



Blu-Mousse® and Green-Mousse® Bite Registration – Catalyst

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 7 November 2022 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Blu-Mousse® and Green-Mousse® Bite Registration – Catalyst
Product code : S457, 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 : Occlusal Registration/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

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

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.
Symptoms/effects after eye contact	: May cause slight temporary irritation.

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.
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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

Carbonic acid, calcium salt (1:1) (471-34-1)	
Belgium - Occupational Exposure Limits	
OEL TWA	10 mg/m ³
Croatia - Occupational Exposure Limits	
Local name	Kalcijev karbonat
GVI (OEL TWA) [1]	10 mg/m ³ (total dust, inhalable particles) 4 mg/m ³ (respirable dust)
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	
PEL (OEL TWA)	10 mg/m ³
Estonia - Occupational Exposure Limits	
OEL TWA	10 mg/m ³

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Carbonic acid, calcium salt (1:1) (471-34-1)	
Finland - Occupational Exposure Limits	
HTP (OEL TWA) [1]	10 mg/m ³
France - Occupational Exposure Limits	
Local name	Calcium (carbonate de) (Calcite) (Marbre)
VME (OEL TWA)	10 mg/m ³
Remark	Valeurs recommandées/admises
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)
Greece - Occupational Exposure Limits	
OEL TWA	10 mg/m ³
Hungary - Occupational Exposure Limits	
AK (OEL TWA)	10 mg/m ³
Ireland - Occupational Exposure Limits	
OEL TWA [1]	10 mg/m ³
Latvia - Occupational Exposure Limits	
Local name	Kalcija karbonāts
OEL TWA	6 mg/m ³
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)
Poland - Occupational Exposure Limits	
Local name	Węglan wapnia
NDS (OEL TWA)	10 mg/m ³ (inhalable fraction)
Remark	Frakcja wdychalna – frakcja aerozolu wnikająca przez nos i usta, która po zdeponowaniu w drogach oddechowych stwarza zagrożenie dla zdrowia.
Regulatory reference	Dz. U. 2018 poz. 1286
Portugal - Occupational Exposure Limits	
OEL TWA	10 mg/m ³ (particulate matter containing no Asbestos and <1% Crystalline silica)
Romania - Occupational Exposure Limits	
OEL TWA	10 mg/m ³
Slovakia - Occupational Exposure Limits	
NPHV (OEL TWA) [1]	10 mg/m ³
Aluminum oxide (Al₂O₃) (1344-28-1)	
Austria - Occupational Exposure Limits	
Local name	Aluminiumoxid
MAK (OEL TWA)	5 mg/m ³ (respirable fraction, smoke)
MAK (OEL STEL)	10 mg/m ³ (respirable fraction) 10 mg/m ³ (respirable fraction, smoke)
Regulatory reference	BGBl. II Nr. 156/2021
Austria - Biological limit values	
Local name	Aluminiumoxid-haltige Stäube und Rauche
BLV	60 µg/g creatinine Parameter: Aluminium - Untersuchungsmaterial: Harn

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Aluminum oxide (Al₂O₃) (1344-28-1)	
Remark	Eignung mit vorzeitiger Folgeuntersuchung: Bei Überschreiten des Grenzwertes für Aluminium im Harn. Bei Vorliegen einer wesentlichen Beeinträchtigung der Lungenfunktion. Diese liegt vor, wenn nach mehrmaliger Messung der beste gemessene Wert den für den/die Untersuchte/n maßgebenden Sollwert um 20% unterschreitet, bzw. den MEF50-Sollwert um 50% unterschreitet. Eine vorzeitige Folgeuntersuchung ist jedoch nicht erforderlich, wenn im Vergleich zu Vorbefunden der altersabhängige physiologische Abfall der 1 Sekundenkapazität (FEV1) von 40 ml/Jahr nicht überschritten wird oder aus der Beurteilung des Kurvenverlaufes der Forcierten Vitalkapazität (FVC) eine eingeschränkte Mitarbeit des Untersuchten/der Untersuchten ersichtlich ist. Der Zeitabstand zwischen den Untersuchungen beträgt bei Eignung: ein Jahr; bei Eignung mit vorzeitiger Folgeuntersuchung: sechs Monate.
Regulatory reference	Verordnung über die Gesundheitsüberwachung am Arbeitsplatz 2017 (VGÜ 2017)
Belgium - Occupational Exposure Limits	
Local name	Aluminium (métal et composés insolubles, fraction alvéolaire) # Aluminium (metaal en onoplosbare verbindingen, inadembare fractie)
OEL TWA	1 mg/m ³
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021
Croatia - Occupational Exposure Limits	
Local name	Aluminijev oksid
GVI (OEL TWA) [1]	10 mg/m ³ (total dust, inhalable particles) 4 mg/m ³ (respirable dust)
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
Denmark - Occupational Exposure Limits	
Local name	Aluminiumoxid
OEL TWA [1]	5 mg/m ³ (total) 2 mg/m ³ (respirable)
Regulatory reference	BEK nr 1054 af 28/06/2022
Estonia - Occupational Exposure Limits	
Local name	Alumiinium, metalliline ja oksiidid
OEL TWA	10 mg/m ³ (total dust) 4 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))
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 15.05.2021, 1)
France - Occupational Exposure Limits	
Local name	Aluminium (Trioxyde de di-)
VME (OEL TWA)	10 mg/m ³
Remark	Valeurs recommandées/admises
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)
Germany - Occupational Exposure Limits (TRGS 900)	
AGW (OEL TWA) [1]	1.25 mg/m ³ (fiber-free, except Aluminum oxide smoke-respirable fraction (dust)) 10 mg/m ³ (fiber-free, except Aluminum oxide smoke-inhalable fraction (dust))
Greece - Occupational Exposure Limits	
Local name	Αλουμίνα, α-

