

Safety Data Sheet

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

 Trade name: **Article 1030 F 7%**
1 Identification of Substance/Preparation and of the Company Undertaking
Product details

- **Trade name:** **Article 1030 F 7%**
- **Article number:** **Amca 1030F7/1**
- **Application of the Substance / the Preparation**
Wetting retarding lubricant for condoms
- **Manufacturer/Supplier** AMCAPHARM Pharmaceutical GmbH
Industriestraße 10-12
D-61191 Rosbach
Germany
Tel.: +49 (0)60 07 / 91 11 0
Fax.: +49 (0)60 07 / 91 11 20
- **Information**
Dr. Michael Bömeke
e-mail: info@amcapharm.de
- **Emergency information**
see: manufacturer/supplier
Tel.: + 49 (0) 6007-9111-0 (24h)

2 Hazards Identification

- **Hazard Designation:**



Xi Irritant

- **Information Pertaining to Particular Dangers for Man and Environment:**
R 43 May cause sensitization by skin contact.
- **Classification System:**
The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

3 Composition/Information on Ingredients

- **Chemical Characterization**
- **Description**
Lubricant for condoms without siliconoil, with retarding properties
- **Dosage**
0.5 g / condom
- **Components**

| | | |
|--------------------------------------|---|--------|
| CAS: 25322-68-3 EINECS: 203-473-3 | Polyethylene glycol 300 (Macrogol 300, Ph. Eur., 6 th Ed.) | 52-62% |
| CAS: 56-81-5 EINECS: 200-289-5 | Glycerol, > 85% (Ph. Eur., 6 th Ed.) | 30-40% |
| CAS: 94-09-7 EINECS: 202-303-5 | Benzocaine (Ph. Eur., 6 th Ed.) Xi; R 38-43 | ~ 7.0% |
| | Preservatives (Parabene) | < 0.5% |

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4 First Aid Measures**• General Information:**

Instantly remove any clothing soiled by the product.

• After Inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm.

Consult doctor if symptoms persist.

In case of unconsciousness bring patient into stable side position for transport.

• After Skin Contact

Clean affected area with soap and plenty of water.

Get medical attentions if irritation develops and persists.

• After Eye Contact

Rinse opened eye for at least 15 minutes under running water.

Get medical attentions.

• After Swallowing

Rinse out mouth with water.

If swallowed, do not induce vomiting. Get medical attentions.

5 Fire Fighting Measures**• Suitable extinguishing agents**CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.**• For safety reasons unsuitable extinguishing agents**

Water with a full water jet.

• Special Hazards Caused by the Material, its Products of Combustion or Resulting Gases

Formation of toxic gases is possible during heating or in case of fire.

• Protective Equipment

Do not inhale explosion gases or combustion gases.

Wear self-contained breathing apparatus.

Wear full protective suit.

• Additional Information

Cool endangered containers with water spray jet.

6 Accidental Release Measures**• Person-related Safety Precautions**

Ensure adequate ventilation.

Particular danger of slipping on leaked/spilled product.

• Measures for Environmental Protection

Do not allow to enter drainage system, surface or ground water.

• Measures for Cleaning/Collecting

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

• Additional Information

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

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7 Handling and Storage

- **Handling / Information for Safe Handling**
Ensure good ventilation/exhaustion at the workplace.
- **Storage / Requirements to be met by Storerooms and Containers**
Keep container tightly closed in a cool and dry place.
- **Information about Storage in one Common Storage Facility**
Store away from foodstuffs.
- **Further information about storage conditions**
Protect from heat and direct sunlight.
Keep container tightly sealed.

8 Exposure Controls and Personal Protection

- **Additional Information about Design of Technical Systems**
Make available emergency shower and eye wash at the workplace.
No further data; see Section 7.

| Components with limit values that require monitoring at the workplace | |
|--|---------------------------------------|
| 25322-68-3 Polyethylene glycol 300 (Macrogol 300, Ph. Eur., 6th Ed.) | |
| MAK (Germany) | 1,000 mg/m ³ |
| 56-81-5 glycerol, > 85% (Ph. Eur., 6th Ed.) | |
| WEL (Great Britain) | Long-term value: 10 mg/m ³ |

Personal Protective Equipment

- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Avoid contact with the eyes and skin.
Do not inhale gases / fumes / aerosols.
Take off immediately all contaminated clothing.
Be sure to clean skin thoroughly after work and before breaks.
- **Breathing Equipment**
Use breathing protection in case of insufficient ventilation.
- **Protection of Hands**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Material of Gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration Time of Glove Material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye Protection**
Safety glasses
- **Body Protection**
Light weight protective clothing.

