

**BIOCHIMICA S.p.A.**

Revision nr. 4

Dated 15/05/2020

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Replaced revision:3 (Dated: 17/03/2020)

**BIOFORM PLUS IGIENIZZANTE CON
ANTICALCARE - SPRAY**

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: **3SLXXDX038200**
Product name: **BIOFORM PLUS IGIENIZZANTE CON ANTICALCARE - SPRAY**

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

Identified Uses	Industrial	Professional	Consumer
detergent	-	✓	✓

1.3. Details of the supplier of the safety data sheet

Name: **BIOCHIMICA S.p.A.**
Full address: **Via Roma, 49**
District and Country: **40069 Zola Predosa (BO)**
Italia
Tel. **+39 051 755269**
Fax **+39 051 752707**

e-mail address of the competent person
responsible for the Safety Data Sheet: **info@biochimicaspa.it**

1.4. Emergency telephone number

For urgent inquiries refer to:
CAVp Osp. Pediatrico Bambino Gesù, Piazza Sant' Onofrio, 4 00165 Roma Tel.: 0668593726
Az. Osp. Univ. Foggia, V.le Luigi Pinto, 1 71122 Foggia Tel.: 0881732326
Az. Osp. A. Cardarelli, Via A. Cardarelli, 9 80131 Napoli Tel.: 0817472870
CAV Policlinico Umberto I, V.le del Policlinico, 155 00161 Roma Tel.: 0649978000
CAV Policlinico A. Gemelli, Largo Agostino Gemelli, 8 00168 Roma Tel.: 063054343
Az. Osp. Careggi U.O. Tossicologia Medica, Largo Brambilla, 3 50134 Firenze Tel.: 0557947819
CAV Centro Nazionale di Inf. Tossicologica, Via Salvatore Maugeri, 10 27100 Pavia Tel.: 038224444
Osp. Niguarda Ca' Granda Piazza Ospedale Maggiore, 3 20162 Milano Tel.: 0266101029
Azienda Ospedaliera Papa Giovanni XXII, Piazza OMS, 1 24127 Bergamo Tel.: 800883300

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

**BIOFORM PLUS IGIENIZZANTE CON
ANTICALCARE - SPRAY****Formic acid**

CAS 64-18-6

 $1 \leq x < 3$ Flam. Liq. 3 H226, Acute Tox. 3 H331, Acute Tox. 4 H302, Skin Corr. 1A
H314, Eye Dam. 1 H318

EC 200-579-1

INDEX -

Reg. no. 01-2119491174-37

CITRIC ACID

CAS 77-92-9

 $1 \leq x < 2$

Eye Irrit. 2 H319

EC 201-069-1

INDEX -

Reg. no. 01-2119457026-42

**Poly (oxy-1,2-ethanediyl), .alpha.-
(2-propylheptyl) -. Omega.-
hydroxy-**

CAS 160875-66-1

 $1 \leq x < 2$

Acute Tox. 4 H302, Eye Dam. 1 H318

EC 605-233-7

INDEX -

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures**4.1. Description of first aid measures**

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.



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5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

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7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection
8.1. Control parameters

Regulatory References:

EU OEL EU Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.

Formic acid
Threshold Limit Value

Type	Country	TWA/8h	STEL/15min	Remarks / Observations
		mg/m3	ppm	
		mg/m3	ppm	

OEL EU 5

Predicted no-effect concentration - PNEC

Normal value in fresh water	2	mg/l
Normal value in marine water	0,2	mg/l
Normal value for fresh water sediment	13,4	mg/kg/d
Normal value for marine water sediment	1,34	mg/kg/d
Normal value of STP microorganisms	7,2	mg/l
Normal value for the terrestrial compartment	1,5	mg/kg/d

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation		9,5 mg/m3		3 mg/m3				
Skin								9,5 mg/kg bw/d

CITRIC ACID
Predicted no-effect concentration - PNEC

Normal value in fresh water	0,44	mg/l
Normal value in marine water	0,044	mg/l
Normal value for fresh water sediment	34,6	mg/kg/d
Normal value for marine water sediment	3,46	mg/kg/d
Normal value of STP microorganisms	1000	mg/l
Normal value for the terrestrial compartment	33,1	mg/kg/d

Legend:



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(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	liquid
Colour	colourless
Odour	Not available
Odour threshold	Not available
pH	2,1-2,5
Melting point / freezing point	Not available
Initial boiling point	Not available

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Boiling range	Not available
Flash point	> 60 °C
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	1,009
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	not classified as explosive, it does not contain explosive substances according to CLP Art (14 (2))
Oxidising properties	the product is not an oxidizing substance

9.2. Other information

Information not available

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials

Information not available

**BIOFORM PLUS IGIENIZZANTE CON
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In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effectsMetabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:

> 20 mg/l

LD50 (Oral) of the mixture:

>2000 mg/kg

LD50 (Dermal) of the mixture:

Not classified (no significant component)

CITRIC ACID

LD50 (Oral) 5400 mg/kg

LD50 (Dermal) 2000 mg/kg

SKIN CORROSION / IRRITATION

Causes skin irritation

**BIOFORM PLUS IGIENIZZANTE CON
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Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential



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Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

**BIOFORM PLUS IGIENIZZANTE CON
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Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006Product

Point 3 - 40

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None



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Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Regulation (EC) No. 648/2004

Ingredients according to Regulation (EC) No. 648/2004

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)

WGK 1: Low hazard to waters

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3	Flammable liquid, category 3
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1A	Skin corrosion, category 1A
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
H226	Flammable liquid and vapour.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.



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H315 Causes skin irritation.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
 16. Regulation (EU) 2019/521 (XII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and



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thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Product's classification is based on the calculation methods set out in Annex I of the CLP Regulation, unless otherwise indicated in sections 11 and 12.

The data for evaluation of chemical-physical properties are reported in section 9.

Changes to previous review:

The following sections were modified:

01 / 02 / 11.