SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

frosty coat

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

Use of the substance/mixture

Silicone based lacquer for use in audiology.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
E-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	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.)	

1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EG) Nr. 1272/2008

Flam. Liq. 2; H225
Acute Tox. 4; H312
Acute Tox. 4; H332
Skin Irrit. 2; H315
Eye Irrit. 2; H319
STOT SE 3; H335
STOT SE 3; H336
STOT RE 2; H373
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EG) Nr. 1272/2008

Hazard components for labelling

xylene
methylcyclohexane
dioctyltin-di(acetate)

Signal word: Danger

Pictograms:

Hazard statements

H225	Highly flammable liquid and vapour.
H312+H332	Harmful in contact with skin or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful 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.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
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.
P370+P378	In case of fire: Use Carbon dioxide (CO2), Foam, Extinguishing powder to extinguish.
P403+P235	Store in a well-ventilated place. Keep cool.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Polydimethylsiloxane with functional groups in organic solvents.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EG) Nr. 1272/2008)			
1330-20-7	xylene			40 - < 60 %
	215-535-7	601-022-00-9	01-2119488216-32	
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Asp. Tox. 1; H226 H332 H312 H315 H319 H335 H373 H304			
108-87-2	methylcyclohexane			20 - < 40 %
	203-624-3	601-018-00-7	01-2119556887-18	
	Flam. Liq. 2, Skin Irrit. 2, STOT SE 3, Asp. Tox. 1, Aquatic Chronic 2; H225 H315 H336 H304 H411			
4253-34-3	triacetoxymethylsilane			0.1 - < 5 %
	224-221-9		01-2119962266-32	
	Acute Tox. 4, Skin Corr. 1B, Eye Dam. 1; H302 H314 H318 EUH014			
17586-94-6	dioctyltin-di(acetate)			< 0,5 %
	241-555-0			
	Acute Tox. 2, Skin Corr. 1A, STOT SE 2; H330 H314 H371			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
1330-20-7	215-535-7	xylene	40 - < 60 %
	inhalation: LC50 = 29,08 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: LD50 = >1700 mg/kg; oral: LD50 = 3500 mg/kg		
108-87-2	203-624-3	methylcyclohexane	20 - < 40 %
	dermal: LD50 = > 2000 mg/kg; oral: LD50 = 4000-4500 mg/kg		
4253-34-3	224-221-9	triacetoxymethylsilane	0.1 - < 5 %
	oral: ATE = 500 mg/kg		
17586-94-6	241-555-0	dioctyltin-di(acetate)	< 0,5 %
	inhalation: LC50 = 0,43 mg/l (vapours); inhalation: ATE = 0,05 mg/l (dusts or mists); oral: LD50 = >2000 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. 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).

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2), Foam, Extinguishing powder.

Unsuitable extinguishing media

Water.

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.

5.3. 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Remove all sources of ignition. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Explosion risk.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. 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.

Advice on general occupational hygiene

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, drink, smoke, sniff. 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.

7.2. 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.

Hints on joint storage

Do not store together with: Oxidizing agent. Pyrophoric or self-heating substances. Oxidising agent

7.3. Specific end use(s)

Liquid for coating of silicone based ear impressions and earmoulds.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
1330-20-7	Xylene: mixed isomers	50	220		TWA (8 h)	WEL
		100	441		STEL (15 min)	WEL

Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
1330-20-7	Xylene, o-, m-, p- or mixed isomers	methyl hippuric acid (creatinine)	650 mmol/mol	urine	Post shift

DNEL/DMEL values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
108-87-2	methylcyclohexane			
Worker DNEL, long-term		inhalation	systemic	64,3 mg/m³
Worker DNEL, acute		inhalation	systemic	1354,6 mg/m³
Worker DNEL, long-term		dermal	systemic	1,7 mg/kg bw/day
Consumer DNEL, long-term		dermal	systemic	0,8 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,4 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	16 mg/m³

PNEC values

CAS No	Substance	
Environmental compartment		Value
108-87-2	methylcyclohexane	
Freshwater		0,00134 mg/l
Marine water		0,00134 mg/l
Freshwater sediment		0,0362 mg/kg
Marine sediment		0,00362 mg/kg
Soil		0,0097 mg/kg

8.2. Exposure controls

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

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.

Thermal hazards

Flame-retardant protective clothing. Wear anti-static footwear and clothing . . .

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid:		
Colour:	faintly pink, light pink		
Odour:	Xylene/ Acetic acid		
			Test method
Melting point/freezing point:		not determined	
Boiling point or initial boiling point and boiling range:		>99 °C	DIN 51356
Flammability:		not determined	
Lower explosion limits:		1,1 vol. %	
Upper explosion limits:		6,7 vol. %	
Flash point:		<1 °C	DIN 51755
Auto-ignition temperature:		not determined	
Decomposition temperature:		not determined	
pH-Value:		not determined	
Viscosity / kinematic:		not determined	
Water solubility:		The study does not need to be conducted because the substance is known to be insoluble in water.	

