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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 1/9



Actoanid Wipes

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

1.1. Product identifier

Trade name/designation:

Actoanid Wipes

Article No.:

05.1210.a

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

Use of the substance/mixture:

Wipe Dispensing Systems

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.: AGBF-A-0-2859 Validity: 06.08.2021 Telephone: +90 535 865 4635 E-mail (competent person): gnhrdi@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		Classification pro cedure
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.

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 2/9



Actoanid Wipes

Supplemental hazard information		
EUH208	Contains Polyhexamethylene biguanide hydrochloride PHMB. May produce an allergic reaction.	

Precautionary Statements Prevention		
P202	Do not handle until all safety precautions have been read and understood.	
P273	Avoid release to the environment.	

Precautionary Stat	ements Disposal
P501	Dispose of contents/container to in accordance with national regulations

2.3. Other hazards

No data available

SECTION 3: Composition / information on ingredients

3.2. Mixtures

Description:

Disinfectant solution saturated wipes

Hazardous ingredients / Hazardous impurities / Stabilisers:

product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concen- tration
CAS No.: 27083-27-8	Polyhexamethylene biguanide hydrochloride PHMB Acute Tox. 2, Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Carc. 2, Eye Dam. 1, STOT RE 1, Skin Sens. 1B Danger H302-H317-H318-H330-H351-H372-H410 M- factor (acute): 10 M-factor (chronic): 10	0 - ≤ 0.25 weight-%
CAS No.: 5538-94-3 EC No.: 226-901-0	dimethyldioctylammonium chloride Acute Tox. 3, Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Eye Dam. 1, Flam. Liq. 3, Skin Corr. 1B Danger H226-H302-H311-H314-H318-H400-H410	0 - ≤ 0.25 weight-%
CAS No.: 160875-66-1	Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy- Acute Tox. 4, Aquatic Acute 1, Eye Dam. 1 1 1302-H318-H400	0 - ≤ 0.1 weight-%

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:

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:

Following skin contact Subsequently wash off with: Water and soap In case of skin irritation, consult a physician.

IF ON CLOTHING: Take off immediately all contaminated clothing. Wash contaminated clothing prior to re-use.

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.

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 3/9



Actoanid Wipes

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:

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

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

Contains: Polyaminopropyl biguanide. May produce an allergic reaction.

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.

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. See protective measures under point 7 and 8.

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

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 (sand, diatomaceous earth, acid- or universal binding agents).

For cleaning up:

Water

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.

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 4/9



Actoanid Wipes

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. Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Environmental precautions:

Avoid release of large amounts to the environment.

Advices on general occupational hygiene

Wash hands before breaks and after work. 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. storage temperature: 5-40 °C

Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Ensure adequate ventilation of the storage area. Keep/Store only in original container.

Hints on storage assembly:

Do not store together with: Food and feedingstuffs

Further information on storage conditions:

Storage at room temperature

7.3. Specific end use(s)

Recommendation:

Disinfectant

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	 long-term occupational exposure limit value short-term occupational exposure limit value Instantaneous value Monitoring and observation processes Remark
TRGS 900 (DE)	ethanol CAS No.: 64-17-5	① 200 ppm (380 mg/m³) ② 800 ppm (1,520 mg/m³)
TRGS 900 (DE)	2,6-di-tert-butyl-p-cresol CAS No.: 128-37-0	 10 mg/m³ 2 40 mg/m³ 5 (Aerosol und Dampf, einatembare Fraktion)

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.

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 5/9



Actoanid Wipes

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: solid Colour: colourless

Odour: Characteristic

Safety relevant basis data

parameter		at °C	Method	Remark
рН	≥ 5.5 - ≤ 7.5			
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	0.95 - ≤ 1.07 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			

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

Prepared by: Erdi Günher (erdi.gunher@actopharma.com); Certificate No.: GBF-A-0-2859

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 6/9



Actoanid Wipes

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

SECTION 11: Toxicological information

11.1. Information on toxicological effects

CAS No.	Substance name	Toxicological information
27083-27-8	Polyhexamethylene biguanide hydrochloride PHMB	LD ₅₀ oral: >2,500 mg/kg (Rat)
		LD ₅₀ dermal:
		>2,000 mg/kg (Rat)
5538-94-3	dimethyldioctylammonium chloride	LD ₅₀ oral: 238 mg/kg (Rat) LD ₅₀ dermal: 191 mg/kg (Rabbit)
160875-66-1	Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-	LD ₅₀ oral: 500 mg/kg (Ratte)

Acute oral toxicity:

No data available

Acute dermal toxicity:

No data available

Acute inhalation toxicity:

No data available

Skin corrosion/irritation:

No data available

Serious eye damage/irritation:

No data available

Respiratory or skin sensitisation:

Contains Polyhexamethylene biguanide hydrochloride PHMB. May produce an allergic reaction.

Germ cell mutagenicity:

No data available

Carcinogenicity:

No data available

Reproductive toxicity:

No data available

STOT-single exposure:

No data available

STOT-repeated exposure:

No data available

Aspiration hazard:

No data available

Additional information:

No data available

SECTION 12: Ecological information

12.1. Toxicity

		,
CAS No.	Substance name	Toxicological information
27083-27-8	Polyhexamethylene biguanide hydrochloride PHMB	IC ₅₀ : 40 mg/l
160875-66-1 Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-		LC ₅₀ : 55 mg/l 4 d (Fische)
omega-hydroxy-	EC₅₀: 55 mg/l 3 d (Algen)	
		EC₅₀: 55 mg/l 2 d (Daphnien) OECD 202 (Daphnien, Immobilisierung)

Prepared by: Erdi Günher (erdi.gunher@actopharma.com); Certificate No.: GBF-A-0-2859

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 7/9



Actoanid Wipes

Aquatic toxicity:

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

CAS No.	Substance name	Biodegradation	Remark
27083-27-8	Polyhexamethylene biguanide hydrochloride PHMB	-	Very toxic to aquatic life with long lasting effects.
	Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)- omega-hydroxy-	Yes, rapidly	Readily biodegradable (according to OECD criteria).

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
27083-27-8	Polyhexamethylene biguanide hydrochloride PHMB	The substance in the mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII.
5538-94-3	dimethyldioctylammonium chloride	_
	Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-	_

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!

Other disposal recommendations:

Dispose waste in accordance with national regulations!

SECTION 14: Transport information

No dangerous good in sense of these transport regulations.

14.1. UN-No.

not relevant

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 8/9



Actoanid Wipes

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-A 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

4 MuSchRiV. 5 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:

2 - Significantly water-hazardous

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"

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

No data available

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

Revision date: 4 Dec 2019 Print date: 14 Oct 2020

Version: 3 Page 9/9



Actoanid Wipes

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://www.dguv.de/ifa/index-2.jsp

https://echa.europa.eu/da/information-on-chemicals/cl-inventory-database

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 pro cedure
Hazardous to the aquatic environment (Aquatic Chronic 3)	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		
H226	Flammable liquid and vapour.	
H302	Harmful if swallowed.	
H311	Toxic in contact with skin.	
H314	Causes severe skin burns and eye damage.	
H317	May cause an allergic skin reaction.	
H318	Causes serious eye damage.	
H330	Fatal if inhaled.	
H351	Suspected of causing cancer.	
H372	Causes damage to organs through prolonged or repeated exposure. (Respiratory tract, Inhalation)	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	

16.6. Training advice

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

16.7. Additional information

DISCLAIMER: The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. ACTO GmbH assumes no liability for damage arising from the use of the information or for any errors or omissions. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific product designated and may not be valid for such product used in combination with any other materials or in any process, unless specified in the text.