

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 1 von 23

Revision date. 26.09.2022

Version 5.1

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Commercial product name: Poliresin
 Product description: Polishing material
 Chemical name: Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
 CAS No.: 68855-54-9
 14464-46-1
 EINECS No.: 272-489-0
 238-455-4
 REACH Registration No.: 01-2119488518-22-0002

1.2 Recommended use of the chemical and restrictions on use

Identified Use(s): 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 | 10 |
| | 2 | 13 |
| | 3 | 16 |
| | 4 | 20 |

Used Advised Against: Anything other than the above.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: SILADENT Dr. Böhme & Schöps GmbH
 Street / mailbox: Im Klei 26
 Country code. / postal code / city: DE - 38644 Goslar
 Phone: +49 (0) 53 21 / 37 79 - 0
 Fax: +49 (0) 53 21 / 38 96 32
 E-mail / Website: info@siladent.de / www.siladent.de
 Further information obtainable from: SILADENT Dr. Böhme & Schöps GmbH

1.4 Emergency telephone number

SILADENT Dr. Böhme & Schöps GmbH: +49 (0) 53 21 / 37 79 - 0 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 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:

Contains: According to Regulation (EC) No. 1272/2008 (CLP)
 Diatomaceous Earth, Flux-Calcined (Kieselguhr)
 (< 1% Crystalline Silica - Cristobolite (Respirable Dust))
 Hazard Pictogram(s): None assigned.
 Signal Word(s): None assigned.

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 2 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

Hazard Statement(s): None assigned.
Precautionary Statement(s): None assigned.

2.3 Other hazards: None.

SECTION 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) | circa. 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.

SECTION 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.

SECTION 5: Firefighting 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.

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 3 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

- 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.

SECTION 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.

SECTION 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.

SECTION 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/m ³) | STEL (ppm) | STEL (mg/m ³) | 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) |

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 4 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

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|---------------|---|---|---|---|---|--|
| Nuisance Dust | - | - | 4 | - | - | Respirable Dust. WEL: Workplace Exposure Limit (UK HSE EH40) |
|---------------|---|---|---|---|---|--|

Source: 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/m ³ | - |
| Consumer - Long Term - Systemic effects | 18.7 mg/kg bw/day | 0.05 mg/m ³ | - |

8.2 Exposure controls

8.2.1 Appropriate engineering controls: Ensure adequate ventilation. Atmospheric levels should be controlled in compliance with the occupational exposure 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.

SECTION 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

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 5 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|---|---|
| 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/cm ³ (H ₂ O = 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. |
| Particle Characteristics: | Not available. |

9.2 Other information: None.

SECTION 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. |

SECTION 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. |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 6 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|--|---|
| 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 Information on other hazards | |
| 11.2.1 Endocrine disrupting properties: | This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria. |
| Other information: | <p>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.</p> <p>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</p> |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 7 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

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).

SECTION 12: Ecological information

| | | |
|------|--|---|
| 12.1 | Toxicity: | Not classified as Marine Pollutant. |
| 12.2 | Persistence and degradability: | Not applicable. |
| 12.3 | Bioaccumulative potential: | The product 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 | Endocrine disrupting properties: | This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria |
| 12.7 | Other adverse effects: | None known. |

SECTION 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. Ensure all waste water is collected and treated via a waste water treatment plant. |
| 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. |

SECTION 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. |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 8 von 23

Revision date: 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

Additional information: None.

SECTION 15: Regulatory information

15.1 Safety, Health and Environmental Regulations/Legislation specific for the substance or mixture

15.1.1 EU regulations

Authorisations and/or restrictions on use: None.

15.1.2 National regulations

Germany: Water hazard class: nwg

15.2 Chemical safety assessment:

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

SECTION 16: Other information

The following sections contain revisions or new statements:

New SDS Regulation 2020/878 format, all sections have been updated to include new information. Please review SDS with care.

References:

Existing Safety Data Sheet (SD), Existing ECHA registration(s) for Diatomaceous Earth (Kieselguhr), soda Flux-Calcined (CAS No. 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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MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 9 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

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 |
| Exposure scenario 4 | Consumer use; Cosmetics, personal care products |

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 | | |
|---------------------|--|-------|
| Number of the ES | Title | Page: |
| Exposure scenario 1 | Manufacture of kieselguhr soda ash flux calcined | 10 |
| Exposure scenario 2 | Use as filter aid in industrial settings | 13 |
| Exposure scenario 3 | Industrial, professional and private use of substance or mixtures containing the substance | 16 |
| Exposure scenario 4 | Consumer use; Cosmetics, personal care products | 20 |

Contributing Scenarios

PROC Codes

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 10 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|--------|--|
| 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 |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 11 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | | |
|---|---|--|
| 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 (m³/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. | |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 12 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| 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 (m³/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 |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 13 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

