



SAFETY DATA SHEET

PREMISE Translucent shades

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

1.1. Product identifier

Product name PREMISE Translucent shades

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

Applications Dental impression material.

1.3. Details of the supplier of the safety data sheet

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

Contact person E-mail: safety@kerrhawe.com (Mobile Phone number 08.00 – 23.00:
+39-340.1721884)

Manufacturer Kerr Corporation
1717 West Collins Avenue
92867 Orange – CALIFORNIA (U.S.A.)
Tel: 00-800-41-050-505
safety@kerrhawe.com

1.4. Emergency telephone number

Emergency telephone number 112 # The UK National Poisons Emergency number: +44 870 600 6266 WEB:
<http://www.toxbase.org>
CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only)
001-800-424-9300
International and Maritime Telephone Number +1 (703) 527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to directives Xi
67/548/EEC, 99/45/EC & 2001/58/EC R-43
(DSD/DPD)

Classification according to directive GHS07, Warning
1272/2008 (CLP) Skin Sens. 1: H317

Hazard The product is seen as a medical device and therefore not subject to labelling, regulation (EC) no 1272/2008 of the european parliament and of the council, article 1d; Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC.

2.2. Label elements

CLP

Hazard pictograms



Signal word	Warning
Hazard statements	Skin Sens. 1: H317 May cause an allergic skin reaction.
Precautionary statements	P262 Do not get in eyes, on skin, or on clothing. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P350 IF ON SKIN: Gently wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
Contains	dibutyl phthalate, DBP hexamethylene diacrylate titanium dioxide metakrylat ester monomer
2.3. Other hazards	
Meets the criteria for vPvB	No.
Meets the criteria for PBT	No.
Other hazards which do not contribute to classification	No known risks.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Ingredients

Name	EC No.	CAS No.	Content	Symbol	Classification
dibutyl phthalate, DBP	201-557-4	84-74-2	<0,5 %	T ,N	R-50, R-62, R-61
hexamethylene diacrylate	235-921-9	13048-33-4	2-5 %	Xi	R-36/38, R-43
titanium dioxide	236-675-5	13463-67-7		-	
metakrylat ester monomer				-	

CLP

Name	REACH No.	Content	Symbol	Classification	CAS No.
dibutyl phthalate, DBP	01-21194930 42-44	<0,5 %	GHS09, GHS08, , Danger	Repr. 1B: H360Df, Aquatic Acute 1: H400	84-74-2
hexamethylene diacrylate	01-21194847 37-22	2-5 %	GHS07, , Warning	Skin Irrit. 2: H315, Skin Sens. 1: H317, Eye Irrit. 2: H319	13048-33-4
titanium dioxide	01-21194893 79-17				13463-67-7
metakrylat ester monomer					

Section 16 contains detailed classification phrases.

SECTION 4: First aid measures

4.1. Description of first aid measures

General	General first aid, rest, warmth and fresh air. Contact physician if discomfort continues.
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4.2. Most important symptoms and effects, both acute and delayed

Specific first aid treatment No specific first aid measures noted.

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

Inhalation Provide rest, warmth and fresh air. Get medical attention if any discomfort continues.

Ingestion Rinse mouth with water. Get medical attention if any discomfort continues.

Skin Wash skin with soap and water. Get medical attention if any discomfort continues.

Eyes Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Extinguishing media Foam, carbon dioxide or dry powder.

Special fire fighting procedures Containers close to fire should be removed or cooled with water.

5.2. Special hazards arising from the substance or mixture

Specific hazards Non-flammable. Heating could result in rapid polymerization, which results in strong heat generation.

Hazardous combustion products Fire or high temperatures create: Carbon monoxide (CO). Carbon dioxide (CO₂).

5.3. Advice for firefighters

Protective measures in fire Firefighters exposed to combustion gases/decomposition products should use a respiratory protective device.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Personal protection Wear appropriate personal protective equipment - see Section 8.

6.2. Environmental precautions

Environmental protection Do not allow to enter drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up

Spill cleanup methods Collect with absorbent material. Collect and reclaim or dispose in sealed containers in licensed waste.

6.4. Reference to other sections

See section 13 for waste handling.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Usage precautions Eliminate all sources of ignition. Keep away from heat, sparks and open flame. Avoid spilling, skin and eye contact.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store at ambient temperature in dry, well-ventilated area. Keep in original container. Store away from all sources of heat and exposed flame. Keep containers tightly closed. Store separated from: Oxidising material. Amines. Peroxides.

7.3. Specific end use(s)

Specific use(s) Contact supplier for more information.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Ingredient name	CAS no.	Reference	LT Exp 8 Hrs	ST Exp 15 Min	Date
dibutyl phthalate, DBP	84-74-2	WEL.	5 mg/m3	10 mg/m3	
titanium dioxide	13463-67-7	WEL.	10 mg/m3		

Ingredient comments

WEL = Workplace exposure limits. SK= Skin absorbance, Rep= Reproduction, Carc= Carcinogenic Senz= Sensitisers, Mut= Carcinogenic

Protective equipment**Ventilation**

Provide adequate general and local exhaust ventilation.

8.2. Exposure controls**Respirators**

If ventilation is insufficient, suitable respiratory protection must be provided. Use respiratory equipment with particle filter, type P2. Standard EN 149.

