in the nanoscale) is not expected during and after the intended biocidal application considered in this dossier. Since exposure to nanoscale primary particles was not expected during the specific intended biocidal use,the hazard and risk related to the **individual particles** of silicon dioxide with a nanometric size were not evaluated in this dossier (ie. individual particles not aggregated). This position will be updated with the evolution of knowledge and specific regulations about nanomaterials or with complementary data showing that use of the active substance leads to exposure to individual particles of silicon dioxide with nanometric size.

The efficacy of silicon dioxide against cockroaches (*Blattella germanica, Blatta orientalis)* has been demonstrated, against pre-adult stages. Silicon dioxide contributes therefore to reduce cockroach infestation through the death by desiccation, as part of an Integrated Pest Management Program.

The physico-chemical properties of the active substance synthetic amorphous silicon dioxide and the biocidal product are deemed acceptable for the appropriate use, storage and transportation.

With regard to human health, it is considered that amorphous silicon dioxide is free of carcinogenic or mutagenic effects and adverse effects on reproduction and development. The results of the risk assessment for primary exposure indicate that users will not be exposed to unacceptable levels of amorphous silicon dioxide during daily use of the product by inhalation. The risk of indirect exposure is also considered as acceptable.

Concerning the exposure of the environment, there are no primary or secondary emissions of amorphous silicon dioxide to surface water, sediments and soil. The risk for the environment was deemed acceptable considering that exposure of environmental compartments is unlikely in this particular case of use in enclosed/inaccessible locations.

There is no evidence of endocrine effects of synthetic amorphous silicon dioxide. The substance cannot be considered as carcinogenic, mutagenic and toxic for the reproduction (CMR). Synthetic amorphous silicon dioxide is not considered as Toxic for the environment, Bioaccumulative and Persistent (PBT).

3.2. Proposed Decision

The active substance synthetic amorphous silicon dioxide is a synthetic amorphous silica gel, described as “wet process silica, CAS 112926-00-8”. All statements and risk assessments in this dossier apply solely to the amorphous silicon dioxide, as marketed by the applicant. **Other forms of**

silica, included under the more general CAS 7631-86-9 are not covered by this assessment and the decision.

The overall conclusion from the evaluation of synthetic amorphous silicon dioxide CAS n° 112926-00-8" for use in Product Type 18 (insecticide), is that it may be possible to issue authorisations of products containing synthetic amorphous silicon dioxide in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore proposed to approve synthetic amorphous silicon dioxide CAS n° 112926-00-8, is an active substance for use in product-type 18 (food and feed area disinfectants), subject to the following specific conditions:

1. This approval covers synthetic amorphous silicon dioxide as a nanomaterial in the form of stable aggregated particles of particle size > 1µm, with primary particles of nanosize.
2. The active substance synthetic amorphous silicon dioxide, as manufactured, shall have a minimum of purity of 800 g/kg.
3. The identity and the maximum content of impurities have to comply with the confidential subsection 2.8 of Document IIIA. Given its classification as carcinogen, crystalline silica impurities must not exceed the maximum level of 0.1 % in the technical material.
4. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorization, but not addressed in the Union level risk assessment of the active substance.

3.3. Elements to be taken into account when authorising products

1. The form of silica assessed as the active substance synthetic amorphous silicon dioxide is only the silica gel described as "wet process silica - CAS 112926-00-8" with the following structural characteristics:
   - Primary particle size < 25nm
   - Volume specific surface area > 600 m²/cm3
   - Particle size of aggregates > 1µm

   It is up to any applicant for technical equivalence to demonstrate that the active substance in his product will share the same identity, and will be technically equivalent to the reference source of this dossier. In particular, any applicant will have to demonstrate that no criteria among the ones listed below has an influence on the different endpoints summarized in Appendix I:
   - surface charge
   - shape
   - crystal structure
   - particle size distribution
   - surface chemistry

   Nota: the Rapporteur Member State would like to avoid a preemption of the debate on the modification of REACH Annexes on the essential characteristics of a nano. The list is inspired by the ISO standard: ISO/PDTR 13014. At the time of finalization of the present assessment report, scientific and regulatory debates on the identification and technical equivalence of nanomaterials are not yet finalized.

2. Given the classification of crystalline silica as carcinogen, it should be checked at the product authorisation stage that no more than 0.1 % of crystalline SiO_2 is present as impurity in the technical grade active substance.

3. Field trials for efficacy against cockroaches should be submitted in order to confirm the operational rate of 20 g of product/m^2 and intervals between applications.

4. The efficacy claimed in this dossier is restricted to cockroaches only, as part of an Integrated Pest Management Program. If any additional target organisms are claimed, efficacy data have to be provided.

5. Personal protective equipment is not normally required with the biocidal product, RID Insect Powder since no unacceptable risk was detected in the Tier 1 assessment. However, silicon dioxide is known as a desiccant agent and drying effects were observed on workers. Therefore the RMS supports the recommendations presented in the SDS of Gasil 23D and RID Insect Powder such as the use of coverall, respiratory mask, goggles and gloves and the washing of hands and exposed skin after use.

6. When performing professional treatments indoors, the operator must apply the powder in confined and poorly accessible areas, in order to minimize the possibility of exposure to the general population, to pets and to the environment.

7. The food risk assessment was not performed due to the intended uses, considering the inaccessibility of treated areas. However, if other places should be treated, this food risk assessment should be considered.

8. Considering the intended use of the product RID Insect powder, no particular environmental measures are necessary. Waste material should be disposed of in sealed containers to landfill. Disposal of empty containers is in accordance with local/national requirements which will normally mean disposal to landfill.

9. According to the intended uses, no direct emission to the environment is expected. However, if at the product authorization level, new intended uses are proposed where direct emission to environment is expected, a new algae study should be provided by the applicant.

3.4. Requirement for further information

The RMS considers that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusion of the risk assessment and permits the approval of the active substance.

However, some further information is required and must be provided at the latest 6 months before the date of approval:

- LOQ for the method of quantification of crystalline silica in the technical active substance

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of synthetic amorphous silicon dioxide.

Appendix I : Listing of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information and Proposed Classification and Labelling

Active substance (ISO Common name)	Silicon dioxide
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	France

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	Silicon dioxide
Chemical name (CA)	Silicon dioxide
CAS No	112926-00-8
EC No.	231-545-4
Other substance No.	None known.
Minimum purity of the active substance as manufactured (g/kg or g/L)	800 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Crystalline silica 0.1%
Molecular formula	SiO_2
Molecular mass	60.08 g/mol
Structural formula	O=Si=O
Structural characteristics	Primary particle size < 25nm Volume specific surface area > 600 m^2/cm^3 Particle size of aggregates > 1µm It is up to any applicant for technical equivalence to demonstrate that no other criteria, among the ones listed below, has an influence on the different endpoints: – surface charge – shape

- crystal structure
- particle size distribution
- surface chemistry

Nota: the Rapporteur Member State would like to avoid a preemption of the debate on the modification of REACH Annexes on the essential characteristics of a nano. The list is inspired by the ISO standard: ISO/PDTR 13014

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	1710°C (purity not reported)
Boiling point (state purity)	Ca. 2230˚C (purity not reported)
Temperature of decomposition	Not applicable. Melting point has been determined.
Appearance (state purity)	Solid (powder), white and odourless (91.5 % purity)
Relative density (state purity)	Tap density = 0.13 g/mL (91.5 % purity)
Surface tension	57.5 mN/m
Vapour pressure (in Pa, state temperature)	Not applicable as melting point >300˚C
Henry's law constant (Pa m^3 mol^{-1})	Not applicable as silicon dioxide with a melting point > 300˚C
Solubility in water (g/L or mg/L, state temperature)	Silicon dioxide is not soluble
Solubility in organic solvents (g/L or mg/L, state temperature) (Annex IIIA, point III.1)	Silicon dioxide is not soluble
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not applicable. There are no organic solvents used in the manufacture of the representative product RID Insect Powder.
Partition coefficient (log Pow) (state temperature)	Not applicable
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII 7.6.2.1)	Not applicable. Method of analysis not applicable for hydrolysis test.
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Silicon dioxide is not expected to dissociate in water based on its structure
UV/VIS absorption (max.) (if absorption >290 nm state Σ at wavelength)	200 nm No absorption was observed above 290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII 7.6.2.2)	Not applicable due to UV absorption maxima.
Flammability	Not highly flammable auto-ignition temperature > 400°C
Explosive properties	Not explosive

Summary of intended uses

Object and/or situation		Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
				Type	Conc. of a.s.	Method kind	Number min max	Intervals between applications (min)	g as/L min max	water L/m^2	g as/m^2 min max	
For professional use**,** indoors in enclosed / inaccessible locations such as wall voids, ceiling voids, floor cavities, pipe ducts and electrical conduits for control of pre-adult stages of cockroaches as part of an Integrated Pest Management Program.		RID Insect Powder	Cockroaches *Blattella germanica* *Blatta orientalis*	Ready-to-use powder	Max.50 %	The powder is dispersed by a hand-operated pump or a motorized blower (dust gun)	At least 4 applications of RID Insect Power are required to obtained a clear impact on the cockroach density (IIIB5.10_2)	Not applicable	RID Insect Powder application dose: 20 g product/m^2 (max. 10g a.s/m^2)			None.

