SAFETY DATA SHEET

1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name	HEARING AID LIQUID
Product Description	Preparation containing acrylic monomers and plasticisers.

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

Identified use(s)	Manufacture of dental and medical products.
Uses advised against	None known.

1.3 Details of the supplier of the safety data sheet

WHW Plastics Ltd, Therm Road, Cleveland Street, Hull, East Yorkshire HU8 7BF, UK

Tel: +44(0)1482 329154

sales@whwplastics.com

1.4 Emergency telephone number

+44(0)1482 329154 (Office hours only)

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 (CLP).

Skin sensitisation Category 1.	H317
STOT - single exposure Category 3	H335
Reproductive toxicity Category 2.	H361
STOT - repeated exposure Category 2	H373
Hazardous to the aquatic environment - Chronic hazard Category 1.	H410

For full text of H/R phrases see section 16.

2.2 Label elements

Signal word	Warning
Hazard statement(s)	H317: May cause an allergic skin reaction. H335: May cause respiratory irritation. H361: Suspected of damaging fertility or the unborn child. H373: May cause damage to organs through prolonged or repeated exposure. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s)	P260: Do not breathe mist/vapour. 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 water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P501: Dispose of contents/container to hazardous waste in accordance with local, state or national legislation. Incinerate under approved controlled conditions, using incinerators suitable for the disposal of noxious chemical waste.

2.3 Other hazards

Exposure to heat and direct sunlight may lead to exothermic polymerization.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

According to Regulation (EC) No. 1272/2008 (CLP).

Hazardous Ingredient(s)	%W/W	EC No.	REACH Registration No.	Hazard Class and Category Code(s)	Hazard statement Code(s)
2-Ethoxyethyl methacrylate	40-60	219-135-3	17-2119544055-45-0000	STOT SE 3 Repr. 2 Aquatic Chronic 3	H335 H361 H412
Dioctyl maleate	40-60	205-524-5	01-2119524002-60-XXXX	STOT RE 2 Aquatic Chronic 1	H373 H410
Ethylene glycol dimethacrylate	<5	202-617-2	01-2119965172-38-XXXX	Skin Sens. 1 STOT SE 3	H317 H335

For full text of H/R phrases see section 16.

4. SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTRE or doctor if you feel unwell.
Skin Contact	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
Eye Contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical attention.
Ingestion	IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Get immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction. May cause respiratory irritation. Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

None necessary.

5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media	Water spray, foam, dry powder or CO_2.
Unsuitable Extinguishing Media	Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Combustion or thermal decomposition will evolve toxic vapours. Exposure to heat and direct sunlight may lead to exothermic polymerization.

5.3 Advice for fire-fighters

A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Eliminate sources of ignition. Ensure suitable personal protection (including respiratory protection) during removal of spillages. Do not breathe mist/vapour. See Section: 8

6.2 Environmental precautions

Avoid release to the environment. Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

6.3 Methods and material for containment and cleaning up

Collect spillage. Adsorb spillages onto sand, earth or any suitable adsorbent material. Do not adsorb onto sawdust or other combustible materials. Transfer to a container for disposal or recovery.

6.4 Reference to other sections

See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood. Do not eat, drink or smoke at the work place. Wash thoroughly after handling. Do not breathe mist/vapour. Avoid inhalation of vapours that may be evolved at elevated temperatures. Use only outdoors or in a well-ventilated area.

7.2 Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. Keep container tightly closed. Keep away from heat, sources of ignition and direct sunlight.
Suitable containers: Mild steel, stainless steel, Aluminium, high density polyethylene, polypropylene, PTFE.
Incompatible materials: Oxidising agents, alkalis, peroxides.
Flammable or combustible materials.

7.3 Specific end use(s)

Manufacture of earmoulds.

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substance	CAS No.	LTEL ppm (8Hr TWA)	LTEL mg/m³ (8Hr TWA)	STEL ppm	STEL mg/m³	Notes
2-Ethoxyethanol	000110-80-5	10	37			Sk*

*NB: Although no OEL limit exists for 2-Ethoxyethyl methacrylate it is suggested that exposure is maintained below the OEL for 2-Ethoxyethanol which can be formed if 2-Ethoxyethyl methacrylate hydrolyses in the body.

