

**Safety Data Sheet**  
**ACRYTEMP****Revision nr. 4**  
**Dated 2022/05/11****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Mixture identification:

Product Name: ACRYTEMP

Code: C700200, C700215, C700205, C700201, C700211

**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

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

**1.4. Emergency telephone number**

UK Emergency number: 999 (24 hours)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

EC regulation criteria 1272/2008 (CLP)

Skin Irrit. 2, H315 Causes skin irritation.

Eye Irrit. 2, H319 Causes serious eye irritation.

Skin Sens. 1, H317 May cause an allergic skin reaction.

STOT SE 3, H335 May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

**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 pictograms:



Warning

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

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#### Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P302+P352 IF ON SKIN: Wash with plenty of 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.

#### Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$

#### Other Hazards:

No other hazards

## 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:

#### Identification.

#### METHACRYLATES

CAS. -

EC. -

INDEX. -

#### Classification 1272/2008 (CLP).

H315, H319, H317, H335

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

In case of skin contact:

Immediately take off all contaminated clothing.

Remove contaminated clothing immediately and dispose off safely.

After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

Protect uninjured eye.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

In case of inhalation, consult a doctor immediately and show him packing or label.

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

None

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Treatment:

None

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#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO<sub>2</sub>).

Extinguishing media which must not be used for safety reasons:

None in particular.

##### 5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

##### 5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Use appropriate respiratory protection.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

##### 6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

##### 6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

##### 6.4. Reference to other sections

See also section 8 and 13

#### SECTION 7: Handling and storage

##### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Use localized ventilation system.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Contaminated clothing should be changed before entering eating areas.

Do not eat or drink while working.

##### 7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

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Storage temperature <25°C.

### 7.3. Specific end use(s)

See section 1.2.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): 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.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

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 (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

## SECTION 9: Physical and chemical properties

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

Properties	Value	Method:	Notes
Physical state:	Paste	--	--
Colour:	A2/ A3/ A3.5/ A1/ B1	--	--
Odour:	Odourless	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition	Not available	--	--

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temperature:			
pH:	Neutral	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	insoluble in water	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	1.52 g/cm <sup>3</sup> (20°C)	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

#### 9.2. Other information

No other relevant information

## SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions

#### 10.2. Chemical stability

Stable under normal conditions

#### 10.3. Possibility of hazardous reactions

None

#### 10.4. Conditions to avoid

Stable under normal conditions.

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

#### 10.5. Incompatible materials

None in particular.

#### 10.6. Hazardous decomposition products

None.

## SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological information of the substance:

ACRYTEMP

a) acute toxicity

Not classified

b) skin corrosion/irritation

The product is classified: Skin Irrit. 2 H315

c) serious eye damage/irritation

The product is classified: Eye Irrit. 2 H319

d) respiratory or skin sensitisation

The product is classified: Skin Sens. 1 H317

e) germ cell mutagenicity

Not classified

f) carcinogenicity

Not classified

g) reproductive toxicity

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Not classified

- h) STOT-single exposure  
The product is classified: STOT SE 3 H335
- i) STOT-repeated exposure  
Not classified
  
- j) aspiration hazard  
Not classified

**11.2. Information on other hazards**

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq$  0.1%

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**

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

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Not classified for environmental hazards

Based on available data, the classification criteria are not met

**12.2. Persistence and degradability**

Not available

**12.3. Bioaccumulative potential**

Not available

**12.4. Mobility in soil**

Not available

**12.5. Results of PBT and vPvB assessment**

vPvB Substances: None - PBT Substances: None

**12.6. Endocrine disrupting properties**

No endocrine disruptor substances present in concentration  $\geq$  0.1%

**12.7. Other adverse effects**

None

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

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

**SECTION 14: Transport information****14.1. UN number**

Not classified as dangerous in the meaning of transport regulations.

**14.2. UN proper shipping name**

Not available

**14.3. Transport hazard class(es)**

Not available

**14.4. Packing group**

Not available

**14.5. Environmental hazards**

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ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

**14.6. Special precautions for user**

Not available

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not Applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

Restriction 3

Restrictions related to the substances contained:

No restriction.

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

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

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

None.

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No Chemical Safety Assessment has been carried out for the substance.

**SECTION 16: Other information**

<b>Hazard class and hazard category</b>	<b>Code</b>	<b>Description</b>
Skin Irrit. 2	3.2/2	Skin irritation, Category 2
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
Skin Sens. 1	3.4.2/1	Skin Sensitisation, Category 1
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECHA – European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance

IARC – International Agency for Research on Cancer

IPCS INCHEM – International Programme on Chemical Safety

ISS – Istituto Superiore di Sanità

PubChem - open chemistry database at the National Institutes of Health (NIH)

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 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.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE:	Acute Toxicity Estimate
ATEmix:	Acute toxicity Estimate (Mixtures)
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.



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KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.

Changes from the previous revision.

Changes have been made to the following sections:

01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.