Classification and proposed labelling (Annex IIA, point IX)

with regard to physical/chemical data	Not classified as hazardous.
with regard to toxicological data	Xn, R48/20. harmful; danger of serious damage to health by prolonged exposure by inhalation (proposed classification)
with regard to fate and behaviour data	Not classified as hazardous.
with regard to ecotoxicological data	Not classified as hazardous.

Chapter 2: Methods of analysis

Methods of analysis for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	ICP-AES
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Crystalline silica: X-Ray analysis

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	No validated method submitted. No exposure of soil compartment is expected (indoor use only).
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Proposed method is "NIOSH, 1994, NIOSH Manual of Analytical Methods (NMAM), Fourth Edition SILICA, AMORPHOUS Method 7501, Issue 2". LOQ not defined.
Water (principle of method and LOQ) (Annex IIA, point 4.2)	No validated method submitted. No exposure of water compartment is expected (indoor use only).
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	The substance is currently not classified as hazardous for supply; therefore it is not necessary to provide an analytical method for detection in body fluids and tissues.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable. Amorphous silicon dioxide under normal conditions of use as a biocide, will not come in contact with food/feed of animal origin.

Chapter 3: Impact on human health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption	No study on oral absorption has been provided. No evidence of oral absorption of silicon dioxide is available. However, its breakdown product, silicic acid, is known to be orally absorbed (breakdown kinetic is however not fully documented).
Rate and extent of dermal absorption	No study on percutaneous absorption has been provided.
Distribution	It has been demonstrated that various human body tissues contain silica physiologically, which is present at varying levels during the life.
Rate and extent of excretion	The kidneys play the main role in silica excretion.
Toxicologically significant metabolite	There are no metabolites of concern which are formed in mammals.

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	LD_{50} > 5 000 mg/kg (various silica gels)
Rat LD_{50} dermal	LD_{50} > 2 000 mg/kg (various silica gels)
Rat LC_{50} inhalation	LC_{50} > 2 mg/L (various silica gels), highest feasible concentration
Skin irritation	Not classified as irritant (various silica gels)
Eye irritation	Not classified as irritant (various silica gels)
Skin sensitisation (test method used and result)	Not classified as a sensitizer (Zeolithe A, microcrystalline silica)

Repeated dose toxicity (Annex IIA, point 6.3)

Species/target/critical effect	Oral chronic/carcinogenicity study (Syloid 244, silica gel) - mice and rats treated 93 weeks 103 weeks, respectively. No critical effect at the highest tested dose. 5-day toxicity study by inhalation route (Syloid 74, silica gel): Wistar rat (10/sex/group). Respiratory local effects were observed.
Lowest relevant oral NOAEL/LOAEL	NOEL = ca. 6600 mg/kg bw/d (female mice; highest tested dose)
Lowest relevant dermal NOAEL/LOAEL	-
Lowest relevant inhalation NOAEL/LOAEL	NOAEC = 5 mg/m^3

Genotoxicity (Annex IIA, point 6.6)

In vitro gene mutation study in bacteria:
Silcron G-910 (silica gel) showed no evidence of inducing increased revertant counts in any of the bacterial strains used (*S. typhimurium* and *E. coli*).
In vitro cell transformation assay in mammalian cells:
Aerosil OX50 (fumed silica) is neither cytotoxic nor morphological transforming with syrian hamster embryo (SHE) cells.
In vivo gene mutation test in mammalian cells:
Negative results with Aerosil 200 (fumed silica).

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumor	Oral chronic/carcinogenicity (Syloid 244, silica gel) - mice and rats treated 93 weeks and 103 weeks, respectively. / no carcinogenic effects
Lowest dose with tumors	Not applicable. See above.

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Developmental target/critical effect	Teratogenicity (Syloid – silica gel) - Mouse (albino CD-1); Rat, (albino Wistar); Hamster (Golden); Rabbit (Dutch-belted) No effects shown except for mice (ossification delay, not considered as adverse)
Lowest relevant maternal NOAEL/LOAEL	NOAEL: 1600 mg/kg bw/day (highest tested dose)
Lowest relevant developmental NOAEL/LOAEL	NOAEL: 1600 mg/kg bw/day (highest tested dose)
Species/ reproduction target/critical effect	No data However, the data gap is accepted given the absence of systemic effects observed, especially effects on the reproductive parameters and the absence of effects on reproductive parameter/organs in the different studies

Neurotoxicity/Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/target/critical effect	There is no data available which indicates that silicon dioxide may have neurotoxic properties.
Lowest relevant developmental NOAEL/LOAEL	Not determined. See above.

Other toxicological studies (Annex IIIA, point VI/X1)

No other toxicological studies carried out.

Medical data (Annex IIA, point 6.9)

Some authors studying amorphous silica-exposed workers (the kind of the silica is not mentioned) demonstrate no evidence of chronic effects or occurrence of tumors in this population. Nevertheless, a literature research was performed and a quite recent study demonstrates fibrosis in lung from workers. Deposits near these damages were identified as amorphous and rarely as crystalline silica (Philippou S. Pulmonary fibrosis after inhalation of amorphous silicic acid. Zentralbl. Pathol. 1992, *English abstract*). Another study shows that amorphous silica particles seem to be responsible for an accumulation of alveolar and interstitial macrophages and for the existence of fibrous interstitial micronodules, in 10 patients working in a silicon factory. The exposure time varied between 7 and 35 years (Brambilla C et al.; Rev Fr Mal Respir. 8 (5) 383-91, 1980, *English abstract*).

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	Not applicable, as not intended for use on food or feed.		
Acute, medium and long-term AEL	Not applicable, no systemic effects		
Acute AEC and medium-term AEC	0.2 mg/m^3		
Long-term AEC	0.1 mg/m^3		
Drinking water limit	Not applicable, as not intended to be applied in water.		

Acceptable exposure scenarios

Professional users	- Loading of application equipment - Application of RID Insect Powder - Removal (vacuuming) and disposal of spilt or old powder
Non-professional users	Not applicable. The formulated product, RID Insect Powder, is for professional use only.
Indirect exposure as a result of use	- Infant in contact with parent's contaminated clothes - Cleaning up old dust with vacuum cleaner (adults) - Child and infant in contact in inaccessible area.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Study of the hydrolysis as a function of pH is technically not feasible for silicon dioxide. Moreover, due to its limited water solubility in natural conditions the transformation in silicic acid from dissolution by water would be negligible.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites.	Amorphous silicon dioxide is not expected to degrade photolytically.
Readily biodegradable (yes/no)	No
Biodegradation in freshwater and seawater	Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. It is scientifically not necessary to determine the biodegradability of inorganic chemicals, because the process applies only to organic compounds.
Non-extractable residues	Not applicable, amorphous silicon dioxide is not intended to be either used or released into the aquatic environment. Silicon dioxide does not degrade in the normal conditions of the environment.
Distribution in water / sediment systems (active substance)	Not applicable, amorphous silicon dioxide is not intended to be either used or released into the aquatic environment.
Distribution in water/sediment systems (metabolites)	Not applicable, amorphous silicon dioxide is not intended to be either used or released into the aquatic environment.

