



Mach-2® Die-Silicone (Base)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 30 November 2022 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Mach-2® Die-Silicone (Base)
Product code : S432S, Various

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Trained Dental Clinicians
Use of the substance/mixture : Impression Material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Parkell Inc.
300 Executive Drive
Edgewood, NY 11717
T (631) 249-1134
Info@parkell.com

Authorized Representative in Europe (Regulatory affairs only)
Directa AB
Finvids väg 8
SE-194 27 Upplands Väsby
Sweden

1.4. Emergency telephone number

Emergency number : INFOTRAC 1-352-323-3500 (International); INFOTRAC 1-800-535-5053 (North America)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Silica, cristobalite substance with a Community workplace exposure limit	CAS-No.: 14464-46-1 EC-No.: 238-455-4	55	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Move the affected person away from the contaminated area and into the fresh air. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Wash with water and soap as a precaution. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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

Symptoms/effects	: No adverse effects expected.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Presents no particular fire or explosion hazard.
Explosion hazard	: No hazard identified.
Hazardous decomposition products in case of fire	: Thermal decomposition may produce : Silicon oxides. Carbon oxides (CO, CO2).

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protective equipment for firefighters	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No additional risk management measures required.
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6.1.1. For non-emergency personnel

Protective equipment : No special protection required.
Emergency procedures : No special requirements.

6.1.2. For emergency responders

Protective equipment : No special protection required.
Emergency procedures : No special requirements.

6.2. Environmental precautions

No special environmental precautions required.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : Wipe up with absorbent material (for example cloth). No special decontamination procedures needed.
Other information : Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Read instructions/label before use. Observe the label precautions. Ensure adequate ventilation.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep container closed when not in use.
Incompatible materials : Strong oxidizing agents. Strong acids.

7.3. Specific end use(s)

For further information see section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Silica, cristobalite (14464-46-1)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Silica crystalline (Cristobalite)
IOEL TWA	0.05 mg/m ³ (respirable dust)
Remark	(Year of adoption 2003)
Regulatory reference	SCOEL Recommendations
Austria - Occupational Exposure Limits	
Local name	Quarzfeinstaub: Cristobalit (alveolengängiges kristallines Siliziumdioxid)
MAK (OEL TWA)	0.05 mg/m ³ (alveolar dust, respirable fraction (Quartz))
Remark	Krebserzeugend: III C

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Silica, cristobalite (14464-46-1)	
OEL chemical category	Group C Carcinogen alveolar dust
Regulatory reference	BGBI. II Nr. 156/2021
Belgium - Occupational Exposure Limits	
Local name	Silices cristallines: cristobalite (poussières alvéolaires) # Siliciumdioxide (kristallijn): cristobaliet (inadempbaar stof)
OEL TWA	0.05 mg/m ³ (alveolar dust)
Remark	C: la mention "C" signifie que l'agent en question relève du champ d'application du titre 2 relatif aux agents cancérogènes, mutagènes et reprotoïques du livre VI du code de bien-être au travail. # C: de vermelding "C" betekent dat het betrokken agens valt onder het toepassingsgebied van titel 2 betreffende kankerverwekkende, mutagene en reprotoxische agentia van boek VI van de codex over het welzijn op het werk.
OEL chemical category	Carcinogen alveolar dust
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021
Croatia - Occupational Exposure Limits	
Local name	Kristalni SiO ₂ (kristobalit)
GVI (OEL TWA) [1]	0.05 mg/m ³
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
Czech Republic - Occupational Exposure Limits	
Local name	Kristobalit
PEL (OEL TWA)	0.1 mg/m ³ (respirable fraction)
Remark	Prachy s převážně fibrogenným účinkem.
Regulatory reference	Nařízení vlády č. 361/2007 Sb. (Předpis 195/2021 Sb.)
Denmark - Occupational Exposure Limits	
Local name	Christobalit
OEL TWA [1]	0.15 mg/m ³ (total) 0.05 mg/m ³ (respirable)
Remark	K (betyder, at stoffet anses for at kunne være kræftfremkaldende)
Regulatory reference	BEK nr 1054 af 28/06/2022
Estonia - Occupational Exposure Limits	
Local name	Kristobaliit
OEL TWA	0.05 mg/m ³ (respirable dust)
Remark	1 (Peentolm koosneb alla 2,5-mikromeetrise läbimõõduga osakestest, mis võivad jõuda koos sissehingatava õhuga kopsu alveoolidesse (respireeritav fraktsioon)), C (Kantserogeenne aine)
OEL chemical category	Carcinogenic substance respirable dust
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 15.05.2021, 1)
Finland - Occupational Exposure Limits	
Local name	Kristobaliitti
HTP (OEL TWA) [1]	0.05 mg/m ³ (respirable dust (Silicon dioxide, crystalline))
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveystieteiden ministeriö)

