

**LB MINERALS, s.r.o.**

**Safety Data Sheet in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010**

**Name of the product: *Kieselguhr soda ash flux calcined (diatomite)***

Version **07.1**

Revision date: **May 2015**

**SECTION 1. Identification of the Substance / Mixture and the Company / Undertaking****1.1. Product identifier**

Substance name: *Kieselguhr soda ash flux calcined*

Trade names:

|                         |                  |                      |
|-------------------------|------------------|----------------------|
| Filtrační křemelina F10 | Kieselgur C 1200 | Kieselgur Mittelfein |
| Filtrační křemelina F15 | Kieselgur C 200  | Kieselgur Fein       |
| Filtrační křemelina F25 |                  |                      |
| Filtrační křemelina F50 |                  |                      |
| Filtrační křemelina F60 |                  |                      |
| Filtrační křemelina F70 | Kieselgur C 3500 | Kieselgur Mittel     |

**INDEX No:** Not applicable

**Authorisation No:** N/A

**EC No:** 272-489-0

**REACH No:** **01-2119488518-22-0003**

Reference date: 25/10/2010 17:56

**CAS No:** 68855-54-9

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance / preparation:**

Fillers, Processing aid, not otherwise listed, filtration material, Laboratory chemicals, pH-regulating agents, Plating agents and metal surface treating agents, Solvents, filter-aid, functional filler, functional additive

**1.2.1. Relevant identified uses:**Industrial use.

**1.2.2. Uses advised against:**

None

**1.3. Details of the supplier of the safety data sheet**

**Supplier:** manufacturer

**E-Mail (competent person):** [MSDS@cz.lasselsberger.com](mailto:MSDS@cz.lasselsberger.com)

**Information contact:** [minerals@cz.lasselsberger.com](mailto:minerals@cz.lasselsberger.com)

**1.4. Emergency telephone number:**

Emergency telephone number:

Toxicology Information Centre (TIS) +420 224 919 293 (non-stop)

Na Bojišti 1, 128 08 Prague 2, ČR +420 224 915 402 (non-stop)

E-mail: [tis@mbox.cesnet.cz](mailto:tis@mbox.cesnet.cz)

Available outside office hours?

 Yes No**SECTION 2. Hazards Identification****2.1. Classification of the substance**

2.1.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]:

***Kieselguhr, soda ash flux-calcined (respirable cristobalite fraction < 1% w/w)***

This substance is not classified as hazardous according to Regulation (EC) No 1272/2008

**2.2. Label elements**

Labelling according Regulation (EC) No 1272/2008 [CLP]

***Kieselguhr, soda ash flux-calcined (respirable cristobalite fraction < 1% w/w)***

No labelling required

**2.3. Other hazards**

No special remarkable hazards.

Please observe the information given in this safety data sheet.

Depending on the type of handling and use (eg grinding, drying), airborne respirable crystalline silica may be generated.

**SECTION 3. Composition / Information on Ingredients****3.1. Substance**Substance name: *Kieselguhr soda ash flux calcined*

CAS No: 68855-54-9

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Purity: 100%

Synonyms: *Diatomite*

Stabilisers: None.

Hazard impurities: None.

Additional information: None

**SECTION 4. First aid measures****4.1. Description of first aid measures**

**General notes**

No adverse effects are expected during normal use of the substance, however if any effects do appear the following recommendations apply.

**Following inhalation:**

Move patient from contaminated area to fresh air. In case of persistent problems consult a physician. If dust inhalation is severe move operator to fresh air.

**Following skin contact:**

Wash the skin with soap and water.

**Following eye contact:**

Wash immediately, abundantly and thoroughly with water. If irritation persists, consult a physician

**Following ingestion:**

Rinse mouth with plenty of water. Do not induce vomiting.

**4.2. Most important symptoms and effects, both acute and delayed**

Breathing dust containing crystalline silica over a prolonged period of time may cause lung damage. Crystalline silica (Cristobalite) is a known cause of silicosis, a progressive, sometimes fatal lung disease.

**4.3. Indication of any immediate medical attention and special treatment needed**

Not applicable.

**SECTION 5. Fire-fighting measures****5.1. Extinguishing media****Suitable extinguishing media:**

The product is not flammable. Fire prevention measures should be chosen according to the environment.

**Unsuitable extinguishing media:** None.

**5.2. Special hazards arising from the substance or mixture :** None.

**5.3. Advice for fire-fighters**

In the event of a fire, wear self-contained breathing apparatus. The self contained breathing apparatus may be required due to other agents, but is not required due to potential Kieselguhr exposure.

**SECTION 6. Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment.

Avoid breathing dust. Ensure adequate ventilation.

Do not crush, avoid the formation and spread of dust in the air.

**6.2 Environmental precautions**

Avoid generating airborne dust.

Prevent product from entering drains.

**6.3 Methods and material for containment and cleaning up**

Pick up and arrange disposal without creating dust.

Keep in suitable, closed containers for disposal.

Broken bags should be taped over or covered with recuperage (slipover) bags.

**6.4. Reference to other sections:** Refer to sections 8 and 13

**SECTION 7. Handling and Storage**

**7.1. Precautions for safe handling****Protective measures**

Avoid dust formation and dust accumulation in enclosed space.  
Use personal protective equipment when handling the substance.

**Advice on general occupational hygiene**

Do not to eat, drink and smoke in work areas  
Wash hands after use  
Remove contaminated clothing and protective equipment before entering eating areas.

**7.2. Conditions for safe storage, including any incompatibilities**

Store in a dry place protected from moisture. Inspect all shipments upon arrival. Powder spills should be removed by vacuum cleaning or wet sweeping. Avoid dry sweeping if possible.

**7.3. Specific end Use(s)**

Worse case exposure scenarios for humans and the environment are attached in Annex I of this safety data sheet.

**SECTION 8. Exposure controls / Personal protection****8.1. Control parameters****8.1.1. Components with occupational exposure limits resp. biological occupational exposure limits requiring monitoring:****8.1.1.1. Occupational exposure limits:**

| <b>Substance: Quartz</b> <b>CAS No: 14808-60-7</b>                    |  |
|---|--|
| <b>Country of origin</b>  | <b>Occupational exposure limit value</b> |
| Belgium, Denmark, US, France, Portugal, Italy, Sweden, Norway, Greece | 0.10 (RD)                                |
| Netherlands   | 0.075 (RD)                               |
| Germany, Switzerland, Austria   | 0.15 (FD)                                |
| Finland   | 0.20 (FD)                                |
| Bulgaria  | 0.07                                     |
| CIS   | 1.0                                      |
| Czech   | 0.1                                      |
| Slovakia  | 1  |
| Ireland   | 0.40 (RD)                                |
| United Kingdom  | 0.30 (RD)                                |

RD: Respirable dust

FD: Fine dust

| <b>Substance: Cristobalite</b> <b>CAS No: 14464-46-1</b>              |  |
|---|--|
| <b>Country of origin</b>  | <b>Occupational exposure limit value</b> |
| Belgium, Denmark, US, France, Portugal, Italy, Sweden, Norway, Greece | 0.05 (RD)                                |
| Netherlands   | 0.075 (RD)                               |
| Germany, Switzerland, Austria   | 0.15 (FD)                                |
| Finland   | 0.10 (FD)                                |
| Bulgaria  | 0.07                                     |
| CIS   | 1.0                                      |
| Czech   | 0.1                                      |
| Slovakia  | 1  |
| Ireland   | 0.40 (RD)                                |
| United Kingdom  | 0.30 (RD)                                |

RD: Respirable dust

FD: Fine dust

Biological limit values: None.

