

BIOLIGHT PLUS



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 : BIOLIGHT PLUS

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

Dental post: article obtained by polymerization of a resin including glass fibers.

1.3. Details of the supplier of the safety data sheet

Registered company name : BIO COMPOSANTS MEDICAUX.

Address : 30, chemin de la Cressonnière.38210.Tullins.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 : INRS.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Skin irritation, Category 2 (Skin Irrit. 2, H315).

Eye irritation, Category 2 (Eye Irrit. 2, H319).

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

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

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

2.2. Label elements

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

Hazard pictograms :



GHS07

Signal Word :

WARNING

Product identifiers :

EC 237-354-2

YTTERBIUM TRIFLUORIDE

EC 203-652-6

2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

Hazard statements :

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

H335

May cause respiratory irritation.

H412

Harmful to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P261

Avoid breathing mist/vapours.

P264

Wash hands thoroughly after handling.

P273

Avoid release to the environment.

P280

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

Precautionary statements - Response :

P302 + P352

IF ON SKIN: Wash with plenty of water.

P304 + P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P312	Call a POISON CENTER/doctor/if you feel unwell.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: 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.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Note	%
CAS: 13760-80-0 EC: 237-354-2 REACH: 01-2120754122-65 YTTERBIUM TRIFLUORIDE	GHS07 Wng Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335		10 \leq x % < 25
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 \leq x % < 10
CAS: 6731-36-8 EC: 229-782-3 REACH: 01-2119735694-30 DI-TERT-BUTYL 3,3,5-TRIMETHYLCYCLOHEXYLIDENE DIPEROXIDE	GHS09, GHS01, GHS02 Dgr Self-react. B, H241 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		0 \leq x % < 1

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

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 exposure by inhalation :**

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.

If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor.

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.

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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

Suitable methods of extinction

In the event of a fire, use :

- carbon dioxide (CO₂)
- powder
- sprayed water or water mist
- foam

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

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 inhaling the vapors.

Avoid any contact with the skin and eyes.

If a large quantity has been spilt, evacuate all personnel and only allow intervention by trained operators equipped with safety apparatus.

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

Clean preferably with a detergent, do not use solvents.

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 :

Handle in well-ventilated areas.

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.

Avoid inhaling vapors.

Avoid inhaling vapors. Carry out any industrial operation which may give rise to this in a sealed apparatus.

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Provide vapor extraction at the emission source and also general ventilation of the premises.

Also provide breathing apparatus for certain short tasks of an exceptional nature and for emergency interventions.

In all cases, recover emissions at source.

Avoid skin and eye contact with this mixture.

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.

Storage

Keep the container tightly closed in a dry, well-ventilated place.

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.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

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 EN374

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing :

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact.

In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034 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 vapours.

If the ventilation is insufficient, wear appropriate breathing apparatus.

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When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device.

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387 :

- A1 (Brown)

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state : Paste.

Important health, safety and environmental information

pH : Not relevant.

Flash Point Interval : FP > 100°C.

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

No data available.

10.5. Incompatible materials

Keep away from :

- oxidising agents
- reducing agents
- acids
- bases
- metals

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Respiratory tract irritation may occur, together with symptoms such as coughing, choking and breathing difficulties.

May cause an allergic reaction by skin contact.

11.1.1. Substances

Acute toxicity :

DI-TERT-BUTYL 3,3,5-TRIMETHYLCYCLOHEXYLIDENE DIPEROXIDE (CAS: 6731-36-8)

Oral route : 2000 < LD50 <= 5000 mg/kg
Species : Rat
OECD Guideline 401 (Acute Oral Toxicity)

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

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OECD Guideline 402 (Acute Dermal Toxicity)

Inhalation route (Dusts/mist) :

LC50 = 5.6 mg/l

Species : Rat

OECD Guideline 403 (Acute Inhalation Toxicity)

Duration of exposure : 4 h

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

Oral route :

LD50 = 10750 mg/kg

Species : Mouse

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

DI-TERT-BUTYL 3,3,5-TRIMETHYLCYCLOHEXYLIDENE DIPEROXIDE (CAS: 6731-36-8)

Fish toxicity :

LC50 > 500 mg/l

Species : Oryzias latipes

Duration of exposure : 48 h

Crustacean toxicity :

EC50 = 0.133 mg/l

Factor M = 1

Species : Daphnia magna

Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

DI-TERT-BUTYL 3,3,5-TRIMETHYLCYCLOHEXYLIDENE DIPEROXIDE (CAS: 6731-36-8)

Biodegradability :

Non-rapidly degradable.

12.3. Bioaccumulative potential

12.3.1. Substances

DI-TERT-BUTYL 3,3,5-TRIMETHYLCYCLOHEXYLIDENE DIPEROXIDE (CAS: 6731-36-8)

Octanol/water partition coefficient :

log K_{ow} = 7

Bioaccumulation :

BCF >= 500.

Species : Cynoscion nebulosus (Fish)

12.4. Mobility in soil

No data available.

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.

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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

-

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. 2018/669 (ATP 11)

- 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.

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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 :

H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Abbreviations :

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.