Protective gloves

Use suitable protective gloves if risk of skin contact. Use protective gloves made of: Impermeable material. Neoprene. Time of breakthrough is not known, change gloves regularly. Suitable glove must be chosen in consultation with the gloves supplier, giving information of the breakthrough time for the glove material. Standard EN 374.

Eye protection

Wear approved safety goggles. Standard EN 166.

Other Protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygienic work practices

Wash at the end of each work shift and before eating, smoking and using the toilet.

DNEL

No data.

PNEC

No data.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties**Appearance**

Paste.

Odour

Fruity. Ester.

Solubility description

Insoluble in water.

Density (g/cm3)

2,5

Temperature (°C)**9.2. Other information****Safety information**

Not known.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactive groups.

10.2. Chemical stability

Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions**Hazardous polymerisation**

May polymerise. Stabilized with non-hazardous polymerization inhibitors.

10.4. Conditions to avoid

Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials**Materials to avoid**

Strong reducing agents. Strong oxidising agents. Peroxides. Amines.

10.6. Hazardous decomposition products

Hazardous decomp. products

No hazardous decomposition products are emitted at recommended use and storage conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Sensitization	May cause an allergic skin reaction.
Genotoxicity	No known heritable or mutagenic effects.
Carcinogenicity	No evidence of carcinogenic properties.
Reproduction toxicity	No known hazardous effects on reproduction, fertility or to the unborn child.
Inhalation	Prolonged or repeated exposure to this chemical may cause: Upper respiratory irritation.
Ingestion	Uncured material may be harmful if swallowed.
Skin	Prolonged or repeated contact may cause irritation.
Eyes	Direct contact may irritate.
COMPONENT:	dibutyl phthalate, DBP
Toxicology data	Acute toxicity. TDL0 Oral. Human. 140 mg/kg (CNS)
Toxic dose - LD50:	3050 mg/kg (oral rat)
Toxic dose - LD50 (skin):	8000 mg/kg (skin rabbit)
Toxic conc. - LC50:	>15,68 mg/l/4h (inhalation rat)
COMPONENT:	hexamethylene diacrylate
Toxic dose - LD50:	5000 mg/kg (oral rat)
Toxic dose - LD50 (skin):	3000 mg/kg (skin rabbit)
COMPONENT:	titanium dioxide
Toxic dose - LD50:	>100000 mg/kg (oral rat)
Toxic dose - LD50 (skin):	>10000 mg/kg (skin rabbit)
Toxic conc. - LC50:	> 4,68 mg/l/4h (inhalation rat)

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	Not classified as dangerous to the environment. However, the product should not be allowed to enter drains or water courses or be deposited where it can affect ground or surface waters.
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12.2. Persistence and degradability

Unknown.

12.3. Bioaccumulative potential

Unknown.

12.4. Mobility in soil

Mobility	The product is insoluble in water.
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12.5. Results of PBT and vPvB assessment

PTB/vPvB	Component(s) is not identified as a PBT or vPvB-substance.
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12.6. Other adverse effects

No known information.

COMPONENT:	dibutyl phthalate, DBP
LC 50, 96 Hrs, Fish mg/l:	0,71 (Lepomis macrochirus)
EC 50, 48 Hrs, Daphnia, mg/l:	3,4 (Daphnia magna)
IC 50, 72 Hrs, Algae, mg/l:	1,2 (Scenedesmus subspictus)
Bioaccumulative potential	BCF:12
Partition coefficient (log Pow)	4,57
Persistence and degradability	BOD5/COD: 0,63 98 % deg., 30 days, Method: OECD 301C
COMPONENT:	hexamethylene diacrylate
Bioaccumulative potential	BCF:46,77
COMPONENT:	titanium dioxide
LC 50, 96 Hrs, Fish mg/l:	>1000 (Fundulus heteroclitus)
EC 50, 48 Hrs, Daphnia, mg/l:	> 1000 (Daphnia magna)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General/cleaning	Waste is classified as hazardous waste.
Disposal methods	Dispose of in accordance with Local Authority requirements.
Waste class	18 01 06* chemicals consisting of or containing dangerous substances The given EWC-code is a guiding, and the code depends on how the waste is formed. User must evaluate the choice of correct code.

SECTION 14: Transport information

General	No dangerous goods (ADR/RID, IMDG, IATA/ICAO)
ROAD TRANSPORT (ADR):	
14.1. UN number	
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
RAIL TRANSPORT (RID):	
SEA TRANSPORT (IMDG):	
TRANSPORT BY INLAND WATERWAYS (ADN):	
14.4. Packing group	
14.5. Environmental hazards	
Transport by inland waterways notes	Not applicable.
14.6. Special precautions for user	
	No particular precautions.
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	
	No IBC-code for bulk transport offshore (MARPOL).

SECTION 15: Regulatory information

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

EU directives	Medical, invasive equipment, EU-regulation 1272/2008, article 1, paragraph 5d, EU-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	
Chemical Safety Assessment	Chemical Safety Report (CSR) has not been carried out for this product.

SECTION 16: Other information

Explanations to R-phrases in section 3	R-36/38 Irritating to eyes and skin.
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R-43 May cause sensitisation by skin contact.
R-50 Very toxic to aquatic organisms.
R-61 May cause harm to the unborn child.
R-62 Possible risk of impaired fertility.

Explanations to classification in section 3

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H400 Very toxic to aquatic life.

DSD/DPD**Labeling**

Xi,

Risk phrases

R-43 May cause sensitisation by skin contact.

*** Information revised since the previous version of the SDS****Revision comments**

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