

SAFETY DATA SHEET

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

1.1 Product identifier

Product Name Radio-Opaque - Poly Methyl Methacrylate Based Cold Cure Powder
Product Description Polymer based on Methyl methacrylate and 2-Ethylhexyl acrylate containing peroxide with Barium sulfate

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 Industrial/professional use only.

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

This product does not meet the criteria for classification in any hazard class according to UK Regulations on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

EUH208: Contains: (Methyl methacrylate, 2-Ethylhexyl acrylate, Dibenzoyl peroxide).
May produce an allergic reaction.
EUH210: Safety data sheet available on request.

2.3 Other hazards

Not classified as PBT or vPvB. Combustible but not readily ignited. May form combustible dust concentrations in air. Low toxicity under normal conditions of handling and use. Does not cause endocrine disruption.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Classification according to DSD-DPD / CLP

Substance identification	ID Numbers		Classification	Hazard Statements (R/H)
Barium sulfate precipitated, BaSO ₄	CAS. EINECS. INDEX: REACH	7727-43-7 231-784-4 - 01-2119491274-35-0001	-	-

Barium sulfate for medical radiography (Radiology)

3.2 Mixtures

According to GB CLP Regulations, UK SI 2019/720 and UK SI 2020/1567

Hazardous Ingredient(s)	%W/W	EC No.	Registration number(s)	Hazard Class and Category Code(s)	Hazard statement Code(s)
Dibenzoyl peroxide	1 - 2	202-327-6	01-2119511472-50	Org. Perox. B Skin Sens. 1 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H241 H317 H319 H400 H410 M Acute=10 M Chronic=10

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. Molten material can cause severe burns. Do NOT try to peel molten polymer from the skin. Cool rapidly with water.
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

Treat symptomatically.

5. SECTION 5: FIREFIGHTING 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

Combustible but not readily ignited. May form combustible dust concentrations in air. The minimum ignition temperature of a dust cloud of a similar polymer has been measured at approximately 480°C (IEC 1241-2-1). Combustion or thermal decomposition will evolve toxic, irritant and flammable vapours. By analogy with similar materials, the product may decompose if heated to temperatures above 280°C.

5.3 Advice for firefighters

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 workplace. Product as supplied: Avoid contact with skin and eyes. 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.

The following constitutes general advice: Extra care should be taken to prevent burns from contact with hot material. Thermal processing requires adequate ventilation to remove any monomer decomposition products, and use of inert atmosphere may be required in some processes to safely decompose the resin when it is used as a binder. Any thermal processing must consider the time-temperature decomposition of the resin. All polymers degrade to some extent at their processing temperature, an effect which increases with increasing temperature. It is therefore impossible to be precise about which substances may be evolved. However, it is only the minor components which vary substantially. The major components are given in Section 10. If the product is to be used in applications for which the hazards are not fully understood it is recommended to consult the supplier before use.

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):

Preferably not exceeding 40°C.

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)

Repair systems for dental materials.

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substance	CAS No.	LTEL ppm (8Hr TWA)	LTEL mg/m ³ (8Hr TWA)	STEL ppm	STEL mg/m ³	Notes
Dust (total inhalable dust) (respirable dust)			10 4			WEL
Dibenzoyl peroxide	000094-36-0		5			WEL
The following values apply to substances which may be evolved during thermal processing.						
Methyl methacrylate	000080-62-6	50	208	100	416	WEL
2-Ethylhexyl acrylate	000103-11-7	5	38			COM, Sk

8.2 Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the workplace. 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.

Thermal hazards

Wear thermal insulating gloves when handling hot masses.

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 unlikely event of formation of particularly high levels of vapour a self contained breathing apparatus may be appropriate.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Fine beads. White.
Odour	Typically methacrylate.
pH	Not available.
Melting Point (°C)	Not available.
Boiling Point (°C)	Not applicable.
Flash Point (°C)	Not applicable.
Relative Evaporation Rate (Ether = 1)	Not applicable.
Flammability (solid, gas)	Not applicable.
Flammable Limits	Not applicable.
Vapour pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	1.1 - 1.18
Bulk Density (g/ml)	0.55 - 0.75
Solubility (Water)	Negligible.
Solubility (Other)	Not available.
Partition Coefficient (n-Octanol/water)	Not applicable.
Auto Ignition Temperature (°C)	Not applicable.
Decomposition Temperature (°C)	Not available.
Viscosity (mPa. s)	Not applicable.
Kinematic Viscosity (mm ² /s)	Not applicable.
Explosive properties	Weakly to moderately explosible.
Oxidising properties	Not applicable.

9.2 Other information

Particle characteristics	Not available.
St Class	1

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. Keep away from heat.

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 products

Methyl methacrylate, 2-Ethylhexyl acrylate, Dibenzoyl peroxide, Carbon dioxide, Carbon monoxide.

11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Ingestion

Based upon the available data, the classification criteria are not met.
Low oral toxicity.

Inhalation

Based upon the available data, the classification criteria are not met.
High concentrations of dust may be irritant to the respiratory tract. High concentrations of vapour from hot operations may be harmful, cause irritation of the respiratory tract and slight narcotic effects.

Skin corrosion/irritation

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

Serious eye damage/irritation

Based upon the available data, the classification criteria are not met.
Dust may cause irritation.

Sensitisation	It is not a skin sensitiser. (By analogy with similar materials) Contains: (Methyl methacrylate, 2-Ethylhexyl acrylate, 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.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT - single exposure	Based upon the available data, the classification criteria are not met.
STOT - repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

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

Avoid release to the environment. 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

Dispose of contents/container to hazardous waste in accordance with local, state or national legislation. 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

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 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

GB CLP Regulations, UK SI 2019/720 and UK SI 2020/1567

EH40/2005 Workplace exposure limits

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 REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758 and SI 2020/1577.

The following sections contain revisions or new statements: 1, 2, 4

Date of preparation: 14 -August- 2023

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

PNEC: Predicted No-Effect Concentration

DNEL: Derived No-Effect Level

STOT: Specific Target Organ Toxicity

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.

H410: Very toxic to aquatic life with long lasting effects.

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

WHW Plastics UK Limited has performed no clinical testing on the use of this product in any medical application. WHW PlasticsUK Limited 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 UK Limited 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.

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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