1. Identification of the substance / Preparation and Company:

1.1 Product identifier

Commercial product name:	Poliresin
Product description:	Polishing material

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:	Used as a carrier, a silica source, or as a functional additive for paint, cosmetics, plastics, rubber or other applications. Use as filter aid in industrial settings.		
Exposure Scenario	No.		Page:
	1	Manufacture of kieselguhr soda ash flux calcined	10
	2	Use as filter aid in industrial settings	13
	3	Industrial, professional and private use of substance or mixtures containing the substance	16
Used Advised Against:	Anything other than the above.		

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:	ERNST HINRICHS Dental GmbH
Street / mailbox:	Borsigstr. 1
Country code. / postal code / city:	D - 38644 Goslar
Phone:	0 53 21 / 5 06 24
Fax:	0 53 21 / 5 08 81
E-mail / Website:	info@hinrichs-dental.de / www.hinrichs-dental.de
Further information obtainable from:	ERNST HINRICHS Dental GmbH
Importer:	Ivoclar Vivadent Ltd 12 Omega St, Rosedale, Auckland, New Zealand Phone +64 9 914 9999 Fax +64 9 914 9990 www.ivoclarvivadent.co.nz

1.4 **Emergency phone number:** 0800 764 766 (National Poison Centre)
Poisons Hotline (24 hours / 7 days)

2. Hazards Identification

2.1 Classification of the substance or mixture: This product contains cristobalite (fine fraction) at: < 1%. Depending on the type of handling and use (e.g. grinding, drying), airborne fine fraction crystalline silica may be generated. Prolonged and/or massive inhalation of fine fraction crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of silicosis are cough and breathlessness.
Occupational exposure to fine fraction crystalline silica dust should be monitored and controlled.

2.1.1 Regulation (EC) No. 1272/2008 (CLP): Not classified as hazardous for supply/use.

2.2 Label elements: According to Regulation (EC) No. 1272/2008 (CLP)

Contains:	Diatomaceous Earth, Flux-Calcined (Kieselguhr) (< 1% Crystalline Silica - Cristabolite (Respirable Dust)
Hazard Pictogram(s):	None assigned.
Signal Word(s):	None assigned.
Hazard Statement(s):	None assigned.
Precautionary Statement(s):	None assigned.

2.3 Other hazards: None.

3. Composition / Information on Ingredients

3.1 Substances:
EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the substance	%W/W	CAS. No.	EC No.
Diatomaceous Earth, Flux-Calcined (Kieselguhr)	approx. 100	68855-54-9	272-489-0

Contains: Cristobalite (Respirable Dust), <1 Fine Fraction Crystalline Silica per SWeRF calculation	<1	14464-46-1	238-455-4

3.2 Mixtures: Not applicable.

4. First aid measures

4.1 Description of first aid measures

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If irritation develops and persists, get medical attention. Blow nose to evacuate dust.

Skin contact: Remove clothing and wash thoroughly before use. Wash affected skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact: Flush eyes with water for at least 15 minutes while holding eyelids open. Get medical attention if eye irritation develops or persists.

Ingestion: Rinse mouth. Give plenty of water to drink. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed: Prolonged and/or massive exposure to fine fraction crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. Acute inhalation can cause dryness of the nasal passage and lung congestion, coughing and general throat irritation. Chronic inhalation of dust should be avoided. May cause irritation to the respiratory system.

4.3 Indication of any immediate medical attention and special treatment needed: Unlikely to be required but if necessary treat symptomatically. There is no specific antidote. Remove person to fresh air and keep comfortable for breathing.

5. Fire-fighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Non-flammable. Extinguish with carbon dioxide, dry chemical, foam or water spray. As appropriate for surrounding fire.

Unsuitable extinguishing media: None.

5.2 Special hazards arising from the substance or mixture: Non-flammable, non-combustible, not explosive.

5.3 Advice for fire-fighters: Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Wear appropriate personal protective equipment, avoid direct contact. Where engineering controls are not fitted or inadequate wear suitable respiratory protective equipment.

6.2 Environmental precautions: No special requirements.

6.3 Methods and material for containment and cleaning up: Sweep spilled substances into containers if appropriate moisten first to prevent dusting. Use vacuum equipment for collecting spilt materials, where practicable. Transfer to a container for disposal.

