

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

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Version: 1

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

1.1. Product identifier

Trade name/designation:

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Article No.:

1.7303.baz.a

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

Use of the substance/mixture:

Medical instrument disinfectant

High-level disinfectant of medical-surgical instruments and endoscopes

Relevant identified uses:

Sector of uses [SU]

SU 20: Health services

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

ACTO GmbH

Quality Management

Büchnerstr. 11

38118 Braunschweig

Germany

Telephone: (+49) (0) 531-239 508-0

Telefax: (+49) (0) 531-239 508-11

E-mail: info@actogmbh.com

Website: http://www.actogmbh.com

E-mail (competent person): info@actogmbh.com

Poison Control Center-Nord (GIZ-Nord) University Medical Center Göttingen Robert-Koch-Str. 40, 37075

Göttingen Emergency number for Citizens: +49 (0) 551-19 24 0 Consulting physician: +49 (0) 551-38 31

80 E-mail: giznord@giz-nord.de Web-Page: http://www.giz-nord.de

1.4. Emergency telephone number

Name: Erdi Günher Profession: Chemist Certificate No.: GBF-A-0-2859 Validity: 06.08.2021 Telephone: +90 5358654635 E-mail (competent person): erdi.gunher@actopharma.com, 24h: GIZ-Nord: +49-551-19 24 0, Safety Officer: +49-531-2395080; +49-172-8560648 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment (Aquatic Chronic 3)	H412: Harmful to aquatic life with long lasting effects.	Calculation method.

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements for environmental hazards

H412 Harmful to aquatic life with long lasting effects.

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Supplemental Hazard information (EU): -

Precautionary statements Prevention

P273 Avoid release to the environment.

Special rules for supplemental label elements for certain mixtures:

5.0 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

2.3. Other hazards

No data available

SECTION 3: Composition / information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 7414-83-7 EC No.: 231-025-7	disodium dihydrogen (1-hydroxyethylidene)bisphosphonate Eye Dam. 1, Met. Corr. 1 Danger H290-H318	1 - ≤ 2 Wt %

Full text of H- and EUH-phrases: 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). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

In case of skin contact:

In case of skin reactions, consult a physician.

After eye contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion:

Rinse mouth. Let water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

No data available

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Advices on general occupational hygiene

When using do not eat, drink or smoke. Avoid contact with eyes and skin.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

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

7.3. Specific end use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

No data available

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	13 mg/kg	① DNEL worker ② oral, long-term, systemic
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	13 mg/kg	① DNEL worker ② Acute - oral, systemic effects

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Substance name	PNEC Value	① PNEC type
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	0.136 mg/l	① PNEC aquatic, freshwater
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	0.0136 mg/l	① PNEC aquatic, marine water
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	5.9 mg/kg	① PNEC sediment, marine water
disodium dihydrogen (1-hydroxyethylidene)bisphosphonate CAS No.: 7414-83-7	59 mg/kg	① PNEC soil, freshwater

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection DIN EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time (maximum wearing time) min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: transparent

Odour: Characteristic

Safety relevant basis data

parameter		at °C	Method	Remark
pH	≥ 5.4 - ≤ 6.6	20 °C		
Melting point	not determined			
Freezing point	not determined			
Initial boiling point and boiling range	not determined			
Decomposition temperature	not determined			
Flash point	not determined			
Evaporation rate	not determined			
Auto-ignition temperature	not determined			
Upper/lower flammability or explosive limits	not determined			
Vapour pressure	not determined			
Vapour density	not determined			
Density	≥ 0.933 - ≤ 1.14 g/ml	20 °C		
Bulk density	not determined			
Water solubility	not determined			
Partition coefficient: n-octanol/water	not determined			
Dynamic viscosity	not determined			
Kinematic viscosity	not determined			

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9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

CAS No.	Substance name	Toxicological information
7414-83-7	disodium dihydrogen (1-hydroxyethylidene)bisphosphonate	LD₅₀ oral: 1,878 mg/kg (Rat) LD₅₀ dermal: >6,000 mg/kg (Rabbit)

Acute oral toxicity:

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

Acute dermal toxicity:

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

Acute inhalation toxicity:

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

Skin corrosion/irritation:

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

Serious eye damage/irritation:

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

Respiratory or skin sensitisation:

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

Germ cell mutagenicity:

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

Carcinogenicity:

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

Reproductive toxicity:

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

STOT-single exposure:

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

STOT-repeated exposure:

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

Aspiration hazard:

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

Additional information:

No data available

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SECTION 12: Ecological information

12.1. Toxicity

CAS No.	Substance name	Toxicological information
7414-83-7	disodium dihydrogen (1-hydroxyethylidene)bisphosphonate	NOEC: 13 mg/l 12 d (Algae/water plant, Daphnia pulex (water flea)) EC₅₀: 527 mg/l 2 d (Algae/water plant, Daphnia magna (Big water flea)) OECD 202 NOEC: 6.8 mg/l 21 d (Algae/water plant, Daphnia magna (Big water flea)) LC₅₀: 868 mg/l 4 d (fish, Lepomis macrochirus (Bluegill)) OECD 203 LC₅₀: 200 mg/l 3 d (fish, Oncorhynchus mykiss (Rainbow trout)) NOEC: 60 mg/l 12 d (fish, Oncorhynchus mykiss (Rainbow trout)) LC₅₀: >1,000 mg/l 3 d (crustaceans, Eisenia foetida) EC₅₀: >960 mg/l (crustaceans, Avena sativa)

Aquatic toxicity:

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

CAS No.	Substance name	Results of PBT and vPvB assessment
7414-83-7	disodium dihydrogen (1-hydroxyethylidene)bisphosphonate	—

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product:

07 06 04 * other organic solvents, washing liquids and mother liquors

*: Evidence for disposal must be provided.

Waste code packaging:

15 01 10 * packaging containing residues of or contaminated by dangerous substances

*: Evidence for disposal must be provided.

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Dispose waste in accordance with national regulations!

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SECTION 14: Transport information

No dangerous good in sense of these transport regulations.

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN-No.			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant			
14.4. Packing group			
not relevant			
14.5. Environmental hazards			
not relevant			
14.6. Special precautions for user			
not relevant			

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
not relevant

SECTION 15: Regulatory information

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

15.1.1. EU legislation

Authorisations:

Class II-B Medical product according to Medical Devices Directive 93/42/EEC with amendment 2007/47/EC.

Other regulations (EU):

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Classification according to Regulation (EC) No 1272/2008 [CLP], according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 453/2010). Classification according to Directive 67/548/EEC or 1999/45/EC Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

15.1.2. National regulations

[DE] National regulations

Restrictions of occupation

5 MuSchRiV. 4 MuSchRiV. 22 JArbSchG.

Annex Chemikalien-Verbotsverordnung (ChemVerbotsV)

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

Water hazard class (WGK)

WGK:

3 - Severely water-hazardous

15.2. Chemical Safety Assessment

No data available

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SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

No data available

16.3. Key literature references and sources for data

You can refer to data sources below to find detailed toxicity information of each component.

<http://www.baua.de/>

<http://gestis.itrust.de/>

<http://www.gefahrstoff-info.de/>

<http://esis.jrc.ec.europa.eu/>

<http://www.echemportal.org/>

<http://www.gischem.de>

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

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

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment (<i>Aquatic Chronic 3</i>)	H412: Harmful to aquatic life with long lasting effects.	Calculation method.

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

Hazard statements	
H290	May be corrosive to metals.
H318	Causes serious eye damage.

16.6. Training advice

Do not handle until all safety precautions have been read and understood.

16.7. Additional information

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