

according to Regulation (EC) No 1907/2006

3Delta HEAR S / SE (transparent)

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

1.1. Product identifier

3Delta HEAR S / SE (transparent)

Further trade names

3Delta HEAR blue S, 1620070 3Delta HEAR red S, 1620080 3Delta HEAR clear SE, 1620370 3Delta HEAR rose SE, 1620380 3Delta HEAR light-brown SE, 1620390

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

Use of the substance/mixture

light curing resin for hearing aid devices

1.3. Details of the supplier of the safety data sheet

Company name: Deltamed GmbH
Street: Raiffeisenstr. 8a
Place: D-61169 Friedberg

Telephone: +49 6031 7283-0 Telefax: +49 6031 7283-29

e-mail: info@deltamed.de Internet: www.deltamed.de

Responsible Department: F&E

Telefax +49 6031 7283-29

1.4. Emergency telephone Giftinformationszentrum Universitätsklinikum Mainz

<u>number:</u> Telefon +49 6131 19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Respiratory or skin sensitisation: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Diacrylat

Dimethacrylate

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.



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Precautionary statements

P261 Do not breathe vapour/aerosol.
P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local regulation.

2.3. Other hazards

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			
	EC No	Index No	REACH No	
	Classification according to Regula	ation (EC) No. 1272/2008 [CLP]	•	
	Acrylic resin			
	Aquatic Chronic 4; H413			
	Diacrylat			
	Skin Sens. 1, Aquatic Chronic 2; H317 H411			
	Dimethacrylate			< 25 %
	Skin Sens. 1, Aquatic Chronic 3; H317 H412			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)			
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361 H317 H411			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Do NOT induce vomiting. Medical treatment necessary.

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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

Foam. Extinguishing powder Carbon dioxide

Unsuitable extinguishing media

High power water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide Carbon dioxide Hazardous decomposition products

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

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

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 to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Larger quantities: Take up mechanically (by pumping). Smaller quantities and/or residues: 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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

In the event of fire, cool the endangered containers with water. Keep away from sources of ignition --- No smoking. Take precautionary measures against static discharges. When heated above the flash point and/or during spraying (atomizing), ignitible mixtures may form in air.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release. Keep container tightly closed.

Advice on storage compatibility

No special measures are necessary.



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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

It is essential for pregnant women to avoid inhaling the product and not to let it come in contact with the skin. 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

tightly fitting goggles

Hand protection

butyl rubber gloves (0.7 mm), Break through time ca. 60 min (EN 374). Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Skin protection

Wear suitable protective clothing.

Respiratory protection

Breathing apparatus in case of high concentrations, short term: filter appliance, filter A In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid

Colour: various, depending on coloration

Odour: characteristic

pH-Value: not determined

Changes in the physical state

Melting point:

Initial boiling point and boiling range:

Flash point:

not determined

not determined

> 150 °C

Flammability

Solid: not applicable
Gas: not applicable
Lower explosion limits: not determined
Upper explosion limits: not determined

Auto-ignition temperature

Solid: not applicable Gas: not applicable Decomposition temperature: not determined Vapour pressure: not determined Density (at 20 °C): 1,1 g/cm³
Water solubility: The study does not need to be conducted

because the substance is known to be insoluble in water



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Solubility in other solvents

The substance is not soluble in water.

Partition coefficient: not determined Viscosity / dynamic: 500 - 1000 mPa·s

(at 20 °C)

Vapour density: not determined Evaporation rate: not determined

9.2. Other information

Solid content: not determined Product has not been tested. The statement is derived from the properties of the components.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

10.5. Incompatible materials

Oxidising agent, Reducing agent, Heavy metals, acids, Alkali (lye)

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
	Diacrylat				
	oral	LD50 > 2000 mg/kg	Rat		
	dermal	LD50 > 2000 mg/kg	Rabbit		
	Dimethacrylate				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)				
	oral	LD50 > 5000 mg/kg	Rat	RTECS	

Irritation and corrosivity

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



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Sensitising effects

May cause an allergic skin reaction. (Diacrylat; Dimethacrylate; Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO))

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

Further information

Product has not been tested. The statement is derived from the properties of the components.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: The classification criteria for this hazard class are not met by definition.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)					
	,	EC50 3,53 mg/l	48 h	Daphnia		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
	Dimethacrylate			
	Biodegradation	22 %	28	OECD 301 F

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

No information available.

Further information

Do not allow uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Advice on disposal

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Waste disposal number of waste from residues/unused products

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic

rubber and man-made fibres: other still bottoms and reaction residues: hazardous waste

Waste disposal number of used product

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic

rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

Waste disposal number of contaminated packaging

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic

rubber and man-made fibres: other still bottoms and reaction residues: hazardous waste

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: Transport information

Land transport (ADR/RID)

Other applicable information (land transport)

No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)

Other applicable information (inland waterways transport)

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

14.6. Special precautions for user

No information available.

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

Water contaminating class (D): 2 - clearly water contaminating

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



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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
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H317 May cause an allergic skin reaction.

H361 Suspected of damaging fertility or the unborn child.
 H411 Toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.
 H413 May cause long lasting harmful effects to aquatic life.

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.

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