



Safety Data Sheet Permlastic Base (Regular Body, Light Body & Heavy Body)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Permlastic Base (Regular Body, Light Body & Heavy Body)

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

Relevant identified uses

Main use category : Professional use

Function or use category : Dental materials

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
E-mail: safety@kerrhawe.com

Manufacturer

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
E-mail: safety@kerrhawe.com

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Repr. 1B H360Df

Aquatic Chronic 2 H411

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08



GHS09

Signal word (CLP) : Danger

Hazardous ingredients : BBP, benzyl butyl phthalate

Hazard statements (CLP) : H360Df - May damage the unborn child. Suspected of damaging fertility
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P273 - Avoid release to the environment
P280 - Wear eye protection, protective gloves, protective clothing
P308+P313 - IF exposed or concerned: Get medical advice/attention

P391 - Collect spillage
 P405 - Store locked up
 P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

Extra phrases : The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1907/2006, article 2, paragraph 6c)

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
BBP, benzyl butyl phthalate substance listed as REACH Candidate (Benzyl butyl phthalate (BBP)) substance listed in REACH Annex XIV (Benzyl butyl phthalate (BBP))	(CAS No) 85-68-7 (EC no) 201-622-7 (EC index no) 607-430-00-3 (REACH-no) 01-2119489376-23	=>5 - <25	Repr. 1B, H360Df Aquatic Acute 1, H400 Aquatic Chronic 1, H410
octamethylcyclotetrasiloxane	(CAS No) 556-67-2 (EC no) 209-136-7 (EC index no) 014-018-00-1 (REACH-no) 01-2119529238-36	=>0,5 - <5	Repr. 2, H361f Aquatic Chronic 4, H413
sulfur	(CAS No) 7704-34-9 (EC no) 231-722-6 (EC index no) 016-094-00-1 (REACH-no) 01-2119487295-27	=>1 - <5	Skin Irrit. 2, H315

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact : Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.

First-aid measures after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Get medical advice/attention.

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

Symptoms/injuries : May damage fertility or the unborn child.

4.3. Indication of any immediate medical attention and special treatment needed

No specific measures identified.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.

Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide. Sulphur oxides. Halogenated compounds. metallic oxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Avoid (reject) fire-fighting water to enter environment.

Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes. Do not breathe vapour. Use personal protective equipment as required. No open flames. No smoking. Do not eat, drink or smoke in areas where product is used. Assure fresh air breathing.

For non-emergency personnel

Protective equipment : See Heading 8.

For emergency responders

No additional information available

6.2. Environmental precautions

Discharging into rivers and drains is forbidden.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

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 : Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes and clothing. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Remove contaminated clothes. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store in a closed container. Store in original container. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

Consult the supplier for further information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

BBP, benzyl butyl phthalate (85-68-7)		
United Kingdom	Local name	Benzyl butyl phthalate
United Kingdom	WEL TWA (mg/m ³)	5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Personal protective equipment : Gloves. Safety glasses.

Hand protection : Wear suitable gloves. Nitrile rubber gloves. Layer thickness : 0,09mm. Breakthrough time : >480 min. STANDARD EN 374

Eye protection : Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166

Skin and body protection : Wear suitable protective clothing

Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation



Other information : Do not eat, drink or smoke during use. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. For even minor contact, immediately remove contaminated clothing. Wash skin thoroughly with mild soap and water.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state : Liquid
 Appearance : Paste.
 Colour : white.
 Odour : Sulfur.
 Odour threshold : No data available
 pH : No data available
 Relative evaporation rate (butylacetate=1) : No data available
 Melting point : No data available
 Freezing point : No data available
 Boiling point : No data available
 Flash point : No data available
 Auto-ignition temperature : No data available
 Decomposition temperature : No data available
 Flammability (solid, gas) : No data available
 Vapour pressure : No data available
 Relative vapour density at 20 °C : No data available
 Relative density : > 1
 Solubility : Material insoluble in water.
 Log Pow : No data available
 Viscosity, kinematic : No data available
 Viscosity, dynamic : No data available
 Explosive properties : Product is not explosive.
 Oxidising properties : Non flammable.
 Explosive limits : No data available

9.2. Other information

Additional information : None to our knowledge.

