



SAFETY DATA SHEET

Revision date: 09-Apr-2018

Version: 4.0

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

Product Identifier

Material Name: Ibuprofen and Diphenhydramine Citrate Caplets

Trade Name: ADVIL PM Caplets (U.S.); ADVIL Cold and Flu Caplets (Canada)
Compound Number: WH-0555-0008
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: P202 - Do not handle until all safety precautions have been read and understood
P201 - Obtain special instructions before use
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P281 - Use personal protective equipment as required
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

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Diphenhydramine citrate	88637-37-0	289-432-0	Not Listed	0.1-1.0
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Ibuprofen	15687-27-1	239-784-6	Acute Tox.4 (H302) Repr.2 (H361fd)	35-40
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
FD & C Blue No. 2, Aluminum lake	16521-38-3	240-589-3	Not Listed	*
Glyceryl behenate	18641-57-1	242-471-7	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Pharmaceutical ink	Not assigned	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Carnauba wax	8015-86-9	232-399-4	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Polydextrose	68424-04-4	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.

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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
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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 firefighting 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 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. Cleanup operations should only be undertaken by trained personnel.

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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 as analgesic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Calcium stearate

Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Diphenhydramine citrate

Pfizer OEL TWA-8 Hr:	0.05 mg/m ³ , (as free base)
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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

Polyethylene glycol

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

Sodium lauryl sulfate

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pfizer OEL TWA-8 Hr:	0.3 mg/m ³
Colloidal silicon dioxide	
Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 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
Slovenia OEL - TWA	0.3 mg/m ³
Switzerland OEL -TWAs	4 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
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
Ibuprofen	
Pfizer OEL TWA-8 Hr:	3000µg/m ³
Starch, pregelatinized	
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
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

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Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
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
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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Film-coated Tablet	Color:	Blue
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	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)	

Titanium dioxide

No data available

Carnauba wax

No data available

Colloidal silicon dioxide

No data available

Croscarmellose sodium

No data available

FD & C Blue No. 2, Aluminum lake

No data available

Glyceryl behenate

No data available

Ibuprofen

No data available

Lactose NF, monohydrate

No data available

Microcrystalline cellulose

No data available

Polydextrose

No data available

Starch, pregelatinized

No data available

Sodium lauryl sulfate

No data available

Sodium starch glycolate

No data available

Stearic acid

No data available

Diphenhydramine citrate

No data available

Hydroxypropyl methylcellulose

No data available

Calcium stearate

No data available

Polyethylene glycol

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

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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.

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. It may also cause prolonged bleeding time. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Additionally drowsiness, sleepiness (somnolence), and sedation may occur.

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

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

Glyceryl behenate

Rat Oral LD50 5 g/kg

Ibuprofen

Rat Oral LD 50 1600 mg/kg

Rat Inhalation LC 50 > 20mg/L

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Stearic acid

Rat Oral LD50 > 4640 mg/kg

Rabbit Dermal LD50 > 5000mg/kg

Diphenhydramine citrate

Rat Oral LD50 856 mg/kg

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Sodium lauryl sulfate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild Moderate

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

Stearic acid

Skin Irritation Rabbit Moderate

Eye Irritation Rabbit Mild

Polyethylene glycol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

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

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

Stearic acid

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

Diphenhydramine citrate

13 Week(s) Rat Oral 313 ppm LOAEL Liver

2 Year(s) Rat Oral 15 mg/kg/day NOAEL Liver

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11. TOXICOLOGICAL INFORMATION

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

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

Ibuprofen

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Stearic acid

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

Carcinogen Status:

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

Titanium dioxide

IARC:

Group 2B (Possibly Carcinogenic to Humans)

Colloidal silicon dioxide

IARC:

Group 3 (Not Classifiable)

NTP:

Reasonably Anticipated To Be A Human Carcinogen

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)

Ibuprofen

<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	108 mg/L
<i>Desmodesmus subcapitata</i> (Green Alga)	EC50	72 Hours	315 mg/L

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Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 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.

15. REGULATORY INFORMATION

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

Calcium stearate

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	216-472-8

Diphenhydramine citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	289-432-0

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15. REGULATORY INFORMATION

FD & C Blue No. 2, Aluminum lake

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	240-589-3

Glyceryl behenate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	242-471-7

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

Lactose NF, monohydrate

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

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
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

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 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

Sodium lauryl sulfate

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

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

Sodium starch glycolate

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

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

Ibuprofen

SAFETY DATA SHEET

Material Name: Ibuprofen and Diphenhydramine Citrate
Caplets
Revision date: 09-Apr-2018

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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 2 Schedule 3 Schedule 4
EU EINECS/ELINCS List	239-784-6

Polydextrose

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

Starch, pregelatinized

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

Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification.

Revision date: 09-Apr-2018
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet