

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

1.1. Product identifier

Trade name / designation : IPERBOND ULTRA.
Article No (user) : IPBDUL-5.

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

Relevant identified uses : Dental products.

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	
	Flam. Liq. 3	H226	Flammable liquid and vapour.
	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.

2.2. Label elements

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

Hazard pictograms	
Signal word	Warning
Product identifiers	-
Hazard Statements	H226 - Flammable liquid and vapour. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation.
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-
Precautionary Statements - Prevention	P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statements - Response	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.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.

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
ethanol CAS N°:64-17-5 EC N°:200-578-6 IDX N°:603-002-00-5	35.0% ≤C≤ 40.0%	Flam. Liq. 2: H225 Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	-	-
2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester CAS N°:72869-86-4 EC N°:276-957-5 IDX N°:607-134-00-4	20.0% ≤C≤ 25.0%	Eye Irrit. 2: H319 Skin Irrit. 2: H315 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
2-hydroxyethyl methacrylate CAS N°:868-77-9 EC N°:212-782-2 IDX N°:607-124-00-X	5.0% ≤C≤ 10.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 Skin Sens. 1: H317	-	-
silicon dioxide CAS N°:7631-86-9 EC N°:231-545-4 IDX N°:	0.0% ≤C≤ 5.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	-	-

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.
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 : Seek medical advice.

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. Strong 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. Adapt the means of extinction to the surrounding environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove persons to safety. Provide adequate ventilation. Remove all sources of ignition.

6.2. Environmental precautions

Ensure that waste is collected and contained. Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations. Wipe up with absorbent material (eg. cloth, fleece).

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

Avoid contact with skin, eyes and clothes. Sewers and ducts must be protected against the entry of the product. Keep away from sources of ignition - No smoking.

Advices on general occupational hygiene

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

After use, immediately close the closure cap.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a cool, well-ventilated place. Recommended storage temperature between 4 and 8 ° C.

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

Not available

Personal protection equipment



Eye/face protection

: Eye glasses.
Suitable eye protection: Eye glasses.

Skin protection

: Lab coat.
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: Wear protective gloves. Disposable gloves.

Respiratory protection

: Ensure adequate ventilation.

Respiratory protection necessary at: If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Remark: The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Use only respiratory protection equipment with CE-symbol including four digit test number. Observe the wear time limits as specified by the manufacturer.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	pale yellow
Odour:	Specific odor
Odour threshold:	Not available
PH:	Not available
Melting point/freezing point:	Not available
Initial boiling point and boiling range:	°C
Flash point:	28 °C
Evaporation rate:	Not available
Flammability:	Not available
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	Not available
Vapour density:	Not available
Relative density:	1.0 g/cm ³
Solubility(ies):	Partially soluble
Partition coefficient: n-octanol/water (Log KOC):	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 safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is chemically stable if the recommended conditions of storage, use and temperature are met.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

10.4. Conditions to avoid

High heat.

10.5. Incompatible materials

Oxidising agent.

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-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl ester (CAS: 72869-86-4)

Species : Rat
Sex : No data
Guideline : OECD Guideline 401 (Acute Oral Toxicity)

subendpoint	Operator	Value	Units
LD50	>	2000	mg/kg bw

ethanol (CAS: 64-17-5)

Species : Rat
Sex : No data
Guideline : Other

subendpoint	Operator	Value	Units
LD50	-	6200	mg/kg bw

2-hydroxyethyl methacrylate (CAS: 868-77-9)

Species : Rat
Sex : No data

subendpoint	Operator	Value	Units
LD50	-	5050	mg/kg bw

11.2. Acute skin toxicity

Data for mixture

Not available

Substances

Not available

11.3. Acute inhalation toxicity

Data for mixture

Substances

ethanol (CAS: 64-17-5)

Species : Rat
Sex : No data
Guideline : Other
Route of administration / default : Inhalation: vapor
Exposure duration / value : 4
Exposure duration / unit : h

subendpoint	Results / Sex	Operator	Value	Units
LC50:	No data	-	95.6	mg/L

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

Substances

Not available

Data for mixture

Not available

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life.

Acute aquatic toxicity

Substances

2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester (CAS: 72869-86-4)

Animals / category : Fish
Species : Brachydanio rerio (zebra-fish)
test Duration : 96
Unit : h
Guideline : OECD 203

subendpoint	Value	Units
LC50:	10.1	mg/l

ethanol (CAS: 64-17-5)

Animals / category : crustacea
Species : Daphnia magna (Big water flea).
test Duration : 48
Unit : h
Guideline : IUCLID

subendpoint	Value	Units
EC50	9268-14221	mg/l

2-hydroxyethyl methacrylate (CAS: 868-77-9)

Animals / category : Fish
Species : Pimephales promelas (fathead minnow)
test Duration : 96
Unit : h

subendpoint	Value	Units
LC50:	227	mg/l

12.2. Persistence and degradability

Not available

12.3. Bioaccumulative potential

Not available

Bioconcentration factor (BCF)

Substances

2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester (CAS: 72869-86-4)

Log kow : 3.39

ethanol (CAS: 64-17-5)

Log kow : -0.31

2-hydroxyethyl methacrylate (CAS: 868-77-9)

Log kow : 0.47

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

According to EC criteria for classification and labeling "harmful to the environment" (93/21 / EEC), the substance / product is not to be labeled as dangerous for the environment.

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: Dispose of waste according to applicable legislation. May be incinerated with household waste in accordance with the regulations and after contact with the waste collection center and the competent authority.

Waste treatment options: Appropriate disposal / Package: Handle contaminated packages in the same way as the substance itself.

13.2. Additional information

Not available

SECTION 14: Transport information

	Land transport (ADR/RID)	Inland waterway transport (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number	1170	1170	1170	1170
14.2. UN proper shipping name	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es)				
Class or Division	3	3	3	3
Hazard label(s)				
14.4. Packing group	II	II	II	II

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

EU legislation

This product is a medical device according to EC directive 93/42.

Not available

15.2. Chemical Safety Assessment

No data available.

15.3. Additional information

Not available

SECTION 16: Other information

Creation date: 21/03/2017
Version date: 21/03/2017
Printing date: 22/05/2017

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)

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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

The information contained in this safety data sheet corresponds to our current knowledge at the time of printing. This information is intended to provide points of reference for safe handling of the product, in particular its storage, processing, transport and disposal.

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.