

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2015/830)

Version: 1 Version date: 18/04/2017 Language: EN

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

1.1. Product identifier

Light-curing urethane dimethacrylic water-based material to protect gums during teeth whitening.

PURE PROTECT. Trade name / designation Article No (user) PRP-BG.

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

Relevant identified uses Dental products. Gingival barrier.

1.3. Details of the supplier of the safety data sheet

Supplier ITENA CLINICAL

> Street: 83, Avenue Foch Postal code / City: 75116 Paris

Country: France

Telephone: +33 1 45 91 30 06 Telefax: + 33 1 45 91 61 31 E-mail: contact@itena-clinical.com

1.4 Emergency Telephone Number

Not available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard statements

Skin Sens. 1

H317 May cause an allergic skin reaction.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms

Warning Signal word

Product identifiers

Hazard Statements H317 - May cause an allergic skin reaction.

Supplemental Hazard information (EU) Precautionary Statements - General

Precautionary Statements - Prevention P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

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

Precautionary Statements - Response P321 - Specific treatment (see ... on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P363 - Wash contaminated clothing before reuse.

Precautionary Statements - Storage

Precautionary Statements - Disposal P501 - Dispose of contents/container to ...

2.3. Other hazards

Not available

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SECTION 3: Composition/information on ingredients

3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
2-Propenoic acid, 2-methyl-, 1,4- butanediyl ester CAS N°:2082-81-7 EC N°:218-218-1	2.5% ≤C≤ 10.0%	Eye Irrit. 2: H319 STOT SE 3: H335 Skin Irrit. 2: H315	STOT SE 3; H335: C ≥ 10 %	-
IDX N°:607-134-00-4				

3.2. Mixtures

Not available

3.3. Remark

Text phrases and H- EUH-: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information : In case of accident or unwellness, seek medical advice immediately (show directions for use

or safety data sheet if possible).

Following inhalation : Provide fresh air. In case of respiratory tract irritation, consult a physician.

Following skin contact : After contact with skin, wash immediately with plenty of water and soap. In case of skin

reactions, consult a physician.

Following eye contact : In case of eye irritation consult an ophthalmologist. Rinse immediately carefully and

thoroughly with eye-bath or water.

Following ingestion : If accidentally swallowed rinse the mouth with plenty of water (only if the person is

conscious) and obtain immediate medical attention.

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

Not available

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

Notes for the doctor : Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Extinguishing powder. Carbon dioxide (CO2). Sand. Water mist.

Unsuitable extinguishing media : Full water jet.

5.2. Special hazards arising from the substance or mixture

Not available

5.3. Advice for firefighters

Not available

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not available

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

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6.4. Reference to other sections

Safe handling: see section 7. Disposal: see section 13. Personal protection equipment: see section 8.

6.5. Additional information

Not available

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Protective measures

Sewers and ducts must be protected against the entry of the product. No special fire protection measures are necessary. No special measures are necessary.

Advices on general occupational hygiene

Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect from high heat and direct sunlight. Storage between 10 ° C and 25 ° C. Keep container tightly closed.

7.3. Specific end uses

Observe instructions for use.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Not available

8.2. Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Personal protection equipment





Eye/face protection : Protective goggles recommended for transfer.

Suitable eye protection: Eye glasses.

Skin protection : Hand protection: Suitable gloves type: Disposable gloves.

Hand protection: Suitable material: Butyl caoutchouc (butyl rubber).

Hand protection: Additional hand protection measures.: Do not wear gloves near machines

and rotating tools. Use gloves only once.

Hand protection: Remark: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Breakthrough times and swelling properties of the material must

be taken into consideration. Hand protection: Hand protection is not required.

Respiratory protection : No special measures are necessary.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state: Solid Colour: Solid

Odour: Low, characteristic
Odour threshold: Not available
PH: Not determined

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Melting point/freezing point:

Initial boiling point and boiling range: = $178 \,^{\circ}\text{C}$ Flash point: = $91 \,^{\circ}\text{C}$

Evaporation rate: Flammability:

Vapour pressure: Vapour density: Not applicable. **Explosive** Not available

Upper/lower flammability or explosive

limits:

Not determined.
Not determined.

