



SAFETY DATA SHEET

CLEANIC without Fluoride

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

1.1. Product identifier

Product name CLEANIC without Fluoride

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

Applications Consistency modifier for dental temporary cement.

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 KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
Tel: 00-800-41-050-505
E-mail: 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 -
67/548/EEC, 99/45/EC & 2001/58/EC
(DSD/DPD)

Classification according to directive
1272/2008 (CLP) EUH210

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 statements EUH210 Safety data sheet available on request.

Contains titanium dioxide

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
titanium dioxide	236-675-5	13463-67-7		-	

CLP

Name	REACH No.	Content	Symbol	Classification	CAS No.
titanium dioxide	01-21194893 79-17				13463-67-7

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. Get medical attention if any discomfort continues.

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 No specific first aid measures noted.

Ingestion Ingestion of large quantities, drink plenty of water to dilute the product.

Skin Promptly wash contaminated skin with water.

Eyes Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention if any discomfort continues.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Extinguishing media Use extinguishing media appropriate for surrounding fire.

Special fire fighting procedures Avoid water in straight hose stream; will scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards Non-flammable.

Hazardous combustion products No hazardous combustion compounds noted.

5.3. Advice for firefighters

Protective measures in fire Wear self-contained breathing apparatus (SCBA) to prevent contact with thermal decomposition products.

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 spilled material using mechanical equipment. Post clean with water.

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**

NOTE! Good personal hygiene is important during handling of the product.
Read and follow manufacturer's recommendations.

7.2. Conditions for safe storage, including any incompatibilities**Storage precautions**

Keep in cool, dry, ventilated storage and closed containers.

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
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

Ventilation

No particular ventilation requirements.

8.2. Exposure controls**Respirators**

Respiratory protection not required.

Protective gloves

Hand protection not required.

Eye protection

Under normal conditions of use eye protection is not required.

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.

Colour

Light blue.

Odour

Mint.

Solubility description

Insoluble in water.

Density (g/cm3)

1,25

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 normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Hazardous polymerisation

Will not polymerise.

10.4. Conditions to avoid

No known hazardous reaction products.

10.5. Incompatible materials

Materials to avoid

No information.

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

No allergic reaction is known.

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

No specific health warnings noted.

Ingestion

Ingestion of large amounts of material may cause a mild irritation to the throat.

Skin

May cause a mild irritation, mainly by mechanical character.

Eyes

May cause a mild irritation, mainly by mechanical character.

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 regarded as dangerous to the environment. This does not, however, rule out the possibility that large or frequent smaller emissions of the product may be harmful to the environment.

12.2. Persistence and degradability

Unknown.

12.3. Bioaccumulative potential

Unknown.

12.4. Mobility in soil

Mobility

The product is insoluble in water.

12.5. Results of PBT and vPvB assessment

PTB/vPvB

Component(s) is not identified as a PBT or vPvB-substance.

12.6. Other adverse effects

No known information.

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	Product is not hazardous waste.
Disposal methods	Dispose of in accordance with Local Authority requirements.
Waste class	18 01 07 chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information

General	No dangerous goods (ADR/RID, IMDG, IATA/ICAO)
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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.
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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	Diagnostic medical devices, EU-directive 98/79/EC, 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.
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15.2. Chemical safety assessment

Chemical Safety Assessment	Chemical Safety Report (CSR) has not been carried out for this product.
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SECTION 16: Other information**Explanations to R-phrases in section 3****Explanations to classification in section 3****DSD/DPD***** Information revised since the previous version of the SDS**

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Signature	R. E. Lunde
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