

KERR

Material Safety Data Sheet

in accordance with Community Regulation 2006/1907/EC (R.E.A.Ch.)

Revision Date: 17th April 2009

SECTION 1

Product & Company identification

1.1 Product name

F.I.T.T. LIQUID

1.2 Uses/Application:

Dental Functional Impression Tissue Toner.

1.3 Company (Name, address and info phone number)

KERR ITALIA s.r.l.

Via Passanti, 332

84018 Scafati (SA) - Italy

+39-081-850-8311

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39.081.8508.325 (08.00-17.00, European time, GMT+1)

E-mail address: safety@kerrhawe.com

SECTION 2

Hazard identification

2.1 Hazard classification (according to communitarian directives 67/548/EEC & 99/45/EC)

Toxic for Reproduction (Cat. 1-2); Toxic to aquatic organisms; Highly flammable.

2.2 Other hazard

None.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 Hazardous ingredients

HAZARDOUS INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
Dibutyl Phtalate (DBP)	75-85	T; N	61-50-62	84-74-2	201-557-4
Ethyl Alcohol	15-22	F	11	64-17-5	200-578-6

3.2 Other non-hazardous ingredients

The product contains traces of Methyl Salicylate (See also Sections 11 and 16).

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15 minutes, including under eyelids. If irritation persists, seek medical attention.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water. If irritation or redness develops, seek medical attention.
- 4.3 Treatment for inhalation (breathing): Move to fresh air. Give artificial respiration if breathing is stopped. Get prompt medical attention.
- 4.4 Treatment for ingestion (swallowing): Do not induce vomiting, dilute with water or milk and get prompt emergency medical attention. Never give anything to an unconscious person.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Chemical Foam, carbon dioxide, dry chemicals. Water may be ineffective.
- 5.2 Forbidden extinguishing media: Direct stream of water.
- 5.3 Special fire fighting measures: Wear respiratory pressure-demand, self-contained breathing apparatus, filter-approved and full protective gear. Use water spray to cool containers. Avoid spreading burning liquid with water used for cooling.
- 5.4 Unusual fire and explosion hazards: Vapors may travel to source of ignition and flash back.
- 5.5 Special protection equipment: Sealed (tinning) overall.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: In case of release, use self contained breathing apparatus and protective clothing.
- 6.2 Environmental Precautions: Keep spills and runoffs from clean up out of sewers and open bodies of water. Spills on porous surfaces can contaminate the groundwater.
- 6.3 Reclaiming Methods: Evacuate the area. Eliminate sources of ignition. Dike and adsorb with inert material. Transfer to proper containers for disposal, use non-sparking tools. Incinerate liquid and dispose of in accordance with local regulations.

SECTION 7**Handling and Storage** (according to article 5 of communitarian directive 98/24/EC)

7.1 Handling Precautions: Use explosion-proof equipment. Keep tightly container after each use.

7.2 Precautions in case of Fire and Explosion: Evacuate area, eliminate ignition sources, wear respiratory and protective clothing. Dike and absorb with inert material.

7.3 Storage Conditions: Store in a cool and dry dark place. Keep away from heat, sparks, flame and direct sunlight. Ground all metal containers when transferring.

7.4 Suggested container(s): Original sealed containers provided by manufacturer.

7.5 Indication for Combined Storage: Avoid contact with oxidizing agents and chlorides.

7.6 Environmental precautions: Do not allow product to reach sewers and rivers.

7.7 Other Precautions: Use according to directions. Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure.

SECTION 8**Exposure controls/personal protection**

<u>8.1 Exposure Limits:</u>	<u>TWA/TLV:</u> 5 mg/m ³ ;(DBP) 1000 ppm (Ethyl alcohol)
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8.2 Exposure control measures8.2.1 Precautionary Measures:

(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)

Ventilation:	<u>Local Exhaust Ventilation:</u> Sufficient to keep concentration below TLV. <u>Special Ventilation:</u> None. <u>Mechanical (General) Ventilation:</u> None. <u>Other Ventilation:</u> None.
Respiratory Protection:	When vapours exceed TLV, use self-contained breathing apparatus.
Hands Protection:	Impervious gloves, nitrile type.
Eyes Protection:	Safety glasses or splash-proof goggles.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	Provide eyewash, safety shower and impervious clothing. Protective creams should not be used for protection, but may be used for ease of clean up.

Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)

8.2.2 Environment exposure control measures

Not Applicable.

