

SAFETY DATA SHEET

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

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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.:

01.2323.a

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

Use of the substance/mixture:

Medical instrument disinfectant

Relevant identified uses:

Sector of uses [SU]

SU 20: Health services

Product Categories [PC]

PC 8: Biocidal product

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
Respiratory or skin sensitisation (<i>Skin Sens. 1A</i>)	H317: May cause an allergic skin reaction.	
Hazardous to the aquatic environment (<i>Aquatic Chronic 3</i>)	H412: Harmful to aquatic life with long lasting effects.	

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2.2. Label elements

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

Hazard pictograms:



GHS07

Exclamation mark



GHS09

Environment

Signal word: Warning

Hazard components for labelling:

phthalaldehyde

hazard statements for health hazards

H317	May cause an allergic skin reaction.
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Hazard statements for environmental hazards

H411	Toxic to aquatic life with long lasting effects.
------	--

Supplemental Hazard information (EU)

EUH208	Contains phthalaldehyde. May produce an allergic reaction.
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Precautionary statements Prevention

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
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/soap.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

Precautionary statements Disposal

P501	Dispose of contents/container to in accordance with national regulations..
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Special rules for supplemental label elements for certain mixtures:

0.1 % percent of the mixture consists of components of unknown hazards to the aquatic environment.

2.3. Other hazards

Adverse environmental effects:

May cause long lasting harmful effects to aquatic life.

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.: 643-79-8 EC No.: 211-402-2	phthalaldehyde Acute Tox. 3, Aquatic Acute 1, Aquatic Chronic 1, Skin Corr. 1B, Skin Sens. 1A Danger H301-H314-H317-H400	1 - ≤ 0.55 Wt %

Full text of H- and EUH-phrases: see section 16.

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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:

Remove casualty to fresh air and keep warm and at rest. If unconscious place in recovery position and seek medical advice. In case of irregular breathing or respiratory arrest provide artificial respiration. Provide fresh air. In case of respiratory tract irritation, consult a physician.

In case of skin contact:

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

After ingestion:

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

Self-protection of the first aider:

Use personal protection equipment.

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

Allergic reactions

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

Treat symptomatically.

You can refer to data sources in section 16 to find detailed toxicity information of each component.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

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. Heating causes rise in pressure with risk of bursting. Move undamaged containers from immediate hazard area if it can be done safely. Use water spray jet to protect personnel and to cool endangered containers.

5.4. Additional information

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Avoid contact with eyes and skin. Wear personal protection equipment. Do not breathe gas/vapour/aerosol. Provide adequate ventilation. Keep out of reach of children. Wash contaminated clothing prior to re-use.

Protective equipment:

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

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Emergency procedures:

Remove persons to safety. Provide eye shower and label its location conspicuously. Avoid contact with skin, eyes and clothes.

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).

For cleaning up:

Water (with cleaning agent)

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:

Handle in accordance with good industrial hygiene and safety practice. Always close containers tightly after the removal of product. Use only in well-ventilated areas. Keep out of the reach of children. Wear personal protection equipment (refer to section 8).

Advices on general occupational hygiene

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. Wash hands before breaks and after work. Avoid contact with eyes and skin. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing. Wash contaminated clothing prior to re-use.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place. Recommended storage temperature: at room temperature. minimum storage temperature: 5 °C maximum storage temperature: 35 °C

Requirements for storage rooms and vessels:

Keep/Store only in original container. Floors should be impervious, resistant to liquids and easy to clean.

Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

Storage class: 12 - non-combustible liquids that cannot be assigned to any of the above storage classes

Further information on storage conditions:

Protect against direct sunlight.

7.3. Specific end use(s)

Recommendation:

Disinfectant. Some of the uses of the product mentioned in Section 1.2. No other specific uses are stipulated. Observe instructions for use.

Industrial sector specific solutions:

Disinfectant cleaner, based on aldehyde (without formaldehyde)

GISCODE:

GD60-alt

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice.

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.

Respiratory protection:

Use only in well-ventilated areas. With correct and proper use, and under normal conditions, breathing protection is not required.

Other protection measures:

General health and safety measures: When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Wash hands before breaks and after work. Wash contaminated clothing prior to re-use. Apply skin care products after work.

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: clear, colorless or light yellow

Odour: characteristic

Safety relevant basis data

parameter		at °C	Method	Remark
pH	≥ 6.5 - ≤ 8.5	20 °C		
Melting point	<i>not determined</i>			
Freezing point	<i>not determined</i>			
Initial boiling point and boiling range	<i>not determined</i>			
Decomposition temperature	<i>not determined</i>			
Flash point	<i>not determined</i>			
Evaporation rate	<i>not determined</i>			
Auto-ignition temperature	<i>not determined</i>			
Upper/lower flammability or explosive limits	<i>not determined</i>			
Vapour pressure	<i>not determined</i>			
Vapour density	<i>not determined</i>			
Density	≥ 0.98 - ≤ 1.03 g/ml	20 °C		
Bulk density	<i>not determined</i>			
Water solubility	<i>not determined</i>			
Partition coefficient: n-octanol/water	<i>not determined</i>			

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parameter		at °C	Method	Remark
Dynamic viscosity	<i>not determined</i>			
Kinematic viscosity	<i>not determined</i>	40 °C		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

There is no dangerous reactions known when use as prescribed and with proper storage..