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Silica, cristobalite (14464-46-1)	
France - Occupational Exposure Limits	
Local name	Silice (poussières alvéolaires de cristobalite)
VME (OEL TWA)	0.05 mg/m³ (restrictive limit-alveolar fraction)
Remark	Valeurs réglementaires contraignantes
Regulatory reference	Article R4412-149 du Code du travail (réf.: INRS ED 984, 2016; Décret n° 2019-1487; Décret n° 2020-1546; Décret n° 2021-434; Décret n° 2021-1849)
Hungary - Occupational Exposure Limits	
AK (OEL TWA)	0.1 mg/m³ (respirable (flying and fibrous powders))
Ireland - Occupational Exposure Limits	
Local name	Cristobalite, respirable dust
OEL TWA [1]	0.1 mg/m³ (respirable dust)
OEL STEL	0.3 mg/m³ (calculated-respirable dust)
Remark	BOELV (Binding Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021
Lithuania - Occupational Exposure Limits	
Local name	Kristobalitas (silicio dioksido atmaina)
IPRV (OEL TWA)	0.05 mg/m³ (respirable fraction)
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Netherlands - Occupational Exposure Limits	
Local name	Respirabel kristallijn silicastof: – cristoballiet
TGG-8u (OEL TWA)	0.075 mg/m³ (respirable fraction (Silica, crystalline))
Remark	Kankerverwekkende stof
Regulatory reference	Arbeidsomstandighedenregeling 2022
Poland - Occupational Exposure Limits	
Local name	Krzemionka krystaliczna – krystobalit
NDS (OEL TWA)	0.1 mg/m³ (respirable fraction)
Remark	Frakcja respirabilna – frakcja aerozolu wnikaćca do dróg oddechowych, która stwarza zagrożenie dla zdrowia po zdeponowaniu w obszarze wymiany gazowej.
Regulatory reference	Dz. U. 2018 poz. 1286
Portugal - Occupational Exposure Limits	
OEL TWA	0.025 mg/m³ (respirable fraction)
OEL chemical category	A2 - Suspected Human Carcinogen
Spain - Occupational Exposure Limits	
Local name	Sílice Cristalina: Cristobalita
VLA-ED (OEL TWA) [1]	0.05 mg/m³ (reclassified IARC group 2A to group 1-respirable fraction)
Remark	v (Agente cancerígeno con valor límite vinculante recogido en el anexo III del Real Decreto 665/1997 y en sus modificaciones posteriores), d (Véase UNE EN 481: Atmosferas en los puestos de trabajo. Definición de las fracciones por el tamaño de las partículas para la medición de aerosoles), y (Reclasificado, por la International Agency for Research on Cancer (IARC) de grupo 2A (probablemente carcinogénico en humanos) a grupo 1 (carcinogénico en humanos)).

