



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

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

SECTION 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 – Base
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 %

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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). Sulphur oxides. Barium oxides (BaOx). Nitrogen oxides. Metal oxides.

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.

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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
Barium sulfate (7727-43-7)	
Belgium - Occupational Exposure Limits	
Local name	Baryum (sulfate de) # Bariumsulfaat
OEL TWA	5 mg/m ³ (without asbestos fibers and <1% crystalline silicon dioxide)
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021
Bulgaria - Occupational Exposure Limits	
Local name	Бариев сулфат
OEL TWA	10 mg/m ³

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Barium sulfate (7727-43-7)	
Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр. 47 от 2021 г., в сила от 04.06.2021 г.)
Croatia - Occupational Exposure Limits	
Local name	Barijev sulfat
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, граничним vrijednostima izloženosti i biološkim граничним vrijednostima (NN 1/2021)
Germany - Occupational Exposure Limits (TRGS 900)	
AGW (OEL TWA) [1]	1.25 mg/m ³ (respirable fraction (dust)) 10 mg/m ³ (inhalable fraction (dust))
Ireland - Occupational Exposure Limits	
Local name	Barium sulphate, respirable dust
OEL TWA [1]	5 mg/m ³ (respirable dust)
OEL STEL	15 mg/m ³ (calculated-respirable dust)
Regulatory reference	Chemical Agents Code of Practice 2021
Portugal - Occupational Exposure Limits	
Local name	Sulfato de bário
OEL TWA	5 mg/m ³ I (Fração inalável), E (O valor aplica-se a partículas sem amianto e contendo menos de 1 % de sílica cristalina)
Regulatory reference	Norma Portuguesa NP 1796:2014
Slovakia - Occupational Exposure Limits	
Local name	Síran (sulfát) bárnatý
NPHV (OEL TWA) [1]	4 mg/m ³ inhalovateľná frakcia 1.5 mg/m ³ respirabilná frakcia
Regulatory reference	Nariadenie vlády č. 355/2006 Z. z. (236/2020 Z. z.)
Spain - Occupational Exposure Limits	
Local name	Sulfato de bario
VLA-ED (OEL TWA) [1]	10 mg/m ³ (this value is for the particulate matter that is free from Asbestos and contains less than 1% of crystalline Silica)
Remark	e (Este valor es para la materia particulada que no contenga amianto y menos de un 1% de sílice cristalina).
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT
USA - ACGIH - Occupational Exposure Limits	
Local name	Barium sulfate
ACGIH OEL TWA	5 mg/m ³ (I - Inhalable particulate matter, E - The value is for particulate matter containing no asbestos and < 1 % crystalline silica)
Remark (ACGIH)	TLV® Basis: Pneumoconiosis
Regulatory reference	ACGIH 2022

8.1.2. Recommended monitoring procedures

No additional information available

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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	: Light blue.
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

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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.

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. Sulphur oxides. Barium oxides (BaO_x). Nitrogen oxides. Metal 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)

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA	ADN	RID
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)

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.

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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.