Permlastic Base (Light Body)

Safety Data Sheet

SDS EU format according to COMMISSION REGULATION (EU) 2020/878
Issue date: 8/9/2024

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

1.1. Product identifier

Product form : Mixture
Product name : Permlastic Base (Light Body)

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

Relevant identified uses

Use of the substance/mixture : Dental Impression Material

Uses advised against

Restrictions on use : None known

1.3. Details of the supplier of the safety data sheet

Manufacturer
Kerr Italia, S.r.L.
Via Passanti, 174
Scafati (SA) 84018, Italy
T +39 081 850 3511
safety@envistaco.com

1.4. Emergency telephone number

Emergency number : (Chemical Spills, Leaks, Fire, Exposure or Accident only): CHEMTREC 1-800-424-9300 (in the US), 1-703-527-3887 (Outside the US)

Country/Area	Organisation/Company	Address	Emergency number	Comment
Germany	Informationszentrale gegen Vergiftungen Klinik und Poliklinik für Allgemeine Pädiatrie, Zentrum für Kinderheilkunde, Universitätsklinikum Bonn	Gebäude 30, ELKI (Eltern-Kind-Zentrum) Venusberg-Campus 1 53127 Bonn	+49 (0) 228 19 240	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Signal word (CLP) : -
Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P273 - Avoid release to the environment.
P501 - Dispose of contents and container to to a hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 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 substance(s) are 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 %

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aliphatic polysulphide polymer	CAS-No.: 68611-50-7 EC-No.: 614-671-8	60-80	Aquatic Chronic 3, H412
Phenethyl benzoate	CAS-No.: 94-47-3 EC-No.: 202-336-5	1-5	Aquatic Chronic 2, H411
Alcohols, C11-14-iso-, C13-rich	CAS-No.: 68526-86-3 EC-No.: 271-235-6	0.1-1	Skin Irrit. 2, H315 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Move the affected person to fresh air. Get medical attention if symptoms occur.
First-aid measures after skin contact : Gently wash with plenty of soap and water. Seek medical attention if irritation develops.
First-aid measures after eye contact : Rinse eyes with water as a precaution. Get medical attention if irritation develops and persists.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Inhalation : Dust of the product, if present, may cause respiratory irritation after excessive inhalation exposure.
Skin : No adverse effects expected.
Eyes : Direct contact with the eyes is likely to be irritating.
Ingestion : May cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Chronic symptoms : None known.

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 : Not determined.

5.2. Special hazards arising from the substance or mixture

Fire hazard : This product is not classified as flammable or combustible.
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2). Sulfur oxides (SOx). Metal oxides. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	:	Fight fire from safe distance and protected location. Cool down the containers exposed to heat with a water spray. Do not allow run-off from firefighting to enter drains or water courses.
Protection during firefighting	:	Do not attempt to take action without suitable protective equipment. Use self-contained breathing apparatus and chemically protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not touch or walk on the spilled product.

For non-emergency personnel

Emergency procedures : Avoid contact with skin, eyes and clothing. Avoid breathing dust, vapours. Ventilate spillage area.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	:	Stop leak if safe to do so.
Methods for cleaning up	:	Absorb and/or contain spill with inert material, then place in suitable container.
Other information	:	Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	:	Avoid contact with eyes, skin and clothing. Ensure adequate ventilation.
Hygiene measures	:	Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Do not freeze. Keep container closed when not in use.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:
Provide local exhaust or general room ventilation.

Personal protection equipment

Eye and face protection

Eye protection:
No special eye protection equipment recommended under normal conditions of use

Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
No personal protective equipment required under normal use. In case of repeated or prolonged contact wear gloves. Wear suitable gloves tested to EN374

Respiratory protection

Respiratory protection:
In operations where exposure limits are exceeded or exposure levels are excessive, an approved respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	White.
Appearance	:	Paste.
Odour	:	slightly sulphurous.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
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 available
Particle characteristics	:	Not applicable

9.2. Other information

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

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Keep away from oxidizers, strong acids and strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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)

Phenethyl benzoate (94-47-3)	
LD50 oral rat	> 2000 mg/kg bodyweight
LD50 dermal rabbit	> 2000 mg/kg bodyweight

Aliphatic polysulphide polymer (68611-50-7)	
LD50 oral rat	> 3000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg

Alcohols, C11-14-iso-, C13-rich (68526-86-3)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method)
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)

Phenethyl benzoate (94-47-3)	
pH	4.7 Temp.: 31 °C Concentration: 1 vol%

Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)

Phenethyl benzoate (94-47-3)	
pH	4.7 Temp.: 31 °C Concentration: 1 vol%

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)

Alcohols, C11-14-iso-, C13-rich (68526-86-3)	
NOAEL (oral, rat, 90 days)	≥ 300 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

Alcohols, C11-14-iso-, C13-rich (68526-86-3)	
Viscosity, kinematic	48 mm²/s Temp.: '20°C' Parameter: 'kinematic viscosity (in mm²/s)'

11.2. Information on other hazards

Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : None known

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.
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) : Harmful to aquatic life with long lasting effects.

Phenethyl benzoate (94-47-3)	
LC50 - Fish [1]	37.5 mg/l Danio rerio (Zebrafish)
EC50 - Crustacea [1]	66.46 mg/l Daphnia magna (Water flea)
EC50 72h - Algae [1]	4.58 mg/l Raphidocelis subcapitata

Alcohols, C11-14-iso-, C13-rich (68526-86-3)	
LC50 - Fish [1]	0.42 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 - Crustacea [1]	0.71 mg/l Daphnia magna (Water flea)
EC50 72h - Algae [1]	2.6 mg/l Pseudokirchneriella subcapitata
ErC50 algae	3.2 mg/l Pseudokirchneriella subcapitata
NOEC (chronic)	0.052 mg/l QSAR
NOEC chronic fish	0.047 mg/l QSAR

12.2. Persistence and degradability

Permlastic Base (Light Body)	
Persistence and degradability	Not rapidly degradable

Phenethyl benzoate (94-47-3)	
Persistence and degradability	Not rapidly degradable
Biodegradation	49 % 28 days

Aliphatic polysulphide polymer (68611-50-7)	
Persistence and degradability	Not rapidly degradable

Alcohols, C11-14-iso-, C13-rich (68526-86-3)	
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

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations.

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 for transport				
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

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)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

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)

National regulations

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

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 2, Significantly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)

Abbreviations and acronyms:	
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor

Full text of H- and EUH-statements:	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
H315	Causes skin irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Aquatic Chronic 3	H412	Calculation method

Safety Data Sheet (SDS), EU

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