



## Safety Data Sheet Hawe Implant Paste

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

#### 1.1. Product identifier

Product name : Hawe Implant Paste

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

##### Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

##### 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

##### Manufacturer

KERRHAWE S.A.  
Via Strecce n°4  
6934 Bioggio (Switzerland)  
T 00-800-41-050-505

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
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
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]

Not classified

#### 2.2. Label elements

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

EUH-statements : EUH208 - Contains (E) -anethole. May produce an allergic reaction.

Extra phrases : The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).  
A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

#### 2.3. Other hazards

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. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
aluminium oxide	(CAS-No.) 1344-28-1 (EC-No.) 215-691-6 (REACH-no) 01-2119529248-35	15 - 35	Not classified
Glycerol	(CAS-No.) 56-81-5 (EC-No.) 200-289-5	1 - 15	Not classified
ethanol, ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	< 1	Flam. Liq. 2, H225
(E) -anethole	(CAS-No.) 4180-23-8 (EC-No.) 224-052-0	< 0.5	Skin Sens. 1, H317

Full text of H-statements: see section 16

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of first aid measures

First-aid measures general	: Move to fresh air. Get medical attention if any discomfort continues.
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: On ingestion in large quantities: Drink plenty of water, Get medical advice/attention. Rinse mouth. Do NOT induce vomiting.

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

No additional information available

#### 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. Dry powder. Carbon dioxide. Water spray. Sand.
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.

#### 5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the 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

##### For non-emergency personnel

Protective equipment	: See Heading 8.
Emergency procedures	: Evacuate unnecessary personnel.

##### For emergency responders

Protective equipment	: Equip cleanup and emergency crew with proper protection.
Emergency procedures	: Ventilate area.

**6.2. Environmental precautions**

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

**6.3. Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

**6.4. Reference to other sections**

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

**SECTION 7: HANDLING AND STORAGE****7.1. Precautions for safe handling**

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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

Storage conditions : Store in a dry place. Store in a closed container. Keep cool. Store in original container. Keep container closed when not in use.

Incompatible products : Strong acids.

**7.3. Specific end use(s)**

No additional information available

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters**

<b>Glycerol (56-81-5)</b>		
Ireland	Local name	Glycerol, mist
Ireland	OEL (8 hours ref) (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
United Kingdom	Local name	Glycerol
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> mist
<b>ethanol, ethyl alcohol (64-17-5)</b>		
Ireland	Local name	Ethanol
Ireland	OEL (15 min ref) (ppm)	1000 ppm
United Kingdom	Local name	Ethanol
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	1920 mg/m <sup>3</sup>
United Kingdom	WEL TWA (ppm)	1000 ppm
<b>aluminium oxide (1344-28-1)</b>		
Ireland	Local name	Aluminium oxides
Ireland	OEL (8 hours ref) (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> total inhalable dust 4 mg/m <sup>3</sup> respirable dust
United Kingdom	Local name	Aluminium oxides
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> inhalable dust 4 mg/m <sup>3</sup> respirable dust

**8.2. Exposure controls**

Personal protective equipment : Avoid all unnecessary exposure.

Hand protection : Not required for normal conditions of use

Eye protection : Not required

Skin and body protection : Not required

Respiratory protection : Not required

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

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****9.1. Information on basic physical and chemical properties**

Physical state : Liquid

Appearance : Paste.

Colour : pink.

Odour : mint.

Odour threshold : Not determined

pH	: 8.5 - 10
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: Not determined
Relative vapour density at 20 °C	: Not determined
Relative density	: 1.45 (g/cm <sup>3</sup> )
Solubility	: In water, material is partially soluble.
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Not explosive.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined

**9.2. Other information**

No additional information available

**SECTION 10: STABILITY AND REACTIVITY**

**10.1. Reactivity**

No incompatible groups noted.

**10.2. Chemical stability**

Stable under normal conditions.

**10.3. Possibility of hazardous reactions**

No polymerization.

**10.4. Conditions to avoid**

None to our knowledge.

**10.5. Incompatible materials**

Acids.

**10.6. Hazardous decomposition products**

No decomposition if stored and used normally.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1. Information on toxicological effects**

Acute toxicity : Not classified

<b>Glycerol (56-81-5)</b>	
LD50 oral rat	12600 mg/kg
LD50 dermal rabbit	> 10000 mg/kg

<b>ethanol, ethyl alcohol (64-17-5)</b>	
LD50 oral rat	7060 mg/kg
LD50 dermal rabbit	> 20000 mg/m <sup>3</sup>
LC50 inhalation rat (Vapours - mg/l/4h)	124.7 mg/l/4h

<b>aluminium oxide (1344-28-1)</b>	
LD50 oral rat	> 5000 mg/kg

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: 8.5 - 10
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: 8.5 - 10
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
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

<b>Glycerol (56-81-5)</b>	
LC50 fish 1	67500 mg/l (96 hours - Rainbow trout)
IC50 algae	2900 mg/l
<b>ethanol, ethyl alcohol (64-17-5)</b>	
LC50 fish 1	13500 mg/l (96 hours - Pimephales promelas)
EC50 Daphnia 1	54000 mg/l (48 hours - Daphnia magna)
IC50 algae	> 10.9 mg/l (IC50, 72 hours - Skeletonema costatum)
<b>aluminium oxide (1344-28-1)</b>	
LC50 fish 1	> 100 mg/l 96 h (Salmo trutta)
EC50 Daphnia 1	> 100 mg/l (48 hours - Daphnia magna)
IC50 algae	> 100 mg/l (IC50, 72 hours - Selenastrum capricornutum)

### 12.2. Persistence and degradability

<b>Hawe Implant Paste</b>	
Persistence and degradability	Not established.
<b>Glycerol (56-81-5)</b>	
Chemical oxygen demand (COD)	1
Biodegradation	63 % (OECD 301C method)
<b>ethanol, ethyl alcohol (64-17-5)</b>	
BOD (% of ThOD)	≥ 0.4 % ThOD BOD5/COD
Biodegradation	85 % (OECD 301D method)

### 12.3. Bioaccumulative potential

<b>Hawe Implant Paste</b>	
Log Pow	Not determined
Bioaccumulative potential	Not established.
<b>Glycerol (56-81-5)</b>	
Bioconcentration factor (BCF REACH)	0.017
Log Pow	-1.76

### 12.4. Mobility in soil

<b>Hawe Implant Paste</b>	
Ecology - soil	In water, material is partially soluble.

### 12.5. Results of PBT and vPvB assessment

<b>Hawe Implant Paste</b>	
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	: Avoid release to the environment.

**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 : Do not discharge into drains.
- Product/Packaging 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 07 - chemicals other than those mentioned in 18 01 06

**SECTION 14: TRANSPORT INFORMATION**

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

<b>14.1. UN number</b>	Not regulated for transport
<b>14.2. UN proper shipping name</b>	
<b>14.3. Transport hazard class(es)</b>	
<b>14.4. Packing group</b>	
<b>14.5. Environmental hazards</b>	
No supplementary information available	

**14.6. Special precautions for user**

**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 2015/830 /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:

1.2	Function or use category	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
3.2	Composition/information on ingredients	Modified	
9.1	Physical and chemical properties	Modified	

Data sources : EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

Other information : None.

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Version : 4.0  
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Full text of H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
H225	Highly flammable liquid and vapour.
H317	May cause an allergic skin reaction.
EUH208	Contains (E) -anethole. May produce an allergic reaction.

*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.*