

## **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, CO<sub>2</sub>..

**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.

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## 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.

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## 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

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## 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

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## 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

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## 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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## Safety data sheet

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

#### 1.1. Product identifier

Code: C700200, C700215, C700205, C700201, C700211  
Product name: ACRYTEMP

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

Intended use: For professional use only. Bisacrylic self-curing composite resin for temporary crown and bridge preparation.

#### 1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a  
Full address: Via Bovazecchino 100  
District and Country: 45021 Badia Polesine (RO)  
Italy  
Tel. +39 0425-597611  
Fax +39 0425-597689

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: 0039 0425597611

### SECTION 2. Hazards identification

#### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

#### 2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

**C700200, C700215, C700205, C700201, C700211  
ACRYTEMP**

Signal words: Warning

Hazard statements:

**H319** Causes serious eye irritation.  
**H315** Causes skin irritation.  
**H335** May cause respiratory irritation.  
**H317** May cause an allergic skin reaction.

Precautionary statements:

**P280** Wear protective gloves / clothing and eye / face protection.  
**P302+P352** IF ON SKIN: wash with plenty of soap and water.  
**P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**2.3. Other hazards**

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

## **SECTION 3. Composition/information on ingredients**

### **3.1. Substances**

Not applicable.

### **3.2. Mixtures**

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

Contains:

<b>Identification.</b>	<b>Classification 1272/2008 (CLP).</b>
<b>METHACRYLATES</b>	
CAS. -	H315, H319, H317, H335
EC. -	
INDEX. -	

## **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**

Specific information on symptoms and effects caused by the product are unknown.

**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**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. 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**

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. 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)**



See section 1.2.

## **SECTION 8. Exposure controls/personal protection**

### **8.1. Control parameters**

Information not available

### **8.2. Exposure controls**

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

#### **HAND PROTECTION**

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

#### **SKIN PROTECTION**

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

#### **EYE PROTECTION**

Wear airtight protective goggles (see standard EN 166).

#### **RESPIRATORY PROTECTION**

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

#### **ENVIRONMENTAL EXPOSURE CONTROLS**

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

## **SECTION 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

Appearance	paste
Colour	A2/ A3/ A3.5/ A1/ B1
Odour	odourless
Odour threshold	Not available
pH	neutral
Melting point / freezing point	Not applicable
Initial boiling point	Not applicable
Boiling range	Not available

**C700200, C700215, C700205, C700201, C700211  
ACRYTEMP**

Flash point	Not available
Evaporation Rate	Not available
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 available
Relative density	1,52 g/cm <sup>3</sup> (20°C)
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
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****11.1. Information on toxicological effects**

Acute toxicity: No data available.

Irritation/Corrosion

Skin irritation: Irritant (MSDS supplier).

Eye irritation: Irritant (MSDS supplier).

Skin Sensitization:

STOT – Repeated exposure: No data available.

Mutagenicity: No data available.

Carcinogenicity: No data available.

Toxicity for reproduction: No data available.

Aspiration toxicity: Not applicable.

**Additional toxicological information:**

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. (MSDS supplier).

**SECTION 12. Ecological information****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. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

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

**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.

**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**

**C700200, C700215, C700205, C700201, C700211  
ACRYTEMP**

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**

Information not relevant

**SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EC: None

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

Product

Point 3

Substances in Candidate List (Art. 59 REACH)

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

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

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

**C700200, C700215, C700205, C700201, C700211  
ACRYTEMP**

German regulation on the classification of substances hazardous to water (VwVwS 2005)

WGK 1: Low hazard to waters

**15.2. Chemical safety assessment**

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

**SECTION 16. Other information**

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

<b>Eye Irrit. 2</b>	Eye irritation, category 2
<b>Skin Irrit. 2</b>	Skin irritation, category 2
<b>STOT SE 3</b>	Specific target organ toxicity - single exposure, category 3
<b>Skin Sens. 1</b>	Skin sensitization, category 1
<b>H319</b>	Causes serious eye irritation.
<b>H315</b>	Causes skin irritation.
<b>H335</b>	May cause respiratory irritation.
<b>H317</b>	May cause an allergic skin reaction.

**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. Regulation (EU) 1907/2006 (REACH) of the European Parliament

**C700200, C700215, C700205, C700201, C700211  
ACRYTEMP**

2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
  3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
  4. Regulation (EU) 2015/830 of the European Parliament
  5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
  6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
  7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
  8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
  9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
  10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
  11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
  - Handling Chemical Safety
  - INRS - Fiche Toxicologique (toxicological sheet)
  - Patty - Industrial Hygiene and Toxicology
  - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
  - IFA GESTIS website
  - ECHA website
  - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

**Note for users:**

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.

This safety data sheet has been created on a voluntary basis.

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.

**Changes to previous review:**

The following sections were modified:

01 / 09.