

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

- **1.1 Product identifier**
- **Trade name: ACRY C&B Dentina - Colletto - Smalto**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
 No further relevant information available.
- **Application of the substance / the mixture** Material for dental use
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 Dental Manufacturing S.p.a.
 Via Cà Mignola Nuova, 1699
 45021 - Badia Polesine (RO) - Italy
 Tel. +39 0425 51628 - Fax +39 0425 590156
- **Further information obtainable from:** info@ruthinium.it
- **1.4 Emergency telephone number:**
 Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
 The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
 EUH208 Contains methyl methacrylate, dibenzoyl peroxide. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture based on polymethyl methacrylate

- **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-xxxx	methyl methacrylate ⚠ Flam. Liq. 2, H225; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	0.1 - <1%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ⚠ Self-react. B, H241; Org. Perox. B, H241; ⚠ Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); ⚠ Eye Irrit. 2, H319; Skin Sens. 1B, H317, EUH208	0.1 - <1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
Rinse your mouth well
Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
CO₂, powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents:** None in particular
- **5.2 Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear personal protective clothing.
See Section 8 for information on personal protection equipment.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 2)

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 80-62-6 methyl methacrylate (0.1-1%)

WEL	Short-term value: 416 mg/m ³ , 100 ppm
	Long-term value: 208 mg/m ³ , 50 ppm

CAS: 94-36-0 dibenzoyl peroxide (0.1-1%)

WEL	Long-term value: 5 mg/m ³
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· **DNELs**

CAS: 80-62-6 methyl methacrylate

Dermal	Long term, local effect	1.5 mg/kg (general population)
		1.5 mg/kg (professional workers)
	Long term, systemic effect	13.67 mg/kg (professional workers)
Inhalative	Long term, systemic effect	8.2 mg/kg bw/day (general population)
	Long term, local effect	105 mg/m ³ (general population)
		210 mg/m ³ (professional workers)
	Long term, systemic effect	74.3 mg/m ³ (general population)
		210 mg/m ³ (professional workers)

· **PNECs**

CAS: 80-62-6 methyl methacrylate

PNEC	5.74 mg/kg (fresh water sediments)
PNEC	0.94 mg/l (freshwater)
	0.094 mg/l (marine water)

- **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**



Protective gloves

The use of gloves is recommended as a preventive measure

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 3)

substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Nitrile rubber, NBR

Neoprene gloves

Recommended thickness of the material: ≥ 0.2 mm

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Value for the permeation: Level 2/3

· **Eye/face protection** Not required.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Solid

· **Colour:**

Various colours

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

> 105 °C

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Auto-ignition temperature:**

Product is not selfigniting.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility**

· **water:**

Insoluble.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density and/or relative density**

· **Density at 20 °C:**

1.16 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

· **9.2 Other information**

· **Appearance:**

· **Form:**

Powder

· **Important information on protection of health and environment, and on safety.**

· **Ignition temperature:**

> 400 °C

· **Explosive properties:**

Product does not present an explosion hazard.

· **Change in condition**

· **Evaporation rate**

Not applicable.

· **Information with regard to physical hazard classes**

· **Explosives**

Void

· **Flammable gases**

Void

· **Aerosols**

Void

· **Oxidising gases**

Void

· **Gases under pressure**

Void

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 4)

· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid**
The product is normally supplied in a stabilized form. Avoid excessive heat for long periods of time, the product can polymerize. Avoid heat, flames and other sources of ignition
- **10.5 Incompatible materials:** No hazardous reactions
- **10.6 Hazardous decomposition products:**
When heated or in case of fire can release gases and vapors which are dangerous to health.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

CAS: 80-62-6 methyl methacrylate

Oral	LD50	7,872 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	33 mg/l (mouse) 29.8 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 5)

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 80-62-6 methyl methacrylate

CL50	>79 mg/l (fish) (Esposizione 96 h)
EC50	69 mg/kg (daphnia)
EC50	>110 mg/l (algae) (Esposizione 72 h)
	69 mg/l (daphnia) (Esposizione 48 h)
NOEC	37 mg/l (daphnia)
	9.4 mg/l (fish)

- **12.2 Persistence and degradability** Easily biodegradable
- **12.3 Bioaccumulative potential** Non significant accumulation in organisms
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities responsible for disposal.

· Uncleaned packaging:

· Recommendation:

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, ADN, IMDG, IATA Void

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA Void

· 14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class Void

· 14.4 Packing group

· ADR, IMDG, IATA Void

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 6)

· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

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

Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 878/2020 as subsequent amendments.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H241 Heating may cause a fire or explosion.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH208 Contains . **May produce an allergic reaction.**

· **Classification according to Regulation (EC) No 1272/2008**

As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).

Procedure used for the classification of the mixture

Skin Sens 1 / 1A / 1B, H317 -Calculation method

Aquatic Chronic 3, H412 - Calculation method

· **Version number of previous version:** 5

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 10.12.2020

Version number 6

Revision: 10.12.2020

Trade name: ACRY C&B Dentina - Colletto - Smalto -

(Contd. of page 7)

*IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**DNEL: Derived No-Effect Level (REACH)**PNEC: Predicted No-Effect Concentration (REACH)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Flam. Liq. 2: Flammable liquids – Category 2**Self-react. B: Self-reactive substances and mixtures – Type B**Org. Perox. B: Organic peroxides – Type B**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1B: Skin sensitisation – Category 1B**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*

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