



Safety Data Sheet F.I.T.T. Powder

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

1.1. Product identifier

Product name : F.I.T.T. Powder

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

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311

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]

Eye Irrit. 2 H319

Full text of H statements : see section 16

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H319 - Causes serious eye irritation.

Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face 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.
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

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. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Propenoic acid, 2-methyl-, ethyl ester, homopolymer	(CAS-No.) 9003-42-3 (EC-No.) 618-365-5	> 75	Eye Irrit. 2, H319
Polymethyl methacrylate	(CAS-No.) 9011-14-7	10 - 25	Eye Irrit. 2, H319

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general	: No particular/specific measures required.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention.
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. Do not remove clothing if it sticks to the skin.
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 advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Get medical advice/attention.

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

Symptoms/effects after inhalation	: May cause respiratory irritation. May cause shortness of breath, tightness of the chest, a sore throat and cough.
Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract.

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

Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

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 : Wear appropriate personal protective equipment - see Section 8. Avoid dust formation. Avoid inhalation of the product.

For non-emergency personnel

Emergency procedures : Keep upwind. Evacuate unnecessary personnel.

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 : Mechanically recover the product.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Do not breathe dust. Ensure good ventilation of the work station. Use only outdoors or in a well-ventilated area. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limit values for the other components

Dust			
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ Dusts non-specific total inhalable 4 mg/m ³ Dusts non-specific respirable	
United Kingdom	WEL TWA (mg/m ³)	10 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. In case of dust production: protective goggles.

Hand protection : Wear suitable gloves. Nitrile rubber gloves. Layer thickness : 0,1 mm. Breakthrough time : > 60 minutes. STANDARD EN 374.

Eye protection : In case of dust production: protective goggles. 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. Dust production: dust mask with filter type P2. Standard EN 143.



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	: Solid
Appearance	: Powder.
Colour	: white.
Odour	: characteristic.
Odour threshold	: Not determined
pH	: Not determined
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: > 93 °C
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	: Not determined
Solubility	: Material insoluble in water.
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Not determined.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

Stable in use and storage conditions as recommended in item 7.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Heat. Water, humidity.

10.5. Incompatible materials

Oxidizing agent.

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
Skin corrosion/irritation	: Not classified May cause slight irritation to the skin Redness pH: Not determined
Serious eye damage/irritation	: Causes serious eye irritation. Lacrimation pH: Not determined
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 May cause shortness of breath, tightness of the chest, a sore throat and cough
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

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - general : No data available.

12.2. Persistence and degradability

F.I.T.T. Powder	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

F.I.T.T. Powder	
Log Pow	Not determined
Bioaccumulative potential	No data.

12.4. Mobility in soil

F.I.T.T. Powder	
Ecology - soil	Material insoluble in water.

12.5. Results of PBT and vPvB assessment

F.I.T.T. Powder	
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.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1. UN number	
Not regulated for transport	
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
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 for the substance or the mixture by the supplier

SECTION 16: OTHER INFORMATION

Indication of changes:

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added	
2.2	Precautionary statements (CLP)	Added	
2.2	Hazard pictograms (CLP)	Added	
2.2	Hazard statements (CLP)	Added	
2.2	Signal word (CLP)	Added	
2.2	EUH-statements	Removed	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after inhalation	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects after inhalation	Modified	
4.2	Symptoms/effects after ingestion	Modified	
4.3	Other medical advice or treatment	Modified	
5.1	Suitable extinguishing media	Modified	
5.2	Hazardous decomposition products in case of fire	Modified	
6.1	Emergency procedures	Added	
7.1	Precautions for safe handling	Modified	
7.2	Storage conditions	Modified	
8.2	Hand protection	Modified	
8.2	Respiratory protection	Modified	

Date of issue : 03/03/2004
Revision date : 30/12/2017
Supersedes : 17/07/2017
Date of total revision : 30/12/2017
Version : 7.0
Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

300716		F.I.T.T. Powder		30/12/2017	
Eye Irrit. 2		Serious eye damage/eye irritation, Category 2			
H319		Causes serious eye irritation.			

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.