

**Safety Data Sheet**

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

 Trade name: **Article 1030 F 3%**
**1 Identification of Substance/Preparation and of the Company Undertaking**
**Product details**

- **Trade name:** **Article 1030 F 3%**
- **Article number:** **Amca 1030F3/1**
- **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 <sup>th</sup> Ed.)	55-65%
CAS: 56-81-5 EINECS: 200-289-5	Glycerol, > 85% (Ph. Eur., 6 <sup>th</sup> Ed.)	30-40%
CAS: 94-09-7 EINECS: 202-303-5	Benzocaine (Ph. Eur., 6 <sup>th</sup> Ed.) Xi; R 38-43	~ 3.0%
	Preservatives (Parabene)	< 0.5%

**Safety Data Sheet**

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

Trade name: **Article 1030 F 3%**

(Contd. of page 1)

**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**

CO<sub>2</sub>, 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.

(Contd. on page 3)

## Safety Data Sheet

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

Trade name: **Article 1030 F 3%**

(Contd. of page 2)

### 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	
<b>25322-68-3 Polyethylene glycol 300 (Macrogol 300, Ph. Eur., 6<sup>th</sup> Ed.)</b>	
MAK (Germany)	1,000 mg/m <sup>3</sup>
<b>56-81-5 glycerol, &gt; 85% (Ph. Eur., 6<sup>th</sup> Ed.)</b>	
WEL (Great Britain)	Long-term value: 10 mg/m <sup>3</sup>

#### 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**

<b>Form:</b>	<b>Fluid</b>
<b>Color:</b>	<b>Colorless / Light yellow</b>
<b>Odor:</b>	<b>Odorless</b>

(Contd. on page 4)

## Safety Data Sheet

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

Trade name: **Article 1030 F 3%**

(Contd. of page 3)

- **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		
<b>56-81-5 Glycerin, &gt; 85% (Ph. Eur. 6<sup>th</sup> Ed.)</b>		
Oral	LD50	>12600 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
<b>25322-68-3 Polyethylene glycol 300 (Macrogol 300, Ph. Eur. 6<sup>th</sup> Ed.)</b>		
Oral	LD50	> 15000 mg/kg (rat)
Dermal	LD50	> 20000 mg/kg (rabbit)
<b>94-09-7 Benzocaine (Ph. Eur., 6<sup>th</sup> Ed.)</b>		
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., 6<sup>th</sup> Ed.)
- **USA TSCA (Toxic Substances Control Act)**  
-
- **Sensitization**  
May cause sensitization by skin contact.

**Safety Data Sheet**

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

 Trade name: **Article 1030 F 3%**

(Contd. of page 4)

**12 Ecological Information**

Information about Elimination (Persistence and Degradability)/ Other Information

Biological degradability

PEG300: &gt; 90 % (10 d) readily degradable (Zahn-Wellens-Test)

Glycerin: readily degradable

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

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

<b>European Waste Catalogue</b>	
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.

**Safety Data Sheet**

According to 1907/2006/EC, Article 31

Printing date: 25.03.2009

Revision: 25.03.2009

Trade name: **Article 1030 F 3%**

(Contd. of page 5)

**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.

**15**

- **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., 6<sup>th</sup> 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.