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 polymerization.

10.4. Conditions to avoid

No flames. Eliminate all sources of ignition.

10.5. Incompatible materials

reducing materials.

10.6. Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Not classified

BBP, benzyl butyl phthalate (85-68-7)

LD50 oral rat	2330 mg/kg
LD50 dermal rat	6700 mg/kg
LD50 dermal rabbit	> 10000 mg/kg
LC50 inhalation rat (mg/l)	> 6.7 mg/l/4h

octamethylcyclotetrasiloxane (556-67-2)

LD50 oral rat	1540 mg/kg
LD50 dermal rat	1770 mg/kg
LC50 inhalation rat (mg/l)	36 mg/l/4h

sulfur (7704-34-9)

LD50 oral rat	> 3000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 0.067 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: May damage the unborn child. Suspected of damaging fertility.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity**

Ecology - water : Toxic to aquatic life with long lasting effects.

BBP, benzyl butyl phthalate (85-68-7)

LC50 fish 1	0.51 mg/l (96 hours - Rainbow trout)
EC50 Daphnia 1	0.76 mg/l EC50 48h - Daphnia magna [mg/l]
EC50 other aquatic organisms 1	0.9 mg/l EC50 48h crustacea
IC50 algae	0.1 mg/l (96 hours - Pseudokirchneriella subcapitata)
NOEC (chronic)	0.06 mg/l

octamethylcyclotetrasiloxane (556-67-2)

LC50 fish 1	> 500 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 Daphnia 1	25.2 mg/l EC50 48h - Daphnia magna [mg/l]

sulfur (7704-34-9)

LC50 fish 1	866 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 Daphnia 1	> 5000 mg/l (48 hours - Daphnia magna)
IC50 algae	12 mg/l

12.2. Persistence and degradability**Permlastic Base (Regular Body, Light Body & Heavy Body)**

Persistence and degradability	No data available.
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BBP, benzyl butyl phthalate (85-68-7)

Biodegradation	93 % (OECD 301B method)
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12.3. Bioaccumulative potential**Permlastic Base (Regular Body, Light Body & Heavy Body)**

Bioaccumulative potential	No data.
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BBP, benzyl butyl phthalate (85-68-7)

Bioconcentration factor (BCF REACH)	663
Log Pow	4.84

octamethylcyclotetrasiloxane (556-67-2)

Bioconcentration factor (BCF REACH)	1698.24
Log Pow	5.09

12.4. Mobility in soil**Permlastic Base (Regular Body, Light Body & Heavy Body)**

Ecology - soil	Insoluble.
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12.5. Results of PBT and vPvB assessment**Permlastic Base (Regular Body, Light Body & Heavy Body)**

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Component	
BBP, benzyl butyl phthalate (85-68-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects	: None to our knowledge.
Additional information	: No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste treatment methods**

Regional legislation (waste)	: Dispose as hazardous waste.
Waste treatment methods	: Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: TRANSPORT INFORMATION

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

14.1. UN number

UN-No. (ADR)	: 3077
UN-No. (IMDG)	: 3077
UN-No. (IATA)	: 3077
UN-No. (ADN)	: 3077
UN-No. (RID)	: 3077

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IMDG)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IATA)	: Environmentally hazardous substance, solid, n.o.s.
Proper Shipping Name (ADN)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (RID)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description (ADR)	: UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide(1314-13-2) ; BBP, benzyl butyl phthalate), 9, III, (E)
Transport document description (IMDG)	: UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS

14.3. Transport hazard class(es)**ADR**

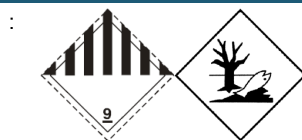
Transport hazard class(es) (ADR)	: 9
Danger labels (ADR)	: 9