**8.1.2. Recommended monitoring procedures: None****8.1.3. Occupational exposure limits and/or biological limits for air contaminants: Not applicable**



#### 8.1.4. Additional exposure limits under the conditions of use:

##### DNEL/DMEL

| Exposure route | Exposure pattern   | DNEL (workers)         |
|----------------|--------------------|------------------------|
| Inhalation     | Long term systemic | 0.33 mg/m <sup>3</sup> |

| Exposure route | Exposure pattern   | DNEL (general population) |
|----------------|--------------------|---------------------------|
| Inhalation     | Long term systemic | 0.08 mg/m <sup>3</sup>    |
| Oral           | Long term systemic | 3.5 mg/kg/bw/day          |

##### PNECS

| Compartment             | PNEC | Remarks  |
|-------------------------|------|--|
| Aquatic (surface water) | n/a  | LC50 values for fish, daphnia and algae study >100% v/v saturated solution (ie greater than the maximum solubility of the substance) . |
| STP micro-organisms     | 100  | NOAEL value<br>AF = 100  |
| Terrestrial             | n/a  | Naturally occurring inert substance  |
| Sediment                | n/a  | Naturally occurring inert substance  |

#### 8.2. Exposure controls

Refer to exposure scenarios in Annex I and Section 7

##### 8.2.1 Appropriate engineering controls

Refer to the engineering controls discussed in the exposure scenarios in Annex I

##### 8.2.2 Individual protection measures such as personal protective equipment

**Respiratory protection:** If dust is raised a respirator is recommended

**Hand protection:** Wear suitable hand protection depending on nature of the task.

**Eye protection:** Use safety goggles.

**Skin and body protection:** Wear suitable work clothing

##### 8.2.3 Environmental exposure controls

Dispose of waste in accordance with local and national regulations

## 9. SECTION 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Physical state:** Solid

**Colour:** White to beige

**Odour:** Odourless



|   | Value  | Method   | Remark     |
|---|--|--|------------|
| pH (20 °C):                                       | 7-9  |  |            |
| Melting point/range (°C):                         | > 450°C  | EU Method A1   | -          |
| Boiling point/range (°C):                         | Not applicable based on melting point                |  |            |
| Flash point (°C):                                 | Not applicable for inorganic substances              |  |            |
| Flammability (auto-ignition temperature):         | Not flammable  | Method N1 (flammability)<br>Method N4 (autoflammability) |            |
| Upper/ lower flammability or explosive limits:    | Not applicable                                       |  | -          |
| Vapour pressure (Pa):                             | Not applicable based on melting point                |  |            |
| Relative density:                                 | 2.36   | OECD 109   | -          |
| Water solubility (20°C in g/L):                   | Insoluble  | EU Method A6   | -          |
| Partition coefficient n-Octanol/Water (log Po/w): | Not applicable                                       |  | Inorganic  |
| Viscosity (cps):                                  | Not applicable for solids                            |  | -          |
| Decomposition temperature:                        | Not applicable                                       |  | -          |
| Explosive properties:                             | No explosive properties predicted from the structure |  | Prediction |
| Oxidising properties:                             | No oxidising properties predicted from the structure |  | Prediction |

9.2. Other information: None

## SECTION 10. Stability and Reactivity

10.1. Reactivity: Stable under recommended storage conditions

10.2. Chemical stability: The product is chemically stable

10.3. Possibility of hazardous reactions: May react violently with Hydrofluoric acid.

10.4. Conditions to avoid: None

10.5. Incompatible materials: Hydrofluoric acid- products

10.6. Hazardous decomposition products: None

## SECTION 11. Toxicological information

### 11.1 Information on toxicological effects

| Relevant hazard class             | Effect dose             | Species        | Method                           | Remark   |
|-----------------------------------|-------------------------|----------------|----------------------------------|--|
| Acute oral toxicity               | LD50<br>> 2000 mg/kg bw | Rat.           | OECD 401                         |  |
| Acute dermal toxicity             | n/a                     |                |                                  | No dermal toxicity envisaged due to low potential for absorption             |
| Acute inhalative toxicity         | LC50 > 2.6 mg/L         | Rat            | OECD 403                         | Maximum attainable dose  |
| Skin corrosion/irritation         | n/a                     | Rabbit         | OECD 404                         | Not irritating   |
| Serious eye damage/irritation     | n/a                     | Rabbit         | OECD 405                         | Not irritating   |
| Respiratory or skin sensitization | n/a                     | Guinea pig     | OECD 429                         | Not a skin sensitizer  |
| Germ cell mutagenicity            | n/a                     | In vitro tests | OECD 471<br>OECD 473<br>OECD 476 | Not mutagenic  |
| Carcinogenicity                   | n/a                     |                |                                  |  |
| Reproductive toxicity             | n/a                     |                |                                  | No effect reported   |
| STOT single exposure              | n/a                     |                |                                  | No effect reported   |
| STOT repeated exposure            | n/a                     | n/a            | n/a                              | STOT RE 1 (If RCS content >10%)<br>STOT RE 2 (If RCS content >1 % - < 10 %.) |
| Aspiration hazard                 | n/a                     |                |                                  | No aspiration hazard envisaged   |



Specific symptoms in animal studies (likely route of exposure):

In case of ingestion:

No acute or long term effects were seen in animal studies following oral exposure.

In case of skin contact:

No acute effects were seen in an animal study following acute dermal exposure.

Kieselguhr soda ash flux calcined is not a skin irritant

In case of inhalation:

No acute effects were seen in an animal study following acute inhalation exposure.

A 90 day repeated dose inhalation study has been proposed

Calcined diatomaceous earth (Kieselgur) contains crystalline silica, which is a known cause of silicosis, a progressive, sometimes fatal lung disease. In a 1997 monograph (Volume 68, "Silica, Some Silicates, Coal Dust and Para-aramid Fibrils"), the International Agency for Research on cancer (IARC) has classified "inhaled crystalline silica from occupational sources" in Group 1 as a substance "carcinogenic to humans". In making the overall evaluation, the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Crystalline silica has also been classified by the German MAK Commission as a human carcinogen (Category A1).

In case of eye contact:

Kieselguhr soda ash flux calcined is not an eye irritant

## SECTION 12. Ecological information

### 12.1. Toxicity

| Aquatic toxicity               | Effect dose                   | Exposure time | Species                        | Method   | Remark                                  |
|--------------------------------|-------------------------------|---------------|--------------------------------|----------|---|
| Acute fish toxicity            | >100% v/v saturated solution. | 96 h          | <i>Oncorhynchus mykiss</i>     | OECD 203 | Exceeds maximum solubility of substance |
| Acute daphnia toxicity         | >100% v/v saturated solution. | 48 h          | <i>Daphnia magna</i>           | OECD 202 | Exceeds maximum solubility of substance |
| Acute algae toxicity           | >100% v/v saturated solution. | 72 h          | <i>Desmodesmus subspicatus</i> | OECD 201 | Exceeds maximum solubility of substance |
| Toxicity to STP microorganisms | > 1000 mg/L                   | 3 h           | Activated sludge               | OECD 209 | Harmless to STP microorganisms          |

### 12.2 Persistence and degradability

#### Abiotic Degradation

Not applicable. The substance is inorganic and does not undergo any abiotic degradation.

#### 12.3 Bioaccumulative potential

Not applicable

#### 12.4 Mobility in soil

Not applicable

#### 12.5 Results of PBT and vPvB assessment:

This substance does not meet the criteria for classification as PBT or vPvB.

#### 12.6 Other adverse effects

No specific adverse effects known

**SECTION 13. Disposal considerations****13.1 Waste treatment methods**

May be disposed of in a non-hazardous sanitary landfill when not mixed with a hazardous substance. Dispose of in accordance with local regulations.

**SECTION 14. Transport information**

Not classified as dangerous in terms of transport regulations

**SECTION 15. Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Classification in compliance with Regulation (EC) 1272/2008 [EU-GHS / CLP]

The substance is not classified as hazardous in accordance with Regulation (EC) 1272/2008.