Route and rate of degradation in soil

Mineralization (aerobic)	Data on fate and behaviour in soil are not required as amorphous silicon dioxide is not intended to be either used or released directly to the soil. Moreover Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. This compound is not expected to undergo any transformation in natural conditions.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Refer to "Mineralization (aerobic)" (above).
Field studies (state location, range or median with number of measurements)	Refer to "Mineralization (aerobic)" (above).
Anaerobic degradation	Refer to "Mineralization (aerobic)" (above).
Soil photolysis	Refer to "Mineralization (aerobic)" (above).
Non extractable residues	Refer to "Mineralization (aerobic)" (above).
Relevant metabolites – name and/or code, % of applied a.i. (range and maximum)	Refer to "Mineralization (aerobic)" (above).
Soil accumulation and plateau concentration	Refer to "Mineralization (aerobic)" (above).

Absorption/desorption

Ka, Kd Ka_{oc}, Kd_{oc}	Not determined. See below. Amorphous silicon dioxide is not expected to reach the soil compartment and there are no indications that it will bioaccumulate No Koc value could be derived because the log Kow is not reliable.
pH dependence (yes / no) (if yes type of dependence)	Not applicable. Calculated value.

Fate and behaviour in air

Direct photolysis in air	It is not considered to be scientifically necessary to determine the phototransformation of silicon dioxide in air because it is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant. Notwithstanding the above, the structure of silicon dioxide is O=Si=O. This structure means that •OH radicals are unlikely to be generated during degradation in air. Silicon dioxide will not have an impact on global warming because it does not exist in the gaseous state at ambient temperature and pressure. The presence of absorption bands in the IR spectrum region 800-1200nm is therefore not applicable. It is also highly unlikely that silicon dioxide will have any impact either on ozone depletion in the stratosphere or ozone formation in the troposphere because silicon dioxide does not contain chlorine substituents, and •OH radicals are unlikely to be generated during degradation of silicon dioxide in air. The final atmospheric risk indicator is acidification. During the oxidation of substances containing Cl, F, N or S substituents, acidifying components (e.g. HCl, HF, NO_2, SO_2 and H_2SO_4) may be formed. As silicon dioxide does not contain Cl, F, N or S substituents, acidification is not considered to be a risk to receiving soil or surface water.
Quantum yield of direct photolysis	Not applicable. See "Direct photolysis in air" (above).
Photo-oxidative degradation in air	Not applicable. See "Direct photolysis in air" (above).
Volatilization	Not applicable. See "Direct photolysis in air" (above).

Monitoring data, if available

Soil (indicate location and type of study)	Monitoring data not available as exposure to soil is not expected.
Surface water (indicate location and type of study)	Monitoring data not available as exposure to water is not expected.
Ground water (indicate location and type of study)	Monitoring data not available as exposure to water is not expected.
Air (indicate location and type of study)	Monitoring data not available as exposure to air is not expected.

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	
		$L(E)C_{50}$	NOEC

Fish			
Rainbow Trout, *Oncorhynchus mykiss*	96 hours	> 110 mg/L	> 110 mg/L
Invertebrates			
Daphnia magna	48 hours	> 86 mg/L	> 86 mg/L
Algae			
Selenastrum capricornutum	72 hours	n.a	n.a
Micro-organisms			
Heterogeneous sample of bacteria, found naturally in domestic sewage	3 hours	-	NOEC > 1000 mg/L

n.a = not available

Effects on earthworms or other soil non-target organisms

Acute toxicity	The information on the environmental exposure scenario for silicon dioxide (as given in Document IIIB, Section 7.1) does not indicate that it poses a risk to the terrestrial compartment. It is on this basis that it is not considered necessary to submit data on the acute toxicity of silicon dioxide to earthworms.
Reproductive toxicity	The environmental risk assessment for silicon dioxide (as given in Document IIIB, Section 7.1) does not indicate that it poses a risk to the terrestrial compartment. On this basis, it is not considered necessary to submit data to determine the effects of silicon dioxide on the reproduction of earthworms or other soil non-target macro-organism.

Effects on soil micro-organisms

Nitrogen mineralisation	The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial compartment. On this basis, it is not considered necessary to submit data on the effect of silicon dioxide on the inhibition of microbial activity in the terrestrial compartment.
Carbon mineralisation.	See above.

Effects on terrestrial vertebrates

Acute toxicity to mammals	The environmental risk assessment for silicon dioxide does not indicate that it poses a risk to the terrestrial environment. The toxicity profile of silicon dioxide as shown in Document IIIA, Section 6 Toxicological and Metabolic Studies does not indicate a concern regarding toxicity to mammals. For these reasons, it is not considered necessary to determine the effect of increased silicon dioxide exposure to mammals.
Acute toxicity to birds	It is not considered necessary to submit data to determine the acute oral toxicity of silicon dioxide to birds for the following reasons: silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only. Data submitted in Document IIIA, section 7.4.2 shows that silicon dioxide is not expected to have an intrinsic potential for bioaccumulation. The environmental risk assessment for silicon dioxide shows there is no risk of secondary poisoning under normal conditions of use in Rentokil Initial's insecticide (PT 18) products. There is no data available to suggest that silicon dioxide is hazardous to birds.
Dietary toxicity to birds	Refer to "Acute toxicity to birds" (above).
Reproductive toxicity to birds	Refer to "Acute toxicity to birds" (above).

Effects on honeybees

Acute oral toxicity	As silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only, it is not considered necessary to conduct this test.
Acute contact toxicity.	Refer to "Acute oral toxicity" (above).

Effects on other beneficial arthropods

Acute oral toxicity	As silicon dioxide, under normal conditions of use in Rentokil Initial's insecticide (PT 18) products will be applied indoors only, it is not considered necessary to conduct this test.
Acute contact toxicity.	Refer to "Acute oral toxicity" (above).
Acute toxicity to ……..	Refer to "Acute oral toxicity" (above).

Bioconcentration

Bioconcentration factor (BCF)	As shown in Document IIIA, section 7.4.2, silicon dioxide is not expected to have an intrinsic potential for bioconcentration in aquatic organisms. For the

	same reasons, silicon dioxide is not expected to have an intrinsic potential for bioconcentration in the terrestrial compartment. It is for these reasons that it is not considered necessary to submit additional data about bioaccumulation in soil.
Depuration time (DT_{50}) (DT_{90})	Refer to "Bioconcentration factor (BCF)" (above).
Level of metabolites (%) in organisms accounting for >10% of residues	Refer to "Bioconcentration factor (BCF)" (above).

Chapter 6: Other End Points

There is no other relevant data available on amorphous silicon dioxide that has not been summarised elsewhere in this document.

Appendix II: List of abbreviations

Stand. term / Abbreviation	**Explanation**
ACGIH	American conference of governmental industrial hygienists
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
AF	assessment factor
AEC	acceptable exposure concentration
AEL	acceptable exposure level
ANOVA	analysis of variance
AP	alkaline phosphatase
ARfD	acute reference dose
BAF	bioaccumulation factor
BALf	bronchoalveolar lavage fluid
BCF	bioconcentration factor
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
bw	body weight
CI	confidence interval
COD	chemical oxygen demand
CPK	creatinine phosphatase
d	day(s)
DOC	dissolved organic carbon
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight

Stand. term / Abbreviation	**Explanation**
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
EUSES	European Union system for the evaluation of substances
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GLP	good laboratory practice
GPC	gel-permeation chromatography
GSH	glutathione
H	Henry's Law constant (calculated as a unitless value)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HDPE	High density polyethylene
HPLC	high pressure liquid

Stand. term / Abbreviation	**Explanation**
	chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPRT	Hypoxanthin-guanin phosphoribosyl transferase
ICP-AES	Inductively coupled plasma - atomic emission spectroscopy
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
Ka	acid dissociation constant
K_{oc}	organic carbon adsorption coefficient
K_{ow}	octanol-water partition coefficient
kPa	kilopascal(s)
IARC	International Agency for Research on Cancer
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level

Stand. term / Abbreviation	**Explanation**
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
MG	Main Group
MMAD	mass median aerodynamic diameter
MOE	margin of exposure
MOS	margin of safety
mp	melting point
MRL	maximum residue level or limit
MS	Member State
MS	mass spectrometry
MSDS	material safety data sheet
MW	molecular weight
n.a.	not applicable
NAG	N-acetyl-glucosaminidase
NMR	Nuclear Magnetic Resonance
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
Pa	pascal
PEC	predicted environmental concentration
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant

Stand. term / Abbreviation	**Explanation**
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RMS	Rapporteur Member State
RPE	Respiratory protective equipment
SAS	Synthetic amorphous silica
SDS	Safety Data Sheet
SHE	Syrian Hamster Embryo
SIDS	Screening Information Data Set
TGD	Technical guidance document
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TWA	time weighted average
UDS	unscheduled DNA synthesis
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight

Appendix III: List of amorphous silica met in the dossier

Name	Type	Related study
Aerosil 200	Amorphous fumed silica	Inhalation subchronic toxicity study Genotoxicity study (HPRT *in vivo*)
Aerosil OX50	Amorphous fumed silica	Genotoxicity study (*in vitro* cell transformation assay in SHE cells)
Aerosil R974	Amorphous surface-treated silica	Inhalation subchronic toxicity study
Cab-O-Sil M5	Amorphous fumed silica	Inhalation subacute toxicity study
FDA 71-48 (Syloid)	Amorphous silica gel	Developmental toxicity study
Gasil 23D (notified active substance)	Amorphous silica gel	Efficacy studies Phototransformation in water Acute toxicity studies in fish, daphnids, algae and micro-organisms
Hi-Sil	Hydrated silica pigments	Epidemiological study
Silcron G910	Amorphous silica gel	Acute toxicity studies Genotoxicity study (Ames)
Silene	Calcium silicate	Epidemiological study
Sipernat 22S	Amorphous precipitated silica	Inhalation subchronic toxicity study
Syloid 244	Amorphous silica gel	Acute toxicity studies Combined chronic / cancerogenicity toxicity study
Syloid 74	Amorphous silica gel	Inhalation subacute toxicity study
Zeolithe A	Microcrystalline silica	Sensitisation study
Zeosil 45	Amorphous precipitated silica	Inhalation subacute toxicity study

REFERENCES LIST

REFERENCES FOR THE ACTIVE SUBSTANCE DOSSIER SUBMITTED IN SUPPORT OF ANNEX I LISTING OF SILICON DIOXIDE UNDER THE BIOCIDAL PRODUCTS DIRECTIVE ON WHICH THE ASSESSMENT OF THE ACTIVE SUBSTANCE RELIES ON