6.4 Reference to other sections: See sections 8 and 13.

7. Handling and Storage

7.1	Precautions for safe handling:	Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the GOOD Practice Guide referred to in section 16. Avoid generation of dust. In case of inadequate ventilation wear respiratory protection. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection. Avoid contact with the skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.
7.2	Conditions for safe storage, including any incompatibilities:	Atmospheric concentrations should be minimised and kept as low as reasonably practicable below the occupational exposure limit.
	Storage life:	Stable under normal conditions. Store in dry place.
	Incompatible material:	Keep away from Hydrofluoric Acid.
7.3	Specific end Use(s):	See section 1.2.

8. Exposure controls / Personal protection

8.1 Control parameters

8.1.1 Occupational Exposure limits

Substance	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note
Silica, Respirable Crystalline	-	-	0.1	-	-	WEL: Workplace Exposure Limit (UK HSE EH40)
Nuisance Dust	-	-	10	-	-	Inhalable Dust. WEL: Workplace Exposure Limit (UK HSE EH40)
Nuisance Dust	-	-	4	-	-	Respirable Dust. WEL: Workplace Exposure Limit (UK HSE EH40)

Note: For the equivalent limits in other countries, please consult a competent occupational hygienist or the local regulatory authority.

8.1.2 Biological limit value: Not established.

8.1.3 PNECs and DNELs: Diatomaceous Earth (Kieselguhr): Not harmful to aquatic organisms. Insoluble in water. On the basis the PNECs for the aquatic compartment have not been derived.

Diatomaceous Earth (Kieselguhr) DNELs	Oral	Inhalation	Dermal
Industry - Long Term - Systemic effects	-	0.05 mg/m³	-
Consumer - Long Term - Systemic effects	18.7 mg/kg bw/day	0.05 mg/m³	-

8.2 Exposure controls

8.2.1 Appropriate engineering controls: Ensure adequate ventilation. Atmospheric levels should be controlled in compliance with the occupational expose limit. Avoid dust generation.

8.2.2 Individual protection measures, such as personal protective equipment (PPE): Use personal protective equipment as required. Wash contaminated clothing before reuse. Avoid contact with skin and eyes. Do not breathe dust.

Eye/Face protection: Wear eye protection with side protection (EN166)

Skin protection: Use skin barrier cream before handling the product. Wear suitable gloves if prolonged skin contact is likely - Wear impervious gloves (EN374). Unsuitable glove materials.

	Respiratory protection: 	Atmospheric levels should be controlled in compliance with the occupational exposure limit. In case of inadequate ventilation wear respiratory protection. Recommended: Half-face mask (DIN EN 140), Filter type P2/P3 - efficiency of at least 90%.
	Thermal hazards:	Not applicable.
8.2.3	Environmental Exposure Control	Avoid wind dispersal.

9. Physical and chemical properties

9.1	Information on basic physical and chemical properties	
	Appearance:	White powder
	Odour:	Odourless
	Odour threshold:	Not available.
	ph (10% Suspension):	10
	Melting point / freezing point:	Not applicable.
	Initial boiling point and boiling range:	Decomposes below boiling point at (°C): >1300°C
	Flash point:	Non-flammable.
	Evaporation rate:	Not applicable.
	Flammability (solid, gas):	Non-flammable.
	Upper/lower flammability or explosive limits:	Non-flammable.
	Vapour pressure:	Not applicable.
	Vapour density:	Not applicable.
	Relative density:	2.3 g/cm³ (H_2O = 1)
	Solubility(ies):	<1% Water Soluble in: Hydrofluoric Acid
	Partition coefficient: n-octanol/water:	Not available.
	Auto-ignition temperature:	Not applicable.
	Decomposition Temperature:	Not available.
	Viscosity:	Not applicable, solid.
	Explosive properties:	Not explosive.
	Oxidising properties:	Not oxidising.
9.2	Other information:	None.

10. Stability and Reactivity

10.1	Reactivity:	Stable under normal conditions.
10.2	Chemical Stability:	Stable under normal conditions.
10.3	Possibility of hazardous reactions:	Stable under normal conditions.
10.4	Conditions to Avoid:	Avoid contact with: Hydrofluoric Acid. Do not leave in enclosed spaces when mixed with highly flammable material, as heat can build up over long periods of time and flammable material may eventually ignite.
10.5	Incompatible Materials:	Reacts violently with Hydrofluoric Acid.
10.6	Hazardous decomposition products:	No hazardous decomposition products known.

