



SAFETY DATA SHEET

Revision date: 17-Sep-2015

Version: 2.2

Page 1 of 17

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 2 of 17
Version: 2.2



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 | * |

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 3 of 17
Version: 2.2

| | | | | |
|-------------|------------|-----------|------------|---|
| 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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 4 of 17
Version: 2.2

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

Corn Starch

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 5 of 17
Version: 2.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|------------------------------------|---|
| Ireland OEL - TWAs | 10 mg/m ³ 4 mg/m ³ |
| OSHA - Final PELS - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| | |
| Glycerin, USP | |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Czech Republic OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| Finland OEL - TWA | 20 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Germany (DFG) - MAK | 50 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| OSHA - Final PELS - TWAs: | 15 mg/m ³ |
| Poland OEL - TWA | 10 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 50 mg/m ³ |
| | |
| Ibuprofen | |
| Pfizer OEL TWA-8 Hr: | 3000µg/m ³ |
| | |
| Microcrystalline cellulose | |
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ 4 mg/m ³ |
| Latvia OEL - TWA | 2 mg/m ³ |
| OSHA - Final PELS - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 10 mg/m ³ 5 mg/m ³ |
| | |
| Phenylephrine hydrochloride | |
| Pfizer OEL TWA-8 Hr: | 0.04 mg/m ³ , Skin |
| | |
| Sodium lauryl sulfate | |
| Pfizer OEL TWA-8 Hr: | 0.3 mg/m ³ |
| | |
| Talc (non-asbestiform) | |

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 6 of 17
Version: 2.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Titanium dioxide

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 7 of 17
Version: 2.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|-----------------------|---------------------|
| Sweden OEL - TWAs | 5 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 6 mg/m ³ |
| | 5 mg/m ³ |

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 8 of 17
Version: 2.2

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.

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 9 of 17
Version: 2.2

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/m³
Rat Dermal LD 50 > 21.9 g/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 10 of 17
Version: 2.2

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 11 of 17
Version: 2.2

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)

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 12 of 17
Version: 2.2

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.

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 13 of 17
Version: 2.2

15. REGULATORY INFORMATION

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

Acesulfame potassium salt

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 259-715-3 |

Caprylic/capric triglyceride

| | |
|---|------------|
| 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 |

Carnauba wax

| | |
|---|------------|
| 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 |

Colloidal silicon dioxide

| | |
|---|------------|
| 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 |

Corn Starch

| | |
|---|------------|
| 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 |

Croscarmellose sodium

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

Flavor

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
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SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 14 of 17
Version: 2.2

15. REGULATORY INFORMATION

| | |
|--|--|
| California Proposition 65 | Not Listed |
| 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 |
| Hydroxypropyl methylcellulose | |
| 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 4 |
| EU EINECS/ELINCS List | Not Listed |
| Ibuprofen | |
| 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 3 Schedule 4 |
| EU EINECS/ELINCS List | 239-784-6 |
| Lactic acid 88% USP | |
| 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 | 200-018-0 |
| Lecithin | |
| 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 | 232-307-2 |

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
 Revision date: 17-Sep-2015

Page 15 of 17
 Version: 2.2

| |
|-----------------------------------|
| 15. REGULATORY INFORMATION |
|-----------------------------------|

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

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 16 of 17
Version: 2.2

15. REGULATORY INFORMATION

| | |
|--|------------|
| 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 |
|------------------------------------|------------|

SAFETY DATA SHEET

Material Name: Advil Congestion Relief Tablets
Revision date: 17-Sep-2015

Page 17 of 17
Version: 2.2

15. REGULATORY INFORMATION

| | |
|---|------------|
| 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