

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:

Actodermanol®

Article No.:

06.1046.a

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

Use of the substance/mixture:

Hand and Skin Disinfectant

Biocides (e.g. disinfectants and parasiticide)

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
flammable liquids (<i>Flam. Liq. 2</i>)	H225: Highly flammable liquid and vapour.	

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2.2. Label elements

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

Hazard pictograms:



GHS02
Flame

Signal word: Danger

hazard statements for physical hazards

H225	Highly flammable liquid and vapour.
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Supplemental Hazard information (EU): -

Precautionary statements

P102	Keep out of reach of children.
------	--------------------------------

Precautionary statements Prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
------	--

P233	Keep container tightly closed.
------	--------------------------------

P280	Wear protective gloves/protective clothing/eye protection/face protection.
------	--

Precautionary statements Response

P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
--------------------	--

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

Precautionary statements Storage

P403 + P235	Store in a well-ventilated place. Keep cool.
-------------	--

Special rules for supplemental label elements for certain mixtures:

69,5 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

2.3. Other hazards

Adverse physicochemical effects:

This material is combustible and can be ignited by heat, sparks, flames, or other sources of ignition (e.g. static electricity, pilot lights, or mechanical/electrical equipment).

SECTION 3: Composition / information on ingredients

3.2. Mixtures

Description:

Aqueous alcoholic solution

Hazardous ingredients / Hazardous impurities / Stabilisers:

product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 64-17-5 EC No.: 200-578-6	ethanol Flam. Liq. 2 Danger H225	65.9 Wt %
CAS No.: 112-34-5 EC No.: 203-961-6	2-(2-butoxyethoxy)ethanol Eye Irrit. 2 Warning H319	0.12 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:

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.

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 drunk in little sips (dilution effect). Get medical advice/attention if you feel unwell.

Self-protection of the first aider:

Warning First aider: Pay attention to self-protection! Use personal protection equipment.

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

Drowsiness Made worse through the drinking of alcohol beverages In rare cases the product can cause temporary erythema of the skin.

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:

Water spray jet alcohol resistant foam Extinguishing powder Carbon dioxide (CO₂)

5.2. Special hazards arising from the substance or mixture

Combustible

Hazardous combustion products:

Nitrogen oxides (NO_x), Carbon monoxide, Carbon dioxide (CO₂). In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Standard procedure for chemical fires. In case of fire and/or explosion do not breathe fumes. Use appropriate respiratory protection.

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.

Emergency procedures:

Provide eye shower and label its location conspicuously

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

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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

See protective measures under point 7 and 8.

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).

Fire prevent measures:

Take precautionary measures against static discharge. Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. When using do not smoke.

Fire class: B

Temperature class: T2

Explosion group: II B

Advices on general occupational hygiene

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

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

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

Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Keep container tightly closed and in a well-ventilated place. Recommended storage temperature +5 - +40 °C Keep away from sources of ignition - No smoking.

Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs. Do not store together with: Oxidising agent
Radioactive substances Explosive Stoffe.

Storage class: 3 - Flammable liquids

7.3. Specific end use(s)

Recommendation:

Biocidal product

Industrial sector specific solutions:

Hand and Skin Disinfectant

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① long-term occupational exposure limit value ② short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
TRGS 900 (DE)	ethanol CAS No.: 64-17-5	① 200 ppm (380 mg/m ³) ② 400 ppm (1,520 mg/m ³)
TRGS 900 (DE)	2-(2-butoxyethoxy)ethanol CAS No.: 112-34-5	① 10 ppm (67 mg/m ³) ② 15 ppm (100.5 mg/m ³)
IOELV (EU)	2-(2-butoxyethoxy)ethanol CAS No.: 112-34-5	① 10 ppm (67.5 mg/m ³) ② 15 ppm (101.2 mg/m ³)

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

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:

Avoid contact with eyes. No particular measures are necessary when used properly. To follow: Berufsgenossenschaftliche Regeln (BGR) 192

Skin protection:

Draw up and observe skin protection programme. Apply skin care products after work.

Respiratory protection:

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. Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

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: light blue

Odour: Characteristic

Safety relevant basis data

parameter		at °C	Method	Remark
pH	≥ 6 - ≤ 8	20 °C		
Melting point	<i>not determined</i>			
Freezing point	<i>not determined</i>			

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parameter		at °C	Method	Remark
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>	50 °C		
Vapour density	<i>not determined</i>			
Density	≥ 0.85 - ≤ 0.9 g/ml	20 °C		
Bulk density	<i>not determined</i>			
Water solubility	<i>not determined</i>			
Partition coefficient: n-octanol/water	0.5	20 °C		
Dynamic viscosity	<i>not determined</i>	20 °C		
Kinematic viscosity	<i>not determined</i>	40 °C		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Reacts with : Oxidising agent, strong

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect against direct sunlight.