8.2 Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. Provide adequate ventilation, including appropriate local extraction, to ensure that the occupational exposure limit is not exceeded. Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required. The following information is given as general guidance.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear eye/face protection. Goggles giving complete protection to eyes.

Skin protection

Wear suitable gloves.
Suitability of gloves should be confirmed with glove manufacturer. Change gloves, if contamination occurs or duration of activity exceeds breakthrough time. Breakthrough time of the glove material: refer to the information provided by the gloves' producer.

Respiratory protection

Wear suitable respiratory protective equipment if exposure to levels above the occupational exposure limit is likely. A suitable mask with filter type A (EN141 or EN405) may be appropriate. In the event of formation of particularly high levels of vapour a self contained breathing apparatus may be appropriate.

Environmental exposure controls

Ensure proper process control to ensure releases to air are within local permits. Monitor and regularly maintain ventilation equipment to ensure performance. Do not empty into drains. Contain and collect spillages for incineration. Fully polymerise before landfill. Only dispose of polymerised material with household waste.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form	Liquid.
Colour.	Colourless.
Odour	Fruity.
pH (Value)	Not available.
Boiling Point (°C)	Not available.
Flash Point (°C)	>70
Relative Evaporation Rate (Ether = 1)	Not available.
Flammability (solid, gas)	Not applicable.
Flammable Limits	Not available.
Vapour pressure (Pascal)	150 at 20°C (2-Ethoxyethyl methacrylate).
Vapour Density (Air=1)	Not available.
Solubility (Water)	~10 (2-Ethoxyethyl methacrylate).
Solubility (Other)	Not available.
Partition Coefficient (n-Octanol/water)	Not available.
Auto Ignition Temperature (°C)	~200
Viscosity (mPa. s)	Not available.
Explosive properties	Not available.
Oxidising Properties	Not applicable.
Density (g/ml)	~0.95 at 20°C

9.2 Other information

None.

10. SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Will exothermically polymerise in the presence of initiators.

10.2 Chemical stability

Stable in the presence of inhibitor.

10.3 Possibility of hazardous reactions

Susceptible to polymerisation initiated by prolonged heating or the presence of catalyst. Polymerisation catalysts, such as peroxy or azo compounds, strong acids, alkalis and oxidising agents.

10.4 Conditions to avoid

Heat and direct sunlight.

10.5 Incompatible materials

Oxidising agents, alkalis, peroxides.
Flammable or combustible materials.

10.6 Hazardous decomposition product(s)

Carbon monoxide, Carbon dioxide

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Ingestion	Low oral toxicity.
Inhalation STOT-single exposure	May cause respiratory irritation.
Skin Contact	May cause slight skin irritation.
Eye Contact	Unlikely to cause eye irritation.

Sensitisation

Skin sensitization data	Ethylene glycol dimethacrylate : May cause an allergic skin reaction.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction).

Carcinogenicity data	No information available.
Germ cell mutagenicity data	No information available.
Reproductive toxicity data	Suspected of damaging fertility or the unborn child.

Repeated exposure toxicity

STOT - repeated exposure data	May cause damage to organs through prolonged or repeated exposure.
Other information	2-Ethoxyethyl methacrylate may hydrolyse in the body to 2-Ethoxyethanol which has been shown to have adverse effects on the kidneys, liver and reproductive system of animals.

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Very toxic to aquatic life.

12.2 Persistence and degradability

2-Ethoxyethyl methacrylate : Not readily biodegradable.
Dioctyl maleate : Readily biodegradable.

12.3 Bioaccumulative potential

2-Ethoxyethyl methacrylate : The substance has low potential for bioaccumulation.
Dioctyl maleate : The substance has high potential for bioaccumulation.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

None known.