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Silica, cristobalite (14464-46-1)	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT
Sweden - Occupational Exposure Limits	
Local name	Kristobalit
NGV (OEL TWA)	0.05 mg/m ³ (respirable fraction)
Remark	C (Ämnet är cancerframkallande. Risk för cancer finns även vid annan exponering än via inandning. För vissa cancerframkallande ämnen som inte har gränsvärden gäller förbud eller tillståndskrav enligt föreskrifterna om kemiska arbetsmiljörisker); M (Medicinska kontroller kan krävas för hantering av ämnet. Se vidare föreskrifterna om medicinska kontroller i arbetslivet. För vissa ämnen ska arbetsgivaren erbjuda läkarundersökning och för andra ämnen gäller krav på periodisk läkarundersökning och tjänstbarhetsbedömning); 3 (Den respirabla fraktionen är de inhaleda partiklar som når längst ner i luftvägarna, till alveolerna i lungorna)
OEL chemical category	Carcinogen
Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)
Norway - Occupational Exposure Limits	
Local name	Kristobalitt
Grenseverdi (OEL TWA) [1]	0.05 mg/m ³ (dust containing .alpha.-Quartz, Cristobalite and/or Tridymite is evaluated by summation formula. At the same time, the values for Nuisance dust must be observed-respirable dust) 0.1 mg/m ³ (the Other mining and quarrying (industry code 08) and Civil engineering (industry code 42) valid until February 1, 2022-respirable dust) 0.15 mg/m ³ (dust containing .alpha.-Quartz, Cristobalite and/or Tridymite is evaluated by summation formula. At the same time, the values for Nuisance dust must be observed-total dust)
Kortidsverdi (OEL STEL)	0.15 mg/m ³ (value calculated-respirable dust) 0.45 mg/m ³ (value calculated-total dust) 0.3 mg/m ³ (value calculated-respirable dust)
Remark	Totalstøv: K: Kjemikalier som skal betraktes som kreftfremkallende; 7) Støv som inneholder α-kvarts, kristobalitt og/eller tridymitt vurderes ut fra summasjonsformel. Samtidig må verdiene for sjenerende støv overholdes. Respirabelt støv: K: Kjemikalier som skal betraktes som kreftfremkallende; G: EU har fastsatt en bindende grenseverdi og/eller anmerkning for stoffet; 7) Støv som inneholder α-kvarts, kristobalitt og/eller tridymitt vurderes ut fra summasjonsformel. Samtidig må verdiene for sjenerende støv overholdes.
OEL chemical category	Carcinogen
Regulatory reference	FOR-2021-06-28-2248
USA - ACGIH - Occupational Exposure Limits	
Local name	Silica crystalline - cristobalite
ACGIH OEL TWA	0.025 mg/m ³ (respirable particulate matter)
Remark (ACGIH)	TLV® Basis: Pulm fibrosis; lung cancer. Notations: A2 (Suspected Human Carcinogen)
ACGIH chemical category	Suspected Human Carcinogen
Regulatory reference	ACGIH 2022

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

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8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure adequate ventilation.

8.2.2. Personal protection equipment

Personal protective equipment:

Not required for normal conditions of use. Normal use of this product shall imply use in accordance with the instructions on the packaging. Read instructions/label before use. Observe the label precautions.

8.2.2.1. Eye and face protection

Eye protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.2. Skin protection

Skin and body protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.3. Respiratory protection

Respiratory protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Do not discharge into drains or the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Beige, orange, grey
Appearance	: Paste.
Odour	: Odourless
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available

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Density	: Not available
Relative density	: > 1
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

Strong acids. Strong oxidizing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce : Carbon oxides (CO, CO₂). Silicon oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met) Silica is in a form that is not available for respiration

Silica, cristobalite (14464-46-1)

IARC group	1 - Carcinogenic to humans
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)

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STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: None known
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11.2.2. Other information

Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye
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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Silica, cristobalite (14464-46-1)

Partition coefficient n-octanol/water (Log Pow)	0.53 Source: QSAR
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

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POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

- | | |
|--|---|
| Employment restrictions | : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG). |
| Water hazard class (WGK) | : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1). |
| Hazardous Incident Ordinance (12. BImSchV) | : Is not subject of the Hazardous Incident Ordinance (12. BImSchV) |

Netherlands

- | | |
|---|-------------------------------------|
| SZW-lijst van kankerverwekkende stoffen | : Silica, cristobalite is listed |
| SZW-lijst van mutagene stoffen | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen – Borstvoeding | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen –
Vruchtbaarheid | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen – Ontwikkeling | : None of the components are listed |