Relative density: Not determined.

Solubility(ies): Not miscible or not

Partition coefficient: n-octanol/water Not determined.

(Log KOC):

Auto-ignition temperature: The product does not ignite spontaneously.

Decomposition temperature: Not determined. **Viscosity**: Not determined.

Explosive properties: The product is not explosive.

Oxidising properties:

9.2. Other safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable with storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Heat Release Polymerization. Reactions to light.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

Oxidising agent, strong. Deoxidizers. Metallic Ions.

10.6. Hazardous decomposition products

Do not decompose when used for intended uses.

10.7. Additional information

Not available

SECTION 11: Toxicological information

11.1. Acute oral toxicity

Data for mixture

Not available

Substances

2-Propenoic acid, 2-methyl-, 1,4-butanediyl ester (CAS: 2082-81-7)

Species : Rat

subendpoint	Operator	Value	Units
LD50	=	10120	mg/kg bw

11.2. Acute skin toxicity

Data for mixture

Not available

Substances

Not available

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11.3. Acute inhalation toxicity

Data for mixture

Not available

Substances

Not available

11.4. Skin corrosion

Data for mixture

Not available

Substances

Not available

11.5. Eye damage

Data for mixture

Not available

Substances

Not available

11.6. Skin sensitisation

Data for mixture

Not available

Substances

Not available

11.7. STOT RE

Data for mixture

Not available

Substances

Not available

11.8. STOT SE

Data for mixture

Not available

Substances

Not available

11.9. Carcinogenicity

Data for mixture

Not available

Substances

Not available

11.10. Reproductive and Developmental Toxicity

Data for mixture

Not available

Substances

Not available

11.11. genotoxicity

Data for mixture

Not available

Substances

Not available

Additional information

No information available.

Substances

Not available

Data for mixture

No information available.

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SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

12.7. Additional ecotoxicological information

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal

Waste codes / waste designations according to EWC / AVV: The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Waste treatment options: Appropriate disposal / Product: Waste requiring special supervision. Dispose of waste according to applicable legislation. Delivery to an approved waste disposal company.

Waste treatment options: Appropriate disposal / Package: Non-contaminated packages must be recycled or disposed of. Packing which cannot be properly cleaned must be disposed of. Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

Other disposal recommendations: Not to be disposed of together with household garbage. Do not allow to enter drains.

13.2. Additional information

Not available

SECTION 14: Transport information

14.1. UN number

No data available.

14.2. UN proper shipping name

No data available.

14.3. Transport hazard class(es)

No data available.

14.4. Packing group

No data available.

14.5. Environmental hazards

No data available.

14.6. Special precautions for user

No data available.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available.

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14.8. Additional information

Not available

SECTION 15: Regulatory information

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

EU legislation

Directive 2012/18 / EU. National regulations

Technical instructions air: Class III / Part in% <2.5.

Not available

15.2. Chemical Safety Assessment

No data available.

15.3. Additional information

Not available

SECTION 16: Other information

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 16/06/2017

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN / ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways. ADR / RID: European Agreement concerning the International Carriage of Dangerous Goods by Road / Regulations concerning the international carriage of dangerous goods by rail. CAS: Chemical Abstract Service Number. CLP: Classification, labeling and packaging. IATA: International Air Transport Association. IMDG: International Maritime Dangerous Goods Code. DPD Dangerous Preparation Directive. UN number: United Nations number. No EC: European Commission Number. VPvB: very persistent and very bioaccumulative substances.

16.3. Key literature references and sources for data

No data available.

16.4. Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008.

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

16.6. Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

16.7. Additional information

Not available

The information given in this Safety Data Sheet is based on our present knowledge and on european and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.

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