13. SECTION 13: DISPOSAL CONSIDERATIONS

Avoid release to the environment. Within the EU this material should be regarded as a 'special waste' (see relevant national legislation for special wastes and EC Hazardous Waste Directive 91/689/EEC, as amended) and disposed of appropriately. In some cases the packaging itself may be regarded as a waste requiring special treatment. If in any doubt please seek specialist advice from a competent authority.

13.1 Waste treatment methods

Dispose of contents/container to hazardous waste in accordance with local, state or national legislation. Incinerate under approved controlled conditions, using incinerators suitable for the disposal of noxious chemical waste. The packaging should be disposed of with due care (e.g. UK Duty of Care regulations), ensuring that the package is completely emptied. Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

14. SECTION 14: TRANSPORT INFORMATION

14.1 UN number

3082

14.2 UN Proper Shipping Name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dioctyl maleate , 2-Ethoxyethyl methacrylate)

14.3 Transport hazard class(es)

Class	9
IMDG Class	9
IMDG EMS	F-A, S-F
IATA	9
ADR Classification Code	M6
ADR HIN	90
ADR Transport Category	3
Tunnel Restriction Code	E
RID	9
ADN	9
UK CDG Road: Emergency Action Code	3Z

14.4 Packing group

III

14.5 Environmental hazards

Classified as a Marine Pollutant.

14.6 Special precautions for user

No special requirements.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

15. SECTION 15: REGULATORY INFORMATION

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

Regulation (EC) No 1272/2008 (Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006).

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this substance/mixture.
Appropriate information from exposure scenarios from component substances relevant to uses of this mixture have been incorporated into the core sections (1-16) of this safety data sheet.

16. SECTION 16: OTHER INFORMATION

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 453/2010.

Date of preparation:	15 -May- 2015
The following sections contain revisions or new statements:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16

Inventory Status

European Union	To the best of our knowledge all chemicals in this product comply with REACH regulations.
United States (TSCA)	Listed in TSCA
Canada (DSL/NDSL)	Not listed in DSL
Japan (ENCS)	Listed in ENCS
Philippines (PICCS)	Listed in PICCS
Australia (AICS)	Listed in AICS
South Korea (KECI)	Not listed in KECI
China (IECSC)	Listed in IECSC

Compliance with other Regulatory Chemical Inventories cannot be assumed, please contact supplier for further information.

LEGEND

Note Not all of the following are necessarily contained in this Safety Data Sheet:
IOELV: Indicative Occupational Exposure Limit Value
WEL: Workplace Exposure Limit (UK HSE EH40)
Bmgv: Biological Monitoring Guidance Value
Sen: Capable of causing respiratory sensitisation
Sk: Can be absorbed through skin
Carc: Capable of causing cancer and/or heritable genetic damage
CHAN: Chemical Hazard Alert Notice
COM: The company aims to control exposure in its workplace to this limit
LTEL: Long Term Exposure Limit
STEL: Short Term Exposure Limit
TWA: Time Weighted Average
STOT SE: Specific Target Organ Toxicity - Single Exposure
Repr.: Reproductive toxicity
Aquatic acute/chronic: Hazardous to the aquatic environment

Full text of H/P/R phrases

H317: May cause an allergic skin reaction.
H335: May cause respiratory irritation.
H361: Suspected of damaging fertility or the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

IMPORTANT: USE IN THE MANUFACTURE OF MEDICAL DEVICES AND RELATED PRODUCTS.

WHW Plastics has performed no clinical testing on the use of this product in any medical application. WHW Plastics has no data to support the use of this product in any medical application. This product has been manufactured to a specification according to high standards of manufacturing practice. WHW Plastics supplies this product on the specific understanding that it is the sole responsibility of the medical device manufacturer to ensure that the medical device is both safe and fit for the intended purpose and that this product is suitable for use in its manufacture.

*NB: Although no OEL limit exists for 2-Ethoxyethyl methacrylate it is suggested that exposure is maintained below the OEL for 2-Ethoxyethanol which can be formed if 2-Ethoxyethyl methacrylate hydrolyses in the body.

It is the responsibility of the end-product manufacturer to identify all market and use-specific regulations and to ensure compliance with these regulations.

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