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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 1/7



Acto® Men Hygiene Spray

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

1.1. Product identifier

Trade name/designation:

Acto[®] Men Hygiene Spray

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

Use of the substance/mixture:

Care product for genital area

Relevant identified uses:

Life cycle stage [LCS]

C: Consumer use

Product Categories [PC]

PC 39: Cosmetics, personal care products

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		Classification proc edure
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: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2



Page 2/7

P501

Acto® Men Hygiene Spray

Supplemental Hazard information (EU)

EUH208 Contains Polyhexamethylene biguanide. May produce an allergic reaction.

Precautionary statements

P102 Keep out of reach of children.

Precautionary statements Prevention

P234	Keep only in original packaging.
P273	Avoid release to the environment.

Precautionary statements Disposal

Dispose of contents/container to in accordance with national regulations..

Special rules for supplemental label elements for certain mixtures:

1.0 % 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

Description:

Aqueous solution

Hazardous ingredients / Hazardous impurities / Stabilisers:

Dyhexamethylene biguanide cute Tox. 2, Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, arc. 2, Eye Dam. 1, STOT RE 1, Skin Sens. 1B	0 - ≤ 0.1 Wt %
> 🏈	> 📀 🄄 Danger H302-H317-H318-H330-H351-H372-H410 M-

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.

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.

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.

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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 3/7

Acto® Men Hygiene Spray

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:

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).

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:

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

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.



with eyes and skin.

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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 4/7

Acto® Men Hygiene Spray

7.3. Specific end use(s)

Recommendation:

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

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 **Odour:** characteristic

Colour: transparent

Safety relevant basis data

parameter		at °C	Method	Remark
рН	5 - 7.5	20 °C		
Melting point	not determined			
Freezing point	not determined			
Initial boiling point and boiling range	not applicable			
Decomposition temperature	not determined			
Flash point	not applicable			
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	0.09 - 1.1 g/ml	20 °C		
Bulk density	not determined			
Water solubility	completely misc ible			
Partition coefficient: n-octanol/ water	not determined			
Dynamic viscosity	not determined			
Kinematic viscosity	not determined	40 °C		

9.2. Other information

No data available



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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 5/7

Acto® Men Hygiene Spray

SECTION 10: Stability and reactivity
10.1. Reactivity The product itself does not burn.
10.2. Chemical stability No data available
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 In case of fire: Gases/vapours, toxic
SECTION 11: Toxicological information
11.1. Information on toxicological effects
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: Contains Polyhexamethylene biguanide. 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. Additional information:
No data available
SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available



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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 6/7

Acto® Men Hygiene Spray

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.Dispose of contents/container to 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

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:

Cosmetic

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).



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

Revision date: 18-Feb-2019 Print date: 18-Feb-2019 Version: 2

Page 7/7

Acto® Men Hygiene Spray

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

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

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		Classification proc edure
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	
H302	Harmful if swallowed.
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)
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 Pharma 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.