11. Toxicological information

11.1	Information on toxicological effects	
	Acute toxicity:	Based upon the available data, the classification criteria are not met.
	Ingestion:	Based upon the available data, the classification criteria are not met.
	Inhalation:	Based upon the available data, the classification criteria are not met.
	Skin contact:	Based upon the available data, the classification criteria are not met.

	Eye contact:	Based upon the available data, the classification criteria are not met.
	Skin corrosion/irritation:	Based upon the available data, the classification criteria are not met.
	Serious eye damage/irritation:	Based upon the available data, the classification criteria are not met.
	Respiratory or skin sensitization:	Based upon the available data, the classification criteria are not met.
	Germ Cell mutagenicity:	Based upon the available data, the classification criteria are not met.
	Reproductive toxicity:	Based upon the available data, the classification criteria are not met.
	STOT - single exposure:	Based upon the available data, the classification criteria are not met.
	STOT - repeated exposure:	Based upon the available data, the classification criteria are not met.
	Aspiration hazard:	Based upon the available data, the classification criteria are not met.
11.2	Other information:	Prolonged and/or massive exposure to fine fraction crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. In 1997, IARC (the International Agency for research on Cancer) concluded the crystalline silica inhaled from occupational sources can cause lung cancer in humans (human carcinogen category 1). However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France). In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012). In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of fine fraction crystalline silica dust is silicosis. “There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefor preventing the onset of silicosis will also reduce the cancer risk…” (SCOEL SUM Doc 94-final, June 2003). So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16 below).

12. Ecological information

12.1	Toxicity:	Not classified as Marine Pollutant.
12.2	Persistence and degradability:	Not applicable.
12.3	Bioaccumulative potential:	The production has no potential for bioaccumulation. Some organisms accumulate Si(OH)4.

12.4	Mobility in soil:	The product is predicted to have low mobility in soil.
12.5	Results of PBT and vPvB assessment:	This product is an inorganic substance and does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH.
12.6	Other adverse effects:	None known.

13. Disposal considerations

13.1	Waste treatment methods:	Dispose of empty containers and waste safely. Dispose of contents in accordance with local, state or national legislation.
13.2	Additional information:	Packaging waste: Remove all packaging for recovery or disposal. Make sure that packaging is completely empty before recycling. Inform consumer about possible hazards of unclean empty packaging for recycling or disposal.

14. Transport information

Not classified according to the United Nations “Recommendations on the Transport of Dangerous Goods”.

ADR/RID / IMDG / ICAO/IATA

14.1	UN number:	Not applicable.
14.2	UN proper shipping name:	Not applicable.
14.3	Transport hazard class:	Not applicable.
14.4	Packaging group	Not applicable.
14.5	Environmental hazards	Not classified as Marine Pollutant.
14.6	Special precautions for users	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Diatomaceous Earth, no special measures are required.
14.8	Additional information:	None.

15. Regulatory information

15.1 Safety, Health and Environmental Regulations/Legislation specific for the substance or mixture
Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.
Standard for the Uniform Scheduling of Medicines and Poisons.
Carcinogen classification under WHS Regulation 2011, Schedule 10.
Notification status in accordance with section 3 and current national legislation.
HSNO Approval: HSR003244
EPA NZ Classes of hazardous properties:
Classification 6.7A Known or presumed human carcinogens
Classification 6.9A (All) Toxic to human target organs or systems

15.2	Chemical safety assessment:	Subject to REACH Registration. A chemical safety assessment has been carried out.

16. Other information

The following sections contain revisions or new statements: 1-16.

References: Existing Safety Data Sheet (SD), Existing ECHA registration(s) for Diatomaceous Earth (Kieselguhr), soda Fklux-Calcined (CAS# 68855-54-9).

Training
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. A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25th of April 2006. This autonomous agreement, which received the European Commission’s financial support, is based on a GOOD Practice Guide. The requirements of the Agreement came into force on 25th of October 2006. The Agreement was published in the Official Journal of the

European Union (2006/C 279/02). The text of the agreement and its annexes, including the Good Practice Guide, are available from http://www.nepsi.eu and provide useful information and guidance for the handling of products containing fine fraction crystalline silica. Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers.