REFERENCE LIST FOR DOCUMENT IIIA, NUMERICAL LIST (BY SECTION NUMBER)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A2.4.1/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.1/02	Rentokil Initial plc	2005	Silicon Dioxide: Characteristics of Different Forms / Unpublished. Applicant's reference number SILICA 86	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A2.4.1/03	Berend K Kirby D	2005	Correspondence about CAS number of Silicon Dioxide Notified under the Biocidal Products Directive / Unpublished.	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A2.4.1/04	International Agency for Research on Cancer (IARC)	1997	Summaries and Evaluations Silica Crystalline Silica – Inhaled in the Form of Quartz or Cristobalite From Occupational Sources (Group I) Amorphous Silica (Group 3) www.inchem.org/documents/iarc/vol68/silica.html / Published. Applicant's Ref. SILICA 74	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.1/05	WHO/International Agency for Research on Cancer	1987	IARC Monographs on the Evaluation of the carcinogenic risk of chemicals to humans. Silica and some silicates. / Published. Applicant's Ref. SILICA 36	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A2.4.1/06	World Health Organisation (WHO)	2000	Silicosis: Fact Sheet 238 dated May 2000. www.who.int/mediacentre/factsheets/fs238/en/print.html / Published. Applicant's Ref. SILICA 75	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.1/07	Environmental Protection Agency (EPA)	1991	Reregistration Eligibility Document Silicon Dioxide and Silica Gel / Published. Applicant's Ref. SILICA 63	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.1/08	Food and Drug Administration (FASEB)	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. (Federation of American Societies of Experimental Biology; Bethesda MD) Ref No. PB - 301 402. / Published. Applicant's Ref. SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.1/09	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant's Ref. SILICA 17	No	PUB	Not applicable	Not applicable	Not applicable
A2.4.2/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A2.5.1/01	Budavari S, O'Neil MJ, Smith A, Heckelman PE Kinneary JF	1996	Entry for Silicon Dioxide, The Merck Index An Encyclopedia of Chemicals, Drugs and Biologicals. Twelfth Edition Page 1460 Merck Research Laboratories, ISBN 0911910-12-3 / Published	No	PUB	Not applicable	Not applicable	Not applicable
A2.5.2/01	Anon	2005	On-line calculation of Partition Coefficient for Silica www.syrres.com/esc/est_kowdemo.htm / Published. Applicant's reference number SILICA 79	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A2.5.3/01	Budavari S, O'Neil MJ, Smith A, Heckelman PE Kinneary JF	1996	Entry for Silicon Dioxide, The Merck Index An Encyclopedia of Chemicals, Drugs and Biologicals. Twelfth Edition Page 1460 Merck Research Laboratories, ISBN 0911910-12-3 / Published	No	PUB	Not applicable	Not applicable	Not applicable
A2.7/01	Harwell Scientifics	2006	Method Investigation and Validation for the Determination of Silicon in Amorphous Silicon Dioxide, Soil, Water and Air / Unpublished. Applicant's reference number SILICA 211	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A2.7/02	Intertek ASG	2011	Analysis of silicon Dioxide (BEL 1008) via SEM, TEM, , Malvern Mastersizer and X-Ray diffraction/ unpublished/ applicant's reference: Silica dioxide - BEL	Yes	ORG	France	Oct-11	Submission for Annex I listing under the BPD
2.7/03	ESG	2011	Characterisation of a Product on Behalf of Rentokil initial / ESG/ non GLP/ Unpublished. Applicant's reference number Silica dioxide – ESG-2011	Yes	ORG	France	Oct-11	Submission for Annex I listing under the BPD
A2.10/01	Anon	2005	Solid Waste Environmental Fact Sheet WMD-SW-15 Recycling Glass: Glass in Solid Waste. From: http://www.des.state.nh.us/factsheets/sw/sw-15.htm / Published. Applicant's reference number SILICA 95	No	PUB	Not applicable	Not applicable	Not applicable
A2.10/02	Anon	2005	Glass (From Wikipedia, the free encyclopedia) From: http://en.wikipedia.org/wiki/Glass / Published. Applicant's reference number SILICA 96	No	PUB	Not applicable	Not applicable	Not applicable
A2.10/03	Rentokil Initial plc	2006	R&D Review Report – Operator Exposure to RID Insect Powder. Project Number 299/5 299/6 Report Number SS06/01 / GLP / Unpublished. Applicant's reference number SILICA 216	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A3.1.1/01	National Institute for Occupational Safety and Health (NIOSH)	1997	Silica, Amorphous NIOSH Pocket Guide to Chemical Hazards (NPG) NIOSH Publication No. 97-140 From: www.cdc.gov/niosh/npg/pgintrod.html / Published. Applicant's reference number SILICA 80	No	PUB	Not applicable	Not applicable	Not applicable
A3.1.1/02	Anon	2005	Ceramics: Scientific Principles. From: http://matse1.mse.uiuc.edu/~tw/ceramics/prin.html / Published. Applicant's reference number SILICA 81	No	PUB	Not applicable	Not applicable	Not applicable
A3.1.2/01	National Institute for Occupational Safety and Health (NIOSH)	1997	Silica, Amorphous NIOSH Pocket Guide to Chemical Hazards (NPG) NIOSH Publication No. 97-140 From: www.cdc.gov/niosh/npg/pgintrod.html / Published. Applicant's reference number SILICA 80	No	PUB	Not applicable	Not applicable	Not applicable
A3.1.2/02	Anon	2005	Ceramics: Scientific Principles. From: http://matse1.mse.uiuc.edu/~tw/ceramics/prin.html / Published. Applicant's reference number SILICA 81	No	PUB	Not applicable	Not applicable	Not applicable
A3.1.3/01	Rentokil Initial plc	2005	GLP Technical Request Report - Determination of Tap Density of Gasil 23D and RID Insect Powder according to CIPAC Method MT33 / Unpublished. Applicant's reference number SILICA 184	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.3/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A3.4/01	Brixham Environmental Laboratory	2006	Report No BL8294/B GASIL 23D: Phototransformation of chemicals in water – Direct photolysis, theoretical screen / Unpublished. Applicant's reference number SILICA 210	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A3.4/02	Intertek Caleb Brett	2005	IR analysis report for Gasil 23D Applicant's refernce number SILICA 172	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.4/03	Intertek Caleb Brett	1999	Preparation methods for infrared spectroscopy SOP No: 151 Revision No: 05 Applicant's reference number SILICA 188	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.4/04	Intertek Caleb Brett	2004	Data acquisition for BioRad FTS-60A spectrometer ICB-SOP-412 04 / Unpublished. Applicant's reference number SILICA 189	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A3.4/05		2000	"Structure and Imperfections in Amorphous and Crystalline Silicon Dioxide" ISBN 0-471-97536-2 / Published. Applicant's refernce number SILICA 150	NO	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A3.10/01	Rentokil Initial plc	2006	Rentokil Pest Control Technical Committee Report 06/02 Accelerated Shelf Life: 10 kg Gasil 23D in a Paper Sack II / Unpublished. Applicant's reference number SILICA 205	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.11/01	Rentokil Initial plc	2006	GLP Technical Request Report No. PC284 Flammability of Silicon dioxide (Gasil 23D) according to EC Method A10 / Unpublished / GLP / Applicant's reference number SILICA 203	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.11/02	Chilworth Technology	2006	EC Test A16 on Amorphous Silicon Dioxide / Unpublished / GLP / Applicant's reference number SILICA 212	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.13/01	Rentokil Initial plc	2006	GLP Technical Request PC285 Surface Tension of a Saturated Solution of Gasil 23D / GLP / Unpublished. Applicant's reference number SILICA 217	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A3.17/01	Rentokil Initial plc	2006	Rentokil Pest Control Technical Committee Report 06/02 Accelerated Shelf Life: 10 kg Gasil 23D in a Paper Sack II / Unpublished. Applicant's reference number SILICA 205	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A4.1/01	Harwell Scientifics	2006	Method Investigation and Validation for the Determination of Silicon in Amorphous Silicon Dioxide, Soil, Water and Air / Unpublished. Applicant's reference number SILICA 211	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A4.1/01	Harwell Scientifics	2007	Report on the measurement of an Elemental Sample Scan on Sample of Gasil 23D / Unpublished. Applicant’s reference number SILICA 232	Yes	ORG	France	Sep-07	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A4.2/03	NIOSH	1994	NIOSH Manual of Analytical Methods (NMAM), Fourth Edition SILICA, AMORPHOUS Method 7501, Issue 2 / Published. Applicant's reference number SILICA 199	No	PUB	Not applicable	Not applicable	Not applicable
A5.3.1/01	Rentokil Ltd	1990	The Effect of Silica Dusts on the Hatching of *B orientalis* Oothecae and the Survival of Newly Hatched Nymphs Technical Committee Report No PCS 90/19 Project No. 217/4 / GLP / Unpublished. Applicant's reference number SILICA 2	No	ORG	United Kingdom	1991	Submission for commodity approval
A5.3.1/03	Rentokil Ltd	1994	Evaluation of the Efficacy of Rentokil Insect Powder (Silica Dust) on Emerging *B orientalis* in Simulated Wall Voids Technical Committee Report No PCS 94/21 Project No 214/15 / Not GLP / Unpublished. Applicant's reference number SILICA 31	Yes	ORG	United Kingdom	1997	Submission for national approval
A5.4.1/01	Tarshis B	1959	Sorptive Dusts on Cockroaches easily applied compounds harmless to animals and humans effectively control cockroaches and other household pests. California Agriculture 13 (2): 3, 4, 5 / Not GLP / Published. Applicant's reference number SILICA 12	No	PUB	Not applicable	Not applicable	Not applicable
A5.4.1/02	European Commission	2003	Question 2.1.7.3 Silica Gel The Manual of Decisions For Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products. Last Modified 30.4.2003 CA-Jun03-Doc 5.1 page 16-17 / Published.	No	PUB	Not applicable	Not applicable	Not applicable
A5.4.1/03	Rentokil Initial plc	1995	RID Insect Powder Rentokil Pest Control Technical Release Number 125 / Published	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A5.4.1/04	Ebeling W, Wagner R E	1959	Rapid Desiccation of Drywood Termites with Inert Sorptive Dusts and Other Substances. Journal of Economic Entomology. Vol 52, No 2 pages 190-207 / Published. Applicant's reference number SILICA 15	No	PUB	Not applicable	Not applicable	Not applicable
A5.7.1/01	Ebeling W, Wagner R E	1959	Rapid Desiccation of Drywood Termites with Inert Sorptive Dusts and Other Substances. Journal of Economic Entomology. Vol 52, No 2 pages 190-207 / Published. Applicant's reference number SILICA 15	No	PUB	Not applicable	Not applicable	Not applicable
A5.7.1/02	Tarshis B	1967	Silica aerogel insecticides for the prevention and control of arthropods of medical and veterinary importance Angew Parasitol 4: pages 210-237 / Published. Applicant's reference number SILICA 9	No	PUB	Not applicable	Not applicable	Not applicable
A5.8/01	Rentokil Initial Supplies	2005	Sales Figures for RID Insect Powder for years 1999 - 2005 / Unpublished. Applicant's reference number SILICA 85	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A6	Health and Safety Executive	2005	Entry for Silica, amorphous and dust. EH40/2005 Workplace Exposure Limits pages 22 and 31. HSE Books ISBN 0717629775 / Published.	No	PUB	Not applicable	Not applicable	Not applicable
A6.1	OECD	2006	Synthetic amorphous silica and silicates / Published / Applicant's reference number SILICA 226	No	PUB	Not applicable	Not applicable	Not applicable
A6.1	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A6.1	Millennium Chemicals	2004	Material Safety Data Sheet: Silcron G-910 / Published. Applicant's reference number SILICA 171	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.1	Environmental Protection Agency (EPA)	1991	Reregistration Eligibility Document Silicon Dioxide and Silica Gel. Applicant's reference number SILICA 63	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.1/01	Anon	2002	Food Additives in the European Union. www.food.gov.uk/foodlabelling/additives / Published. Applicant's reference number SILICA 65	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.1/02	Federation of American Societies of Experimental Biology	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. Ref. No. PB - 301 402. Applicant's reference number SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.1/04	FAO / WHO	1974	Joint FAO/WHO Expert Committee on Food Additives Toxicological Evaluation of Some Food Additives Including Anti Caking Agents. Pt 5 Pages 21-30 Applicant's reference number SILICA 93	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.1	Food and Drug Research Labs	1973	Teratologic Evaluation of FDA 71-48 (Syloid; Silica aerogel) / Published / Applicant's reference number SILICA 234	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.5/03	Gloxhuber C, Potokar M, Pittermann W, Wallat S, Bartnik F, Reuter H and Braig S	1983	Zeolithe A - A phosphate substitute for detergents: toxicological investigation. Food and Chemical Toxicology, 21, 209-220 / Published / Applicant's reference number SIILICA 230	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/01	Bailey CB	1981	Silica metabolism and silica urolithiasis in ruminants: A review, Canadian Journal of Animal Science, 61: 219-235 / Published. Applicant's reference number SILICA 177	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.2/02		1959	Silica Metabolism in Guinea Pigs, Can J Biochem Physiol 37: 183-191 / Published. Applicant's reference number SILICA 102	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.2/03	Reffitt DM, Jugdaohsingh R, Thompson RPH, Powell JJ	1999	Silicic acid: its gastrointestinal uptake and urinary excretion in man and effects on aluminium excretion, Journal of Inorganic Biochemistry, 76: 141-147 / Published. Applicant's reference number SILICA 178	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/04	Popplewell JF, King SJ, Day JP, Ackrill P, Fifield LK, Cresswell RG, di Tada ML, Liu K	1998	Kinetics and elimination of silicic acid by a human subject: A novel application of 32Si and accelerator mass spectrometry, Journal of Inorganic Biohemistry, 69: 177-180 / Published. Applicant's reference number SILICA 176	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/05	Bellia JP, Birchall JD, Roberts NB	1994	Beer: A dietary source of silicon, The Lancet, 343: p235 / Published. Applicant's reference number SILICA 175	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/10	King EJ, McGeorge M	1938	The Biochemistry of Silicic Acid VI: The Solution and Excretion of Silica, Biochem J, 32, 426-432 / Published. Applicant's reference number SILICA 104	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/11	Adler AJ and Berlyne GM	1986	Silicon Metabolism: II. Renal handling in chronic renal failure patients, Nephron 44: 36-39 / Published. Applicant's reference number SILICA 180	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/12	Reuzel PGJ, Bruijntjes JP, Feron VJ and Woutersen RA	1991	Subchronic Inhalation Toxicity of Amorphous Silicas and Quartz Dust in Rats Fd Chem Toxic Vol 29, No. 5 pp 341-354 / Published. Applicant's reference number SILICA 87	No	PUB	Not applicable	Not applicable	Not applicable