SECTION 9	
Physical and Chemical Properties	
<i>9.1 General information</i>	
<u>Appearance</u> : Clear, pale yellow, oily liquid.	<u>Odour</u> : Pleasant minty odour.
<i>9.2 Information related to health, safety and environment</i>	
<u>pH</u> : Not determined (N/D)	<u>Relative density</u> : Not available
<u>Boiling point</u> : N/D	<u>Specific gravity</u> : 0,983 g/ml @ 25°C
<u>Flash point</u> : Not established (N/E)	<u>Solubility</u> : Not established
<u>Flammability</u> : Yes.	<u>Partition coefficient n-octanol/water</u> : N/D
<u>Lower Explosivity Limit (L.E.L.)</u> : N/E	<u>Viscosity</u> : 12 – 1000 mPa*s @ 25°C
<u>Upper Explosivity Limit (U.E.L.)</u> : N/E	<u>Vapour density (air = 1)</u> : N/D
<u>Oxidizing properties</u> : None	<u>Evaporation rate (n-butane = 1)</u> : N/D
<u>Vapour pressure</u> : N/D	<u>Melting point</u> : N/D
<i>9.3 Other information (according to communitarian directives 94/9/EC):</i>	
<u>Miscibility</u> : N/D.	<u>Conducibility</u> : Not applicable
<u>Solubility in Lipids</u> : N/D	<u>Gases Group</u> : N/D

SECTION 10
Stability and Reactivity
<u>Stability</u> : Stable.
<u>10.1 Conditions to avoid</u> : Heat and ignition sources.
<u>10.2 Materials to avoid (incompatibility)</u> : Oxidizing agents and chlorides.
<u>10.3 Hazardous decomposition products</u> : Carbon oxides when burned.
<i>Other precautions:</i>
<u>Hazardous Polymerization Products</u> : Will not occur.
<u>Safety significance in case of change in physical appearance</u> : None known
<u>Stabilizers</u> : No stabilizers are present in this product.

SECTION 11**Toxicological Information**CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

Toxic for reproduction. Additionally the product contains traces of Methyl Salicylate, which has shown evidence of teratogenic effects in animals. See also Section 16.

Effects and hazards of eye contact: May cause irritation, burning, tearing and redness.

Effects and hazards of skin contact: Prolonged or repeated contact may cause redness, burning and defatting.

Effects and hazards of Inhalation (Breathing): May cause irritation to the respiratory tract and throat.
Prolonged or excessive inhalation may cause headaches, drowsiness, lassitude, loss of appetite and ability to concentrate.

Effects and hazards of Ingestion (Swallowing): Excessive quantities may cause nausea, vomiting, abdominal pain, diarrhea and central nervous system depression.

Effects for prolonged Exposure: Traces of Methyl Salicylate contained in this product may generate following hazards: lung damage in case of prolonged or excessive inhalation and kidney damage if swallowed in very large amounts.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

DBP	LD ₅₀ (acute oral rat)	8000 mg/Kg
	LD ₅₀ (dermal rabbit)	>20ml/Kg
	Eye irritation human	Slight
	TD _{L0} (acute oral CNS man)	140mg/Kg
	Feeding study	Rats were fed a diet containing phtalate for 4 months which showed slower weight gain, body/organ ratio showed small testes and increased liver weights with all other studies giving normal results. The relevance of these findings to humans is uncertain.
Ethyl Alcohol	LC ₅₀ (inhalation mouse/4hrs)	39g/m ³
	LC ₅₀ (inhalation rat/10hrs)	20000ppm
	LD _{L0} (intraperitoneal dog)	3000mg/Kg
	LD ₅₀ (intraperitoneal guinea pig)	3414mg/Kg
	LD ₅₀ (intraperitoneal hamster)	5068mg/Kg
	LD ₅₀ (intraperitoneal mammal)	4300mg/Kg
	LD ₅₀ (intraperitoneal mouse)	933mg/Kg
LD ₅₀ (intraperitoneal rat)	3750mg/Kg	

Ethyl Alcohol (continued)	LD ₅₀ (intraperitoneal rabbit)	963mg/Kg
	LD _{L0} (intravenous cat)	3945mg/Kg
	LD _{L0} (intravenous chicken)	8216mg/Kg
	LD _{L0} (intravenous dog)	1600mg/Kg
	LD ₅₀ (intravenous mouse)	1973mg/Kg
	LD ₅₀ (intravenous rat)	1440mg/Kg
	LD ₅₀ (intravenous rabbit)	2374mg/Kg
	LD _{L0} (oral cat)	6000mg/Kg
	LD _{L0} (oral child)	2000mg/Kg
	LD _{L0} (oral dog)	5500mg/Kg
	LD ₅₀ (oral guinea pig)	5560mg/Kg
	LD _{L0} (oral human)	1400mg/Kg
	TD _{L0} (oral man)	700mg/Kg
	TD _{L0} (oral man)	50mg/Kg
	TD _{L0} (oral man)	1430mg/Kg
	LD ₅₀ (oral mouse)	7500mg/Kg
	LD ₅₀ (oral rat)	7060 mg/Kg
	LD ₅₀ (oral rabbit)	6300mg/Kg
	TD _{L0} (oral woman)	6300mg/Kg
	LD _{L0} (subcutaneous chicken)	5g/Kg
	LD _{L0} (subcutaneous dog)	6000mg/Kg
	LD _{L0} (subcutaneous frog)	7100mg/Kg
	LD _{L0} (subcutaneous infant)	19440mg/Kg
	LD _{L0} (subcutaneous mouse)	4g/Kg
	LD _{L0} (subcutaneous pigeon)	5g/Kg
	LD _{L0} (skin rabbit)	20g/Kg
	Methyl Salicylate	LD _{L0} (intraperitoneal rat)
LD _{L0} (oral child)		228mg/Kg
LD ₅₀ (oral dog)		2100mg/Kg
LD ₅₀ (oral guinea pig)		1060mg/Kg
LD _{L0} (oral human)		506mg/Kg
LD _{L0} (oral infant)		1480mg/Kg
LD _{L0} (oral man)		101mg/Kg
LD ₅₀ (oral mouse)		1110mg/Kg
LD ₅₀ (oral rat)		887mg/Kg
LD ₅₀ (oral rabbit)		1300mg/Kg
LD _{L0} (oral woman)		355mg/Kg
LD _{L0} (subcutaneous dog)		2250mg/Kg
LD _{L0} (subcutaneous guinea pig)		1500mg/Kg
LD _{L0} (subcutaneous rabbit)		4250mg/Kg
LD _{L0} (unreported route man)		522mg/Kg

