

FAST SPLINT CLINIQUE/FIBER FORCE



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : FAST SPLINT CLINIQUE/FIBER FORCE

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

Light-curing preimpregnated fibre system for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Registered company name : BIO COMPOSANTS MEDICAUX.

Address : 215 Route de Bavonne - ZA Le Talamud .38140.Saint Blaise du Buis.France.

Telephone : +33 (0)4 76 07 79 57. Fax : +33 (0)4 76 07 42 98.

Email : contact@biomedicaux.com

1.4. Emergency telephone number : +33 (0) 1 45 42 59 59.

Association/Organisation : FRANCE : INRS / ORFILA <http://www.centres-antipoison.net>.

Other emergency numbers

National Poisons Information Service of England: <http://npis.org> - NHS 111: dial 111 - National Poisons Information Centre of Ireland: 353 (1) 809 2166 - European Emergency Number Association (EENA) : 112

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS07

Signal Word :

WARNING

Product identifiers :

EC 203-652-6 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

Hazard statements :

H317 May cause an allergic skin reaction.

Precautionary statements - Prevention :

P261 Avoid breathing mist.

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

Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of water.

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

P362 + P364 Take off contaminated clothing and wash it before reuse.

Precautionary statements - Disposal :

P501 Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

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SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
CAS: 109-16-0 EC: 203-652-6 REACH: 01-2119969287-21 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE	GHS07 Wng Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319 STOT SE 3, H335		2.5 <= x % < 10
CAS: 10287-53-3 EC: 233-634-3 REACH: 01-2120766020-67 ETHYL 4-DIMETHYLAMINO BENZOATE	GHS08, GHS09 Dgr Repr. 1B, H360FD Aquatic Chronic 2, H411	[2]	0 <= x % < 1

(Full text of H-phrases: see section 16)

Information on ingredients :

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

In the event of an allergic reaction, seek medical attention.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Seek medical attention immediately, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

No data available.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming).

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

Individuals with a history of skin sensitisation should not, under any circumstance, handle this mixture.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

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Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Recommended properties :

- Impervious gloves in accordance with standard EN ISO 374-2

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1/A1 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149/A1.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****General information :**

Physical state : Solid.
- Preimpregnated fibre system.

Important health, safety and environmental information

pH : Not relevant.
Flash point interval : Not relevant.
Vapour pressure (50°C) : Not relevant.
Density : > 1
Water solubility : Insoluble.

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY**10.1. Reactivity**

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- formation of dusts

Do not expose to temperatures above 50°C.

Polymerisation occurs when exposed to white light, ultraviolet light or heat.

10.5. Incompatible materials

Avoid contact with radical forming initiators, peroxides, strong alkalies or reactive metals to prevent exothermic polymerisation.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

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SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause an allergic reaction by skin contact.

11.1.1. Substances**Acute toxicity :**

ETHYL 4-DIMETHYLAMINO BENZOATE (CAS: 10287-53-3)

Oral route : 2000 < LD50 <= 5000 mg/kg
Species : Rat

Dermal route : 2,000 < LD50 <= 5000 mg/kg
Species : Rat

2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE (CAS: 109-16-0)

Oral route : LD50 = 10750 mg/kg
Species : Mouse

Germ cell mutagenicity :

ETHYL 4-DIMETHYLAMINO BENZOATE (CAS: 10287-53-3)

Mutagenesis (in vitro) : Negative.
Species : Bacteria
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

11.1.2. Mixture

No toxicological data available for the mixture.

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 13463-67-7 : IARC Group 2B : The agent is possibly carcinogenic to humans.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity**12.1.1. Substances**

ETHYL 4-DIMETHYLAMINO BENZOATE (CAS: 10287-53-3)

Fish toxicity : LC50 = 1.9 mg/l
Duration of exposure : 96 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 = 31.8 mg/l
Duration of exposure : 48 h
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity : ECr50 = 2.8 mg/l
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability**12.2.1. Substances**

ETHYL 4-DIMETHYLAMINO BENZOATE (CAS: 10287-53-3)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

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12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 1 : Slightly hazardous for water.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

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SECTION 15 : REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2020/217 (ATP 14)

- Container information:

No data available.

- Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 1 : Slightly hazardous for water.

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704) :

NFPA 704, Labelling: Health=2 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360FD	May damage fertility. May damage the unborn child.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations :

CMR: Carcinogenic, mutagenic or reprotoxic.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS07 : Exclamation mark

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.