

BIOFORM PLUS PRESIDIO MEDICO CHIRURGICO REG. N. 19606 DEL MINISTERO DELLA SALUTE

Issued on 05/15/2015 - Rel. # 3 on 06/20/2017

#1/11

In conformity to Regulation (EU) 2015/830

SECTION1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product code: BIOFORM PLUS Trades code: 3SLXXIX040501

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

Disinfecting detergent

Sectors of use:

Private households (= general public = consumers)[SU21], Public domain (administration, education, entertainment,

services, craftsmen)[SU22]

Uses advised against

Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

Biochimica S.p.A. Via Roma, 49 40069 Zola Predosa (BO) tel. +39 051 755269 fax +39 051 752707 email: info@biochimicaspa.it www.biochimicaspa.it

Indirizzo persona responsabile della SDS: sds@chimicahts.it

Produced by Biochimica S.p.A. Via Roma, 49 40069 Zola Predosa (BO)

1.4. Emergency telephone number

CAVp Osp. Pediatrico Bambino Gesù, Piazza Sant'Onofrio, 4 00165 Roma - Tel.: 06 68593726 Az. Osp. Univ. Foggia, V.le Luigi Pinto, 1 71122 Foggia - Tel.: 0881-732326 Az. Osp. "A. Cardarelli", Via A. Cardarelli, 9 80131 Napoli - Tel.: 081-7472870 CAV Policlinico "Umberto I", V.le del Policlinico, 155 00161 Roma - Tel.: 06-49978000 CAV Policlinico "A. Gemelli", Largo Agostino Gemelli, 8 00168 Roma - Tel.: 06-3054343 Az. Osp. "Careggi" U.O. Tossicologia Medica, Largo Brambilla, 3 50134 Firenze - Tel.: 055-7947819 CAV Centro Nazionale di Inf. Tossicologica, Via Salvatore Maugeri, 10 27100 Pavia - Tel.: 0382-24444 Osp. Niguarda Ca' Granda Piazza Ospedale Maggiore, 3 20162 Milano - Tel.: 02-66101029 Azienda Ospedaliera Papa Giovanni XXII, Piazza OMS, 1 24127 Bergamo - Tel.: 800883300

SECTION2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms:

GHS07

Hazard Class and Category Code(s): Skin Irrit. 2, Eye Irrit. 2, Aquatic Chronic 3

Hazard statement Code(s):



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H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H412 - Harmful to aquatic life with long lasting effects.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs, or edema. The product is dangerous to the environment as it is harmful to aquatic life with long lasting effects

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):

GHS07 - Warning

Hazard statement Code(s):

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H412 - Harmful to aquatic life with long lasting effects.

Supplemental Hazard statement Code(s):

not applicable

Precautionary statements:

Genera

P101 - If medical advice is needed, have product container or label at hand.

P102 - Keep out of reach of children.

Response

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

Disposal

P501 - Dispose of contents/container in compliance with the regulations.

Contains (Reg.EC 648/2004):

< 5% Cationic surfactants, disinfectants, Perfumes, EDTA and salts thereof, non-ionic surfactants, Linalool

2.3. Other hazards

The substance / mixture does NOT contains substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

No information on other hazards

SECTION3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration	Classification	Index	CAS	EINECS	REACh
Alcohols, C12-13- branched and linear, ethoxylated	> 0,1 <= 1%	Acute Tox. 4, H302; Eye Dam. 1, H318; Aquatic Chronic 3,	N.A.	160901-19-9	931-954-4	01-2119490 233-42





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Substance	Concentration	Classification	Index	CAS	EINECS	REACh
		H412				
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	> 0,1 <= 1%	Acute Tox. 4, H302; Skin Corr. 1B, H314; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410	n.a.	68424-85-1	270-325-2	01-2119983 287-23

SECTION4. First aid measures

4.1. Description of first aid measures

Inhalation

Air the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product).:

Take contaminated clothing Immediately off.

Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product).:

Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately

Ingestion:

Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine

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

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs, or edema

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

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

If medical advice is needed, have product container or label at hand.

SECTION5. Firefighting measures

5.1. Extinguishing media

Advised extinguishing agents:

Water spray, CO2, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing means to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective suit.

The spray water can be used to protect the people involved in the extinction

You may also use selfrespirator, especially when working in confined and poorly ventilated area and if you use halogenated extinguishers (Halon 1211 fluobrene, Solkan 123, NAF, etc...)



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Keep containers cool with water spray

SECTION6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke

Wear gloves and protective clothing

6.1.2 For emergency responders:

Wear gloves and protective clothing

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provision of sufficient ventilation.

Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand.

If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify it to the authorities.

Discharge the remains in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 For containment:

Rapidly recover the product, wear a mask and protective clothing

Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material.

Prevent it from entering the sewer system.

6.3.2 For cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION7. Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors

At work do not eat or drink.

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

See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers.

Keep containers upright and safe by avoiding the possibility of falls or collisions.

Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Private households (= general public = consumers):

Store in cool and dry places.

Public domain (administration, education, entertainment, services, craftsmen):

Handle with care.

Store in ventilated place away from heat sources,



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Keep the container tightly closed.

SECTION8. Exposure controls/personal protection

8.1. Control parameters

No data available on the mixture.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated:

DNEL, inhalation, long term systemic effects, workers: 294 mg/m3 DNEL, dermal, long term systemic effects, workers: 2080 mg/kg bw/day DNEL, dermal, short term, systemic effects, workers: 87 mg/kg bw/day DNEL, dermal, long term systemic effects, population: 1250 mg/kg bw/day

DNEL, oral, long term systemic effects, population: 25 mg/kg bw/day

PNEC freshwater: 0.022 mg/l PNEC marine water: 0.022 mg/l

PNEC water (intermittent release): 0.00282 mg/l PNEC, wastewater treatment plant: 10 mg/l

PNEC (freshwater) sediment: 5.91 mg/kg dw sediment PNEC sediments (sea water): 5.91 mg/kg dw sediment

PNEC soil: 1 mg/kg dw soil

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

Long-term Inhalation DNEL: 3.96 mg/m Systems Workers Long-term Skin DNEL: 5.7 mg/kg bw/day Systemic Workers Long-term Inhalation DNEL: 1.64 mg/m Systemic Consumers Long-term Skin DNEL: 3.4 mg/kg bw/day Systemic Consumers Long-term Oral DNEL: 3.4 mg/kg bw/day Systemic Consumers

8.2. Exposure controls

Appropriate engineering controls:

Private households (= general public = consumers): Open with caution. Close the container immediately after its use.

Adopt the appropriate protective measures.

Public domain (administration, education, entertainment, services, craftsmen):

Open with caution. Close the container immediately after its use.

Adopt the appropriate protective measures.

Individual protection measures:

(a) Eye / face protection Not needed for normal use.

(b) Skin protection

(i) Hand protection

When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

(ii) Other

Wear normal work clothing.

(c) Respiratory protection



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Not needed for normal use.

(d) Thermal hazards No hazard to report

Environmental exposure controls:

Use according to good working practices to avoid pollution into the environment.

SECTION9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method		
Appearance	blue liquid			
Odour	characteristic			
Odour threshold	not determined			
рН	10,5 - 11,3			
Melting point/freezing point	this property is not suitable for safety and product classification			
Initial boiling point and boiling range	this property is not suitable for safety and product classification			
Flash point	not determined	ASTM D92		
Evaporation rate	this property is not suitable for safety and product classification			
Flammability (solid, gas)	not determined			
Upper/lower flammability or explosive limits	this property is not suitable for safety and product classification			
Vapour pressure	this property is not suitable for safety and product classification			
Vapour density	not determined			
Relative density	1.002			
Solubility	not determined			
Water solubility	not determined			
Partition coefficient: n-octanol/water	not determined			
Auto-ignition temperature	this property is not suitable for safety and product classification			
Decomposition temperature	this property is not suitable for safety and product classification			
Viscosity	not determined			
Explosive properties	not classified as explosive, does not contain explosives according to reg. CLP Art. (14 (2))			
Oxidising properties	the product is not an oxidizing substance			

9.2. Other information

No data available.

SECTION10. Stability and reactivity

10.1. Reactivity

Related to contained substances: Alcohols, C12-13- branched and linear, ethoxylated:



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Nothing to report.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

If contact with acids may cause strong exothermic reactions

10.4. Conditions to avoid

Avoid contact with acids

10.5. Incompatible materials

Acids

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION11. Toxicological information

11.1. Information on toxicological effects

No toxicological tests have been performed on the mixture.

- (a) acute toxicity: based on available data, the classification criteria are not met.
- (b) skin corrosion/irritationIf brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.
- (c) serious eye damage/irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
- (d) respiratory or skin sensitization: based on available data, the classification criteria are not met.
- (e) germ cell mutagenicity: based on available data, the classification criteria are not met.
- (f) carcinogenicity: based on available data, the classification criteria are not met.
- (g) reproductive toxicity: based on available data, the classification criteria are not met.
- (h) specific target organ toxicity (STOT) single exposure: based on available data, the classification criteria are not met.
- (i) specific target organ toxicity (STOT) repeated exposurebased on available data, the classification criteria are not met.
- (j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated: Acute toxicity



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Acute oral toxicity:

DL50 rat:> 300 - 2,000 mg / kg; Test values / own bibliographic values; Harmful if swallowed.

Acute dermal toxicity.

DL50 rat:> 2.000 mg / kg; Test values / own bibliographic values; Based on available data, classification criteria are not met. Corrosion / skin irritation.

Irritating to skin:

On rabbit: not irritating; Test values / own bibliographic values.

Based on available data, classification criteria are not met.

Serious eye / eye irritation.

Irritating to eyes:

On rabbit: irritating; Test values / own bibliographic values.

