



# SAFETY DATA SHEET

Revision date: 26-Aug-2015

Version: 3.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Anbesol Maximum Strength Gel

**Trade Name:** ANBESOL  
**Compound Number:** WH-0700-0002  
**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Consumer healthcare product used as anesthetic agent

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
1 Giralda Farms  
Madison, NJ 07940

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Skin Corrosion/Irritation: Category 2  
Skin Sensitization: Category 1

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction

**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P264 - Wash hands thoroughly after handling  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P363 - Wash contaminated clothing before reuse  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards Note:**

No data available  
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Benzocaine	94-09-7	202-303-5	Skin Irrit. 2 (H315) Skin Sens. 1 (H317)	20.0
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Carbomer	9003-01-4	Not Listed	Not Listed	*
Saccharin	81-07-2	201-321-0	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
D & C yellow No. 10	8004-92-0	Not Listed	Not Listed	*
FD & C Red No. 40	25956-17-6	247-368-0	Not Listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Minimize generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Consumer healthcare product used as anesthetic agent

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Polyethylene glycol

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	1000 ppm

#### Glycerin, USP

Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	50 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 mg/m <sup>3</sup>

#### Benzocaine

Pfizer OEL TWA-8 Hr:	500µg/m <sup>3</sup> , Sensitizer, Skin
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#### Propylene glycol

Australia TWA	150 ppm
	474 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	150 ppm
	470 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Latvia OEL - TWA	7 mg/m <sup>3</sup>
Lithuania OEL - TWA	7 mg/m <sup>3</sup>

#### Carbomer

Switzerland OEL -TWAs	0.05 mg/m <sup>3</sup>
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#### Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	40 mg/m <sup>3</sup>
Finland OEL - TWA	10 ppm
	45 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Poland OEL - TWA	240 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Gel	<b>Color:</b>	Clear Reddish brown
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### **Benzocaine**

No data available

#### **Methylparaben**

No data available

#### **Saccharin**

No data available

#### **FD & C Blue No. 1**

No data available

#### **FD & C Red No. 40**

No data available

#### **Benzyl Alcohol**

No data available

#### **Glycerin, USP**

No data available

#### **Polyethylene glycol**

No data available

#### **Propylene glycol**

No data available

#### **D & C yellow No. 10**

No data available

#### **Carbomer**

No data available

#### **Flavor**

No data available

#### **Polysorbate 80**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** No data available  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Viscosity:** No data available

**Flammability:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.  
**Short Term:** Topical anesthetic drug; may cause localized numbness  
**Known Clinical Effects:** Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Benzocaine**

Rat Oral LD 50 3042 mg/kg  
Mouse Oral LD 50 2500mg/kg  
Mouse Intraperitoneal LD 50 216mg/kg

**Benzyl Alcohol**

Rat Oral LD50 1230 mg/kg  
Rat Para-periosteal LD50 53mg/kg  
Rat Inhalation LC50 >4.178mg/L

**Glycerin, USP**

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

#### Propylene glycol

Rat Oral LD 50 22,000 mg/kg  
Mouse Oral LD 50 24,900mg/kg  
Rabbit Dermal LD 50 20,800mg/kg

#### D & C yellow No. 10

Rat Oral LD50 2000 mg/kg

#### Polysorbate 80

Rat Oral LD50 25 g/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Benzyl Alcohol

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Minimal  
Skin Irritation Guinea Pig Moderate

##### Glycerin, USP

Eye Irritation Rabbit Mild

##### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

##### Saccharin

IARC: Group 3 (Not Classifiable)

##### FD & C Blue No. 1

IARC: Group 3 (Not Classifiable)

##### Carbomer

IARC: Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Benzocaine**

*Pimephales promelas* (Fathead Minnow) LC50 96 Hours 35.4 mg/L

**Benzyl Alcohol**

*Pimephales promelas* (Fathead Minnow) EPA LC50 96 Hours 460 mg/L

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 230 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 Hours 500 mg/L

**Glycerin, USP**

*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L

*Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

**Benzyl Alcohol**

*Daphnia magna* (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

**Persistence and Degradability:**

**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

**Benzyl Alcohol**

OECD Activated sludge Ready 92% After 14 Day(s) Ready

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

##### Glycerin, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

##### Benzocaine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4
EU EINECS/ELINCS List	202-303-5

##### Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

##### Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
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**15. REGULATORY INFORMATION**

California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Carbomer</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Benzyl Alcohol</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9
<b>Saccharin</b>	
CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-321-0
<b>Methylparaben</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7
<b>D &amp; C yellow No. 10</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>FD &amp; C Red No. 40</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-368-0
<b>FD &amp; C Blue No. 1</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	223-339-8

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### 15. REGULATORY INFORMATION

#### Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Serious eye damage/eye irritation-Cat.2A; H315 - Causes skin irritation  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 16 - Other Information.

**Revision date:** 26-Aug-2015

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**