

according to Regulation (EC) No 1907/2006

frosty	coat
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Revision date: 26.02.2021

Product code: 619

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

1.1. Product identifier

frosty coat

UFI:

F2TY-E0U2-500A-7DYW

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 & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	
	+49 7243/510-0	
	This number is only obtainable of	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	+49 7243/510-0	
number:	This number is only obtainable of	during office hours (Monday - Thursday 8.00 a.m.
	- 5.00 p.m., Friday 8.00 - 4.00 p	.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories: Flammable liquid: Flam. Liq. 2 Acute toxicity: Acute Tox. 4 Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Dam. 1 Specific target organ toxicity - single exposure: STOT SE 3 Specific target organ toxicity - repeated exposure: STOT RE 2 Hazardous to the aquatic environment: Aquatic Chronic 3 Hazard Statements: Highly flammable liquid and vapour. Harmful if inhaled. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

xylene triacetoxymethylsilane dioctyltin-di(acetate)

Signal word: Danger

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Pictograms:



Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
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.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing 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 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					
	GHS Classification	GHS Classification						
1330-20-7	xylene			45 - < 50 %				
	215-535-7	601-022-00-9	01-2119488216-32					
	Flam. Liq. 3, Acute Tox. 4, Acute To Tox. 1, Aquatic Chronic 3; H226 H		· · · · ·					
108-87-2	methylcyclohexane	15 - < 20 %						
	203-624-3	601-018-00-7						
	Flam. Liq. 2, Skin Irrit. 2, STOT SE H411	3, Asp. Tox. 1, Aquatic Chr	onic 2; H225 H315 H336 H304					
4253-34-3	triacetoxymethylsilane			1 - < 5 %				
	224-221-9		01-2119962266-32					
	Acute Tox. 4, Skin Corr. 1C, Eye D	am. 1; H302 H314 H318 EL	H014					
17586-94-6	6-94-6 dioctyltin-di(acetate)							
	241-555-0							
	Acute Tox. 2, Skin Corr. 1A, Eye D	am. 1, STOT SE 2; H330 H	314 H318 H371					

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

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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 polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with 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).

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

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.

6.2. Environmental precautions

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

6.3. 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.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8 Disposal: see section 13

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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.

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: Oxidising agent . Pyrophoric or self-heating substances.

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		Post shift

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.

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



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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.

SECTION 9: Physical and chemical properties

<u>9.</u>

Physical state:	liquid:		
Colour:	opaque		
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	
Oxidizing properties Not oxidizing.			
Vapour pressure: (at 20 °C)		48 hPa	
Density (at 20 °C):		0,94 g/cm³	DIN 51757
Water solubility:		insoluble	
Solubility in other solvents not determined			
Partition coefficient:		not determined	
Viscosity / dynamic: (at 23 °C)		250 mPa·s	СР
Vapour density:		not determined	
Evaporation rate:		not determined	
.2. Other information			

9.2. Other information

Solid content:

SECTION 10: Stability and reactivity

not determined

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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 toxicological effects

Acute toxicity

Harmful if inhaled.

ATEmix calculated

ATE (inhalation vapour) 19,26 mg/l; ATE (inhalation aerosol) 2,465 mg/l

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
1330-20-7	xylene					
	oral	LD50 mg/kg	3500	Rat	GESTIS	
	dermal	LD50 mg/kg	>1700	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 mg/l	29,08	Rat	GESTIS	
	inhalation aerosol	ATE	1,5 mg/l			
108-87-2	methylcyclohexane					
	oral	LD50 mg/kg	> 3200	Rat	GESTIS	
	dermal	LD50 mg/kg	86000	Rabbit		
4253-34-3	triacetoxymethylsilane					
	oral	LD50 mg/kg	1600	Rat	OECD 401	
17586-94-6	dioctyltin-di(acetate)					
	oral	LD50 mg/kg	>2000	Rat		
	inhalation vapour	ATE	0,5 mg/l			
	inhalation aerosol	ATE	0,05 mg/l			

Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.



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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)

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.

Additional information on tests

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

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name								
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method		
1330-20-7	xylene	xylene							
	Acute fish toxicity	LC50 4,093 mg/l	2,661-		Oncorhynchus mykiss (Rainbow trout)				
	Acute crustacea toxicity	EC50 mg/l	3,82	48 h					
108-87-2	methylcyclohexane								
	Acute fish toxicity	LC50 mg/l	58,5	96 h		GESTIS			
	Acute crustacea toxicity	EC50 mg/l	1,47	48 h	Daphnia magna	ECOTOX			

12.2. Persistence and degradability

The product has not been tested.

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

Not identivied as PBT/ vPvB substances

12.6. 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.

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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

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION	14:	Transpor	t information
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Land transport (ADR/RID)

<u>14.1. UN number:</u>	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
Limited quantity:	5 L/ 30 kg
Hazard No:	33
Tunnel restriction code:	D/E
Other applicable information (land trans Flammable licquid	sport)
Marine transport (IMDG)	
<u>14.1. UN number:</u>	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
Marine pollutant:	-
Special Provisions:	-
Limited quantity:	5 L/ 30 kg
EmS:	F-E, S-E
Other applicable information (marine tra Flash point: -4°C c.c.	ansport)
Air transport (ICAO-TI/IATA-DGR)	
<u>14.1. UN number:</u>	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
Limited quantity Passenger:	1 L/ 30 kg
Passenger LQ:	Y341
IATA-packing instructions - Passenger:	
IATA-max. quantity - Passenger:	
IATA-packing instructions - Cargo:	
IATA-max. quantity - Cargo:	

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14.6. Special precautions for user

Warning: Combustible liquid.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). 2 - obviously hazardous to water

Water hazard class (D):

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%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Acute Tox. 4; H332	Calculation method
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	Calculation method
STOT SE 3; H335	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.
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.



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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				
	ased on the present level of our knowledge. It does not however, give assurance of			

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.)