

Safety Data Sheet

Smearclear

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

1.1. Product identifier

Product name : Smearclear

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

KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T 00-800-41-050-505
[E-mail: safety@kerrhawe.com](mailto:safety@kerrhawe.com)

Manufacturer

SybronEndo Endodontics
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
[E-mail: safety@kerrhawe.com](mailto: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]

Eye Irrit. 2 H319

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) :



GHS07



GHS09

Signal word (CLP) : Warning

Hazard statements (CLP) : H319 - Causes serious eye irritation
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear eye protection
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 - If eye irritation persists: Get medical advice/attention

P391 - Collect spillage

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

No additional information available

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] |
|---|--|-------------|---|
| ethylenediaminetetraacetic acid disodium salt dihydrate | (CAS No) 6381-92-6 (EC no) 205-358-3 (REACH-no) N/A | =>1 - <5 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 |
| cetyltrimethylammonium bromide | (CAS No) 57-09-0 (EC no) 200-311-1 (REACH-no) 01-2119989160-35 | =>1 - <2,5 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
| Triton X-100 reduced | (CAS No) 92046-34-9 (REACH-no) N/A | =>0,25 - <1 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES**4.1. Description of first aid measures**

- First-aid measures general : Call a poison center or a doctor if you feel unwell.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.
- First-aid measures after ingestion : Do not induce vomiting. If vomiting occurs, the head should be kept low so that stomach vomit doesn't enter the lungs. Call a poison center or a doctor if you feel unwell.

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

Symptoms/injuries after eye contact : Causes serious eye irritation. Redness, pain.

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

No specific first aid measures noted.

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 : Avoid water in straight hose stream; will scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Non flammable.
- Explosion hazard : Product is not explosive.
- Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂). Nitrogen oxides. Halogenated hydrocarbons. metallic oxide. irritating gases.

5.3. Advice for firefighters

- Protection during firefighting : 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

General measures : Ensure adequate ventilation, especially in confined areas. Avoid all contact with skin, eyes, or clothing. Spill area may be slippery.

For non-emergency personnel

Protective equipment : Wear appropriate personal protective equipment - see Section 8.

For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

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

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 : Wear appropriate personal protective equipment - see Section 8. Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Keep only in original container. Protect from sunlight. Store in a well-ventilated place. Store in a dry place.

Incompatible materials : Oxidizing substances.

Storage temperature : 18 - 34 °C

7.3. Specific end use(s)

Contact supplier for more information. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : In case of splash hazard: safety glasses. Gloves.

Hand protection : Chemical resistant PVC gloves (to European standard EN 374 or equivalent). Layer thickness : 0,1 mm. Breakthrough time : 8 (> 480 minutes)

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



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state : Liquid

| | |
|--|-------------------------------|
| Colour | : clear. |
| Odour | : none to slight. |
| Odour threshold | : No data available |
| pH | : 7.4 - 8.3 |
| 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) | : Not applicable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : In water, material soluble. |
| 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

No incompatible groups noted.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. No polymerization.

10.4. Conditions to avoid

Heat. Moisture.

10.5. Incompatible materials

oxidizing materials.

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 toxicological effects

Acute toxicity : Not classified

ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)

| | |
|---------------|------------|
| LD50 oral rat | 2214 mg/kg |
|---------------|------------|

cetyltrimethylammonium bromide (57-09-0)

| | |
|---------------|-----------|
| LD50 oral rat | 410 mg/kg |
|---------------|-----------|

| | |
|--|---|
| Skin corrosion/irritation | : Not classified pH: 7.4 - 8.3 |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 7.4 - 8.3 |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| 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.

ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)

| | |
|----------------|---|
| LC50 fish 1 | 121 mg/l (96 hours - Lepomis macrochirus) |
| EC50 Daphnia 1 | < 625 mg/l |
| IC50 algae | 11 mg/l |

12.2. Persistence and degradability

Smearclear

Persistence and degradability : No data.

cetyltrimethylammonium bromide (57-09-0)

Biodegradation : 63 % (28 days, method: OECD 301E)

12.3. Bioaccumulative potential

Smearclear

Bioaccumulative potential : No data.

ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)

| | |
|-------------------------------------|---------|
| Bioconcentration factor (BCF REACH) | 1 |
| Log Pow | < -3.86 |

cetyltrimethylammonium bromide (57-09-0)

| | |
|-------------------------------------|-----|
| Bioconcentration factor (BCF REACH) | < 1 |
| Log Pow | 0.5 |

12.4. Mobility in soil

Smearclear

Ecology - soil : soluble in water.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : None to our knowledge.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Waste treatment methods : Follow the instructions for destruction of used packing.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to an authorised waste collection point.

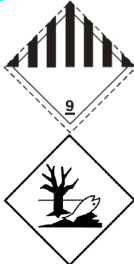

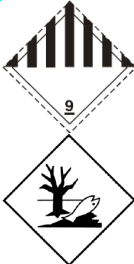
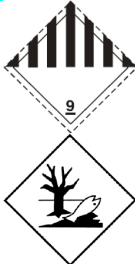
Ecology - waste materials : Avoid release to the environment.

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

| ADR | IMDG | IATA | RID |
|--|--|---|---|
| 14.1. UN number | | | |
| 3082 | 3082 | 3082 | 3082 |
| 14.2. UN proper shipping name | | | |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | Environmentally hazardous substance, liquid, n.o.s. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. |
| Transport document description | | | |
| UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, III, MARINE | | |

| ADR | IMDG | IATA | RID |
|---|---|---|---|
| (cetyltrimethylammonium bromide ; Triton X-100 reduced), 9, III, (E) | POLLUTANT/ENVIRONMENTALLY HAZARDOUS | | |
| 14.3. Transport hazard class(es) | | | |
| 9 | 9 | | 9 |
|  |  |  |  |
| 14.4. Packing group | | | |
| III | III | III | III |
| 14.5. Environmental hazards | | | |
| Dangerous for the environment : Yes | Dangerous for the environment : Yes Marine pollutant : Yes | Dangerous for the environment : Yes | Dangerous for the environment : Yes |
| No supplementary information available | | | |

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

| | |
|---|---|
| Classification code (ADR) | : M6 |
| Special provisions (ADR) | : 274, 335, 601, 375 |
| Limited quantities (ADR) | : 5I |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P001, IBC03, LP01, R001 |
| Special packing provisions (ADR) | : PP1 |
| Mixed packing provisions (ADR) | : MP19 |
| Portable tank and bulk container instructions (ADR) | : T4 |
| Portable tank and bulk container special provisions (ADR) | : TP1, TP29 |
| Tank code (ADR) | : LGBV |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 3 |
| Special provisions for carriage - Packages (ADR) | : V12 |
| 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 | : •3Z |

- Transport by sea

| | |
|-----------------------------------|-----------------|
| Special provisions (IMDG) | : 274, 335, 969 |
| Limited quantities (IMDG) | : 5 L |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : P001, LP01 |
| Special packing provisions (IMDG) | : PP1 |
| IBC packing instructions (IMDG) | : IBC03 |
| Tank instructions (IMDG) | : T4 |
| Tank special provisions (IMDG) | : TP2, TP29 |
| 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) : Y964
 PCA limited quantity max net quantity (IATA) : 30kgG
 PCA packing instructions (IATA) : 964
 PCA max net quantity (IATA) : 450L
 CAO packing instructions (IATA) : 964
 CAO max net quantity (IATA) : 450L
 Special provisions (IATA) : A97, A158, 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 no substance on the REACH candidate list
 Contains no REACH Annex XIV substances

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

SECTION 16: OTHER INFORMATION

Indication of changes:

Hazards identification. Regulatory information.

| | | | |
|-----|--|---------|--------------|
| 2 | Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD] | Removed | |
| 2 | Hazard statements (CLP) | Added | Eye Irrit. 2 |
| 2 | Hazard symbols | Added | GHS07 |
| 2 | Signal word (CLP) | Added | Warning |
| 3.2 | Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD] | Removed | |

Data sources : 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. according to Regulation (EU) 2015/830. Classification according to Regulation (EC) No. 1272/2008 [CLP].

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Revision date : 01/02/2016

Supersedes : 20/10/2014

Version : 2.0

Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

| | |
|---------------------|---|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| 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 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |

| 301308 Smearclear 01/02/2016 | |
|------------------------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H302 | Harmful if swallowed |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |
| 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 |

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.