**IMDG**

Transport hazard class(es) (IMDG)	: 9
Danger labels (IMDG)	: 9

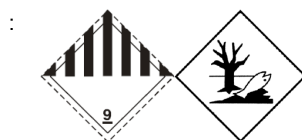
**IATA**

Transport hazard class(es) (IATA)	: 9
Hazard labels (IATA)	: 9

**ADN**

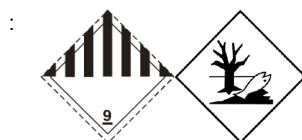
Transport hazard class(es) (ADN) : 9

Danger labels (ADN) : 9

**RID**

Transport hazard class(es) (RID) : 9

Danger labels (RID) : 9

**14.4. Packing group**

Packing group (ADR) : III

Packing group (IMDG) : III

Packing group (IATA) : III

Packing group (ADN) : III

Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : Yes

Marine pollutant : Yes

Other information : No supplementary information available

14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : M7

Special provisions (ADR) : 274, 335, 601, 375

Limited quantities (ADR) : 5kg

Excepted quantities (ADR) : E1

Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : PP12, B3

Mixed packing provisions (ADR) : MP10

Portable tank and bulk container instructions (ADR) : T1, BK1, BK2

Portable tank and bulk container special provisions (ADR) : TP33

Tank code (ADR) : SGAV, LGBV

Vehicle for tank carriage : AT

Transport category (ADR) : 3

Special provisions for carriage - Packages (ADR) : V13

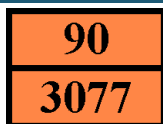
Special provisions for carriage - Bulk (ADR) : VC1, VC2

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13

Hazard identification number (Kemler No.) : 90

Orange plates

:



Tunnel restriction code (ADR)

:

E

EAC code

:

2Z

- Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969
 Limited quantities (IMDG) : 5 kg
 Excepted quantities (IMDG) : E1
 Packing instructions (IMDG) : P002, LP02
 Special packing provisions (IMDG) : PP12
 IBC packing instructions (IMDG) : IBC08
 IBC special provisions (IMDG) : B3
 Tank instructions (IMDG) : T1, BK1, BK2, BK3
 Tank special provisions (IMDG) : TP33
 EmS-No. (Fire) : F-A
 EmS-No. (Spillage) : S-F
 Stowage category (IMDG) : A

- Air transport

PCA Excepted quantities (IATA) : E1
 PCA Limited quantities (IATA) : Y956
 PCA limited quantity max net quantity (IATA) : 30kgG
 PCA packing instructions (IATA) : 956
 PCA max net quantity (IATA) : 400kg
 CAO packing instructions (IATA) : 956
 CAO max net quantity (IATA) : 400kg
 Special provisions (IATA) : A97, A158, A179, A197
 ERG code (IATA) : 9L

Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU-Regulations**

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Benzyl butyl phthalate (BBP) (EC 201-622-7, CAS 85-68-7)

Contains REACH Annex XIV substances:

Substance name	Authorisation number	Sunset date	REACH authorisation exemptions
Benzyl butyl phthalate (BBP) (EC 201-622-7, CAS 85-68-7)		21/01/2015	

National regulations

EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: OTHER INFORMATION

Indication of changes:

Hazards identification. Composition/information on ingredients.

2.1	Classification according to Regulation (EC) No.	Modified	
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	1272/2008 [CLP]		
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
5.2	Hazardous decomposition products in case of fire	Modified	

Date of issue : 24/02/2004
 Revision date : 04/03/2016
 Supersedes : 14/09/2015
 Version : 6.0
 Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Repr. 1B	Reproductive toxicity, Category 1B
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H315	Causes skin irritation
H360Df	May damage the unborn child. Suspected of damaging fertility
H361f	Suspected of damaging fertility
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.