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined	
Vapour pressure: (at 20 °C)	48 hPa	
Density (at 20 °C):	0,884 g/cm³	DIN 51757
Relative vapour density:	not determined	
Particle characteristics:	not applicable	

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Sustaining combustion:	Not sustaining combustion

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:	not determined	
Solid content:	not determined	
Viscosity / dynamic: (at 23 °C)	20 mPa·s	CP

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : strong oxidising agents. The product may attack same plastic materials.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air.

10.5. Incompatible materials

No information available.

10.6. 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.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EG) Nr. 1272/2008

Acute toxicity

Harmful in contact with skin.
Harmful if inhaled.

ATEmix calculated

ATE (oral) 23671 mg/kg; ATE (dermal) 1915 mg/kg; ATE (inhalation vapour) 17,38 mg/l; ATE (inhalation dust/mist) 2,292 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1330-20-7	xylene				
	oral	LD50 3500 mg/kg	Rat	GESTIS	
	dermal	LD50 >1700 mg/kg	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 29,08 mg/l	Rat	GESTIS	
	inhalation dust/mist	ATE 1,5 mg/l			
108-87-2	methylcyclohexane				
	oral	LD50 4000-4500 mg/kg	Rabbit		
	dermal	LD50 > 2000 mg/kg	Rabbit		
4253-34-3	triacetoxymethylsilane				
	oral	ATE 500 mg/kg			
17586-94-6	dioctyltin-di(acetate)				
	oral	LD50 >2000 mg/kg	Rat		
	inhalation (4 h) vapour	LC50 0,43 mg/l	Maus		
	inhalation dust/mist	ATE 0,05 mg/l			

Irritation and corrosivity

Causes skin irritation.
Causes serious eye irritation.

Sensitising effects

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.

STOT-single exposure

May cause respiratory irritation. (xylene)

May cause drowsiness or dizziness. (methylcyclohexane)

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure. (xylene)

Aspiration hazard

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

11.2. Information on other hazards

Other information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] | [d]	Species	Source	Method
1330-20-7	xylene					
	Acute fish toxicity	LC50 2,661-4,093 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute crustacea toxicity	EC50 3,82 mg/l	48 h			
108-87-2	methylcyclohexane					
	Acute fish toxicity	LC50 2,07 mg/l	96 h	Oryzias latipes		OECD 203
	Acute algae toxicity	ErC50 0,134 mg/l	72 h	Pseudokirchneriella subcapitata		OECD 201
	Acute crustacea toxicity	EC50 0,326 mg/l	48 h	Daphnia magna		OECD 202
	Algae toxicity	NOEC 0,022 mg/l	3 d	Pseudokirchneriella subcapitata		OECD 201

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
108-87-2	methylcyclohexane			
	OECD 301F	0%	28	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
1330-20-7	xylene	3,15
108-87-2	methylcyclohexane	3,88

BCF

CAS No	Chemical name	BCF	Species	Source
1330-20-7	xylene	0,6-15		

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.
Not identivied as PBT/ vPvB substances

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

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

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	UN 1866
14.2. UN proper shipping name:	RESIN SOLUTION
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Special Provisions:	640D
Limited quantity:	5 L
Excepted quantity:	E2
Transport category:	2
Hazard No:	33
Tunnel restriction code:	D/E

Other applicable information (land transport)

Flammable licquid

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Special Provisions:	640D
Limited quantity:	5 L

Excepted quantity:	E2

Marine transport (IMDG)

14.1. UN number or ID number:	UN 1866
14.2. UN proper shipping name:	RESIN SOLUTION
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Special Provisions:	-
Limited quantity:	5 L
Excepted quantity:	E2
EmS:	F-E, S-E

Other applicable information (marine transport)

Flash point: -4°C c.c.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 1866
14.2. UN proper shipping name:	RESIN SOLUTION
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Special Provisions:	A3
Limited quantity Passenger:	1 L
Passenger LQ:	Y341
Excepted quantity:	E2
IATA-packing instructions - Passenger:	353
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	364
IATA-max. quantity - Cargo:	60 L

14.6. Special precautions for user

Warning: Combustible liquid.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

2004/42/EC (VOC):	78,398 % (693 g/l)
Information according to 2012/18/EU (SEVESO III):	P5c FLAMMABLE LIQUIDS

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	2 - obviously hazardous to water
Skin resorption/Sensitization:	Permeates easily through outer skin and causes poisoning.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 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%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
VOC: Volatile Organic Compounds
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).
Flam. Liq: Flammable liquids
Acute Tox: Acute toxicity
Asp. Tox: Aspiration hazard
Skin Corr: Skin corrosion
Skin Irrit: Skin irritation
Eye Dam: Eye damage
Eye Irrit: Eye irritation
STOT SE: Specific target organ toxicity - single exposure
STOT RE: Specific target organ toxicity - repeated exposure
Aquatic Chronic: Chronic aquatic hazard

Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Acute Tox. 4; H312	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
STOT SE 3; H335	Calculation method
STOT SE 3; H336	Calculation method
STOT RE 2; H373	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (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.
H312+H332	Harmful in contact with skin or if inhaled.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H371	May cause damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH014	Reacts violently with water.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)