Legend

LTEL:	Long Term Exposure Limit
STEL:	Short Term Exposure Limit
DNEL:	Derived No Effect Level
PNEC	Predicted No Effect Concentration
PBT:	Persistent, Bioaccumulative and Toxic
vPvB:	very Persistent and very bioaccumulative
OECD	Organisation for Economic Cooperation and Development
SCOEL:	The EU Scientific Committee on Occupational Exposure Limits.
IARS:	International Agency for Research on Cancer
SWeRF:	Size-Weighted Fine Fraction

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Annex to the extended Safety Data Sheet (eSDS)
The following scenarios were addressed in the chemical safety report (CSR) for Kieselguhr, Soda Ash Flux-Calcined Fine Cristobalite Fraction as prepared as part of the registration dossier required by the EU REACH Regulation:

Exposure scenario 1	Manufacture of kieselguhr soda ash flux calcined
Exposure scenario 2	Use as filter aid in industrial settings
Exposure scenario 3	Industrial, professional and private use of substance or mixtures containing the substance

Kieselguhr, Soda Ash Flux-Calcined Fine Cristobalite Fraction < 1%

CAS No.	68855-54-9
EC No.	272-489-0

Summary of Parameters

Physical parameters	
Melting point/freezing point	> 450 °C
Partition Coefficient (log KOW)	Not applicable
Solubility (Water) (mg/l)	3.7 mg/l @ 20 °C
Molecular weight	66.0843
Biodegradability	The methods for determining the biological degradability are not applicable to inorganic substances.

Human Health (DNEL)			
Workers	Short term	Inhalation (mg/m³)	0.05 mg/m³
		Dermal (mg/kg bw/day)	Not determined
	Long Term	Inhalation (mg/m³)	Not determined
		Dermal (mg/kg bw/day)	Not determined

Consumer	Inhalation (mg/m³)	0.05 mg/m³
	Dermal (mg/kg bw/day)	Not determined
	Oral (mg/kg bw/day)	3.5 mg/kg bw/day

Environmental Parameters (PNECs)		
Exposure Scenario	**PEC Environment Reasonable worst case**	**PNEC STP**
ES1 Manufacture of kieselguhr soda ash flux calcined	Not defined	Not defined
ES2 Use as filter aid in industrial settings	3.87 mg/l	100 mg/l
ES3 Industrial, professional and private use of substance or mixtures containing the substance	0.329 mg/l	100 mg/l

Contents

Contributing Scenarios
PROC Codes

PROC1	Use in closed process, no likelihood of exposure
PROC2	Use in closed, continuous process with occasional controlled exposure
PROC3	Use in closed batch process (synthesis or formulation)
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
PROC7	Industrial spraying
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC10	Roller application or brushing
PROC11	Non industrial spraying
PROC13	Treatment of articles by dipping and pouring
PROC15	Use as laboratory reagent
PROC19	Hand-mixing with intimate contact and only PPE available

Exposure Scenario 1 – Manufacture of kieselguhr soda ash flux calcined

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
Process category [PROC]	PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Chemical product category [PC]	PC0 Other Adsorbents, Filling material PC14 Metal surface treatment products, including galvanic and electroplating products
Article Categories [AC]	Not applicable
Environmental release categories [ERC]	ERC1 Manufacture of substances
Specific Environmental Release Categories SPERC	Not applicable

2.0 Operational conditions and risk management measures		
2.1 Control of worker exposure		
Product characteristics		
Physical form of product	White/Beige Powder	
Concentration of substance in product	Covers concentrations up to 100%	
Human factors not influenced by risk management		
Potential exposure area	Not defined	
Frequency and duration of use		
Exposure duration per day	Covers daily exposures up to 8 hours (unless stated differently).	
Exposure time per week	Covers frequency up to: 5 days per week.	
Other operational conditions affecting worker exposure		
Area of use	All contributing scenarios	Indoor
Characteristics of the surroundings	Not defined	
General measures applicable to all activities Assumes a good basic standard of occupational hygiene is implemented. Assumes use at not more than 20°C above ambient temperature, unless stated differently. Do not breathe dust. Avoid dust generation. Clear spills immediately. After contact with skin, wash immediately with plenty of: Water. Provide basic employee training to prevent / minimize exposures.		
Organisational measures		
All contributing scenarios	Control any potential exposure using measures such as contained or enclosed systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and clear transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; Ensure suitable personal protective equipment is available; Clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.	
Technical conditions of use		
PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	Local exhaust ventilation is required.	
PROC1, PROC2, PROC3	Use in closed systems. Local exhaust ventilation is required.	
Risk management measures related to human health		
Respiratory protection	PROC4, PROC8b, PROC9	Half-face mask (DIN EN 140), Filter type P2/P3 - efficiency of at least 90%
	PROC2, PROC3	No special measures are required.
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).