The label elements in accordance with Regulation (EC) No. 1272/2008 [CLP]: There is no need for labeling

The following regulations / directives should be reviewed when handling products containing crystalline silica:

**Great Britain:** Control of Substances Hazardous to Health, Regulations 1988, No 1857.

**Germany:** UBG 119 – Quartz-protection against mineral dusts injurious to health.

UBG 100 – Rule G.1.1 – Legislation concerning medical care.

Gefstoff 8.86 – specifies labeling requirements.

**France:** Decree No. 50.1289 of October 16, 1950 modified by Decree No. 63.576 of June 11, 1963 establishes special medical preventive measures for occupational silicosis.

- Circular No. 11453 of July 19, 1982 establishes the levels accepted for concentrations in the air of work areas
- Decree No. 87-200 of March 25, 1987 safety data sheets for hazardous substances.
- Code of Labour Article L 231-6 – Decree of October 10, 1983 modified by Decree of November 28, 1984 lists hazardous substances and establishes packing and labeling requirements.

**Spain:** Royal Decree of November 27, 1985 relating to the classification and labeling of dangerous substances.

**Italy:** Law No. 256 of May 29, 1974 Decree No. 927 of November 24, 1981 and No. 141 of February 20, 1988 on classification and labeling for warning of hazardous materials.

**15.2 Chemical Safety Assessment:**

For this substance a chemical safety assessment is provided in Annex I.

**SECTION 16. Other information****16.1 Indication of changes**

Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version 07.1 - Sec. 2.1.2 - removed section. Sec. 15.1.

**16.2 Abbreviations and acronyms**

|        |                               |
|--------|-------------------------------|
| AF =   | Assessment factor             |
| BCF =  | Bioconcentration factor       |
| CAS =  | Chemical Abstracts Service    |
| C & L  | Classification and labelling  |
| RCS =  | Respirable crystalline silica |
| DNEL = | Derived no effect level       |
| LC50 = | Median lethal concentration   |
| LD50 = | Medial lethal dose            |
| EC -   | European Commission           |

|         |                                      |
|---------|--------------------------------------|
| NOAEL = | No observed adverse effect level     |
| PBT     | Persistent bioaccumulative toxic     |
| PEC =   | Predicted effect level               |
| PNEC =  | Predicted no effect level            |
| SDS =   | Safety data sheet                    |
| STOT =  | Specific target organ toxicity       |
| STP =   | Sewage treatment plant               |
| vPvB    | Very persistent very bioaccumulative |



**16.3 Training advice**

According to appropriate national legislation

Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.

**16.4 Additional information:**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

**Third party material**

Insofar as materials not manufactured or supplied by LB MINERALS, s.r.o., are used in conjunction with, or instead of LB MINERALS, s.r.o., materials, it is the responsibility of the customer himself to obtain, from the manufacturer or supplier, all technical data and other properties relating to these and other materials and to obtain all necessary information relating to them. No liability can be accepted in respect of the use of LB MINERALS, s.r.o., Kieselguhr soda-ash flux calcined in conjunction with materials from another supplier.

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The end of the safety data sheet

**Annex I****Exposure Scenario 1: Manufacture of Kieselguhr soda ash flux-calcined**

|  |  |
|--|--|
| <b>1. Short title of exposure scenario 1</b>                                       |  |
| <b>Manufacture of Kieselguhr soda ash flux-calcined</b>                            |  |
| <b>2. Description of activities and processes covered in the exposure scenario</b> |  |
| Sector of use (SU)   | SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites .   |
| Product category (PC)  | PC 0: (adsorbent, filling material)<br>PC 14: Metal surface treatment products, including galvanic and electroplating products (This covers substances permanently binding with the metal surface)   |
| Process category (PROC)  | PROC 2: Use in closed, continuous process with occasional controlled exposure.<br>PROC 3: Use in closed batch process<br>PROC 4: Use in batch or other process where opportunity for exposure arises. Industrial setting<br>PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities.<br>PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing). |
| Article category (AC)  | Not applicable   |
| Environmental release category (ERC)   | ERC 1: Manufacture of substances   |
| <b>3. Operational conditions</b>   |  |
| <b>3.1 Operational conditions related with frequency and quantities of use</b>     |  |
| Duration of exposure at workplace:   | 8 hours per day  |
| Frequency of exposure at workplace:  | 5 days/week for each worker  |
| Annual amount used per site:   | The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario   |
| <b>3.2 Operational conditions related with substance/ product</b>                  |  |
| Physical state   | Solid ranging from a fine powder with high dustiness to coarser granules with low dustiness  |
| Concentration of substance in mixture  | 100% w/w   |
| <b>3.3 Other relevant operational conditions</b>                                   |  |
| No information about frequency and duration of the various tasks is available.     |  |
| <b>4. Risk Management Measures</b>   |  |
| <b>4.1 RMMs related to workers</b>   |  |
| Organisational measures  | Local exhaust ventilation is installed at manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.   |



|                          |   |
|--------------------------|---|
| Technical measures       | Safe conditions were defined by taking into account local exhaust ventilation in the present scenario                                     |
| Respiratory protection   | Workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air. |
| Hand protection          | Workers use gloves during the handling of the pure, solid substance   |
| Eye protection           | Workers use safety glasses during the handling of the pure, solid substance   |
| Skin and body protection | Wearing of suitable protective clothing.  |
| Hygiene measures         | Standard occupational hygiene measures should be adopted.   |

**4.2 RMMs related to the environment**

|  |  |
|--|--|
| Organisational measures                      | Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated                                    |
| Abatement measures related with wastewater   | The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more. |
| Abatement measures waste air and solid waste | It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.   |

**4.3 Waste related measures**

|   |  |
|---|--|
| Type of waste   | Solid and liquid waste   |
| Disposal technique                                      | Solid and liquid wastes are disposed of in landfills or may be incinerated.  |
| Fraction released to environment during waste treatment | Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution). |

**5. Prediction of exposure resulting from the conditions described above and the substance properties.****5.1. Human exposure**

|   |   |
|---|---|
| Workers (oral)  | Good hygiene practice will minimise oral exposure   |
| Workers (inhalation)<br><br><i>DNEL: Worker, long-term, systemic, inhalation: 0.33 mg/m<sup>3</sup></i> | <p>The workers' inhalation exposure to kieselguhr soda ash flux-calcined is estimated with the ECETOC TRA tool (ECETOC 2010). The assessment of exposure concentrations was performed with the three grades of dustiness that can be selected in the TRA tool: low, medium and high. The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table for all activities. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure. This applies also to storage, repackaging and distribution of the substance.</p> <p>Safe conditions were defined by taking into account local exhaust ventilation in the present scenario. To achieve acceptable airborne concentrations of kieselguhr soda ash flux-calcined the efficiency of LEV and the duration of exposure were modified. Safe conditions can also be</p> |



achieved by the use of personal respiratory equipment in addition or as an alternative to LEV. Consequently, the presentation of safe conditions is not exhaustive in the present ES.