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

No additional information available

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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Issue date: 30 November 2022 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Mach-2® Die-Silicone (Catalyst)
Product code : S432S, Various

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Trained Dental Clinicians
Use of the substance/mixture : Impression Material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Parkell Inc.
300 Executive Drive
Edgewood, NY 11717
T (631) 249-1134
Info@parkell.com

Authorized Representative in Europe (Regulatory affairs only)
Directa AB
Finvids väg 8
SE-194 27 Upplands Väsby
Sweden

1.4. Emergency telephone number

Emergency number : INFOTRAC 1-352-323-3500 (International); INFOTRAC 1-800-535-5053 (North America)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Silica, cristobalite substance with a Community workplace exposure limit	CAS-No.: 14464-46-1 EC-No.: 238-455-4	60	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Move the affected person away from the contaminated area and into the fresh air. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Wash with water and soap as a precaution. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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

Symptoms/effects	: No adverse effects expected.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Presents no particular fire or explosion hazard.
Explosion hazard	: No hazard identified.
Hazardous decomposition products in case of fire	: Thermal decomposition may produce : Silicon oxides. Carbon oxides (CO, CO ₂).

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protective equipment for firefighters	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No additional risk management measures required.
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6.1.1. For non-emergency personnel

Protective equipment : No special protection required.
Emergency procedures : No special requirements.

6.1.2. For emergency responders

Protective equipment : No special protection required.
Emergency procedures : No special requirements.

6.2. Environmental precautions

No special environmental precautions required.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : Wipe up with absorbent material (for example cloth). No special decontamination procedures needed.
Other information : Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Read instructions/label before use. Observe the label precautions. Ensure adequate ventilation.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep container closed when not in use.
Incompatible materials : Strong oxidizing agents. Strong acids.

7.3. Specific end use(s)

For further information see section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Silica, cristobalite (14464-46-1)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Silica crystalline (Cristobalite)
IOEL TWA	0.05 mg/m ³ (respirable dust)
Remark	(Year of adoption 2003)
Regulatory reference	SCOEL Recommendations
Austria - Occupational Exposure Limits	
Local name	Quarzfeinstaub: Cristobalit (alveolengängiges kristallines Siliziumdioxid)
MAK (OEL TWA)	0.05 mg/m ³ (alveolar dust, respirable fraction (Quartz))
Remark	Krebserzeugend: III C

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Silica, cristobalite (14464-46-1)	
OEL chemical category	Group C Carcinogen alveolar dust
Regulatory reference	BGBI. II Nr. 156/2021
Belgium - Occupational Exposure Limits	
Local name	Silices cristallines: cristobalite (poussières alvéolaires) # Siliciumdioxide (kristallijn): cristobaliet (inadempbaar stof)
OEL TWA	0.05 mg/m ³ (alveolar dust)
Remark	C: la mention "C" signifie que l'agent en question relève du champ d'application du titre 2 relatif aux agents cancérigènes, mutagènes et reprotoïques du livre VI du code de bien-être au travail. # C: de vermelding "C" betekent dat het betrokken agens valt onder het toepassingsgebied van titel 2 betreffende kankerverwekkende, mutagene en reprotoxische agentia van boek VI van de codex over het welzijn op het werk.
OEL chemical category	Carcinogen alveolar dust
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021
Croatia - Occupational Exposure Limits	
Local name	Kristalni SiO ₂ (kristobalit)
GVI (OEL TWA) [1]	0.05 mg/m ³
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
Czech Republic - Occupational Exposure Limits	
Local name	Kristobalit
PEL (OEL TWA)	0.1 mg/m ³ (respirable fraction)
Remark	Prachy s převážně fibrogenným účinkem.
Regulatory reference	Nařízení vlády č. 361/2007 Sb. (Předpis 195/2021 Sb.)
Denmark - Occupational Exposure Limits	
Local name	Christobalit
OEL TWA [1]	0.15 mg/m ³ (total) 0.05 mg/m ³ (respirable)
Remark	K (betyder, at stoffet anses for at kunne være kræftfremkaldende)
Regulatory reference	BEK nr 1054 af 28/06/2022
Estonia - Occupational Exposure Limits	
Local name	Kristobaliit
OEL TWA	0.05 mg/m ³ (respirable dust)
Remark	1 (Peentolm koosneb alla 2,5-mikromeetrise läbimõõduga osakestest, mis võivad jõuda koos sissehingatava õhuga kopsu alveoolidesse (respireeritav fraktsioon)), C (Kantserogeenne aine)
OEL chemical category	Carcinogenic substance respirable dust
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 15.05.2021, 1)
Finland - Occupational Exposure Limits	
Local name	Kristobaliitti
HTP (OEL TWA) [1]	0.05 mg/m ³ (respirable dust (Silicon dioxide, crystalline))
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveystieteiden ministeriö)