Other operational conditions affecting worker exposure	
Assumes a good basic standard of occupational hygiene is implemented.	
2.2 Control of environmental exposure	
Amounts used	
Fraction of EU tonnage used in region:	Not considered to influence the exposure as such for this scenario
Regional use tonnage (tons/year):	
Fraction of Regional tonnage used locally: tons/year	
Annual site tonnage (tons/year):	
Maximum daily site tonnage (kg/day):	
Environment factors not influenced by risk management	
Flow rate of receiving surface water (m^3/d):	Not defined (default = 18,000)
Local freshwater dilution factor:	10
Local marine water dilution factor:	100
Operational conditions	
Emission days (days/year):	Not defined
Release fraction to air from process (initial release prior to RMM):	No risk is anticipated: Atmospheric concentrations are expected to be low.
Release fraction to wastewater from process (initial release prior to RMM):	100 mg/l
Release fraction to soil from process (initial release prior to RMM):	No risk is anticipated: Deposition is expected to be low.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Treat air emission to provide a typical removal efficiency of (%):	Not defined. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of (%):	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.
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of (%):	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.
Treat soil emission to provide a typical removal efficiency of (%)	Not defined.
Note: Common practices vary across sites thus conservative process release estimates used.	
Organisational measures to prevent/limit release from site	
Prevent discharge of undissolved substance to or recover from onsite wastewater. Do not apply industrial sludge to natural soils. Sludge should be incinerated, contained or reclaimed.	
Conditions and measures related to municipal sewage treatment plant	
Size of municipal sewage system/treatment plant (m^3/d)	Not defined
Degradation effectiveness (%)	Not defined
Conditions and measures related to external treatment of waste for disposal	
Type of waste	Solid and Liquid and Gas
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.
Substance release quantities after risk management measures	

Release to waste water from process (mg/l)	< 3.87 mg/l
Maximum allowable site tonnage (MSafe) (kg/d):	Not defined

3. Exposure estimation and reference to its source	
3.1 Human exposure prediction	
Exposure assessment (method/calculation model)	ECETOC TRA 2010

			Inhalation	
Process category [PROC]	**Duration**	**Local Exhaust Ventilation**	**inhalation exposure (mg/m³)**	**Risk characterization ratio (RCR)**
PROC1	4 – 8	None	0.01	0.028
PROC2	4 – 8	90%	0.1	0.278
PROC3	4 – 8	90%	0.1	0.278
PROC4	≤ 1	95%	0.25	0.694
PROC5	≤ 1	95%	0.25	0.694
PROC8a	≤ 1	95%	0.25	0.694
PROC8b	≤1	95%	0.25	0.694
PROC9	≤ 1	95%	0.2	0.556
PROC15	4 – 8	95%	0.25	0.694
PROC19	< 1	95%	0.25	0.694

Dermal exposure is considered to be not relevant. Oral exposure is not expected to occur.

3.2 Environmental exposure prediction	
Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	Not defined: After sedimentation, wastewater sent to the waste water treatment plant contains: < 3.87 mg/l. No effects are observed at this level.
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 mg/l): 0.387/0.039 mg/l
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.
Soil	No risk is anticipated: Deposition is expected to be low.
Atmospheric Compartment	No risk is anticipated: Atmospheric concentrations are expected to be low.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.

4. Evaluation guidance to downstream user	
For scaling see	Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Available hazard data do not support the need for a DNEL to be established for other health effects. Further details on scaling and control technologies are provided in SpERC factsheet (http://cefic.org/en/reach-for- industries-libraries.html).