| Process Category   | LEV | Duration | PRE | Content (%) | Inhalation exposure (mg/m <sup>3</sup> ) | RCR   |
|--|-----|----------|-----|-------------|--|-------|
| <b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING HIGH DUSTINESS</b>                           |     |          |     |             |  |       |
| 1 – Use in closed process, no likelihood of exposure                                     | No  | 4 to 8   | No  | 100         | 0.01                                     | 0.028 |
| 2 – Use in closed, continuous process with occasional controlled exposure                | 90% | 4 to 8   | No  | 100         | 0.1                                      | 0.278 |
| 3 – Use in closed batch process (synthesis or formulation)                               | 90% | 4 to 8   | No  | 100         | 0.1                                      | 0.278 |
| 4 – Use in batch and other process (synthesis) where opportunity for exposure arises     | 95% | Up to 1  | No  | 100         | 0.25                                     | 0.694 |
| 5 – Mixing or blending in batch processes (multistage and/or significant contact)        | 95% | Up to 1  | No  | 100         | 0.25                                     | 0.694 |
| 8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities | 95% | Up to 1  | No  | 100         | 0.25                                     | 0.694 |
| 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities     | 95% | Up to 1  | No  | 100         | 0.25                                     | 0.694 |
| 9 – Transfer of chemicals into small containers (dedicated filling line)                 | 95% | Up to 1  | No  | 100         | 0.2                                      | 0.556 |
| 15 – Use of laboratory reagents in small scale laboratories                              | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 19 – Hand-mixing with intimate contact (only PPE available)                              | 95% | Up to 1  | No  | 100         | 0.25                                     | 0.694 |
| <b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING MEDIUM DUSTINESS</b>                         |     |          |     |             |  |       |
| 1 – Use in closed process, no likelihood of exposure                                     | No  | 4 to 8   | No  | 100         | 0.01                                     | 0.028 |
| 2 – Use in closed, continuous process with occasional controlled exposure                | 90% | 4 to 8   | No  | 100         | 0.1                                      | 0.278 |
| 3 – Use in closed batch process (synthesis or formulation)                               | 80% | 4 to 8   | No  | 100         | 0.2                                      | 0.556 |
| 4 – Use in batch and other process (synthesis) where opportunity for exposure arises     | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 5 – Mixing or blending in batch processes (multistage and/or significant contact)        | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities     | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 9 – Transfer of chemicals into small containers (dedicated filling line)                 | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 15 – Use of laboratory reagents in small scale laboratories                              | 50% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 19 – Hand-mixing with intimate contact (only PPE available)                              | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| <b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING LOW DUSTINESS</b>                            |     |          |     |             |  |       |
| 1 – Use in closed process, no likelihood of exposure                                     | No  | 4 to 8   | No  | 100         | 0.01                                     | 0.028 |
| 2 – Use in closed, continuous process with occasional controlled exposure                | No  | 4 to 8   | No  | 100         | 0.01                                     | 0.028 |
| 3 – Use in closed batch process (synthesis or formulation)                               | No  | 4 to 8   | No  | 100         | 0.1                                      | 0.278 |
| 4 – Use in batch and other process (synthesis) where opportunity for exposure arises     | 50% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 5 – Mixing or blending in batch processes (multistage and/or significant contact)        | 50% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 8a – Transfer of chemicals from/to   | 50% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |



|  |  |     |        |    |     |      |       |
|--|--|-----|--------|----|-----|------|-------|
|  | vessels/ large containers at non dedicated facilities                                |     |        |    |     |      |       |
|  | 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities | No  | 4 to 8 | No | 100 | 0.1  | 0.278 |
|  | 9 – Transfer of chemicals into small containers (dedicated filling line)             | No  | 4 to 8 | No | 100 | 0.1  | 0.278 |
|  | 15 – Use of laboratory reagents in small scale laboratories                          | No  | 4 to 8 | No | 100 | 0.1  | 0.278 |
|  | 19 – Hand-mixing with intimate contact (only PPE available)                          | 50% | 4 to 8 | No | 100 | 0.25 | 0.694 |

**Workers (dermal)** Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.

**Indirect exposure via the environment** It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

**Consumer exposure** No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.

**5.2. Environmental exposure (qualitative assessment)**

**Waste water treatment plants (WWTP)** According to unpublished monitoring data, wastewater released at manufacturing sites may contain up to 100 mg kieselguhr soda ash flux-calcined per litre. This is exceeding the amount that can be dissolved in one litre of water at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering the local sewage treatment plant (STP), the wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of kieselguhr soda ash flux-calcined. The sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.

**Aquatic pelagic compartment** To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters

**Sediments** The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.

**Soil and groundwater** Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure



|                         |   |
|-------------------------|---|
|                         | concentrations in soil is undertaken  |
| Atmospheric compartment | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the manufacture of the substance and waste air is expected to be filtered before released to the environment. ed WAS. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken. |
| Secondary poisoning     | The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |

### Exposure Scenario 2: Use as filter aid in industrial settings

|  |  |
|--|--|
| <b>1. Short title of exposure scenario 2</b>                                       |  |
| <b>Use as a filter aid in industrial settings</b>                                  |  |
| <b>2. Description of activities and processes covered in the exposure scenario</b> |  |
| Sector of use (SU)   | SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites<br>SU 4: Manufacture of food products<br>SU 6: Manufacture of pulp, paper and paper products<br>SU 8: Manufacture of bulk, large scale chemicals<br>SU 10: Formulation mixing) of preparations and/or re-packaging<br>SU 14: Manufacture of basic metals<br>SU 17: General manufacturing, eg machner, equipment, vehicles, other transport equipment .  |
| Product category (PC)  | PC 2: Adsorbents<br>PC 14: Metal surface treatment products, including galvanic and electroplating products<br>PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents<br>PC 25: Metal working fluids<br>PC 35: Washing and cleaning products (including solvent based products)<br>PC 0: Other: Filtration material   |
| Process category (PROC)  | PROC 1: Use in closed process, no likelihood of exposure<br>PROC 2: Use in closed, continuous process with occasional controlled exposure<br>PROC 3: Use in closed batch process (synthesis or formulation)<br>PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises<br>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)<br>PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities<br>PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities<br>PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)<br>PROC 15: Use as laboratory reagent<br>PROC 19: Hand-mixing with intimate contact and only PPE available. |
| Article category (AC)  | Not applicable   |
| Environmental release category (ERC)   | ERC 1: Manufacture of substances<br>ERC 2: Formulation of preparations<br>ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles<br>ERC 6b: Industrial use of reactive processing aids<br>ERC 7: Industrial use of substances in closed systems   |
| <b>3. Operational conditions</b>   |  |



|  |  |
|--|--|
| <b>3.1 Operational conditions related with frequency and quantities of use</b> |  |
| Duration of exposure at workplace:   | 4-8 hours per day  |
| Frequency of exposure at workplace:  | 5 days/week for each worker  |
| Annual amount used per site:   | The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.   |
| <b>3.2 Operational conditions related with substance/ product</b>              |  |
| Physical state   | Solid and liquid   |
| Concentration of substance in mixture  | A concentration of 100% w/w was used to assess exposure to the solid substance.<br>The exposure concentrations due to contact with liquid mixtures were calculated by taking into account a concentration of the substance in the liquid phase ranging from 5% to 25%. |
| <b>3.3 Other relevant operational conditions</b>                               |  |
| No information about frequency and duration of the various tasks is available. |  |
| <b>4. Risk Management Measures</b>   |  |
| <b>4.1 RMMs related to workers</b>   |  |
| Organisational measures  | Solid substance: Local exhaust ventilation is installed at the manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.  |
| Technical measures   | Solid substance: Safe conditions were defined by taking into account local exhaust ventilation in the present scenario<br>Liquid substance: Outdoor activity – natural ventilation   |
| Respiratory protection   | In addition, workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air.<br>Liquid substance: N/A  |
| Hand protection  | Skin protection may be used.   |
| Eye protection   | Eye protection may be used.  |
| Skin and body protection   | Wearing of suitable protective clothing.   |
| Hygiene measures   | Standard occupational hygiene measures should be adopted.  |
| <b>4.2 RMMs related to the environment</b>                                     |  |
| Organisational measures  | Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated  |
| Abatement measures related with wastewater                                     | The wastewater can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.   |
| Abatement measures waste air and solid waste                                   | Waste air may be filtered eg by bag filters or scrubber units.   |



**4.3 Waste related measures**

|   |  |
|---|--|
| Type of waste   | Solid and liquid waste.  |
| Disposal technique                                      | Solid and liquid waste may be incinerated or disposed of in landfills.   |
| Fraction released to environment during waste treatment | Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution). |

