Safety data sheet according to Regulation (EC) No 1907/2006

1. Identification of the substance/mixture and of the company/undertaking

Product identifier: Impression lacquer
Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture: Silicone based lacquer for use in audiology.
Details of the supplier of the safety data sheet
Manufacturer/distributor identification:
Frisch Labor Systems GmbH
Lenzhalde 4
D-88179 Oberreute, Germany
Phone: +49 (0) 8387-9228-0
Fax: +49 (0) 8387-9228-30
Emergency number: +49 (0) 7243-510-0 This number is only obtainable during office hours (Monday – Thursday 8.00 a.m. – 5.00 p.m., Friday 8.00 a.m. – 4.00 p.m.)

2. Hazards identification

Classification of the substance or mixture
Hazard categories:
Flammable liquid: Flam. Liq. 2
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Dam. 1
Specific target organ toxicity - single exposure: STOT SE 3
Hazardous to the aquatic environment: Aquatic Chronic 2
Hazard Statements:
Highly flammable liquid and vapour.
Causes skin irritation.
Causes serious eye damage.
May cause drowsiness or dizziness.
Toxic to aquatic life with long lasting effects.
Label elements
Hazardous components which must be listed on the label: Methylcyclohexane, Triacetoxymethylsilan
Signal word: Danger
Pictograms:

Hazard statements:

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P235	Keep cool.
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.
P310	Immediately call a POISON CENTER/doctor.
P370+P378	In case of fire: Use SECTION 5: Firefighting measures to extinguish.
Other hazards :	No information available.

3. Composition / information on ingredients

Mixtures

Chemical characterization: Polydimethylsiloxane with functional groups in organic solvents.

Hazardous components

CAS-No.	Chemical name			Quantity
	EG-No.	Index-No.	REACH-No.	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
108-87-2	Methylcyclohexane			25 - < 30 %
	203-624-3	601-018-00-7		
	Flam.Liq. 2, Skin Irrit. 2, STOT SE 3, Asp.Tox.1, Aquatic Chronic 2; H225 H315 H336 H304, H411			
1330-20-7	Xylene			20 - < 25 %
	215-535-7	601-022-00-9		
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2; H226 H332 H312 H315			
100-41-4	Ethylbenzene			5 - < 10 %
	202-849-4	601-023-00-4		
	Flam. Liq. 2, Acute Tox. 4, STOT RE 2, Asp. Tox. 1; H225 H332 H373 H304			
4253-34-3	Triacetoxymethylsilan			1 - < 5 %
	224-221-9		01-2119962266-32	
	Acute Tox. 4, Skin Corr. 1C, Eye Dam. 1; H302 H314 H318 EUH014			

Full text of R-, H- and EUH-phrases: see section 16.

4. First aid measures

Description of first aid measures

After inhalation: Provide fresh air. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After contact with the skin: After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

After contact with the eyes: In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion: Rinse mouth immediately and drink plenty of water. Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

Most important symptoms and effects, both acute and delayed: No information available.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

5. Firefighting measures

Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO2), Foam, Extinguishing powder.

Unsuitable extinguishing media: Water.

Special hazards arising from the substance or mixture: Flammable. Vapours can form explosive mixtures with air.

Advice for firefighters: Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information: Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition. Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

Environmental precautions: Do not allow uncontrolled discharge of product into the environment. Danger of explosion.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Reference to other sections:

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

7. Handling and storage

Precautions for safe handling

Advice on safe handling: If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion: Keep away from sources of ignition. - No smoking. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels: Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Advice on storage compatibility: Do not store together with: Oxidising agent. Pyrophoric or self-heating substances.

Specific end use(s): Liquid for coating of silicone based ear impressions. For use by trained specialist staff.

