

# SAFETY DATA SHEET

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

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## Acto® Baby Gel

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

#### 1.1. Product identifier

Trade name/designation:

Acto® Baby Gel

Article No.:

08.4799.a

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

Use of the substance/mixture:

Skin Care Product

Diaper Rash Area Cleaning Gel

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

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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](mailto: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](mailto: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.

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### Hazard statements for environmental hazards

H412 Harmful to aquatic life with long lasting effects.

### 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

P273 Avoid release to the environment.

### 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

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 27083-27-8	<b>Polyhexamethylene biguanide</b> Acute Tox. 2, Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Carc. 2, Eye Dam. 1, STOT RE 1, Skin Sens. 1B  <b>Danger</b> H302-H317-H318-H330-H351-H372-H410 M- factor (acute): 10 M-factor (chronic): 10	0 - ≤ 0.1 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.

#### 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.

### 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

#### Suitable extinguishing media:

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

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### 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.

### 7.3. Specific end use(s)

No data available

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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)	Poloxamer 188 CAS No.: 9003-11-6	① 1,000 mg/m <sup>3</sup> ② 8,000 mg/m <sup>3</sup>
DFG (DE)	Poloxamer 188 CAS No.: 9003-11-6	① 200 mg/m <sup>3</sup> ② 400 mg/m <sup>3</sup> ⑤ (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

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 - ≤ 6.5	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			

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parameter		at °C	Method	Remark
Density	≥ 0.92 - ≤ 1.04 g/ml	20 °C		
Bulk density	<i>not determined</i>			
Water solubility	completely miscible			
Partition coefficient: n-octanol/water	<i>not determined</i>			
Dynamic viscosity	≥ 450 - ≤ 750 mPa*s	20 °C		
Kinematic viscosity	<i>not determined</i>			

### 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

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

CAS No.	Substance name	Toxicological information
27083-27-8	Polyhexamethylene biguanide	<b>LD<sub>50</sub> oral:</b> ≥300 - ≤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:

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.

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### 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

CAS No.	Substance name	Toxicological information
27083-27-8	Polyhexamethylene biguanide	<b>LC<sub>50</sub>:</b> 0.026 mg/l 4 d (Oncorhynchus mykiss (Rainbow trout)) <b>EC<sub>50</sub>:</b> 0.09 mg/l 2 d (Daphnia magna (Big water flea)) <b>EC<sub>50</sub>:</b> 0.015 mg/l 3 d (Pseudokirchneriella subcapitata) <b>NOEC:</b> 0.0098 mg/l 4 d (Oncorhynchus mykiss (Rainbow trout))

### 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
27083-27-8	Polyhexamethylene biguanide	—

### 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 99	Wastes not otherwise specified
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#### Waste code packaging:

07 06 99	Wastes not otherwise specified
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### Waste treatment options

#### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

#### Appropriate disposal / Package:

Do not mix with other wastes.

### 13.2. Additional information

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)
<b>14.1. UN-No.</b>			
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.
<b>14.2. UN proper shipping name</b>			
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.
<b>14.3. Transport hazard class(es)</b>			
not relevant			
<b>14.4. Packing group</b>			
not relevant			
<b>14.5. Environmental hazards</b>			
not relevant			
<b>14.6. Special precautions for user</b>			
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 Product

**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

**Technische Anleitung Luft (TA-Luft)**

**Remark:**

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

**Water hazard class (WGK)**

**WGK:**

Not specified

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### 15.2. Chemical Safety Assessment

For the following substances of this mixture a chemical safety assessment has been carried out: PHMB

## 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	
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

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