**5. Prediction of exposure resulting from the conditions described above and the substance properties.**

**5.1. Human exposure**

|                |   |
|----------------|---|
| Workers (oral) | Good hygiene practice will minimise oral exposure |
|----------------|---|

|   |   |
|---|---|
| Workers (inhalation)<br><i>DNEL: Worker, long-term, systemic, inhalation: 0.33 mg/m<sup>3</sup></i> | Safe conditions for the handling of solid kieselguhr soda ash flux-calcined are given in for the manufacture of the substance. These apply also to the use of the substance as filter aid covered in exposure scenario 2. The modelled long-term exposure concentrations resulting from the handling of liquid mixtures containing the substance are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in <b>Chyba! Nenalezen zdroj odkazů.</b> for all activities described in exposure scenario 1. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure. |
|---|---|

| Process Category   | LEV | Duration | PRE | Content (%) | Inhalation exposure (mg/m <sup>3</sup> ) | RCR   |
|--|-----|----------|-----|-------------|--|-------|
| INDUSTRIAL USE OF LIQUID MATERIAL  |     |          |     |             |  |       |
| 2 – Use in closed, continuous process with occasional controlled exposure                | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 3 – Use in closed batch process (synthesis or formulation)                               | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 4 – Use in batch and other process (synthesis) where opportunity for exposure arises     | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 5 – Mixing or blending in batch processes (multistage and/or significant contact)        | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities     | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 9 – Transfer of chemicals into small containers (dedicated filling line)                 | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 15 – Use of laboratory reagents in small scale laboratories                              | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |
| 19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo      | No  | 8        | No  | 10          | 0.0002                                   | 0.001 |

|                  |   |
|------------------|---|
| Workers (dermal) | Dermal exposure was not assessed, as no risks are anticipated with dermal exposure. |
|------------------|---|

|                                       |  |
|---------------------------------------|--|
| Indirect exposure via the environment | It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux- |
|---------------------------------------|--|





|   |   |
|---|---|
|   | calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |
| Consumer exposure   | No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.   |
| <b>5.2. Environmental exposure (qualitative assessment)</b> |   |
| Waste water treatment plants (WWTP)                         | The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L. |
| Aquatic pelagic compartment                                 | To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters  |
| Sediments   | The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water.<br>Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out   |
| Soil and groundwater  | Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken   |
| Atmospheric compartment                                     | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken   |
| Secondary poisoning   | The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |

**Exposure Scenario 3: Use as additive in formulation of liquid, viscous or solid mixtures****1. Short title of exposure scenario 3**

Use as an additive in formulation of liquids, viscous or solid mixtures

**2. Description of activities and processes covered in the exposure scenario**



|  |   |
|--|---|
| Sector of use (SU)   | SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites<br>SU 10: Formulation (mixing) of preparations and/or re-packaging<br>SU 11: Manufacture of rubber products<br>SU 13: Manufacture of other non-metallic mineral products, eg plasters, cement.   |
| Product category (PC)  | PC 2: Adsorbents<br>PC 9: Coatings and paints, fillers, putties, thinners<br>PC 21: Laboratory chemicals<br>PC 29: Pharmaceuticals<br>PC 35: Washing and cleaning products (including solvent based products)   |
| Process category (PROC)  | PROC 1: Use in closed process, no likelihood of exposure<br>PROC 2: Use in closed, continuous process with occasional controlled exposure<br>PROC 3: Use in closed batch process (synthesis or formulation)<br>PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises<br>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)<br>PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities<br>PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities<br>PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)<br>PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation<br>PROC 15: Use as laboratory reagent<br>PROC 19: Hand-mixing with intimate contact and only PPE available. |
| Article category (AC)  | AC 10: Rubber products<br>AC 13: Plastic products   |
| Environmental release category (ERC)   | ERC 2: Formulation of preparations<br>ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles<br>ERC 7: Industrial use of substances in closed systems<br>ERC 8b: Wide dispersive indoor use of reactive substances in open systems   |
| <b>3. Operational conditions</b>   |   |
| <b>3.1 Operational conditions related with frequency and quantities of use</b> |   |
| Duration of exposure at workplace:   | 8 hours per day   |
| Frequency of exposure at workplace:  | 5 days/week for each worker   |
| Annual amount used per site:   | The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.  |
| <b>3.2 Operational conditions related with substance/ product</b>              |   |
| Physical state   | Solid and liquid  |
| Concentration of substance in mixture  | The concentration of the substance in the final mixtures may range from <1 % (liquid) to 60 % (dental fillings).  |
| <b>3.3 Other relevant operational conditions</b>                               |   |
| No information about frequency and duration of the various tasks is available. |   |
| <b>4. Risk Management Measures</b>   |   |



| <b>4.1 RMMs related to workers</b>           |  |
|--|--|
| Organisational measures                      | The employer has also to ascertain that the required PPE is available and used according to instructions.  |
| Technical measures                           | LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used  |
| Respiratory protection                       | LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air.   |
| Hand protection                              | Skin protection may be used.   |
| Eye protection                               | Eye protection may be used.  |
| Skin and body protection                     | Wearing of suitable protective clothing.   |
| Hygiene measures                             | Standard occupational hygiene measures should be adopted.  |
| <b>4.2 RMMs related to the environment</b>   |  |
| Organisational measures                      | Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated                                    |
| Abatement measures related with wastewater   | The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more. |
| Abatement measures waste air and solid waste | It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.   |
| <b>4.3 Waste related measures</b>            |  |
| Type of waste                                | Solid and liquid waste.  |
| Disposal technique                           | Solid and liquid waste may be incinerated or disposed of in landfills.   |

|   |  |
|---|--|
| Fraction released to environment during waste treatment | Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution). |
|---|--|

### **5. Prediction of exposure resulting from the conditions described above and the substance properties.**

#### **5.1. Human exposure**

|  |  |
|--|--|
| Workers (oral)   | Good hygiene practice will minimise oral exposure  |
| Workers (inhalation)<br><i>DNEL: Worker, long-term, systemic, inhalation: 0.36mg/m<sup>3</sup></i> | The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 3 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2. |
| Workers  | Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.  |



|   |   |
|---|---|
| (dermal)  |   |
| Indirect exposure via the environment                       | It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |
| Consumer exposure   | No direct consumer exposure is resulting from the use of kieselguhr soda-ash flux calcined as an additive in the formulation of liquid, viscous or solid mixtures.  |
| <b>5.2. Environmental exposure (qualitative assessment)</b> |   |
| Waste water treatment plants (WWTP)                         | The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L. |
| Aquatic pelagic compartment                                 | To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters  |
| Sediments   | The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water.<br>Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out   |
| Soil and groundwater  | Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken   |
| Atmospheric compartment                                     | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken   |
| Secondary poisoning   | The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |

**Exposure Scenario 4: Use as process aid in manufacture of chemicals, resins, rubbers and plastics****1. Short title of exposure scenario 4**



| <b>Use as an additive in formulation of liquids, viscous or solid mixtures</b>     |  |
|--|--|
| <b>2. Description of activities and processes covered in the exposure scenario</b> |  |
| Sector of use (SU)   | SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites<br>SU 8: Manufacture of bulk, large scale chemicals<br>SU 9: Manufacture of fine chemicals<br>SU 11: Manufacture of rubber products<br>SU 12: Manufacture of plastics products, including compound and conversion .   |
| Product category (PC)  | PC 16: Heat transfer fluids<br>PC 17: Hydraulic fluids<br>PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents<br>PC 24: Lubricants, greases, release products<br>PC 25: Metal working fluids<br>PC 32: Polymer preparations and compounds  |
| Process category (PROC)  | PROC 1: Use in closed process, no likelihood of exposure<br>PROC 2: Use in closed, continuous process with occasional controlled exposure<br>PROC 3: Use in closed batch process (synthesis or formulation)<br>PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises<br>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)<br>PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities<br>PROC 15: Use as laboratory reagent<br>PROC 19: Hand-mixing with intimate contact and only PPE available. |
| Article category (AC)  | Not applicable   |
| Environmental release category (ERC)   | ERC 1: Manufacture of substances<br>ERC 2: Formulation of preparations<br>ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles  |
| <b>3. Operational conditions</b>   |  |
| <b>3.1 Operational conditions related with frequency and quantities of use</b>     |  |
| Duration of exposure at workplace:   | 8 hours per day  |
| Frequency of exposure at workplace:  | 360 days/year for each worker  |
| Annual amount used per site:   | The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.   |
| <b>3.2 Operational conditions related with substance/ product</b>                  |  |
| Physical state   | Solid and liquid   |
| Concentration of substance in mixture  | 100% w/w   |
| <b>3.3 Other relevant operational conditions</b>                                   |  |
| No information about frequency and duration of the various tasks is available.     |  |
| <b>4. Risk Management Measures</b>   |  |
| <b>4.1 RMMs related to workers</b>   |  |



|                          |   |
|--------------------------|---|
| Organisational measures  | The employer has also to ascertain that the required PPE is available and used according to instructions.   |
| Technical measures       | LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used |
| Respiratory protection   | LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air.  |
| Hand protection          | Skin protection may be used.  |
| Eye protection           | Eye protection may be used.   |
| Skin and body protection | Wearing of suitable protective clothing.  |
| Hygiene measures         | Standard occupational hygiene measures should be adopted.   |