	In accordance with ECHAs recommendations, the “worst case” approach has been taken and only the most stringent RMMs recommended for each route of exposure have been taken.	
Exposure assessment instrument/tool/method	Workers	ECETOC TRA 2010
	Environmental exposure	EUSES
Exposure Scenario 2 – Use as filter aid in industrial settings **1.0 Contributing Scenarios**		
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU4 Manufacture of food products SU6a Manufacture of wood and wood products SU6b Manufacture of pulp, paper and paper products SU8 Manufacture of bulk, large scale chemicals (including petroleum products) SU9 Manufacture of fine chemicals SU15 Manufacture of fabricated metal products, except machinery and equipment SU19 Building and construction work	
Process category [PROC]	PROC1 Use in closed process, no likelihood of exposure PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC15 Use as laboratory reagent PROC19 Hand-mixing with intimate contact and only PPE available	
Chemical product category [PC]	PC0 Other Filtration material PC2 Adsorbents PC14 Metal surface treatment products, including galvanic and electroplating products PC20 Products such as ph-regulators, flocculants, precipitants, neutralization agents PC25 Metal working fluids PC35 Washing and cleaning products (including solvent based products)	
Article Categories [AC]	Not applicable	
Environmental release categories [ERC]	ERC1 Manufacture of substances ERC2 Formulation of preparations ERC4 Industrial use of processing aids in processes and products, not becoming part of articles. ERC6b Industrial use of reactive processing aids ERC7 Industrial use of substances in closed systems	
Specific Environmental Release Categories SPERC	Not applicable	

2.0 Operational conditions and risk management measures	
2.1 Control of worker exposure	
Product characteristics	
Physical form of product	white powder
Concentration of substance in product	White/Beige Powder Covers concentrations up to 100%

Human factors not influenced by risk management		
Potential exposure area	Not defined	
Frequency and duration of use		
Exposure duration per day	Covers daily exposures up to 8 hours (unless stated differently).	
Exposure time per week	Covers frequency up to: 5 days per week.	
Other operational conditions affecting worker exposure		
Area of use	All contributing scenarios	Indoor
Characteristics of the surroundings	Room volume	50 m³
	Ventilation rate	0.6 / 1 hour(s)
General measures applicable to all activities Assumes a good basic standard of occupational hygiene is implemented. Assumes use at not more than 20°C above ambient temperature, unless stated differently. Do not breathe dust. Avoid dust generation. Clear spills immediately. After contact with skin, wash immediately with plenty of: Water. Provide basic employee training to prevent / minimize exposures.		
Organisational measures		
All contributing scenarios	Control any potential exposure using measures such as contained or enclosed systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and clear transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; Ensure suitable personal protective equipment is available; Clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.	
Technical conditions of use		
PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	Use with local exhaust ventilation or breathing protection.	
PROC2, PROC3	Use in closed systems.	
Risk management measures related to human health		
Respiratory protection	PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	Wear respiratory protection.
	PROC2, PROC3	No special measures are required.
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Fraction of EU tonnage used in region:	Not considered to influence the exposure as such for this scenario	
Regional use tonnage (tons/year):		
Fraction of Regional tonnage used locally: tons/year		
Annual site tonnage (tons/year):	2 - 12500	

Maximum daily site tonnage (kg/day):	Not determined.
Environment factors not influenced by risk management	
Flow rate of receiving surface water (m^3/d):	Not defined (default = 18,000)
Local freshwater dilution factor:	10 Release fraction to soil from process (initial release prior to RMM):
Local marine water dilution factor:	100
Operational conditions	
Emission days (days/year):	Not defined
Release fraction to air from process (initial release prior to RMM):	No risk is anticipated: Atmospheric concentrations are expected to be low.
Release fraction to wastewater from process (initial release prior to RMM):	100 mg/l
Release fraction to soil from process (initial release prior to RMM):	No risk is anticipated: Deposition is expected to be low.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Treat air emission to provide a typical removal efficiency of (%):	Not defined. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of (%):	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.
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of (%):	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.
Treat soil emission to provide a typical removal efficiency of (%):	Not defined
Note: Common practices vary across sites thus conservative process release estimates used.	
Organisational measures to prevent/limit release from site	
Prevent discharge of undissolved substance to or recover from onsite wastewater. Do not apply industrial sludge to natural soils. Sludge should be incinerated, contained or reclaimed.	
Conditions and measures related to municipal sewage treatment plant	
Size of municipal sewage system/treatment plant (m^3/d)	Not defined
Degradation effectiveness (%)	Not defined
Conditions and measures related to external treatment of waste for disposal	
Type of waste	Solid and Liquid and Gas
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.
Substance release quantities after risk management measures	
Release to waste water from process (mg/l)	< 3.87 mg/l
Maximum allowable site tonnage (MSafe) (kg/d):	Not defined

3. Exposure estimation and reference to its source	
3.1 Human exposure prediction	
Exposure assessment	ECETOC TRA 2010

(method/calculation model)				
			Inhalation	
Process category [PROC]	Duration	Local Exhaust Ventilation	inhalation exposure (mg/m³)	Risk characterization ratio (RCR)
PROC2	4 – 8	None	0.147	0.408
PROC3	4 – 8	None	0.147	0.408
PROC4	4 – 8	None	0.147	0.408
PROC5	4 – 8	None	0.147	0.408
PROC8a	4 – 8	None	0.147	0.408
PROC8b	4 – 8	None	0.147	0.408
PROC9	4 – 8	None	0.147	0.408
PROC15	4 – 8	None	0.147	0.408
PROC19	8	None	0.147	0.408

Dermal exposure is considered to be not relevant. Oral exposure is not expected to occur.

