

SAFETY DATA SHEET

AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name HEARING AID POLYMER - POLY(EMA) BASED
 Product Description Polymer based on Ethyl methacrylate containing peroxide.
 This data sheet covers the following grades: HEARING AID POLYMER P1101/1, TS1326, TS1364/1, TS1742

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, Thern Road, Cleveland Street, Hull, East Yorkshire HU8 7BF, UK Tel: +44 (0)1325 300990
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

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

Not applicable.

2.3 Other hazards

Not classified as PBT or vPvB. Combustible but not readily ignited. May form explosible dust clouds in air. Low toxicity under normal conditions of handling and use.

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)
Dibenzoyl peroxide	<1	202-327-6	01-2119511472-50-XXXX	Org. Perox. B Skin Sens. 1 Eye Irrit. 2 Aquatic Acute 1	H241 H317 H319 H400

For full text of H 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.
Skin Contact	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical attention.
Eye Contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Obtain medical attention if ill effects occur.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

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 CO₂.

Unsuitable Extinguishing Media Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Combustible but not readily ignited. Combustion or thermal decomposition will evolve toxic, irritant and flammable vapours. This product can form flammable dust clouds at elevated temperatures. The minimum ignition temperature of a dust cloud of a similar polymer has been measured at approximately 480°C (IEC 1241-2-1).

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

Caution - spillages may be slippery.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Collect in containers for disposal using approved dust respirator.

6.4 Reference to other sections

See Section: 8, 13

7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not eat, drink or smoke at the work place.

Product as supplied: Avoid contact with eyes. Avoid prolonged skin contact. Unlikely to represent a dust hazard under normal handling conditions.

Dental resins are usually processed in conjunction with reactive monomers and this may require the use of a higher level of PPE than that necessary for the polymer itself. Please also see the advice in Sections 8 and 11.

7.2 Conditions for safe storage, including any incompatibilities

Acrylic polymers are supplied in either bags or bulk containers. Keep containers in a clean, cool and dry area away from heat sources. Natural ventilation is adequate.

Storage temperature (°C): Ambient.

Incompatible materials: Polymer contains residual benzoyl peroxide. This may react with oxidising agents, reducing agents, acids, bases and amines leading to decomposition.

7.3 Specific end use(s)

Manufacture of formulated dental products and earmoulds.

Not intended for thermal processing.

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substance	CAS No.	LEL ppm (8Hr TWA)	LEL mg/m ³ (8Hr TWA)	STEL ppm	STEL mg/m ³	Notes
Dibenzoyl peroxide	000094-36-0		5			WEL
Dust (total inhalable dust) (respirable dust)			10 4			

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. Safety spectacles/goggles/full face shield.

Skin protection



Wear suitable gloves.

Suitable materials: Butyl; EN 374.

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



A suitable dust mask or dust respirator with filter type P3 or FFP3 (EN143 or EN149) may be appropriate. In the unlikely event of formation of particularly high levels of dust a self contained breathing apparatus may be appropriate.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form	Fine beads.
Colour.	White.
Odour	Typically methacrylate.
Odour Threshold (ppm)	Not available.
pH (Value)	Not applicable.
Melting Range (°C)	150 - 230
Boiling Point (°C)	Not applicable.
Flash Point (°C)	~390
Relative Evaporation Rate (Ether = 1)	Not applicable.
Flammable Limits	Not applicable.
Vapour pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Solubility (Water)	Negligible.
Solubility (Other)	Not available.
Partition Coefficient (n-Octanol/water)	Not applicable.
Auto Ignition Temperature (°C)	~465
Viscosity (mPa. s)	Not available.
Explosive properties	Weakly to moderately explosible.
Oxidising Properties	Not applicable.
Density (g/ml)	1.1 - 1.18 g/cm ³
Bulk Density (g/ml)	0.60 - 0.70

9.2 Other information

St Class

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10. SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Non-reactive material.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Avoid dust generation.

10.5 Incompatible materials

Polymer contains residual benzoyl peroxide. This may react with oxidising agents, reducing agents, acids, bases and amines leading to decomposition.

10.6 Hazardous decomposition product(s)

Ethyl methacrylate, Dibenzoyl peroxide, Carbon dioxide, Carbon monoxide.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Ingestion

Low oral toxicity.

Inhalation

Unlikely to be hazardous by inhalation.

Skin Contact

Unlikely to cause skin irritation.

Contains greater than 0.1% residual (Ethyl methacrylate, Dibenzoyl peroxide). During normal handling this will not constitute a hazard. If the polymer matrix is destroyed e.g. when the product is dissolved in organic solvent, chemical residues will be released from the polymer matrix. Under these conditions, they may produce an allergic reaction in persons already sensitised.

Eye Contact

Dust may cause irritation.

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product is predicted to have low toxicity to aquatic organisms.

12.2 Persistence and degradability

The product is non-biodegradable in soil. There is no evidence of degradation in soil and water.

12.3 Bioaccumulative potential

The product has low potential for bioaccumulation.

12.4 Mobility in soil

The product is predicted to have low mobility in soil.

12.5 Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6 Other adverse effects

None known.

13. SECTION 13: DISPOSAL CONSIDERATIONS

The waste is considered to be non hazardous. Clean scrap may be reprocessed. Certain packages are returnable. Please consult your local office for further details. Ensure that all packaging is disposed of safely.

13.1 Waste treatment methods

May be disposed of by landfill in accordance with local regulations. Incineration may be used to recover energy value. 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

Not Classified as Dangerous for Transport.

14.1 UN number

Not applicable.

14.2 UN Proper Shipping Name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

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. Not required.

16. SECTION 16: OTHER INFORMATION

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

Date of preparation: 23 -July- 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)	Listed in DSL
Japan (ENCS)	Listed in ENCS
Philippines (PICCS)	Listed in PICCS
Australia (AICS)	Listed in AICS
South Korea (KECI)	Listed in KECI
China (IECSC)	Listed in IECSC
Taiwan (TCSI)	Listed in TCSI
New Zealand (NZIoC)	Listed in NZIoC

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 phrases
H241: Heating may cause a fire or explosion.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.

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.

IMPORTANT NOTICE: This product must not be used in the manufacture or formulation of artificial finger nails or nail sculpture products.

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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