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) | |

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) &

Seite 14 von 23

2020/878

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|---|---|
| | <p>PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities</p> <p>PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities</p> <p>PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)</p> <p>PROC15 Use as laboratory reagent</p> <p>PROC19 Hand-mixing with intimate contact and only PPE available</p> |
| Chemical product category [PC] | <p>PC0 Other Filtration material PC2 Adsorbents</p> <p>PC14 Metal surface treatment products, including galvanic and electroplating products PC20 Products such as ph-regulators, flocculants, precipitants, neutralization agents PC25 Metal working fluids</p> <p>PC35 Washing and cleaning products (including solvent based products)</p> |
| Article Categories [AC] | Not applicable |
| Environmental release categories [ERC] | <p>ERC1 Manufacture of substances ERC2 Formulation of preparations</p> <p>ERC4 Industrial use of processing aids in processes and products, not becoming part of articles. ERC6b Industrial use of reactive processing aids</p> <p>ERC7 Industrial use of substances in closed systems</p> |
| 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 | <p>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;</p> |
|----------------------------|--|

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 15 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | | |
|---|--|--|
| | 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 (m³/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 | The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the | |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 16 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|---|--|
| onsite wastewater removal efficiency of (%): | 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 (m³/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) |
| 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. | | |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 17 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | | |
|---|--|-----------------|
| 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 | |

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 18 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|---|---|
| | 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 flux calcined | Professional: 60 min/Use Consumer: 20 min/Days |
| 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 m ³ |
| | | Ventilation rate | 0.6 / 1 hour(s) |
| | | Release area | 200 cm ² |
| | Professional use of hand cleaners | Room volume | 2.5 m ³ |
| | | Ventilation rate | 2 / 1 hour(s) |
| | | Release area | 5 m ² |
| | 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

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 19 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | | |
|---|---|--|
| 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. |
| 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 | | |
| 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 (m³/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 | |

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 20 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | |
|--|--|
| 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 (m³/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 (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 | | | | |
|--|---------|---------------------------|----------|-------------------------|-----------------------------|-----------------------------|
| Risk characterisation ratio | | | | | | |
| 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 |

| | | | |
|------------------------------------|----------|-------|--------|
| 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 | - |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 21 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| | | | |
|-------------------|---------|---|---------|
| 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} = $\frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \text{ mg/L}$ | |

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 |

According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 22 von 23

Revision date. 26.09.2022

Version 5.1

Printing date: 05.04.2023

Poliresin®

| Exposure Scenario 4 – Consumer use; Cosmetics, personal care products | |
|--|---|
| 1.0 Contributing Scenarios | |
| Sector of uses SU | SU21 Consumer uses: Private households (= general public = consumers) |
| Process category [PROC] | Not applicable |
| Chemical product category [PC] | PC39 Cosmetics, personal care products |
| Article Categories [AC] | Not applicable |
| Environmental release categories [ERC] | ERC8a Wide dispersive indoor use of processing aids in open 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 | Not defined |
| Concentration of substance in product | Not defined |
| Conditions of use affecting exposure | |
| In accordance to the Article 14 (5b) of the REACH Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC. | |
| Risk management measures | |
| Respiratory protection | No specific measures identified. |
| Hand/Skin protection | No specific measures identified. |
| Eye Protection | No specific measures identified. |
| 2.2 Control of environmental exposure | |
| Conditions of use affecting exposure | |
| Daily local widespread use amount | < 300 g/Day |
| Dispose of waste product or used containers according to local regulations. Waste water of facility is assumed to be treated in municipal waste water treatment. | |

| 3. Exposure estimation and reference to its source | | |
|--|------------------------------------|-----------------------------|
| 3.1 Human exposure prediction | | |
| In accordance to the Article 14 (5b) of the REACH Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC. | | |
| 3.2 Environmental exposure prediction | | |
| Exposure assessment (method/calculation model) | EUSES | |
| Environmental Release | | |
| Water | 0.302 kg/day (ERC) | |
| Air | 0.302 kg/day (ERC) | |
| Soil | 0 kg/day (ERC) | |
| Risk characterisation ratio | | |
| Protection target | Exposure estimation | Risk characterisation ratio |
| Sewage Treatment Plant | 0.151 mg/l (EUSES 2.1.2) | < 0.01 |
| Man via environment - Inhalation | 2.06E-6 mg/m³ (EUSES 2.1.2) | < 0.01 |
| Man via environment - Oral | 5.67E-4 mg/kg bw/day (EUSES 2.1.2) | < 0.01 |
| Man via environment - Combined | - | < 0.01 |

MATERIAL SAFETY DATA SHEET



According to Regulation (EC) 1907/2006, (REACH), 1272/2008 (CLP) & 2020/878

Seite 23 von 23

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4. Evaluation guidance to downstream user

If safe use conditions stated in the exposure scenario cannot be enforced, alternatives measures must be equivalent or better than those stated in this exposure scenario

For scaling see

EUSES v. 2.1.2

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.