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Silica, cristobalite (14464-46-1)	
France - Occupational Exposure Limits	
Local name	Silice (poussières alvéolaires de cristobalite)
VME (OEL TWA)	0.05 mg/m³ (restrictive limit-alveolar fraction)
Remark	Valeurs réglementaires contraignantes
Regulatory reference	Article R4412-149 du Code du travail (réf.: INRS ED 984, 2016; Décret n° 2019-1487; Décret n° 2020-1546; Décret n° 2021-434; Décret n° 2021-1849)
Hungary - Occupational Exposure Limits	
AK (OEL TWA)	0.1 mg/m³ (respirable (flying and fibrous powders))
Ireland - Occupational Exposure Limits	
Local name	Cristobalite, respirable dust
OEL TWA [1]	0.1 mg/m³ (respirable dust)
OEL STEL	0.3 mg/m³ (calculated-respirable dust)
Remark	BOELV (Binding Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021
Lithuania - Occupational Exposure Limits	
Local name	Kristobalitas (silicio dioksido atmaina)
IPRV (OEL TWA)	0.05 mg/m³ (respirable fraction)
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Netherlands - Occupational Exposure Limits	
Local name	Respirabel kristallijn silicastof: – cristoballiet
TGG-8u (OEL TWA)	0.075 mg/m³ (respirable fraction (Silica, crystalline))
Remark	Kankerverwekkende stof
Regulatory reference	Arbeidsomstandighedenregeling 2022
Poland - Occupational Exposure Limits	
Local name	Krzemionka krystaliczna – krystobalit
NDS (OEL TWA)	0.1 mg/m³ (respirable fraction)
Remark	Frakcja respirabilna – frakcja aerozolu wnikaćca do dróg oddechowych, która stwarza zagrożenie dla zdrowia po zdeponowaniu w obszarze wymiany gazowej.
Regulatory reference	Dz. U. 2018 poz. 1286
Portugal - Occupational Exposure Limits	
OEL TWA	0.025 mg/m³ (respirable fraction)
OEL chemical category	A2 - Suspected Human Carcinogen
Spain - Occupational Exposure Limits	
Local name	Sílice Cristalina: Cristobalita
VLA-ED (OEL TWA) [1]	0.05 mg/m³ (reclassified IARC group 2A to group 1-respirable fraction)
Remark	v (Agente cancerígeno con valor límite vinculante recogido en el anexo III del Real Decreto 665/1997 y en sus modificaciones posteriores), d (Véase UNE EN 481: Atmosferas en los puestos de trabajo. Definición de las fracciones por el tamaño de las partículas para la medición de aerosoles), y (Reclasificado, por la International Agency for Research on Cancer (IARC) de grupo 2A (probablemente carcinogénico en humanos) a grupo 1 (carcinogénico en humanos)).