10.5. Incompatible materials

Strong acid, Oxidising agent, strong

10.6. Hazardous decomposition products

Nitrogen oxides (NOx) Carbon monoxide Carbon dioxide Do not breathe gas/vapour. In case of fire: Gases/vapours, toxic

SECTION 11: Toxicological information

11.1. Information on toxicological effects

CAS No.	Substance name	Toxicological information
64-17-5	ethanol	LD₅₀ oral: 7,060 mg/kg (Mouse) LD₅₀ dermal: ≥20,000 mg/kg (Kaninchen) LC₅₀ Acute inhalation toxicity (gas): ≥11,200 mg/l (Maus)
112-34-5	2-(2-butoxyethoxy)ethanol	LD₅₀ oral: 5,660 mg/kg (Ratte) LD₅₀ dermal: 2,700 mg/kg (Kaninchen)

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Skin corrosion/irritation:

In rare cases the product can cause temporary erythema of the skin. slightly irritant but not relevant for classification. Apply skin care products after work.

Serious eye damage/irritation:

slightly irritant but not relevant for classification.

Respiratory or skin sensitisation:

May cause sensitization by inhalation. Following inhalation: Headache Nausea

Additional information:

The product has not been tested. The statement is derived from the properties of the single components.

Exposure route Inhalation, Skin contact, accidental ingestion and Eye contact.

SECTION 12: Ecological information

12.1. Toxicity

CAS No.	Substance name	Toxicological information
64-17-5	ethanol	LC₅₀ : 42 - 14,200 mg/l (Aquatic toxicity) EC₅₀ : 2 - 17,500 mg/l (Aquatic toxicity) LC₅₀ : 3,720 - 20,700 mg/l (Aquatic toxicity) LC₅₀ : ≥11,000 mg/l 4 d (Fische) EC₅₀ : ≥9,950 mg/l 2 d (Daphnien)

Assessment/classification:

The substance/mixture does not fulfill the criteria of the acute aquatic toxicity according to Regulation (EC) No 1272/2008 [CLP], Annex I.

12.2. Persistence and degradability

CAS No.	Substance name	Biodegradation	Remark
64-17-5	ethanol	Yes, rapidly	

Biodegradation:

The single components are biodegradable.

Additional information:

Further ecological information: Ethanol Readily biodegradable (according to OECD criteria).

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water:

0.5 at °C: 20

Accumulation / Evaluation:

Does not accumulate in organisms.

12.4. Mobility in soil

If product enters soil, it will be mobile and may contaminate groundwater.

12.5. Results of PBT and vPvB assessment

CAS No.	Substance name	Results of PBT and vPvB assessment
64-17-5	ethanol	—
112-34-5	2-(2-butoxyethoxy)ethanol	—

This substance does not meet the criteria for classification as PBT or vPvB.

12.6. Other adverse effects

Further ecological information: slightly hazardous to water (WGK 1) Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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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 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:

Consult the appropriate local waste disposal expert about waste disposal. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN-No.			
UN 1170	UN 1170	UN 1170	UN 1170
14.2. UN proper shipping name			
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) (ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION))	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es)			
 3	 3	 3	 3
14.4. Packing group			
III	III	III	III
14.5. Environmental hazards			
No	No	No	No

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Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.6. Special precautions for user			
Special provisions: 144, 601 Limited quantity (LQ): 5 L - E1 Excepted Quantities: Hazard identification number (Kemler No.): 30 Classification code: F1 tunnel restriction code: (D/E) Remark:	Special provisions: 144, 601 Limited quantity (LQ): 5 L - E1 Excepted Quantities: Classification code: F1 Remark:	Special provisions: 144, 223 Limited quantity (LQ): 5 L - E1 Excepted Quantities: EmS-No.: F-E; S-D Remark:	Special provisions: A58, A180 Limited quantity (LQ): E1: Y344 - 10 L, 355 - 60 L, 366 - 220 L Excepted Quantities: Remark: ERG: 3L

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No data available

SECTION 15: Regulatory information

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

15.1.1. EU legislation

Authorisations:

Regulation (EU) No. 528/2012 on biocides Main group 1: Disinfectants Product-type 1: Human hygiene

Restrictions on use:

Not suitable for the disinfection of mucous membranes and wounds

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

Störfallverordnung

Remark:

To follow: 12. BImSchV (Störfallverordnung)

Betriebssicherheitsverordnung (BetRSichV)

Highly flammable

Technische Anleitung Luft (TA-Luft)

Klasse 1:

III

Ziffer 1:

5.2.5

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Anteil 1:

90 %

Remark:

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

Water hazard class (WGK)

WGK:

1 - Mildly water-hazardous

Description:

Ethanol

Source:

Anh. 4, Nr. 3

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"

15.2. Chemical Safety Assessment

For this substance a chemical safety assessment has not been carried out.

15.3. Additional information

No further relevant information available

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
flammable liquids (<i>Flam. Liq. 2</i>)	H225: Highly flammable liquid and vapour.	

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

Hazard statements	
H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.

16.6. Training advice

Use biocides safely. Always read the label and product information before use.

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16.7. Additional information

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