A6.2/13	Johnston CJ, Driscoll KE, Finkelstein JN, Baggs R, O'Reilly MA, Carter J, Gelein R and Oberdörster G	2000	Pulmonary Chemokine and Mutagenic Responses in Rats after Subchronic Inhalation of Amorphous and Crystalline Silica, Toxicological Sciences 56, 405-413 / Published. Applicant's reference number SILICA 90	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.3.1	Food and Drug Research Labs	1973	Teratologic Evaluation of FDA 71-48 (Syloid; Silica aerogel) / Published / Applicant's reference number SILICA 234	No	PUB	Not applicable	Not applicable	Not applicable
A6.4.1/01	FAO / WHO	1974	Joint FAO/WHO Expert Committee on Food Additives Toxicological Evaluation of Some Food Additives Including Anti Caking Agents. Pt 5 Pages 21-30 / Published. Applicant's reference number SILICA 93	No	PUB	Not applicable	Not applicable	Not applicable
A6.4.1/02	Federation of American Societies of Experimental Biology	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. Ref. No. PB - 301 402 / Published. Applicant's reference number SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable
A6.4.3/16	Reuzel PGJ, Bruijntjes JP, Feron VJ and Woutersen RA	1991	Subchronic Inhalation Toxicity of Amorphous Silicas and Quartz Dust in Rats Fd Chem Toxic Vol 29, No. 5 pp 341-354 / Published. Applicant's reference number SILICA 87	No	PUB	Not applicable	Not applicable	Not applicable
A6.4.3/17	Johnston CJ, Driscoll KE, Finklestein JN, Baggs R, O'Reilly MA, Carter J, Gelein R, Oberdorster G	2000	Pulmonary Chemokine and Mutagenic Responses in Rats after Subchronic Inhalation of Amorphous and Crystalline Silica Toxicological Sciences 56, 405-413 (2000) / Published. Applicant's reference number SILICA 90	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/01	Federation of American Societies of Experimental Biology	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. Ref. No. PB - 301 402 / Published Applicant's reference number SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.5/04	Anon	2002	Food Additives in the European Union From: www.fst.rdg.ac.uk/foodlaw/additive.htm / Published. Applicant's reference number SILICA 65	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/05	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant's reference number SILICA 17	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/07	Groth DH, Moorman WJ, Lynch DW, Stettler LE, Wagner WD and Hornung RW	1981	Chronic Effects of Inhaled Amorphous Silicas in Animals **In** D D Dunnom Ed. Health Effects of Synthetic Silica Particulates. Astm Special Technical Publication 732. American Society for Testing and Materials pages 118-143 / Published. Applicant's reference number SILICA 89	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/14	Environmental Protection Agency (EPA)	1991	Reregistration Eligibility Document Silicon Dioxide and Silica Gel List D Case 4081 Environmental Protection Agency, Office of Pesticide Programs Special Review and Re-Registration Division Washington D.C. / Published. Applicant's reference number SILICA 63	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/17	Choudat D, Frisch C, Barrat G, El Kholti A, Conso F	1990	Occupational Exposure to Amorphous Silica Dust and Pulmonary Function British Journal of Industrial Medicine 47, 763-766. / Published. Applicant's reference number SILICA 126	No	PUB	Not applicable	Not applicable	Not applicable
A6.5/18	Takizawa, Y; Hirasawa, F.; Noritomi, E.; Aida, M; Tsunoda, H.; Uesugi, S.	1998	Oral ingestion of syloid to mice and rats and its chronic toxicity and carcinogenicity. Acta Medica et Biologica, 36, 27-56 / Published / Applicant's reference number SILICA 229	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.6.1/16	Prival Michael J. Vincent F. Simmon and Kristien E. Mortelmans	1991	Bacterial mutagenicity testing of 49 food ingredients gives very few positive results, Mutation Research, 260: 321-329 / Published. Applicant's reference number SILICA 113	No	PUB	Not applicable	Not applicable	Not applicable
A6.6.1/17	Millennium Chemicals	2004	Material Safety Data Sheet: Silcron G-910 / Published. Applicant's reference number SILICA 171	No	PUB	Not applicable	Not applicable	Not applicable
A6.6.2/18	Degussa	2005	Specification of Aerosil OX 50 from www.aerosil.com / Published. Applicant's reference number SILICA 170	No	PUB	Not applicable	Not applicable	Not applicable
A6.6.2/19	Elias Z, Poirot O, Danière MC, Terzeti F, Marande AM, Dzwigaj S, Pezerat H, Fenoglio I and Fubini B	2000	Cytotoxic and transforming effects of silica particles with different surface properties in Syrian hamster embryo (SHE) cells, Toxicology in vitro 14; 409-422 / Published. Applicant's reference number SILICA 121	No	PUB	Not applicable	Not applicable	Not applicable
A6.6.4/18	Morita T, Asano N, Awogi T, Sasaki YF, Sato S, Shimada H, Sutou S, Suzuki T, Wakata A, Sofuni T, Hayashi M	1997	Evaluation of the rodent micronucleus assay in the screening of IARC carcinogens (Groups 1, 2A and 2B). The summary report of the 6th collaborative study by CSGMT/JEMS.MMS Mutation Research 389; 3-122 / Published. Applicant’s reference number SILICA 227	No	PUB	Not applicable	Not applicable	Not applicable
A6.6.5/01	Johnston CJ, Driscoll KE, Finklestein JN, Baggs R, O'Reilly MA, Carter J, Gelein R, Oberdorster G	2000	Pulmonary Chemokine and Mutagenic Responses in Rats after Subchronic Inhalation of Amorphous and Crystalline Silica Toxicological Sciences 56, 405-413 (2000) / Published. Applicant's reference number SILICA 90	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.7/02	Federation of American Societies of Experimental Biology	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. Ref. No. PB - 301 402 / Published Applicant's reference number SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable
A6.7/06	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant's reference number SILICA 17	NO	PUB	Not applicable	Not applicable	Not applicable
A6.7/15	Environmental Protection Agency (EPA)	1991	Reregistration Eligibility Document Silicon Dioxide and Silica Gel List D Case 4081 Environmental Protection Agency, Office of Pesticide Programs Special Review and Re-Registration Division Washington D.C. / Published. Applicant's reference number SILICA 63	No	PUB	Not applicable	Not applicable	Not applicable
A6.7/17	Choudat D, Frisch C, Barrat G, El Kholti A, Conso F	1990	Occupational Exposure to Amorphous Silica Dust and Pulmonary Function British Journal of Industrial Medicine 47, 763-766. / Published. Applicant's reference number SILICA 126	No	PUB	Not applicable	Not applicable	Not applicable
A6.7/18	Wilson M.D., Keith R.; Stevens M.D., P.M.; Lovejoy M.D, H.B.; Bell D.Sc, Z.G.; Richie M.D., R.C.	1979	"Effects of Chronic Amorphous Silica Exposure on Sequential Pulmonary Function", Journal of Occupational Medicine, Volume 21, No. 6 (June 1979). /Published. Applicant's reference number SILICA 108.	No	PUB	Not applicable	Not applicable	Not applicable
A6.7/19	Plunkett M.D., E.R.; DeWitt, B.J.	1962	Exposure to Hi-Sil and Silene: Report of an 18 year study", Arch Environ Health 5: 75-78, 1962 / Published. Applicant's reference number SILICA 145	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.7/21	Takizawa, Y; Hirasawa, F.; Noritomi, E.; Aida, M; Tsunoda, H.; Uesugi, S.	1998	Oral ingestion of syloid to mice and rats and its chronic toxicity and carcinogenicity. Acta Medica et Biologica, 36, 27-56 / Published / Applicant's reference number SILICA 229	No	PUB	Not applicable	Not applicable	Not applicable
A6.8.1/16	Food and Drug Research Labs	1973	Teratologic Evaluation of FDA 71-48 (Syloid; Silica aerogel) / Published / Applicant's reference number SILICA 234	No	PUB	Not applicable	Not applicable	Not applicable
A6.12.5/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A6.12.7/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A6.12.8/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A6.13/01	Newberne, P.M., Wilson, Robert B.	1970	Renal Damage Associated with Silicon Compounds in Dogs. Proceedings of the National Academy of Sciences Vol. 65 No. 4 pages 872-875, April 1970 / Published. Applicant's reference number SILICA 72	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.13/02	FAO / WHO	1974	Joint FAO/WHO Expert Committee on Food Additives Toxicological Evaluation of Some Food Additives Including Anti Caking Agents. Pt 5 Pages 21-30 / Published. Applicant's reference number SILICA 93	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/01	Environmental Protection Agency (EPA)	1991	Reregistration Eligibility Document Silicon Dioxide and Silica Gel / Published. Applicant's reference number SILICA 63	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/02	Federation of American Societies of Experimental Biology	1979	Evaluation of the Health Aspects of Certain Silicates as Food Ingredients. Ref. No. PB - 301 402 / Published. Applicant's reference number SILICA 19	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/03	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant's reference number SILICA 17	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/04	Lewinson, J., Mayr, W., Wagner, H.	1994	Characterisation and toxicological Behaviour of Synthetic Amorphous Hydrophobic Silica. Regulatory Toxicology and Pharmacology 20, 37-57 / Published. Applicant's reference number SILICA 61	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/05	King and Belt	1938	"The physiological and pathological aspects of silica." Physiol Rev 18: 329-365 / Published. Applicant's reference number SILICA 139	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/06	Akiya, S., Misawa, T., Motohashi, N.	1959	"Studies on the silica in drinks and foods and in human blood vessels" Bull Tokyo Med Den Univ 6: 383-411 / Published. Applicant's reference number SILICA 138	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6.15/07	Anon	2002	Food Additives in the European Union From: www.fst.rdg.ac.uk/foodlaw/additive.htm / Published. Applicant's reference number SILICA 65	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/08	Council of Europe	1982	Substances used in plastic materials coming into contact with food 2nd Edition / Published. Applicant's reference number SILICA 24	No	PUB	Not applicable	Not applicable	Not applicable
A6.15/09	Groth DH, Moorman WJ, Lynch DW, Stettler LE, Wagner WD and Hornung RW	1981	Chronic Effects of Inhaled Amorphous Silicas in Animals **In** D D Dunnom Ed. Health Effects of Synthetic Silica Particulates. Astm Special Technical Publication 732. American Society for Testing and Materials pages 118-143 / Published. Applicant's reference number SILICA 89	No	PUB	Not applicable	Not applicable	Not applicable
A7.1.1.1.2/01	Brixham Environmental Laboratory	2006	Report No BL8294/B GASIL 23D: Phototransformation of chemicals in water – Direct photolysis, theoretical screen / Unpublished. Applicant's reference number SILICA 210	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A7.4.1.1/01	Brixham Environmental Laboratory	2006	Report No BL8290/B GASIL 23D: Acute toxicity to rainbow trout (*oncorhynchus mykiss*) / Unpublished. Applicant's reference number SILICA 206	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A7.4.1.2/01	Brixham Environmental Laboratory	2006	Report No BL8291/B GASIL 23D: Acute toxicity to *Daphnia magna/* Unpublished. Applicant's reference number SILICA 207	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A7.4.1.3/01	Brixham Environmental Laboratory	2006	Report No BL8292/B GASIL 23D: Toxicity to the green alga *Selenastrum capricornutum* / Unpublished. Applicant's reference number SILICA 208	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
A7.4.1.4/01	Brixham Environmental Laboratory	2006	Report No BL8293/B GASIL 23D: Effect on the respiration rate of activated sludge / Unpublished. Applicant's reference number SILICA 209	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A8.1/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A8.2/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A8.3/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A8.4/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published. Applicant's reference number SILICA 174	No	PUB	Not applicable	Not applicable	Not applicable
A8.6/01	Tarshis B	1959	Sorptive Dusts on Cockroaches easily applied compounds harmless to animals and humans effectively control cockroaches and other household pests. California Agriculture 13 (2): 3, 4, 5 / Not GLP / Published. Applicant's reference number SILICA 12	No	PUB	Not applicable	Not applicable	Not applicable
A8.6/02	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant’s reference number SILICA 17	No	PUB	Not applicable	Not applicable	Not applicable
A8.6/03	Anon	2002	Food Additives in the European Union From: www.fst.rdg.ac.uk/foodlaw/additive.htm / Published. Applicant’s reference number SILICA 65	No	PUB	Not applicable	Not applicable	Not applicable

