

SAFETY DATA SHEETS

This SDS packet was issued with item:

077704034

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077703978 077703986 077703994 077704026 077704067

ZHERMACK S.P.A.

Safety Data Sheet according to the Dir. 2001/58/EEC

ACRYTEMP

Revision date: 07/02/2011

Print Date: 02/09/11

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

1.1 Identification of the preparation:

Trade name: ACRYTEMP A2,A3, A3.5,

Trade code: C700200/C700215/C700205

1.2 Utilization of the substance or of the preparation:

Bis-Acrylic resin for Crown and Bridge.

1.3 Identification of the company:

Supplier: ZHERMACK S.p.A. via Bovazecchino, 100 – 45021 – Badia Polesine (RO) ITALY

Emergency telephone number of the company: 0039 0425 597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components within the meaning of EEC directive 67/548 and corresponding classification: None

3. HAZARDS IDENTIFICATION

PREPARATION NOT CLASSIFIED DANGEROUS

No specific hazards are encountered under normal product use.

4. FIRST AID MEASURES

4.1 Contact with skin: Wash with plenty of water and soap.

4.2 Contact with eyes: Wash immediately with water for at least 10 minutes. If the irritation persists, seek medical attention.

4.3 Swallowing: SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety-data sheet..

4.4 Inhalation: Ventilate the premises.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: water, CO₂..

5.2 Extinguishers not to be used: none in particular.

5.3 Risks arising from combustion: avoid inhaling the fumes.

5.4 Protective equipment: use protection for the respiratory tract.

6. ACCIDENTAL RELEASE MEASURES

6.1 Measures for personal safety: none in particular

6.2 Environmental measures: limit leakage with earth or sand. If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

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REVISION	DATE	DESCRIPTION	ISSUED BY	APPROVED BY
1	09/03/00	First issue		
2	28/07/03	Updated according to Dir. 2001/58/EEC		
3	13/03/07	Enclosed A1, B1 version	R&D	RQ
4	07/02/2011	Re-issued without modification	R&D	HSEQ
5	23/05/2011	Removed product shades out of production	R&D	HSEQ

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- 6.3 **Cleaning methods:** recover the product for re-use if possible, or for elimination. The product might, where appropriate, be absorbed by inert material. After the product has been recovered, rinse the area and materials involved with water.

7. HANDLING AND STORAGE

- 7.1 **Handling precautions:** See, too, paragraph 8 below. Do not eat or drink while working.
7.2 **Incompatible materials:** none in particular. See, too, paragraph 10 below.
7.3 **Storage conditions:** keep the closed container a temperature of 20°C (77°F).
7.4 **Technical measures:** satisfactory room ventilation.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1 **Precautionary measures:** give adequate ventilation to the premises where the product is stored and/or handled.
8.2 **Respiratory protection:** not needed for normal use
8.3 **Protection for hands:** not needed for normal use
8.4 **Eye protection:** not needed for normal use
8.5 **Protection for skin:** no special precaution must be adopted for normal use
8.6 **Exposure limit(s) (ACGIH):** none

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 **Appearance and colour:**
A2: Bicomponent fluid, one part (base) is coloured (ivory).
B3: Bicomponent fluide, one part (base) is coloured (yellow)
A3.5: Bicomponent fluide, one part (base) is coloured (yellow)
A1: Bicomponent fluide, one part (base) is coloured (light ivory)
B1: Bicomponent fluide, one part (base) is coloured (light yellow)
9.2 **Odour:** odourless
9.3 **Relative density:** 1.52 g/cc (20°C)
9.4 **Solubility:** insoluble in water, soluble dans toluene and alcohol

10. STABILITY AND REACTIVITY

- 10.1 **Conditions to avoid:** stable under normal conditions.
10.2 **Substances to avoid:** avoid warmth and the direct sunlight.
10.3 **Hazardous decomposition products:** none

11. TOXICOLOGICAL INFORMATION

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Is possible an allergic reaction to methacrylate following prolonged exposition in the time. In this case is possible a light to the skin and eye. Is possible a toxicity in case of swallowing, not known sensitisation to the product

12. **ECOLOGICAL INFORMATION**

Adopt sound working practices, so that the product is not released into the environment.

13. **DISPOSAL CONSIDERATIONS**

Recover if possible. In so doing, comply with the local and national regulations currently in force.

14. **TRANSPORT INFORMATION**

Not classified as dangerous in the meaning of transport regulations.

15. **REGULATORY INFORMATION**

The preparation should not be considered as dangerous accordingly to dir. 88/379/EEC. Medical Device CE marked according to the Directive 93/42/EEC.

16. **OTHER INFORMATION**

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended. This MSDS cancels and replaces any preceding release.

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Information Sheet

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

1.1. Product identifier

Code: C700200/ C700215/ C700205
Product name: ACRYTEMP

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

Intended use: For professional use only. Bisacrylic composite resin for temporary crowns and bridges.

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-53596

e-mail address of the competent person
responsible for the Safety Data Sheet

msds@zhermack.com

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN Tel.:0551/19 240

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:

2.2. Label elements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

This product is not subject to hazard labeling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

2.3. Other hazards.

Information not available.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions set forth in Directives 67/548/EEC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

3.2. Mixtures.

Mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

Not specifically necessary. Observance of good industrial hygiene is recommended.

4.2. Most important symptoms and effects, both acute and delayed.

No episodes of damage to health ascribable to the product have been reported.

4.3. Indication of any immediate medical attention and special treatment needed.

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.**7.1. Precautions for safe handling.**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities.

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details. Storage temperature <25°C.

7.3. Specific end use(s).

Information not available.

SECTION 8. Exposure controls/personal protection.**8.1. Control parameters.**

Information not available.

8.2. Exposure controls.

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

SECTION 9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Appearance	paste
Colour	A2/ A3/ A3.5
Odour	odourless
Odour threshold.	Not available.
pH.	neutral
Melting point / freezing point.	Not applicable.
Initial boiling point.	Not applicable.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not applicable.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not applicable.
Relative density.	1,520 Kg/l
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.**10.1. Reactivity.**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

Heat, direct sunlight, peroxides, metal powders, strong oxidizers, free radical initiators.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

Information not available.

SECTION 11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects.

Acute toxicity: No data available.

Irritation/Corrosion

Skin irritation: Repeated and prolonged exposure may cause skin irritations (MSDS supplier).

Eye irritation: Irritating (MSDS supplier).

Skin Sensitization: Allergic reaction to methacrylate by chronic exposure to product are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

STOT – Repeated exposure: No data available.

CMR effects: No data available.

Aspiration toxicity: Not applicable.

SECTION 12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

SECTION 15. Regulatory information.

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

Seveso category.

None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.