**4.2 RMMs related to the environment**

|  |  |
|--|--|
| Organisational measures                      | Not applicable   |
| Abatement measures related with wastewater   | The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more. |
| Abatement measures waste air and solid waste | It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.   |

**4.3 Waste related measures**

|   |  |
|---|--|
| Type of waste   | Solid and liquid waste.  |
| Disposal technique                                      | Solid and liquid waste may be incinerated or disposed of in landfills.   |
| Fraction released to environment during waste treatment | Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution). |

**5. Prediction of exposure resulting from the conditions described above and the substance properties.****5.1. Human exposure**

|  |  |
|--|--|
| Workers (oral)   | Good hygiene practice will minimise oral exposure  |
| Workers (inhalation)<br><i>DNEL: Worker, long-term, systemic, inhalation: 0.36mg/m<sup>3</sup></i> | The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 4 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2.   |
| Workers (dermal)   | Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.  |
| Indirect exposure via the environment  | It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially |



|   |   |
|---|---|
|   | unavailable to organisms.   |
| Consumer exposure   | No direct consumer exposure is resulting from the use of kieselguhr soda ash flux-calcined as a process aid in the manufacture of chemicals, resins, rubbers and plastics   |
| <b>5.2. Environmental exposure (qualitative assessment)</b> |   |
| Waste water treatment plants (WWTP)                         | The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L. |
| Aquatic pelagic compartment                                 | To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters  |
| Sediments   | The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water.<br>Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out   |
| Soil and groundwater  | Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken   |
| Atmospheric compartment                                     | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance as a process aid in the manufacture of chemicals, resins, rubbers and plastics. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken  |
| Secondary poisoning   | The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |

**Exposure Scenario 5: Professional use by dental technicians and dentists**

|  |   |
|--|---|
| <b>1. Short title of exposure scenario 4</b>                                       |   |
| Use as an additive in formulation of liquids, viscous or solid mixtures            |   |
| <b>2. Description of activities and processes covered in the exposure scenario</b> |   |
| Sector of use (SU)   | SU 9: Manufacture of fine chemicals<br>SU 10: Formulation mixing) of preparations and/or re-packaging |



|  |  |
|--|--|
|  | SU 12: Manufacture of plastics products, including compound and conversion<br>SU 20: Health surfaces.  |
| Product category (PC)  | PC 32: Polymer preparations and compounds  |
| Process category (PROC)  | PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)<br>PROC 19: Hand-mixing with intimate contact and only PPE available. |
| Article category (AC)  | Not applicable   |
| Environmental release category (ERC)   | ERC 2: Formulation of preparations<br>ERC 3: Formulation in materials<br>ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix  |
| <b>3. Operational conditions</b>   |  |
| <b>3.1 Operational conditions related with frequency and quantities of use</b> |  |
| Duration of exposure at workplace:   | Up to 1 h/day  |
| Frequency of exposure at workplace:  | Performed on up to 220 days/year   |
| Annual amount used per site:   | The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.   |
| <b>3.2 Operational conditions related with substance/ product</b>              |  |
| Physical state   | Solid and liquid   |
| Concentration of substance in mixture  | Such materials can contain the substance at levels up to 60% w/w   |
| <b>3.3 Other relevant operational conditions</b>                               |  |
| No information about frequency and duration of the various tasks is available. |  |
| <b>4. Risk Management Measures</b>   |  |
| <b>4.1 RMMs related to workers</b>   |  |
| Organisational measures  | The employer has also to ascertain that the required PPE is available and used according to instructions.  |

|                          |   |
|--------------------------|---|
| Technical measures       | Professionals normally do the mixing in the absence of LEV. |
| Respiratory protection   | N/A   |
| Hand protection          | Skin protection may be used.                                |
| Eye protection           | Eye protection may be used.                                 |
| Skin and body protection | Wearing of suitable protective clothing.                    |
| Hygiene measures         | Standard occupational hygiene measures should be adopted.   |



**4.2 RMMs related to the environment**

|  |   |
|--|---|
| Organisational measures                      | Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer. Solid waste may be incinerated or deposited in landfills   |
| Abatement measures related with wastewater   | Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer   |
| Abatement measures waste air and solid waste | Solid waste may be incinerated or deposited in landfills. Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken. |

**4.3 Waste related measures**

| Type of waste   | Solid and liquid waste.  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
|---|--|-----------|-------|------------------------|-------|---------------------------|------|------------------------|-------|-------------------------------|-------|----------------|-------|-------------------------------------|---|---|-----|--------------------------------------|---|-------------------------------|--------------|
| Disposal technique                                      | Solid waste may be incinerated or deposited in landfills. Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer.   |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Fraction released to environment during waste treatment | <p>Emissions from filling and alginate impression material may occur on 260 days per year. About 300 tonnes kieselguhr soda ash flux-calcined are used per year for dental filling and impression material in the EU. A fraction of 10%, i.e. 30 t/year, is considered for regional use. For the local use, 0.2% of the regional tonnage is considered, i.e. 60 kg/year. Part of the substance may be release to the wastewater when cleaning materials which were in contact with preparations containing kieselguhr soda ash flux-calcined. It is expected that at most 10% of the filling and impression materials are released to the sewer, i.e. 6 kg per year on the local scale. This results in a reasonable worst-case emission of substance into the wastewater of 0.023 kg/day. Emissions of the substance into the atmosphere or the soil compartment are negligible</p> <table border="1"> <thead> <tr> <th>Parameter</th> <th>Value</th> </tr> </thead> <tbody> <tr> <td>Tonnage in EU per year</td> <td>300 t</td> </tr> <tr> <td>Regional tonnage per year</td> <td>30 t</td> </tr> <tr> <td>Local tonnage per year</td> <td>60 kg</td> </tr> <tr> <td>Fraction of main local source</td> <td>0.002</td> </tr> <tr> <td>Number of days</td> <td>260 d</td> </tr> <tr> <td>Fraction of tonnage released to air</td> <td>0</td> </tr> <tr> <td>Fraction of tonnage released to waste water</td> <td>0.1</td> </tr> <tr> <td>Fraction of tonnage released to soil</td> <td>0</td> </tr> <tr> <td>Local emissions to wastewater</td> <td>0.023 kg/day</td> </tr> </tbody> </table> | Parameter | Value | Tonnage in EU per year | 300 t | Regional tonnage per year | 30 t | Local tonnage per year | 60 kg | Fraction of main local source | 0.002 | Number of days | 260 d | Fraction of tonnage released to air | 0 | Fraction of tonnage released to waste water | 0.1 | Fraction of tonnage released to soil | 0 | Local emissions to wastewater | 0.023 kg/day |
| Parameter   | Value  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Tonnage in EU per year                                  | 300 t  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Regional tonnage per year                               | 30 t   |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Local tonnage per year                                  | 60 kg  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Fraction of main local source                           | 0.002  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Number of days  | 260 d  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Fraction of tonnage released to air                     | 0  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Fraction of tonnage released to waste water             | 0.1  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Fraction of tonnage released to soil                    | 0  |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |
| Local emissions to wastewater                           | 0.023 kg/day   |           |       |                        |       |                           |      |                        |       |                               |       |                |       |                                     |   |   |     |                                      |   |                               |              |