3.2 Environmental exposure prediction	
Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	Not defined: After sedimentation, wastewater sent to the waste water treatment plant contains: < 3.87 mg/l. No effects are observed at this level.
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 mg/l): 0.387/0.0387 mg/l
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.
Soil	No risk is anticipated: Deposition is expected to be low.
Atmospheric Compartment	No risk is anticipated: Atmospheric concentrations are expected to be low.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.
4. Evaluation guidance to downstream user	
For scaling see	Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Available hazard data do not support the need for a DNEL to be established for other health effects. Further details on scaling and control technologies are provided in SpERC factsheet (http://cefic.org/en/reach-for- industries-libraries.html). In accordance with ECHAs recommendations, the “worst case” approach has been taken and only the most stringent RMMs recommended for each route of exposure have been taken.
Exposure assessment instrument/tool/method	Workers: ECETOC TRA 2010 Environmental exposure: EUSES

Exposure Scenario 3 – Industrial, professional and private use of substance or mixtures containing the substance	
1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU21 Consumer uses: Private

	households (= general public = consumers) SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Process category [PROC]	PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC7 Industrial spraying PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC10 Roller application or brushing PROC11 Non industrial spraying PROC13 Treatment of articles by dipping and pouring PROC19 Hand-mixing with intimate contact and only PPE available
Chemical product category [PC]	PC35 Washing and cleaning products (including solvent based products) PC37 Water treatment chemicals
Article Categories [AC]	AC10 Rubber articles AC13 Plastic articles
Environmental release categories [ERC]	ERC1 Manufacture of substances ERC2 Formulation of preparations ERC8a Wide dispersive indoor use of processing aids in open systems ERC8c Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC8d Wide dispersive outdoor use of processing aids in open systems ERC8f Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC10b Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)
Specific Environmental Release Categories SPERC	Not applicable

2.0 Operational conditions and risk management measures		
2.1 Control of worker exposure		
Product characteristics		
Physical form of product	Solid and Liquid	
Concentration of substance in product	Covers concentrations up to 15%	
Human factors not influenced by risk management		
Potential exposure area	Not defined	
Frequency and duration of use		
Exposure duration	Use of coatings and paints containing kieselguhr soda ash flux-calcined	4 – 8 hours
	Use of kieselguhr soda ash flux calcined for filtering water	1 hour/days
	Use of cleaners containing kieselguhr soda-ash	Professional: 60 min/Use Consumer: 20 min/Days

	flux calcined		
Exposure frequency	Use of coatings and paints containing kieselguhr soda ash flux-calcined		225 days per year
	Use of kieselguhr soda ash flux calcined for filtering water		Professional: Weekly Consumer: Monthly
	Use of cleaners containing kieselguhr soda-ash flux calcined		Professional: < 8 Uses per day Consumer: 1 Uses per day
Other operational conditions affecting worker exposure			
Area of use	All contributing scenarios	Indoor	
Characteristics of the surroundings	Professional: Use of coatings and paints containing kieselguhr soda ash flux-calcined	Room volume	1 m³
		Ventilation rate	0.6 / 1 hour(s)
		Release area	200 cm²
	Professional use of hand cleaners	Room volume	2.5 m³
		Ventilation rate	2 / 1 hour(s)
		Release area	5 m²
	All other uses	Not defined	
General measures applicable to all activities Assumes a good basic standard of occupational hygiene is implemented. Assumes use at not more than 20°C above ambient temperature, unless stated differently. Do not breathe dust. Avoid dust generation. Clear spills immediately. After contact with skin, wash immediately with plenty of: Water. Provide basic employee training to prevent / minimize exposures.			
Organisational measures			
All contributing scenarios	Control any potential exposure using measures such as contained or enclosed systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and clear transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; Ensure suitable personal protective equipment is available; Clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.		
Technical conditions of use			
All contributing scenarios	Local exhaust recommended.		
Risk management measures related to human health			
Respiratory protection	All contributing scenarios	Wear respiratory protection.	
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.	
	All contributing scenarios	Wear eye protection with side protection (EN166).	
Other operational conditions affecting worker exposure			
Assumes a good basic standard of occupational hygiene is implemented.			
2.2 Control of environmental exposure			
Amounts used			
Tonnage in EU per year	120, tonnes		

