

TENA IPERBOND ULTRA ACTIVATOR

Safety Data Sheet

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

Version date: 22/03/2017 Version: 1 Language: EN

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

1.1. Product identifier

Trade name / designation IPERBOND ULTRA ACTIVATOR.

Article No (user) IPBACTUL-3.

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

Classification

Hazard statements

Flam. Lig. 2 H225 Highly flammable liquid and vapour.

2.2. Label elements

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

Hazard pictograms

Signal word

Danger **Product identifiers**

Hazard Statements H225 - Highly flammable liquid and vapour.

Supplemental Hazard information (EU) Precautionary Statements - General

Precautionary Statements - Prevention P210 - Keep away from heat, hot surfaces, sparks, open flames and all other ignition sources.

Do not smoke.

P233 - Keep container tightly closed.

Precautionary Statements - Response Precautionary Statements - Storage Precautionary Statements - Disposal

P403+P235 - Store in a well-ventilated place. Keep cool.

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
ethanol	85.0% ≤C<	Flam. Liq. 2: H225	-	-
CAS N°:64-17-5	90.0%	Skin Irrit. 2: H315		
EC N°:200-578-6		Eye Irrit. 2: H319		
IDX N°:603-002-00-5		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 : Provide fresh air.

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

Following eye contact : In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15

minutes holding eyelids apart and consult an ophthalmologist.

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 extinguishing measures to the surrounding environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove persons to safety. Remove all sources of ignition.

6.2. Environmental precautions

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

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SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Protective measures

Avoid contact with skin, eyes and clothes. For professional use only. Follow instructions for use. Keep away from sources of ignition - No smoking. Always close containers tightly after the removal of product.

7.2. Conditions for safe storage, including any incompatibilities

Keep cool. Store in a well-ventilated place. Requirements for storage rooms and vessels Keep container tightly closed. Further information on storage conditions

Recommended storage temperature: 4-8 ° 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 Skin protection

Goggles.
Lab coat.

Hand protection: Additional hand protection measures.: Use gloves only once.

Hand protection: Remark: 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. Breakthrough times and swelling properties of the material must be taken into consideration. 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. When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

Hand protection: Disposable gloves.

Body protection: Suitable protective clothing: Chemical protection clothing.

Respiratory protection : Ensure adequate ventilation.

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: colorless
Odour: feature
Odour threshold: Not available

PH:

Melting point/freezing point:

Initial boiling point and boiling range: = 78 °C Flash point: = 15 °C

Evaporation rate: Flammability:

Upper/lower flammability or explosive Not available

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limits:

Vapour pressure: Vapour density: Relative density:

Solubility(ies):

= 0.84 g/cm3 Easily soluble

Partition coefficient: n-octanol/water

(Log KOC):

Auto-ignition temperature: Decomposition temperature:

Viscosity:

Explosive properties: Oxidising properties:

9.2. Other safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Not available

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

Oxidizing agents.

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

ethanol (CAS: 64-17-5)

Species : Rat Guideline : Other

subendpoint	Operator	Value	Units
LD50	=	6200	mg/kg bw

11.2. Acute skin toxicity

Data for mixture

Not available

Substances

Not available

11.3. Acute inhalation toxicity

Data for mixture

Not available

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Substances

ethanol (CAS: 64-17-5)

Species : Rat Guideline : Other

Route of administration / default : Inhalation: vapor

Exposure duration / value : 4
Exposure duration / unit : h

subendpoint	Results / Sex	Operator	Value	Units
LC50:	-	=	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

Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.

Substances

Not available

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SECTION 12: Ecological information

12.1. Toxicity

Not available

Acute aquatic toxicity

Substances

ethanol (CAS: 64-17-5)

Animals / category : crustacea

Species : Daphnia magna (Big water flea).

test Duration : 48 Unit : h

subendpoint	Value	Units
EC50	9268-14221	mg/l

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

Not available

Bioconcentration factor (BCF)

Substances

ethanol (CAS: 64-17-5)

Log kow : -0.31

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 (93/21 / EEC), the substance / product does not have 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.

Properties of waste which render it hazardous: Highly flammable liquid and vapour.

Waste treatment options: Appropriate disposal / Product: May be incinerated with household waste in accordance with the regulations and after contact with the waste collection center and the competent authority.

13.2. Additional information

Not available

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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	ETHANOL (ETHYL	ETHANOL (ETHYL	ETHANOL (ETHYL
	ALCOHOL) or	ALCOHOL) or	ALCOHOL) or	ALCOHOL) or ETHANOL
	ETHANOL	ETHANOL	ETHANOL	SOLUTION (ETHYL
	SOLUTION (ETHYL	SOLUTION (ETHYL	SOLUTION (ETHYL	ALCOHOL SOLUTION)
	ALCOHOL	ALCOHOL	ALCOHOL	
	SOLUTION)	SOLUTION)	SOLUTION)	
14.3. Transport hazard class(es)				
Class or Division	3	3	3	3
Hazard label(s)	3	3	3	3
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:
 22/03/2017

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 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.

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

H225 Highly flammable liquid and vapour.

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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