**5. Prediction of exposure resulting from the conditions described above and the substance properties.****5.1. Human exposure**

|   |   |
|---|---|
| Workers (oral)  | Good hygiene practice will minimise oral exposure   |
| Workers (inhalation)<br><i>DNEL: Worker, long-term,</i> | The modelled reasonable worst-case long-term exposure concentrations resulting from the handling of small amounts of dental filling or impression materials (about 50 g/application) is 0.024 mg/m <sup>3</sup> . The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.36 mg/m <sup>3</sup> is 0.067 showing that the potential health risk for workers is controlled for the professional use of kieselguhr soda ash flux-calcined as dental filling and |



|   |   |
|---|---|
| systemic, inhalation:0.36 mg/m <sup>3</sup>                 | impression material by dental technicians and dentists.   |
| Workers (dermal)  | Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.   |
| Indirect exposure via the environment                       | It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. It is concluded that indirect human exposure to kieselguhr soda ash flux-calcined via the environment is not relevant  |
| Consumer exposure   | Patients may ingest small amounts of substance during dental treatment. In general exposure is expected to be negligible as the dental treatment is performed under professional surveillance.  |
| <b>5.2. Environmental exposure (qualitative assessment)</b> |   |
| Waste water treatment plants (WWTP)                         | In the present assessment, the wastewater passes through a sewage treatment plant (STP) which has a capacity of 2000000 L/day. No removal of kieselguhr soda ash flux-calcined during wastewater treatment is taken into account for the present exposure scenario. The resulting reasonable worst-case concentration of the substance in the effluent of a local STP is $23000/2000000=0.012$ mg/L   |
| Aquatic pelagic compartment                                 | A dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water, leading to a surface water concentration of 0.0012 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00012 mg/L in marine waters   |
| Sediments   | The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water.<br>Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.  |
| Soil and groundwater  | Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken |
| Atmospheric compartment                                     | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken  |
| Secondary poisoning   | The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.  |

**Exposure Scenario 6: Industrial, professional and private use of substance or mixtures containing the substance**

**1. Short title of exposure scenario 6**

Use as an additive in formulation of liquids, viscous or solid mixtures

**2. Description of activities and processes covered in the exposure scenario**



|  |  |
|--|--|
| Sector of use (SU)   | SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites<br>SU 21: Consumer uses: Private households (= general public = consumers)<br>SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)  |
| Product category (PC)  | PC 35: Washing and cleaning products (including solvent based products)<br>PC 37: Water treatment chemicals  |
| Process category (PROC)  | PROC 2: Use in closed, continuous process with occasional controlled exposure<br>PROC 3: Use in closed batch process (synthesis or formulation)<br>PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises<br>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)<br>PROC 7: Industrial spraying<br>PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities<br>PROC 10: Roller application or brushing<br>PROC 11: Non industrial spraying<br>PROC 13: Treatment of articles by dipping and pouring<br>PROC 19: Hand-mixing with intimate contact and only |
| Article category (AC)  | AC 10: Rubber products<br>AC 13: Plastic products  |
| Environmental release category (ERC)   | ERC 1: Manufacture of substances<br>ERC 2: Formulation of preparations<br>ERC 8a: Wide dispersive indoor use of processing aids in open systems<br>ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix<br>ERC 8d: Wide dispersive outdoor use of processing aids in open systems<br>ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix<br>ERC 10b: Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)   |
| <b>3. Operational conditions</b>   |  |
| <b>3.1 Operational conditions related with frequency and quantities of use</b> |  |
| Duration of exposure at workplace:   | Use of coatings and paints containing kieselguhr soda ash flux-calcined: 4-8 hours<br>Use of kieselguhr soda ash flux calcined for filtering water: Approximately 1 hour per day.<br>Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 60 minutes per use, consumers up to 20 minutes per day.   |
| Frequency of exposure at workplace:  | Use of coatings and paints containing kieselguhr soda ash flux-calcined: Up to 225 days per year<br>Use of kieselguhr soda ash flux calcined for filtering water: Weekly for professional use and monthly consumer use<br>Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 8 times a day.   |
| Annual amount used per site:   | The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.   |
| <b>3.2 Operational conditions related with substance/ product</b>              |  |
| Physical state   | Solid and liquid   |
| Concentration of substance in mixture  | A variety of articles made from rubbers or plastics contain the substance. The average weight fraction of kieselguhr soda ash flux-calcined in such articles is about 7% w/w and the maximum weight fraction is approximately 15% w/w.   |
| <b>3.3 Other relevant operational conditions</b>                               |  |
| No information about frequency and duration of the various tasks is available. |  |

**4. Risk Management Measures****4.1 RMMs related to workers**

|                         |   |
|-------------------------|---|
| Organisational measures | The employer has also to ascertain that the required PPE is available and used according to instructions.   |
| Technical measures      | Safe conditions were defined by considering that workers use respiratory equipment during industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively safe conditions may also be achieved by ensuring very good ventilation in the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr is expected. |
| Respiratory protection  | If elevated exposure is to be expected LEV may be present and industrial and professional users may wear breathing masks reducing the amount of inhaled aerosols  |
| Hand protection         | Skin protection may be used.  |
| Eye protection          | Eye protection may be used.   |

|                          |   |
|--------------------------|---|
| Skin and body protection | Wearing of suitable protective clothing.                  |
| Hygiene measures         | Standard occupational hygiene measures should be adopted. |

**4.2 RMMs related to the environment**

|  |   |
|--|---|
| Organisational measures                      | Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP). |
| Abatement measures related with wastewater   | Any liquid waste that results will be disposed of via the public sewer  |
| Abatement measures waste air and solid waste | Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills Waste air at industrial and professional sites may be filtered before released to the atmosphere.                     |

**4.3 Waste related measures**

|   |  |
|---|--|
| Type of waste   | Liquid/solid waste.  |
| Disposal technique                                      | Wastewater that is generated during cleaning operations may be treated in an onsite treatment plant or be released to the public sewer system and treated in a municipal STP. Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills. |
| Fraction released to environment during waste treatment | A worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs  |

**5. Prediction of exposure resulting from the conditions described above and the substance properties.****5.1. Human exposure**

|                      |  |
|----------------------|--|
| Workers (oral)       | Good hygiene practice will minimise oral exposure  |
| Workers (inhalation) | The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in exposure |



*DNEL: Worker, long-term, systemic, inhalation 0.36: mg/m<sup>3</sup>*

| Process Category   | LEV | Duration | PRE | Content (%) | Inhalation exposure (mg/m <sup>3</sup> ) | RCR   |
|--|-----|----------|-----|-------------|--|-------|
| INDUSTRIAL USE OF LIQUID MATERIAL                                |     |          |     |             |  |       |
| 7 – Industrial spraying based on TNsG (European Commission 2002) | No  | Up to 6  | 95% | 10          | 0.325                                    | 0.903 |
| 10 – Roller application or brushing                              | No  | 4 to 8   | No  | 5 to 25     | 0.125                                    | 0.347 |
| 13 – Treatment of articles by dipping and pouring                | No  | 4 to 8   | No  | 5 to 25     | 0.147                                    | 0.408 |

scenario 5. Safe conditions for additional activities are shown in the table below Safe conditions were defined by considering that workers use personal respiratory equipment during industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the industrial use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure.