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Silica, cristobalite (14464-46-1)	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT
Sweden - Occupational Exposure Limits	
Local name	Kristobalit
NGV (OEL TWA)	0.05 mg/m ³ (respirable fraction)
Remark	C (Ämnet är cancerframkallande. Risk för cancer finns även vid annan exponering än via inandning. För vissa cancerframkallande ämnen som inte har gränsvärden gäller förbud eller tillståndskrav enligt föreskrifterna om kemiska arbetsmiljörisker); M (Medicinska kontroller kan krävas för hantering av ämnet. Se vidare föreskrifterna om medicinska kontroller i arbetslivet. För vissa ämnen ska arbetsgivaren erbjuda läkarundersökning och för andra ämnen gäller krav på periodisk läkarundersökning och tjänstbarhetsbedömning); 3 (Den respirabla fraktionen är de inhaleda partiklar som når längst ner i luftvägarna, till alveolerna i lungorna)
OEL chemical category	Carcinogen
Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)
Norway - Occupational Exposure Limits	
Local name	Kristobalitt
Grenseverdi (OEL TWA) [1]	0.05 mg/m ³ (dust containing .alpha.-Quartz, Cristobalite and/or Tridymite is evaluated by summation formula. At the same time, the values for Nuisance dust must be observed-respirable dust) 0.1 mg/m ³ (the Other mining and quarrying (industry code 08) and Civil engineering (industry code 42) valid until February 1, 2022-respirable dust) 0.15 mg/m ³ (dust containing .alpha.-Quartz, Cristobalite and/or Tridymite is evaluated by summation formula. At the same time, the values for Nuisance dust must be observed-total dust)
Korttidsverdi (OEL STEL)	0.15 mg/m ³ (value calculated-respirable dust) 0.45 mg/m ³ (value calculated-total dust) 0.3 mg/m ³ (value calculated-respirable dust)
Remark	Totalstøv: K: Kjemikalier som skal betraktes som kreftfremkallende; 7) Støv som inneholder α-kvarts, kristobalitt og/eller tridymitt vurderes ut fra summasjonsformel. Samtidig må verdiene for sjenerende støv overholdes. Respirabelt støv: K: Kjemikalier som skal betraktes som kreftfremkallende; G: EU har fastsatt en bindende grenseverdi og/eller anmerkning for stoffet; 7) Støv som inneholder α-kvarts, kristobalitt og/eller tridymitt vurderes ut fra summasjonsformel. Samtidig må verdiene for sjenerende støv overholdes.
OEL chemical category	Carcinogen
Regulatory reference	FOR-2021-06-28-2248
USA - ACGIH - Occupational Exposure Limits	
Local name	Silica crystalline - cristobalite
ACGIH OEL TWA	0.025 mg/m ³ (respirable particulate matter)
Remark (ACGIH)	TLV® Basis: Pulm fibrosis; lung cancer. Notations: A2 (Suspected Human Carcinogen)
ACGIH chemical category	Suspected Human Carcinogen
Regulatory reference	ACGIH 2022

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

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8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure adequate ventilation.

8.2.2. Personal protection equipment

Personal protective equipment:

Not required for normal conditions of use. Normal use of this product shall imply use in accordance with the instructions on the packaging. Read instructions/label before use. Observe the label precautions.

8.2.2.1. Eye and face protection

Eye protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.2. Skin protection

Skin and body protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.3. Respiratory protection

Respiratory protection:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Do not discharge into drains or the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Beige, orange, grey
Appearance	: Paste.
Odour	: Odourless
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available

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Density	: Not available
Relative density	: >1
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

Strong acids. Strong oxidizing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce : Carbon oxides (CO, CO₂). Silicon oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met) Silica is in a form that is not available for respiration

Silica, cristobalite (14464-46-1)

IARC group	1 - Carcinogenic to humans
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)

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STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: None known
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11.2.2. Other information

Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye
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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Silica, cristobalite (14464-46-1)

Partition coefficient n-octanol/water (Log Pow)	0.53 Source: QSAR
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

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POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

- | | |
|--|---|
| Employment restrictions | : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG). |
| Water hazard class (WGK) | : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1). |
| Hazardous Incident Ordinance (12. BImSchV) | : Is not subject of the Hazardous Incident Ordinance (12. BImSchV) |

Netherlands

- | | |
|---|-------------------------------------|
| SZW-lijst van kankerverwekkende stoffen | : Silica, cristobalite is listed |
| SZW-lijst van mutagene stoffen | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen – Borstvoeding | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen –
Vruchtbaarheid | : None of the components are listed |
| SZW-lijst van reprotoxische stoffen – Ontwikkeling | : None of the components are listed |

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

No additional information available

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.