9 Physical and Chemical Properties

- **General Information**

| | |
|---------------|---------------------------------|
| Form: | Fluid |
| Color: | Colorless / Light yellow |
| Odor: | Odorless |

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- **Change in Condition**
 - Melting Point/ Melting Range:** Not determined
 - Boiling Point/ Boiling Range:** Not determined
- **Flash Point:** > 100°C
- **Self-inflammability:** Product is not self igniting
- **Danger of Explosion:** Product is not explosive
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **pH-Value:** 5-6

10 Stability and Reactivity

- **Thermal Decomposition / Conditions to be Avoided:**
 No decomposition if used and stored according to specifications.
 Stable (at room temperature) for 5 years
- **Dangerous Reactions**
 No dangerous reactions known.
- **Dangerous Products of Decomposition:**
 Nitrous gases
 No further dangerous decomposition products known.

11 Toxicological Information

- **Acute toxicity**

| LD/LC50 values that are relevant for classification | | |
|---|------|------------------------|
| 56-81-5 Glycerin, > 85% (Ph. Eur. 6th Ed.) | | |
| Oral | LD50 | >12600 mg/kg (rat) |
| Dermal | LD50 | >10000 mg/kg (rabbit) |
| 25322-68-3 Polyethylene glycol 300 (Macrogol 300, Ph. Eur. 6th Ed.) | | |
| Oral | LD50 | > 15000 mg/kg (rat) |
| Dermal | LD50 | > 20000 mg/kg (rabbit) |
| 94-09-7 Benzocaine (Ph. Eur., 6th Ed.) | | |
| Oral | LD50 | 3042 mg/kg (rat) |

- **Primary Irritant Effect**
 On the skin: Irritations of the skin are possible.
 On the eye: Irritations of the mucous membranes are possible.
- **Sensitization**
 Sensitization possible by skin contact.
- **Additional Toxicological Information**
 The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:
 Irritant
 The product contains:
 Benzocaine (Ph. Eur., 6th Ed.)
- **USA TSCA (Toxic Substances Control Act)**
 -
- **Sensitization**
 May cause sensitization by skin contact.

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12 Ecological Information

Information about Elimination (Persistence and Degradability)/ Other Information

Biological degradability

PEG300: > 90 % (10 d) readily degradable (Zahn-Wellens-Test)

Glycerin: readily degradable

- **Ecotoxic Effects / Behavior in Sewage Processing Plants**

| Type of test Effective concentration Method Assessment | |
|---|-------------------------------------|
| 25322-68-3 Polyethylene glycol 300 (Macrogol 300, Ph. Eur. 6th Ed.) | |
| EC 50 | > 1000 mg/l (Bacteria) |
| LC50 / 48 h | > 10 g/l (Leuciscus idus melanotus) |
| 56-81-5 Glycerin, > 85% (Ph. Eur. 6th Ed.) | |
| EC 50 | > 10 g/l (Bacteria) |
| LC50 | > 10 g/l (Pisces) |
| 94-09-7 Benzocaine (Ph. Eur., 6th Ed.) | |
| LC50 / 96h | > 111 mg/l (Pisces) |

- **General notes:**

Water hazard class 2 (German Regulation) (Self-assessment): hazard to waters.

Do not allow product to reach underground or surface water or sewage system.

Danger to drinking water if even small quantities leak into soil.

13 Disposal Considerations

- **Product Recommendation**

Remove in accordance with the local official recommendations.

| European Waste Catalogue | |
|---------------------------------|--|
| 16 05 08 | discarded organic chemicals consisting of or containing dangerous substances |
| | |

- **Uncleaned Packaging / Recommendation**

Packaging that cannot be cleaned are to be disposed of in the same manner as the product.

- **Recommended Cleaning Agent**

Water, if necessary with cleaning agent.

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14 Transport Information

- **Land transport ADR/RID**
ADR/RID Class: -
- **Maritime Transport IMDG**
Marine pollutant: No
- **Transport/Additional Information**
No dangerous good according to international transport regulations.

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- **Designation according to EC guidelines**
The product has been classified and labeled in accordance with EC Directives / Ordinance on Hazardous Materials (GefStoffV)
- **Code Letter and Hazard Designation of Product**



Xi Irritant

- **Hazard-determining Components of Labeling**
Benzocaine (Ph. Eur., 6th Ed.)
- **Risk Phrases**
R 38 Irritating to skin.
R 43 May cause sensitization by skin contact.
- **Safety Phrases**
S 23 Do not breathe vapor/aerosol.
S 24 Avoid contact with skin and eyes.
S 37 Wear suitable gloves.
S 46 If swallowed, seek medical advice immediately and show this container or label.
S 56 Dispose of this material and its container to hazardous or special waste collection point.

16 Other Information

This data is based on our present knowledge. However, it shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant R-phrases**
R 38 Irritating to skin.
R 43 May cause sensitization by skin contact.