REFERENCES FOR THE ACTIVE SUBSTANCE DOSSIER NOT SUBMITTED BY THE APPLICANT BUT USED IN SUPPORT OF ANNEX I LISTING OF SILICON DIOXIDE UNDER THE BIOCIDAL PRODUCTS DIRECTIVE

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
A6	Pennington, J.A.T	1991	Silicon in foods and diets Food Additives and Contaminants, 1991;8, 97-118	No	PUB	Not applicable	Not applicable	Not applicable
A6	Sripanyakorn S. et al	2005	Dietary silicon and bone health. British Nutrition Foundation, Nutrition Bulletin, 2005; 30, 222-230	No	PUB	Not applicable	Not applicable	Not applicable
A6	Bowen, H.J.M. and Peggs, A	1990	Determination of the silicon content of food. Journal of Science Food and Agriculture, 1984; 35, 1225-1229 + Pennington, J.A.T. "Silicon in foods and diets", Food Additives and Contaminants, 1990;8, 97-118	No	PUB	Not applicable	Not applicable	Not applicable
A6	HERA	2005	Human Environmental Risk Assessment (HERA) on Ingredient of European Household Cleaning Products Soluble silicates (Draft), February 2005; 17-28	No	PUB	Not applicable	Not applicable	Not applicable
A6	European Commission	2008	Additive authorised in feed (Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003, Appendixes 3&4, Annex: List of additives, Released 21 October 2008 [Rev. 35]).	No	PUB	Not applicable	Not applicable	Not applicable
A6	European parliament and council of the European Union	1995	European parliament and council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ No L 61, 18.3.1995, p.1)	No	PUB	Not applicable	Not applicable	Not applicable

A6	UK government	2003	Expert Group on Vitamins and Minerals of the UK Food Standards Agency: Safe Upper Levels for Vitamins and Minerals: www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf. p.306- 312	No	PUB	Not applicable	Not applicable	Not applicable
A6.1	ECETOC	2006	ECETOC JACC report No.51 (September 2006) on synthetic amorphous silica	No	PUB	Not applicable	Not applicable	Not applicable
A6.1.3	Arts JHE, Muijser H, Duistermaat E, Junker K, Kuper CF	2007	Five-day inhalation toxicity study of three types of synthetic amorphous silicas in Wistar rats and post-exposure evaluations for up to 3 months Food and Chemical Toxicology 45 (2007) 1856–1867	No	PUB	Not applicable	Not applicable	Not applicable
A6.2	Arts JHE, Muijser H, Duistermaat E, Junker K, Kuper CF	2007	Five-day inhalation toxicity study of three types of synthetic amorphous silicas in Wistar rats and post-exposure evaluations for up to 3 months Food and Chemical Toxicology 45 (2007) 1856–1867	No	PUB	Not applicable	Not applicable	Not applicable
A6.3.3	Arts JHE, Muijser H, Duistermaat E, Junker K, Kuper CF	2007	Five-day inhalation toxicity study of three types of synthetic amorphous silicas in Wistar rats and post-exposure evaluations for up to 3 months Food and Chemical Toxicology 45 (2007) 1856–1867	No	PUB	Not applicable	Not applicable	Not applicable
A6.6	World Health Organisation (WHO), International Agency for Research on Cancer (IARC)	1997	IARC Monographs on the evaluation of carcinogenic risks to humans. Silica. IARC Monographs Volume 68 / Published.	No	PUB	Not applicable	Not applicable	Not applicable

A6.7	World Health Organisation (WHO), International Agency for Research on Cancer (IARC)	1997	IARC Monographs on the evaluation of carcinogenic risks to humans. Silica. IARC Monographs Volume 68 / Published.	No	PUB	Not applicable	Not applicable	Not applicable

REFERENCES FOR THE REPRESENTATIVE PRODUCT DOSSIER SUBMITTED IN SUPPORT OF ANNEX I LISTING OF SILICON DIOXIDE UNDER THE BIOCIDAL PRODUCTS DIRECTIVE ON WHICH THE ASSESSMENT OF THE ACTIVE SUBSTANCE RELIES ON

