



# SAFETY DATA SHEET

Revision date: 17-Sep-2015

Version: 2.2

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

### Product Identifier

**Material Name:** Advil Congestion Relief Tablets

**Trade Name:** ADVIL  
**Compound Number:** WH-1233-0009  
**Synonyms:** Advil Sinus Congestion and Pain Tablets  
**Chemical Family:** Not determined

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

**Intended Use:** Consumer healthcare product used for Upper respiratory

### 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

Acute Oral Toxicity: Category 4  
Reproductive Toxicity: Category 2

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H302 - Harmful if swallowed  
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P281 - Use personal protective equipment as required  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

**Additional Information:** For a more detailed discussion of potential health hazards and toxicity see Section 11.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Ibuprofen	15687-27-1	239-784-6	Acute Tox.4 (H302) Repr.2 (H361fd)	45-50
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Phenylephrine hydrochloride	61-76-7	200-517-3	Acute Tox. 4, H302	2-5
Propyl gallate	121-79-9	204-498-2	Acute Tox. 4 (H302) Skin Sens. 1 (H317)	<1
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Acesulfame potassium salt	55589-62-3	259-715-3	Not Listed	*
Caprylic/capric triglyceride	65381-09-1	265-724-3	Not Listed	*
Carnauba wax	8015-86-9	232-399-4	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Lactic acid 88% USP	50-21-5	200-018-0	Not Listed	*
Lecithin	8002-43-5	232-307-2	Not Listed	*
Maltodextrin	9050-36-6	232-940-4	Not Listed	*
Pharmaceutical ink	Not assigned	Not Listed	Not Listed	*
Polydextrose	68424-04-4	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	Not Listed	Not Listed	*
Sucralose	56038-13-2	259-952-2	Not Listed	*
Synthetic iron oxide	1332-37-2	215-570-8	Not Listed	*

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Triacetin	102-76-1	203-051-9	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	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.

**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

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**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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 dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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 for Upper respiratory and/or non-steroidal, anti-inflammatory drug (nsaid)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Colloidal silicon dioxide

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Switzerland OEL - TWAs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>

#### Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m <sup>3</sup> 4 mg/m <sup>3</sup>
OSHA - Final PELS - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
<b>Glycerin, USP</b>	
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>
<b>Ibuprofen</b>	
Pfizer OEL TWA-8 Hr:	3000µg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup> 4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELS - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
<b>Phenylephrine hydrochloride</b>	
Pfizer OEL TWA-8 Hr:	0.04 mg/m <sup>3</sup> , Skin
<b>Sodium lauryl sulfate</b>	
Pfizer OEL TWA-8 Hr:	0.3 mg/m <sup>3</sup>
<b>Talc (non-asbestiform)</b>	

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup>
	6.0 mg/m <sup>3</sup>
	3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup>
	1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Romania OEL - TWA	2 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sweden OEL - TWAs	5 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

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.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### Respiratory protection:

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

**Physical State:** Film-coated Tablet  
**Odor:** No data available.  
**Molecular Formula:** Mixture

**Color:** Tan  
**Odor Threshold:** No data available.  
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available  
**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

##### Stearic acid

No data available

##### Acesulfame potassium salt

No data available

##### Flavor

No data available

##### Carnauba wax

No data available

##### Colloidal silicon dioxide

No data available

##### Croscarmellose sodium

No data available

##### Lecithin

No data available

##### Maltodextrin

No data available

##### Polydextrose

No data available

##### Polyvinyl alcohol

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Sucralose**

No data available

**Titanium dioxide**

No data available

**Triacetin**

No data available

**Xanthan gum**

No data available

**Glycerin, USP**

No data available

**Sodium lauryl sulfate**

No data available

**Talc (non-asbestiform)**

No data available

**Propyl gallate**

No data available

**Ibuprofen**

No data available

**Phenylephrine hydrochloride**

No data available

**Pharmaceutical ink**

No data available

**Synthetic iron oxide**

No data available

**Caprylic/capric triglyceride**

No data available

**Hydroxypropyl methylcellulose**

No data available

**Microcrystalline cellulose**

No data available

**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:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

### 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.



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### 10. STABILITY AND REACTIVITY

**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:

Accidental ingestion may cause effects similar to those seen in clinical use. Acute overdosage and/or chronic abuse of ibuprofen may cause kidney effects.

##### Long Term:

Animal studies indicate that this material may cause adverse effects on the fertility, the developing fetus.

##### Known Clinical Effects:

Adverse effects associated with therapeutic use include gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation. Adverse effects associated with the therapeutic use of phenylephrine hydrochloride include fast or irregular heart rate, increased blood pressure, anxiety, restlessness, headache, difficulty breathing, and gastrointestinal disturbances. Systemic side-effects have occurred following the use of phenylephrine eye drops and nasal drops. It may also cause prolonged bleeding time. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

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

##### Stearic acid

Rat Oral LD50 > 4640 mg/kg  
Rabbit Dermal LD50 > 5000mg/kg

##### Lecithin

Rat Oral LD50 > 8 ml/kg

##### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

##### Triacetin

Mouse Oral LD50 1100 mg/kg

##### Xanthan gum

Rat Oral LD50 > 5000 mg/kg

##### Glycerin, USP

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

##### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

#### Ibuprofen

Rat Oral LD 50 1600 mg/kg  
Rat Inhalation LC 50 > 20mg/L

#### Phenylephrine hydrochloride

Rat Oral LD50 350 mg/kg  
Mouse Oral LD50 120mg/kg

#### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

#### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/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)