Fraction of EU tonnage used in region:	10 %
Regional use tonnage (tons/year):	12 tonnes
Fraction of Regional tonnage used locally:	Not defined
Annual site tonnage (tons/year):	Not defined
Maximum daily site tonnage (kg/day):	Not defined
Environment factors not influenced by risk management	
Flow rate of receiving surface water (m^3/d):	2000
Local freshwater dilution factor:	10
Local marine water dilution factor:	100
Operational conditions	
Emission days (days/year):	260
Release fraction to air from process (initial release prior to RMM):	0
Release fraction to wastewater from process (initial release prior to RMM):	0.1
Release fraction to soil from process (initial release prior to RMM):	0
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Treat air emission to provide a typical removal efficiency of (%):	Not defined
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of (%):	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.
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of (%):	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.
Treat soil emission to provide a typical removal efficiency of (%):	Not defined
Note: Common practices vary across sites thus conservative process release estimates used. No wastewater treatment required.	
Organisational measures to prevent/limit release from site	
Vent waste air only via suitable separators or scrubbers. Prevent discharge of undissolved substance to or recover from onsite wastewater. Do not apply industrial sludge to natural soils. Sludge should be incinerated, contained or reclaimed.	
Conditions and measures related to municipal sewage treatment plant	
Size of municipal sewage system/treatment plant (m^3/d)	Not defined
Degradation effectiveness (%)	Not defined
Conditions and measures related to external treatment of waste for disposal	
Type of waste	Solid and Liquid
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions. Discharge cleaning water into sewer. Do not discharge cleaning water into small water bodies.
Substance release quantities after risk management measures	
Release to waste water from process (mg/l)	0.012 mg/l
Maximum allowable site tonnage	Not defined

(MSafe) (kg/d):	

3. Exposure estimation and reference to its source						
3.1 Human exposure prediction						
Exposure assessment (method/calculation model)		ECETOC TRA 2010				
Risk characterisation ratio						
					Inhalation	
Type	**Content**	**Local Exhaust Ventilation**	**Duration**	**Process category [PROC]**	**inhalation exposure (mg/m³)**	**Risk characterisation ratio**
Industrial	10%	NO	6	PROC7	0.325	0.903
Professional	95%	NO	6	PROC11	0.325	0.903

Consumer Use	**Long Term inhalation exposure /mg/m³)**	**Short Term inhalation exposure /mg/m3)**	**Risk characterisation ratio (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)	-	37.5	-
Spray painting (pneumatic sprayer)	-	0.676	-
Filtration material	-	0.14	-
Cleaning products	0.00002	-	0.00025

3.2 Environmental exposure prediction	
Exposure assessment (method/calculation model)	
Risk characterisation ratio	
Waste water treatment	$C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}$ $AMOUNT_{STP}$ Amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/Year(s), DAYS Number of release days (365 Days//Year(s)), INHAB Number of inhabitants in EU (500 million inhabitants) $WASTEW_{inhab}$ Wastewater per inhabitant (200 L/day) C_{STP} Concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/l). Estimated STP Concentration (g/L): $C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329$ mg/L
Aquatic Compartment (Pelagic)	Surface Water: 0.333 mg/l marine water: 0.00033 mg/l
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.

Soil	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.
Atmospheric Compartment	No risk is anticipated: Deposition is expected to be low.
Secondary Poisoning	No risk is anticipated: Atmospheric concentrations are expected to be low.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.

4. Evaluation guidance to downstream user		
For scaling see	Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. Available hazard data do not support the need for a DNEL to be established for other health effects. Further details on scaling and control technologies are provided in SpERC factsheet (http://cefic.org/en/reach-for- industries-libraries.html). In accordance with ECHAs recommendations, the “worst case” approach has been taken and only the most stringent RMMs recommended for each route of exposure have been taken.	
Exposure assessment instrument/tool/method	Workers	ECETOC TRA 2010 / RIVM 2008
	Consumer	RIVM 2008
	Environmental exposure	EUSES