SECTION 12**Ecological Information**

The product is not biodegradable. Very toxic to aquatic organisms.

12.1 Eco-toxicity: Not available

12.2 Mobility: Not available

12.3 Persistence and degradability: The product is not biodegradable.

12.4 Bioaccumulative potential: Not available.

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for single ingredient:

DBP	LC ₅₀ / 96 hours (daphnia):	1-10 mg/l
	LC ₅₀ / 96 hours (fishes):	1,2 mg/l
Ethyl Alcohol	EC ₅₀ /48 hours (daphnia magna):	> 10 mg/l
	IC ₅₀ /72 hours (algae):	5000 mg/l
	LC ₅₀ (fishes):	> 10000 mg/l

SECTION 13**Disposal considerations**

Dispose of in accordance of local regulations.

SECTION 14**Transport information**14.1 Sea transportation (IMDG)

UN number: 1986 Class: 3 Packing group: III
EMS-No: F-E, S-D Stowage/segregation: Category A;
Limited Quantity: 5 Lt
Proper shipping name: Flammable alcohols, toxic, n.o.s.

14.2 Air transportation (ICAO/IATA)

UN number: 1986 Class: 3 Packing group: III Labels: 3 + 6.1
Maximum quantities: 60 Lt (Passenger Aircraft); 220 Lt (Cargo Aircraft only)
Limited Quantity: 2 Lt Proper shipping name: Flammable alcohols, toxic, n.o.s.

14.3 Transportation by Road/Railway (RID/ADR)

UN number: 1986 Class: 3 Packing group: III Labels: 3 + 6.1
Limited Quantity: LQ7 (5 Lt/30 Kg for combined, 5 Lt/20 Kg for bandaged trays).
External package type: carton (4G) both for simple and combined packages;
Proper shipping name: Flammable alcohols, toxic, n.o.s.

SECTION 15 (Classification according to communitarian directives 67/548/EEC & 99/45/EC)

Regulatory information

Hazard labelling not required.

This product is an exempted medical device (directive 1999/45/EC, article 1, paragraph 5g).

SECTION 16

Other information

16.1 Risk phrases of all ingredients

- 11 Highly flammable.
- 61 May cause harm to the unborn child.
- 62 Possible risk of impaired fertility.
- 50 Very toxic to aquatic organisms.

16.1.1 Safety phrases of all ingredients

- 53 Avoid exposure – see instructions before use.
- 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- 61 Avoid release to the environment. Refer to special instructions / safety data sheets.
- 7 Keep container tightly closed.
- 16 Keep away from sources of ignition – No smoking.

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – www.ecb.jrc.it)

European chemical Substances Information System (ESIS - www.ecb.jrc.it/esis)

A.C.G.I.H. (www.acgih.org)

N.I.O.S.H. (www.cdc.gov/niosh/)

O.S.H.A. (www.osha.gov/)

U.E. (www.europa.eu/index_it.htm)

I.A.R.C. (www.iarc.fr/)

N.T.P. (www.ntp.niehs.nih.gov)

Evidence of Methyl Salicylate teratogenicity in animals:

-Dangerous Properties of Industrial Materials, Ed. Sax & Lewis, 7th Ed.

-Dushyant Gulati et al., Environmental Health Perspectives Supplements Volume 105, Number S1, February 1997.

-George P. Daston et al., Functional Teratogens of the Rat Kidney, Toxicological Sciences, Volume 11, Number 1 - Pp. 381-400, 1988.

European Community Directives:

67/548/EEC:	Classification, packaging and labelling of dangerous substances.
99/45/EC:	Directive concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
2001/58/EC:	Second amendment of directive 91/155/EEC for the definition of a detailed arrangement of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and substances (art. 27 of 67/548/EEC).
89/656/EEC:	Directive on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
89/686/EEC:	Approximation of the laws of the Member States relating to personal protective equipment.
94/9/EC:	Approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres
98/24/EC:	Protection of the health and safety of workers from the risks related to chemical agents at work.

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CAUTION: PRODUCT FOR PROFESSIONAL USE

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