##### Stearic acid

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Mild

##### Glycerin, USP

Eye Irritation Rabbit Mild

##### Sodium lauryl sulfate

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild Moderate  
Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - LLNA Mouse Negative

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Stearic acid

30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

##### Ibuprofen

4 Day(s) Rat Oral 200 mg/kg Gastrointestinal System  
30 Day(s) Dog Oral 480 mg/kg Gastrointestinal system  
2 Week(s) Rat Oral 1300 mg/kg Liver

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### 11. TOXICOLOGICAL INFORMATION

#### Phenylephrine hydrochloride

12 Week(s) Rat Oral 10,000 ppm Death

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Ibuprofen

Fertility and Embryonic Development Rat rectal 100 mg/kg/day Fertility  
Fertility and Embryonic Development Rat rectal 200 mg/kg/day Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 60 mg/kg/day Not Teratogenic  
Embryo / Fetal Development Rat Oral 180 mg/kg/day Not Teratogenic

#### Phenylephrine hydrochloride

Prenatal & Postnatal Development Rabbit Subcutaneous 15 mg/kg/day LOAEL Maternal toxicity, Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Stearic acid

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Unscheduled DNA Synthesis *E. coli* Negative

#### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Ibuprofen

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Phenylephrine hydrochloride

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Equivocal  
Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Stearic acid

26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic  
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

#### Phenylephrine hydrochloride

2 Year(s) Rat Oral 50 mg/kg/day Not carcinogenic

Carcinogen Status: See below

#### Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

#### Polyvinyl alcohol

IARC: Group 3 (Not Classifiable)

#### Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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### 11. TOXICOLOGICAL INFORMATION

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

**Toxicity:**

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

**Glycerin, USP**

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 50 mg/L

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

**Sodium lauryl sulfate**

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 3.6 mg/L

**Ibuprofen**

*Daphnia magna* (Water Flea) EC50 48 Hours 108 mg/L

*Desmodesmus subcapitata* (Green Alga) EC50 72 Hours 315 mg/L

**Persistence and Degradability:** No data available

**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

<b>Acesulfame potassium salt</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-715-3
<b>Caprylic/capric triglyceride</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	265-724-3
<b>Carnauba wax</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	232-399-4
<b>Colloidal silicon dioxide</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	231-545-4
<b>Corn Starch</b>	
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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
<b>Croscarmellose sodium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Flavor</b>	
CERCLA/SARA 313 Emission reporting	Not Listed

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### 15. REGULATORY INFORMATION

<p><b>California Proposition 65</b> <b>EU EINECS/ELINCS List</b></p>	<p>Not Listed Not Listed</p>
<b>Glycerin, USP</b>	
<p><b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>REACH - Annex V - Exemptions from the obligations of Register:</b></p>	<p>Not Listed Not Listed Present Present 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</p>
<b>EU EINECS/ELINCS List</b>	200-289-5
<b>Hydroxypropyl methylcellulose</b>	
<p><b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>Standard for the Uniform Scheduling for Drugs and Poisons:</b> <b>EU EINECS/ELINCS List</b></p>	<p>Not Listed Not Listed Present Present Schedule 4 Not Listed</p>
<b>Ibuprofen</b>	
<p><b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>Standard for the Uniform Scheduling for Drugs and Poisons:</b></p>	<p>Not Listed Not Listed Present Present Schedule 2 Schedule 3 Schedule 4</p>
<b>EU EINECS/ELINCS List</b>	239-784-6
<b>Lactic acid 88% USP</b>	
<p><b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>EU EINECS/ELINCS List</b></p>	<p>Not Listed Not Listed Present Present 200-018-0</p>
<b>Lecithin</b>	
<p><b>CERCLA/SARA 313 Emission reporting</b> <b>California Proposition 65</b> <b>Inventory - United States TSCA - Sect. 8(b)</b> <b>Australia (AICS):</b> <b>REACH - Annex IV - Exemptions from the obligations of Register:</b> <b>EU EINECS/ELINCS List</b></p>	<p>Not Listed Not Listed Present Present Present 232-307-2</p>

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#### Maltodextrin

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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-940-4

#### Microcrystalline cellulose

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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

#### Pharmaceutical ink

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Phenylephrine hydrochloride

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	200-517-3

#### Polydextrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Polyvinyl alcohol

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

#### Propyl gallate

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	204-498-2

#### Sodium lauryl sulfate

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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 6
EU EINECS/ELINCS List	205-788-1

**Stearic acid**

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	200-313-4

**Sucralose**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-952-2

**Synthetic iron oxide**

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	215-570-8

**Talc (non-asbestiform)**

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	238-877-9

**Titanium dioxide**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

**Triacetin**

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	203-051-9

**Xanthan gum**

CERCLA/SARA 313 Emission reporting	Not Listed
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California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	234-394-2

### 16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

**Revision date:** 17-Sep-2015

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

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**End of Safety Data Sheet**