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

There is no dangerous reactions known when use as prescribed and with proper storage.

10.4. Conditions to avoid

See chapter 7. No additional measures necessary.

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. In case of fire: Gases/vapours, toxic. Do not breathe gas/vapour.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

CAS No.	Substance name	Toxicological information
643-79-8	phthalaldehyde	LD₅₀ oral: =178 mg/kg (Rat) LD₅₀ dermal: >2,000 mg/kg (Rat)

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:

May cause an allergic skin reaction. Contains phthalaldehyde. May produce an allergic reaction.

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.

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Additional information:

No data available

SECTION 12: Ecological information

12.1. Toxicity

CAS No.	Substance name	Toxicological information
643-79-8	phthalaldehyde	LC₅₀: 0.072 mg/l 4 d (Oncorhynchus mykiss (rainbow trout)) EC₅₀: 0.087 mg/l 2 d (Daphnia magna (Water flea))

Aquatic toxicity:

Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

CAS No.	Substance name	Log K _{OW}	Bioconcentration factor (BCF)
643-79-8	phthalaldehyde	0.934	

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
643-79-8	phthalaldehyde	—

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Consult the appropriate local waste disposal expert about waste disposal.

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product:

07 06 99	Wastes not otherwise specified
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Waste code packaging:

15 01 10 *	packaging containing residues of or contaminated by dangerous substances
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*: Evidence for disposal must be provided.

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Other disposal recommendations:

Dispose waste in accordance with national regulations!

SECTION 14: Transport information

No dangerous good in sense of these transport regulations.

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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. 22 JArbSchG. 4 MuSchRiV.

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)

Source:

Total dust emission value may not be exceeded. (see No. 5.2.1).

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Other regulations, restrictions and prohibition regulations

TRGS 401 "Risks resulting from skin contact - identification, assessment, measures"

TRGS 510 "Storage of hazardous substances in non-stationary containers"

BGI 595 "Instructions M 004: Irritating substances / corrosive substances"

TRGS 900 "Occupational exposure limit values"

TRGS 903 Minimum protective measures according to TRGS 500. Berufsgenossenschaftliche Informationen (BGI): 536, 564, 595, 621, 623 & 660. Berufsgenossenschaftliche Vorschriften (BGV). Berufsgenossenschaftliche Regeln (BGR): 180, 189, 190, 192, 195 & 197.

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

WEL: İşyeri Maruziyet Limiti

TWA: İşyeri Maruz Kalma Limitleri

STEL: Kısa Süreli Maruz Kalma Sınırı

ATE: Akut Toksikite Tahmini

EC No: Avrupa Topluluğu Numarası

CAS: Kimyasal Kuramlar Servisi

ADR: Tehlikeli Malların Karayolu ile Uluslararası Taşımacılığına İlişkin Avrupa Anlaşması

ADN: Tehlikeli Malların Kıta İçi Su Yolları ile Uluslararası Taşımacılığına İlişkin Avrupa Anlaşması

IATA: Uluslararası Hava Taşımacılığı Birliği

ICAO-TI: Tehlikeli Malların Havayoluyla Emniyetli Taşınması için Teknik Şartname

IMDG: Uluslararası Denizcilik Tehlikeli Mallar

RID: Tehlikeli Malların Demiryolu ile Uluslararası Taşımacılığına İlişkin Avrupa Anlaşması

LC50: Test hayvanları grubunda % 50 (yarı) ölüme neden olan madde konsantrasyonu

LD50: Test hayvanları grubunda % 50 (yarı) ölüme neden olan madde dozu (Medyan Ölümcül Doz)

PBT: Kalıcı, Biyobirikimli ve Toksik Madde

vPvB: Çok Kalıcı, Çok Biyobirikimli

Marpol 73/78 : 1978 tarihli Protokol ile değişik 1973 tarihli Gemilerden Kirliliğin Önlenmesi için Uluslararası Konvansiyon.

IBC: Tehlikeli Dökme Kimyasallar Taşıyan Gemilerin İnşaatı ve Ekipmanları için Uluslararası Kod (Uluslararası Dökme Kimyasal Kodu).

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>

<https://adrbook.com/en/>

<https://echa.europa.eu/>

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
Respiratory or skin sensitisation (<i>Skin Sens. 1A</i>)	H317: May cause an allergic skin reaction.	
Hazardous to the aquatic environment (<i>Aquatic Chronic 3</i>)	H412: Harmful to aquatic life with long lasting effects.	

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

Hazard statements	
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.

16.6. Training advice

No data available

16.7. Additional information

No data available