**Safe conditions for industrial activities performed during the use of mixtures containing kieselguhr soda ash flux-calcined**

The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table above. Safe conditions were defined by considering that workers use personal respiratory equipment during non-industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the workplace. The reasonable worst-case airborne concentration of the substance resulting from professional cleaning was 1.86E-05 mg/m<sup>3</sup>. The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.36 mg/m<sup>3</sup> is 5.2E-05 showing that the potential health risk for workers is controlled for the professional use of cleaners. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the professional use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure

| Process Category   | LEV | Duration | PRE | Content (%) | Inhalation exposure (mg/m <sup>3</sup> ) | RCR   |
|--|-----|----------|-----|-------------|--|-------|
| PROFESSIONAL USE OF SOLID MATERIAL WITH MEDIUM DUSTINESS                                 |     |          |     |             |  |       |
| 2 – Use in closed, continuous process with occasional controlled exposure                | 75% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 3 – Use in closed batch process (synthesis or formulation)                               | 75% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 4 – Use in batch and other process (synthesis) where opportunity for exposure arises     | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 5 – Mixing or blending in batch processes (multistage and/or significant contact)        | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |
| 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities     | 95% | 4 to 8   | No  | 100         | 0.25                                     | 0.694 |



|                                       | 9 – Transfer of chemicals into small containers (dedicated filling line)   | 95%  | 4 to 8  | No  | 100     | 0.25   | 0.694 |              |  |  |     |  |  |  |  |
|---------------------------------------|--|--|---------|-----|---------|--------|-------|--------------|--|--|-----|--|--|--|--|
|                                       | 19 – Hand-mixing with intimate contact (only PPE available)  | 95%  | 4 to 8  | No  | 100     | 0.25   | 0.694 |              |  |  |     |  |  |  |  |
|                                       | PROFESSIONAL USE OF LIQUID MATERIAL  |  |         |     |         |        |       |              |  |  |     |  |  |  |  |
|                                       | 2 – Use in closed, continuous process with occasional controlled exposure  | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 3 – Use in closed batch process (synthesis or formulation)   | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 4 – Use in batch and other process (synthesis) where opportunity for exposure arises   | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 5 – Mixing or blending in batch processes (multistage and/or significant contact)  | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities   | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities   | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 9 – Transfer of chemicals into small containers (dedicated filling line)   | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 10 – Roller application or brushing  | No   | 4 to 8  | No  | 5 to 25 | 0.125  | 0.347 |              |  |  |     |  |  |  |  |
|                                       | 11 – Non industrial spraying based on TNSG (European Commission 2002)  | No   | Up to 6 | 95% | 10      | 0.325  | 0.903 |              |  |  |     |  |  |  |  |
|                                       | 13 – Treatment of articles by dipping and pouring  | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 15 – Use of laboratory reagents in small scale laboratories  | No   | 4 to 8  | No  | 5 to 25 | 0.15   | 0.417 |              |  |  |     |  |  |  |  |
|                                       | 19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo  | No   | 8       | No  | 10      | 0.0002 | 0.001 |              |  |  |     |  |  |  |  |
| Workers (dermal)                      | Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.  |  |         |     |         |        |       |              |  |  |     |  |  |  |  |
| Indirect exposure via the environment | No indirect exposure of humans to kieselguhr soda ash flux-calcined is anticipated.  |  |         |     |         |        |       |              |  |  |     |  |  |  |  |
| Consumer exposure (inhalation)        | <p>Consumer exposure to kieselguhr soda ash flux-calcined resulting from the use of mixtures was described as long-term exposure in the case of use of paints and cleaning products and as short-term exposure in the case of spray painting and use of filtration materials. The long-term and acute airborne concentrations of the substance for the different uses are given in the table below. The RCRs for all consumer uses resulting in long-term exposure to the substance are well below 1 indicating that potential health risks for consumers are adequately controlled. Spray painting may result in relatively high acute exposure to kieselguhr soda ash flux-calcined and should be performed only in well-ventilated areas. It is recommended that particles of the substance used in spray paints available to consumers exhibit diameters greater than 0.015 mm. As particles with larger diameters generally are not inhaled this helps to avoid elevated consumer exposure to particles of kieselguhr soda ash flux-calcined during spray painting. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the potential health risks for consumers are adequately for the uses of the substance described in the present exposure scenario.</p> <table border="1" style="width: 100%; margin-top: 10px;"> <thead> <tr> <th style="background-color: #ffff00;">Consumer use</th> <th style="background-color: #ffff00;">Mean inhalation concentration (long-term) in mg/m<sup>3</sup></th> <th style="background-color: #ffff00;">Mean inhalation concentration (acute) in mg/m<sup>3</sup></th> <th style="background-color: #ffff00;">RCR</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> |  |         |     |         |        |       | Consumer use | Mean inhalation concentration (long-term) in mg/m <sup>3</sup> | Mean inhalation concentration (acute) in mg/m <sup>3</sup> | RCR |  |  |  |  |
| Consumer use                          | Mean inhalation concentration (long-term) in mg/m <sup>3</sup>   | Mean inhalation concentration (acute) in mg/m <sup>3</sup> | RCR     |     |         |        |       |              |  |  |     |  |  |  |  |
|                                       |  |  |         |     |         |        |       |              |  |  |     |  |  |  |  |



|  |                                    |                |       |                |
|--|------------------------------------|----------------|-------|----------------|
|  | Use of high-solid paints           | 0.000122       |       | 0.0015         |
|  | Use of water-based paints          | 0.000186       |       | 0.0023         |
|  | Use of solvent-based paints        | 0.000864       |       | 0.011          |
|  | Use of water-based wall paints     | 0.00044        |       | 0.0055         |
|  | Spray painting (trigger cans)      | Not applicable | 37.5  | Not applicable |
|  | Spray painting (pneumatic sprayer) | Not applicable | 0.676 | Not applicable |
|  | Filtration material                | Not applicable | 0.14  | Not applicable |
|  | Cleaning products                  | 0.00002        |       | 0.00025        |

**5.2. Environmental exposure (qualitative assessment)**

|                                     |  |
|-------------------------------------|--|
| Waste water treatment plants (WWTP) | <p>Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP). As the tonnages of kieselguhr soda ash flux-calcined for these uses are not known, a worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs due to industrial, professional and private use of mixtures containing the substance and not covered by other exposure scenarios. The total EU tonnage is 120,000 tonnes per year resulting in 12,000 tonnes of kieselguhr soda ash flux-calcined released to municipal STPs in the present scenario. This amount is evenly distributed over the EU as dispersive use of mixtures containing the substance can be assumed. The EU has approximately 500 millions inhabitants. The average volume of wastewater per inhabitant equivalent is 200 L per day (EUSES default). The concentration in a municipal STP can then be calculated as:</p> $C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}, \text{ where}$ <p><i>AMOUNT<sub>STP</sub></i> : amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/year),<br/> <i>DAYS</i> : number of release days (365 days/year),<br/> <i>INHAB</i> : number of inhabitants in EU (500 millions inhabitants),<br/> <i>WASTEW<sub>inhab</sub></i> : wastewater per inhabitant (200 L/d) ,<br/> <i>C<sub>STP</sub></i> : concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/L).</p> <p>The predicted concentration of kieselguhr soda ash flux-calcined in municipal sewage treatment plants is then:</p> $C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \frac{mg}{L}.$ |
| Aquatic pelagic compartment         | A dilution factor of 10 is taken into account at the point of mixing of the waste water with surface water, leading to a surface water concentration of 0.033 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00033 mg/L in marine waters  |
| Sediments                           | Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out   |
| Soil and                            | If paints containing soda ash flux-calcined are used outdoors small amounts of kieselguhr  |



|                         |   |
|-------------------------|---|
| groundwater             | soda ash flux-calcined may leach to the soil. Further, kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As leaching from paints and atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken |
| Atmospheric compartment | Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of mixtures containing the substances by industrial workers, professionals or consumers. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken.  |
| Secondary poisoning     | It is expected that emissions of the substance resulting from the industrial, professional or private use of the substance or mixtures containing the substance will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. Therefore, it is not necessary to assess secondary poisoning via the food chain  |