8. Exposure controls/personal protection

Control parameters

Exposure limits (EH40)

CAS-No.	Substance	ppm	mg/m³	Fibres/ml	Category	Origin
100-41-4	Ethylbenzene	100	441		TWA (8h)	WEL
		125	552		STEL (15min)	WEL
1330-20-7	Xylene (mixed isomers)	50	220		TWA (8h)	WEL
		100	441		STEL (15min)	WEL

Biological Monitoring Guidance Values (EH40)

CAS-No.	Substance	Parameter	Value	Test material	Sampling time
1330-20-7	Xylene, o-,m-,p- or mixed	Methyl hippuric acid	650 mmol/mol	Urine	Post shift

Exposure controls

Appropriate engineering controls: If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures: Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection: Suitable eye protection: goggles.

Hand protection: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous

substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Suitable are gloves of the following material: FKM (fluoro rubber)
Skin protection: Flame-retardant protective clothing. Wear anti-static footwear and clothing.
Respiratory protection: In case of inadequate ventilation wear respiratory protection.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:	Transparent	
Odour:	Xylene/Acetic acid	
		Test Method
pH-value:	Not determined	
Changes in the physical state		
Melting point:	Not determined	
Initial boiling point and boiling range:	> 99°C	DIN 51356
Flash point:	< 1°C	DIN 51755
Sustaining combustion:	Not sustaining combustion	
Flammability		
Solid:	Not applicable	
Gas:	Not applicable	
Lower explosion limits:	1,1 vol%	
Upper explosion limits:	6,7 vol%	
Auto-ignition temperature		
Solid:	Not applicable	
Gas:	Not applicable	
Decomposition temperature:	Not determined	
Oxidising properties:	Not oxidising	
Vapour pressure (at 20°C):	48 hPa	
Density (at 20°C):	0,90 g/cm³	DIN 51757
Water solubility:	Insoluble	
Solubility ion other solvents:	Not determined	
Partition coefficient:	Not determined	
Viscosity, dynamic (at 23°C):	100 mPa.s CP	
Vapour density:	Not determined	
Evaporation rate:	Not determined	
Other informations		
Solid content:	Not determined	

10. Stability and reactivity

Reactivity: Flammable, Ignition hazard.
Chemical stability: The product is stable under storage at normal ambient temperatures**.**
Possibility of hazardous reactions: Reacts with : strong oxidising agents. The product may attack same plastic materials.
Conditions to avoid: Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air.
Incompatible materials: No information available.
Hazardous decomposition products: The following applies for the silicone content of the product: At temperature of appr. 150°C/ 302 °F a small amount of formaldehyde can be released by oxidative degradation.

11. Toxicological information

Information on toxicological effects

Acute toxicity: Based on available data, the classification criteria are not met.

ATEmix calculated: ATE (oral) 1238,3 mg/kg

CAS-No.	Chemical name				
	Exposure routes	Method	Dose	Species	Source
108-87-2	Methylcyclohexane				
	oral	LD50	>3200mg/kg	Rat	GESTIS
	dermal	LD50	86000mg/kg	Rabbit	
1330-20-7	Xylene				
	oral	LD50	4300 mg/kg	Rat	GESTIS
	dermal	LD50	> 1700 mg/kg	Rabbit	GESTIS
	inhalativ (4h) vapour	LC50	21,7 mg/l	Rat	GESTIS
	Inhalative aerosol	ATE	1,5 mg/l		
100-41-4	Ethylbenzene				
	oral	LD50	3500 mg/kg	Rat	GESTIS
	dermal	LD50	15400 mg/kg	Rabbit	GESTIS
	inhalativ (4h) vapour	LC50	17,2 mg/l	Rat	
	Inhalative aerosol	ATE	1,5 mg/l		
4253-34-3	Triacetoxymethylsilan				
	oral	LD50	1600 mg/kg	Rat	OECD 401

Irritation and corrosivity: Causes skin irritation. Causes serious eye damage.

Sensitising effects: Based on available data, the classification criteria are not met.