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Aluminum oxide (Al ₂ O ₃) (1344-28-1)	
OEL TWA	10 mg/m ³ (inhalable fraction) 5 mg/m ³ (respirable fraction)
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους
Hungary - Occupational Exposure Limits	
Local name	ALUMÍNIUM OXID (Al-ra számitva)
AK (OEL TWA)	5 mg/m ³ 2 mg/m ³ respirábilis frakció
Remark	N (Irritáló anyagok, egyszerű fojtógázok, csekély egészségkárosító hatással bíró anyagok)
Regulatory reference	5/2020. (II. 6.) ITM rendelet - A kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
Ireland - Occupational Exposure Limits	
Local name	Aluminium oxides
OEL TWA [1]	10 mg/m ³ total inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	Chemical Agents Code of Practice 2021
Latvia - Occupational Exposure Limits	
Local name	Alumīnija oksīds
OEL TWA	6 mg/m ³ dezintegrācijas aerosola veidā 4 mg/m ³ maisījumā ar niķeli (līdz 15%), (elektrokorunds)
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)
Lithuania - Occupational Exposure Limits	
IPRV (OEL TWA)	5 mg/m ³ (inhalable fraction) 2 mg/m ³ (respirable fraction)
Poland - Occupational Exposure Limits	
Local name	Tritlenek glinu
NDS (OEL TWA)	2.5 mg/m ³ (inhalable fraction) 1.2 mg/m ³ (respirable fraction)
Remark	Frakcja wdychalna – frakcja aerozolu wnikająca przez nos i usta, która po zdeponowaniu w drogach oddechowych stwarza zagrożenie dla zdrowia. Frakcja respirabilna – frakcja aerozolu wnikająca 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	10 mg/m ³ (particulate matter containing no Asbestos and <1% Crystalline silica)
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen
Romania - Occupational Exposure Limits	
Local name	Oxid de aluminiu
OEL TWA	2 mg/m ³ (aerosols) 3 mg/m ³ (dust (Aluminium and Aluminium oxides)) 1 mg/m ³ (fume (Aluminium and Aluminium oxides))
OEL STEL	5 mg/m ³ (aerosols) 10 mg/m ³ (dust (Aluminium and Aluminium oxides)) 3 mg/m ³ (fume (Aluminium and Aluminium oxides))

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Aluminum oxide (Al ₂ O ₃) (1344-28-1)	
Regulatory reference	Hotărârea Guvernului nr. 1.218/2006 (Hotărârea nr. 53/2021)
Slovakia - Occupational Exposure Limits	
Local name	Oxid hlinitý
NPHV (OEL TWA) [1]	4 mg/m ³ (inhalable dust) 1.5 mg/m ³ (respirable dust)
Regulatory reference	Nariadenie vlády č. 355/2006 Z. z. (236/2020 Z. z.)
Spain - Occupational Exposure Limits	
Local name	Óxido de aluminio (Corindón)
VLA-ED (OEL TWA) [1]	10 mg/m ³
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT
Sweden - Occupational Exposure Limits	
NGV (OEL TWA)	5 mg/m ³ (total dust) 2 mg/m ³ (respirable fraction)
Norway - Occupational Exposure Limits	
Local name	Aluminiumoksid
Grønseverdier (OEL TWA) [1]	10 mg/m ³ (set equal to the limit value for Nuisance dust)
Korttidsverdier (OEL STEL)	20 mg/m ³ (set equal to the limit value for Nuisance dust)
Remark	1) Grønseverdier er fastsatt lik verdier for sjenerende støv.
Regulatory reference	FOR-2021-06-28-2248

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

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

No additional information available

8.2.2.2. Skin protection

No additional information available

8.2.2.3. Respiratory protection

No additional information available

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White.
Appearance	: Paste.
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Non flammable.
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
Density	: Not available
Relative density	: Not available
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.

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10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Excessive 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)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
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

11.2.2. Other information

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

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

No additional information available

12.4. Mobility in soil

No additional information available

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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.

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

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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)

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

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).
WGK remark : Most stringent classification due to insufficient data.
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are 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 chemical safety assessment has been carried out

SECTION 16: Other information

Other information : None.

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.