REFERENCE LIST FOR DOCUMENT IIIB, NUMERICAL LIST (BY SECTION NUMBER)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
B2.2/01	INEOS Silicas	2003	Safety Data Sheet for Gasil 23D (synthetic amorphous silica) MSDS 0051100 Ref 1005 Revision v3 dated 13/02/2003 / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B2.2/02	Budavari S, O'Neil MJ, Smith A, Heckelman PE Kinneary JF	1996	Entry for Silicon Dioxide, The Merck Index An Encyclopedia of Chemicals, Drugs and Biologicals. Twelfth Edition Page 1460 Merck Research Laboratories, ISBN 0911910-12-3 / Published	No	PUB	Not applicable	Not applicable	Not applicable
B2.2/03	European Chemicals Bureau	2005	Details for Water ECB-EINECS Information System. From: http://ecb.jrc.it/esis-pgm/einecs_IS_response.php / Published. Applicant's reference number SILICA 83	No	PUB	Not applicable	Not applicable	Not applicable
B2.2/04	Anon	2005	Structural Formulas From: http://ed.augie.edu/~jmthrust/structural.htm / Published. Applicant's reference number SILICA 82	No	PUB	Not applicable	Not applicable	Not applicable
B3.5/01	Rentokil Initial plc	2005	GLP Technical Request Report - Measurement of pH of a 1% aqueous solution of RID Insect Powder according to CIPAC MT75 / Unpublished. Applicant's reference number SILICA 183	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
B3.6/01	Rentokil Initial plc	2005	GLP Technical Request Report - Determination of Tap Density of Gasil 23D and RID Insect Powder according to CIPAC Method MT33 / Unpublished. Applicant's reference number SILICA 184	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B3.7/01	Rentokil Initial plc	1988	Shelf Life Trial on RID Insect Powder packed in 50g HDPE Plastic Pack under Ambient Conditions. Technical Committee Report PCD 98/13. Project No. 244/40 (26/02/98). / GLP / Unpublished. Applicant's reference number SILICA 45	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B3.8/01	Rentokil Initial plc	2006	GLP Technical Request Report No. PC281 Determination of dustability of RID Insect Powder after Tropical Storage / GLP / Unpublished. Applicant's reference number SILICA 215	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B3.11/01	University of Leeds	2005	Characterisation of Insect Repellent Powders. PCLM-05-80-1 / Unpublished. Applicant's reference number SILICA 213	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B4.1/01	Harwell Scientifics	2006	Method Investigation and Validation for the Determination of Silicon in Amorphous Silicon Dioxide, Soil, Water and Air / Unpublished. Applicant's reference number SILICA 211	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B4.1/02	ESG	2012	Validation of a method for the determination of silicon in Gasil 23D on the behalf of Rentokil initial / ESG/ non GLP/ Unpublished. Applicant's reference number SILICA 247	Yes	ORG	France	Feb-12	Submission for Annex I listing under the BPD
B5.1.2/01	Rentokil Initial plc	2006	MANUFACTURING PROCESS Amorphous silicon dioxide technical grade / Unpublished. Applicant's reference number SILICA 195	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
B5.1.2/02	Rentokil Initial plc	2006	Manufacturing Process RID Insect Powder / Unpublished. Applicant's reference number SILICA 196	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.1.2/03	Anon	2003	Waste not, Want not - A Strategy for Tackling the Waste Problem in England. From: www.number-10.gov.uk/su/waste/report/02.html / Published. Applicant's reference number ALPHCHL 214	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.1.2/04	Environmental Agency	2003	Environmental Facts and Figures: Landfill. From: www.environmental-agency.gov.uk/yourenv/eff/resources_waste/213982/207743/?1 / Published. Applicant's reference number ALPHCHL 215	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.3/01	Rentokil Initial plc	1998	Pest Control Division Technical Committee Report No. PCD 98/ "The effect on mortality against Blatta orientalis demonstrated by aged RID Insect Powder" Project No 214/26	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.10/01	Rentokil Initial plc	1998	Investigation into the efficacy of RID Insect Powder against nymphs of *Blatella germanica* hatching from oothecae (GLP Study). Pest Control Division Technical Committee Report No. PCD 98/33 Project No 214/27 / GLP / Unpublished. Applicant's reference number SILICA 47	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.10/02	Rentokil Initial plc	1997	Investigation into the efficacy of RID Insect Powder against *Blatta orientalis* and *Blattella germanica* in a simulated field situation (GLP study) Pest Control Division Technical Committee Report No. PCD 97/36 Project No. 214/24 / GLP / Unpublished. Applicant's reference number SILICA 40	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
B5.10/04	Rentokil Ltd	1994	Evaluation of the Efficacy of Rentokil Insect Powder (Silica Dust) on Emerging B orientalis in Simulated Wall Voids Technical Committee Report No. PCS 94/21 Project No. 214/15 / Not GLP / Unpublished. Applicant's reference number SILICA 31	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B5.10/06	Rentokil Ltd	1990	The Effect of Silica Dusts on the Hatching of B orientalis Oothecae and the Survival of Newly-Hatched Nymphs Technical Committee Report No. PCS 90/19 Project No. 217/4 / GLP / Unpublished. Applicant's reference number SILICA 2	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B6.6/05	Rentokil Initial plc	2006	R&D Review Report - Operator Exposure to RID Insect Powder. Project Number 299/5 299/6 Report Number SS06/01 / Unpublished. Applicant's reference number SILICA 216	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B7.1/01	Rentokil Initial plc	2006	MANUFACTURING PROCESS Amorphous silicon dioxide technical grade / Unpublished. Applicant's reference number SILICA 195	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B7.1/02	Rentokil Initial plc	2006	Manufacturing Process RID Insect Powder / Unpublished. Applicant's reference number SILICA 196	Yes	ORG	France	Apr-06	Submission for Annex I listing under the BPD
B7.1/03	Anon	2003	Waste not, Want not - A Strategy for Tackling the Waste Problem in England. From: www.number-10.gov.uk/su/waste/report/02.html / Published. Applicant's reference number ALPHCHL 214	No	PUB	Not applicable	Not applicable	Not applicable

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Member State where study first submitted	Date of 1st submission	Reason for submission
B7.1/04	Environmental Agency	2003	Environmental Facts and Figures: Landfill. From: www.environmental-agency.gov.uk/yourenv/eff/resources_waste/213982/207743/?1 / Published. Applicant's reference number ALPHCHL 215	No	PUB	Not applicable	Not applicable	Not applicable
B8.1/01	Rentokil Initial plc	2006	Safety Data Sheet for RID Insect Powder dated 24/03/2006 Issue 04. / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B8.1/02	Rentokil Initial plc	2006	Draft export supply label for RID Insect Powder. / Unpublished.	No	PUB	Not applicable	Not applicable	Not applicable
B8.2/01	Rentokil Initial plc	2006	Safety Data Sheet for RID Insect Powder dated 24/03/2006 Issue 04. / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B8.4/01	Rentokil Initial plc	2006	Safety Data Sheet for RID Insect Powder dated 24/03/2006 Issue 04. / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B8.5/01	Rentokil Initial plc	2006	Safety Data Sheet for RID Insect Powder dated 24/03/2006 Issue 04. / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B8.6/01	Rentokil Initial plc	2006	Safety Data Sheet for RID Insect Powder dated 24/03/2006 Issue 04. / Published.	No	PUB	Not applicable	Not applicable	Not applicable
B8.7/01	Tarshis B	1959	Sorptive Dusts on Cockroaches easily applied compounds harmless to animals and humans effectively control cockroaches and other household pests. California Agriculture 13 (2): 3, 4, 5 / Not GLP / Published. Applicant's reference number SILICA 12	No	PUB	Not applicable	Not applicable	Not applicable
B8.7/02	Anon	2002	Food Additives in the European Union From: www.fst.rdg.ac.uk/foodlaw/additive.htm / Published. Applicant's reference number SILICA 65	No	PUB	Not applicable	Not applicable	Not applicable
B8.7/03	FAO/WHO	1973	Toxicological Evaluation of certain food additives with a review of general principles and of specifications. Food and Agriculture Organisation of the United Nations / Published. Applicant's reference number SILICA 17	No	PUB	Not applicable	Not applicable	Not applicable