STOT-single exposure: May cause drowsiness or dizziness (Methylcyclohexane).

Severe effects after repeated or prolonged exposure: Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Additional information on tests: This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

12. Ecological information

Toxicity: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS-No.	Chemical name					
	Aquatic toxicity	Method	Dose	(h) (d)	Species	Source
108-87-2	Methylcyclohexane					
	Acute fish toxicity	LC50	58,5 mg/l	96h		GESTIS
	Acute crustacea toxicity	EC50	1,47 mg/l	48h	Daphnia magna	ECOTOX
1330-20-7	Xylene					
	Acute fish toxicity	LC50	15,7 mg/l	96h		GESTIS
	Acute crustacea toxicity	EC50	8,5 mg/l	48h		GESTIS
100-41-4	Ethylbenzene					
	Acute algae toxicity	ErC50	3,6 mg/l	96h		GESTIS

Persistence and degradability: The product has not been tested.

Bioaccumulative potential: The product has not been tested.

Partition coefficient n-octanol/water

CAS-No.	Chemical name	Log Pow
108-87-2	Methycyclohexane	3,88
100-41-4	Ethylbenzene	3,15

Mobility in soil: The product has not been tested.
Results of PBT and vPvB assessment: Not identivied as PBT/ vPvB substances.
Other adverse effects: No information available.
Further information: Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

13. Disposal considerations

Waste treatment methods
Advice on disposal: Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.
Contaminated packaging: Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

14. Transportation information

Land transport (ADR/RID)

UN number:	UN 2924
UN proper shipping name:	FLAMMABLE LIQUID, CORROSIVE, N.O.S. Contains: methylcyclohexane, triacetoxymethylsilane
Transport hazard class(es):	3
Packing group:	II
Hazard label:	3+8
Classification code:	FC
Limited quantity:	1 L/ 30 kg
Hazard No:	338
Tunnel restriction code:	D/E
Other applicable information (land transport):	Contains: methylcyclohexane, triacetoxymethylsilane

Marine transport (IMDG)

UN number:	UN 2924
UN proper shipping name:	FLAMMABLE LIQUID, CORROSIVE, N.O.S. Contains: methylcyclohexane, triacetoxymethylsilane
Transport hazard class(es):	3
Packing group:	II
Hazard label:	3+8
Limited quantity:	1 L/ 30 kg
EmS:	F-E, S-C
Other applicable information (marine transport):	Flash point: -4°C c.c.,contains: methylcyclohexane, triacetoxymethylsilane

Air transport (ICAO)

UN number:	UN 2924
UN proper shipping name:	FLAMMABLE LIQUID, CORROSIVE, N.O.S. Contains: methylcyclohexane, triacetoxymethylsilane
Transport hazard class(es):	3
Packing group:	II
Hazard label:	3+8
Limited quantity Passenger:	0,5L/ 30 kg
Passenger LQ:	Y340
Expected quantity:	E2
IATA-packing instructions - Passenger:	352
IATA-max. quantity - Passenger:	1L

IATA-packing instructions
- Cargo: 363
IATA-max. quantity
- Cargo: 5L
Other applicable information (air transport): Contains: methylcyclohexane, triacetoxymethylsilane
Environmental hazards: Environmental hazardous: yes
Special precautions for user: Warning: Combustible liquid, strongly corrosive.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
EU regulatory information:
2010/75/EU (VOC): 35,721 % (321,491 g/l)
2004/42/EC (VOC): 35,721 % (321,491 g/l)
Additional information: To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC
National regulatory information
Employment restrictions: Observe employment restrictions for young people.
Water contaminating class (D): 3 - highly water contaminating
Chemical safety assessment: Chemical safety assessments for substances in this mixture were not carried out.

16. Other information

Abbreviations and acronyms
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
Relevant H- and EUH-phrases (Number and full text)
H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H332 Harmful if inhaled.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
EUH014 Reacts violently with water.
Further Information: The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.