

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

1.1. Product identifier

Trade name / designation : REFLECTYS.
 Article No (user) : CPTYS-A1 / CPTYS-A2 / CPTYS-A3 / CPTYS-A3,5 / CPTYS-A4 / CPTYS-B1 / CPTYS-B2 / CPTYS-B3 / CPTYS-C2 / CPTYS-C3 / CPTYS-D3 / CPTYS-A20 / CPTYS-A30 / CPTYS-I / CPTYS-P / CPTYS-E.
 SRTYS-A1 / SRTYS-A2 / SRTYS-A3 / SRTYS-A3,5 / SRTYS-A4 / SRTYS-B1 / SRTYS-B2 / SRTYS-B3 / SRTYS-C2 / SRTYS-C3 / SRTYS-D3 / SRTYS-A20 / SRTYS-A30 / SRTYS-I / SRTYS-P / SRTYS-E.

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

Relevant identified uses : Dental product.

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](tel:+33145913006)
 Telefax: [+ 33 1 45 91 61 31](tel:+33145916131)
 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 according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Hazard statements
 Skin Irrit. 2	H315 Causes skin irritation.
 Skin Sens. 1	H317 May cause an allergic skin reaction.
 Eye Irrit. 2	H319 Causes serious eye irritation.
 STOT SE 3	H335 May cause respiratory irritation.

2.2. Label elements

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

Hazard pictograms	
Signal word	Warning
Product identifiers	-
Hazard Statements	H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-

Precautionary Statements - Prevention
Precautionary Statements - Response

P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
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P501 - Dispose of contents/container to ...

Precautionary Statements - Storage
Precautionary Statements - Disposal

2.3. Other hazards

Not available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester CAS N°:1565-94-2 EC N°:216-367-7 IDX N°:607-134-00-4	0.0% ≤ C < 30.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
2-Propenoic acid, 2-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester CAS N°:109-16-0 EC N°:203-652-6 IDX N°:607-134-00-4	0.0% ≤ C < 10.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-

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	:	Remove person to fresh air and keep comfortable for breathing. If the victim is unconscious but breathing normally, place in recovery position and seek medical advice. No resuscitation mouth-to-mouth or mouth-to-nose. Ambu use a mask or respirator.
Following skin contact	:	In case of skin irritation, consult a physician. 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. Remove contact lenses, if present and easy to do. Continue rinsing.
Following ingestion	:	Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water. Take an antacid. Seek medical attention.
Self-protection of the first aider	:	First aider: Pay attention to self-protection!

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.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Extinguishing powder. Carbon dioxide (CO₂). Alcohol resistant foam. Water spray.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Do not inhale vapors and fumes. Co-ordinate fire-fighting measures to the fire surroundings. Move undamaged containers from immediate hazard area if it can be done safely. Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen. Use water spray jet to protect personnel and to cool endangered containers. 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

Use personal protection equipment. Remove persons to safety. Use appropriate respiratory protection. Provide adequate ventilation.

6.2. Environmental precautions

Ensure that waste is collected and contained. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3. Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal. Collect in closed and suitable containers for disposal. Clean contaminated objects and areas thoroughly observing environmental regulations. Ventilate affected area.

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

Avoid exposure - obtain special instructions before use.

Protective measures

Avoid contact with skin, eyes and clothes. Wear personal protective clothing (see section 8). Sewers and ducts must be protected against the entry of the product.

Advices on general occupational hygiene

In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously.

Wash hands before breaks and after work. Street clothing should be stored separately from work clothing. Remove contaminated, saturated clothing immediately.

7.2. Conditions for safe storage, including any incompatibilities

Ensure adequate ventilation of the storage area. Store in a well-ventilated place.

Requirements for storage rooms and vessels

Avoid exposure to intense light and elevated heat. Store in room temperature.

Advice on joint storage

Keep away from food, drink and animal feedingstuffs.

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

Technical measures and the application of suitable work processes have priority over personal protection equipment. Fresh air (open windows and doors) is necessary.

Personal protection equipment



Eye/face protection

- : Wear eye protection equipment.
- Suitable eye protection: Eye glasses with side protection.

Skin protection

- : Hand protection: Additional hand protection measures.: 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: Wear protective gloves.
- Body protection: Suitable protective clothing: Protective work clothing.
- Body protection: Wear protective clothing.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid - Paste
Colour:	Tooth colored
Odour:	Slight acrylic odour
Odour threshold:	Not available
PH:	Not applicable
Melting point/freezing point:	Undetermined
Initial boiling point and boiling range:	Undetermined
Flash point:	Not applicable
Evaporation rate:	Not applicable
Flammability:	Not applicable
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	Not applicable
Vapour density:	Not applicable
Relative density:	>1
Solubility(ies):	Insoluble
Partition coefficient: n-octanol/water (Log KOC):	Not applicable
Auto-ignition temperature:	Not applicable
Decomposition temperature:	Not applicable
Viscosity:	Not applicable
Explosive properties:	Not applicable
Oxidising properties:	Not applicable

9.2. Other safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

This material is considered to be non reactive under normal use conditions.

10.2. Chemical stability

The product is stable with storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

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

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.2. Acute skin toxicity

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.3. Acute inhalation toxicity

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.4. Skin corrosion

Data for mixture

Conclusion : Testing according to ISO 10993-1/10993-10 showed no irritation for this product when fully cured.

Substances

Not available

11.5. Eye damage

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.6. Skin sensitisation

Data for mixture

Conclusion : May cause an allergic skin reaction.

Substances

Not available

11.7. STOT RE

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.8. STOT SE

Data for mixture

Not available

Substances

Not available

11.9. Carcinogenicity

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.10. Reproductive and Developmental Toxicity

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

11.11. Genotoxicity

Data for mixture

Conclusion : Base on available data, the classification criteria are not met.

Substances

Not available

Additional information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Substances

Not available

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

Not applicable.

12.6. Other adverse effects

No data available.

12.7. Additional ecotoxicological information

Not available

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.

Properties of waste which render it hazardous: Irritant. Harmful.

Waste treatment options: Appropriate disposal / Product: 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. Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

13.2. Additional information

Not available

SECTION 14: Transport information

14.1. UN number

The product is not hazardous according to the applicable transport regulations (ADR / RID / ADN / IMDG / ICAO / ITA).

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.

14.8. Additional information

Not available

SECTION 15: Regulatory information

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

Medical Device according to the directive 93/42/EEC. SARA Section 355 : None of the ingredients is listed. SARA Section 313 : None of the ingredients is listed. TSCA : Medical devices are exempted from TSCA.

Not available

15.2. Chemical Safety Assessment

No data available.

15.3. Additional information

Not available

SECTION 16: Other information

Creation date: 05/04/2017

Version date: 05/04/2017

Printing date: 22/05/2017

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN / ADNRR: 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 responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.