It causes serious eye injuries.

Respiratory or skin sensitization.

Sensitization:

Maximisation India's Pigment Test: Not Sensitizing; Test values / own bibliographic values.

Based on available data, classification criteria are not met.

Mutagenicity of germ cells.

In vitro genotoxicity:

Ames method; Salmonella typhimurium; With and without metabolic activation: non-mutagenic; Test values / own bibliographic values.

Remarks Based on available data, classification criteria are not met.

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

LD50 Oral (rat) (mg / kg Bodyweight) = 334

LD50 Cutaneous (rat or rabbit) (mg / kg body weight) = 3340

SECTION12. Ecological information

12.1. Toxicity

The product has not been tested for environmental impact in the event of accidental release in the environment.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated:

Toxicity to fish:

CL50 (96 h) Cyprinus carpio:> 1 - 10 mg / I; Continuous flow test;

OECD TG 203; Test values / own bibliographic values

Toxicity to Dafnia:

CE50 (48 h) Daphnia magna:> 1 - 10 mg / I; Static test;

OECD TG 202; Test values / own bibliographic values

Toxicity to algae:

CE50 (72 h) Desmodesmus subspicatus (green algae):> 1 - 10 mg / I; Static test;

OECD TG 201; Test values / own bibliographic values

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

ErC50 (96h - alghe) = 0.049 mg/l

EC50 (48h - daphnia magna) = 0.016 mg/l

LC50 (96h - pesci) = 0.28 mg/l

The product is dangerous for the environment as it is toxic for aquatic organisms following acute exposure.

Use according to good working practices to avoid pollution into the environment.



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12.2. Persistence and degradability

No data available for the mixture.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated:

biodegradation:

Rapidly biodegradable .; > 70%; 28 d; aerobic; OECD TG 301 A (new

version); Test values / own bibliographic values

Rapidly biodegradable .; > 60%; 28 d; aerobic; OECD TG 301 B; Values of

Test / own bibliographic values

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

Not biodegradable

12.3. Bioaccumulative potential

No data available for the mixture.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated:

No data available

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

Potential for bioaccumulation:

12.4. Mobility in soil

No data available for the mixture.

Related to contained substances:

Alcohols, C12-13- branched and linear, ethoxylated:

No data available

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

Easily absorbed into the soil

12.5. Results of PBT and vPvB assessment

The substance / mixture does NOT contains substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

12.6. Other adverse effects

Related to contained substances:

Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides:

Toxic to aquatic organisms

Toxic to soil organisms

Regulation (EC) No 2006/907 - 2004/648

The surfactant (s) contain (s) in this formulation comply (ies) with the criteria set out in Regulation (EC)

biodegradability/648/2004 on detergents. All supporting data shall be kept at the disposal of the competent authorities of the Member States and will be provided, at their explicit request or at the request of a manufacturer of the formulation, the above authority.

SECTION13. Disposal considerations



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13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.

Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to local and National rules in force

SECTION14. Transport information

14.1. UN number

Not included in the scope of application regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

It is not intended to carry bulk

SECTION15. Regulatory information

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

Reg. 648/2004/EC (detergents)

Decree 2/2/2002 n. 25 (risks related to chemical agents at work)

D.M. 2/26/2004 Work (occupational exposure limits)

D.M. 4/3/2007 (implementation of Directive 2006/8/EC)

Regulation (EC) No 1907/2006 (REACH)

Regulation (EC) no 1272/2008 (CLP)

Regulation (EC) no 790/2009, 2012/18/EU

Directive (cd. Seveso III)

REGULATION (EU) No 1357/2014 - waste:

HP4 - Irritant — skin irritation and eye damage

HP14 - Ecotoxic

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier



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SECTION16. Other information

16.1. Other information

Points modified compared to previous release: 1.2. Relevant identified uses of the substance or mixture and uses advised against, 2.2. Label elements, 2.3. Other hazards, 4.2. Most important symptoms and effects, both acute and delayed, 7.1. Precautions for safe handling, 8.1. Control parameters, 10.3. Possibility of hazardous reactions, 10.5. Incompatible materials, 11.1. Information on toxicological effects, 12.1. Toxicity, 12.2. Persistence and degradability, 12.3. Bioaccumulative potential, 12.4. Mobility in soil, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Description of the hazard statements exposed to point 3

H302 = Harmful if swallowed.

H318 = Causes serious eve damage.

H412 = Harmful to aquatic life with long lasting effects.

H314 = Causes severe skin burns and eye damage.

H400 = Very toxic to aquatic life.

H410 = Very toxic to aquatic life with long lasting effects.

Classification based on data of all mixture components

Main normative references: Regulation 2008/1272/EC Regulation 2015/830/EC

Link ECHA (source of information on chemical substances produced or imported in Europe) https://echa.europa.eu/information-on-chemicals MSDS provided by the customer and on the same raw material

*** This Board cancels and replaces any previous edition.