



# SAFETY DATA SHEET

Revision date: 09-Apr-2018

Version: 3.0

Page 1 of 14

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

### Product Identifier

**Material Name:** Advil Tablets/Caplets

**Trade Name:** ADVIL  
**Compound Number:** WH-0432-0033, -0037  
**Chemical Family:** Not determined

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

**Intended Use:** Consumer healthcare product used as non-steroidal, anti-inflammatory drug (nsaid)

### 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  
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  
P501 - Dispose of contents/container in accordance with all local and national regulations

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 2 of 14  
Version: 3.0



**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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Ibuprofen	15687-27-1	239-784-6	Acute Tox.4 (H302) Repr.2 (H361fd)	40-45

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Acetylated monoglycerides	308068-38-4	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Pharmaceutical glaze	Not assigned	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*
Synthetic iron oxide	1332-37-2	215-570-8	Not Listed	*
Pharmaceutical ink	Not assigned	Not Listed	Not Listed	*
Beeswax	8012-89-3	232-383-7	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**

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 3 of 14  
Version: 3.0

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

- Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- Skin Contact:** Due to the nature of this material first aid is not normally required. If irritation occurs or persists, get 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:** Not applicable

#### 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.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 4 of 14  
Version: 3.0

### 7. HANDLING AND STORAGE

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 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.

#### Microcrystalline cellulose

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>

#### Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:	0.3 mg/m <sup>3</sup>
----------------------	-----------------------

#### 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>
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>

#### Sucrose

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 5 of 14  
Version: 3.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
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>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 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	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Synthetic iron oxide</b>	
Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
	6.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
<b>Titanium dioxide</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
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>
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>
<b>Ibuprofen</b>	
Pfizer OEL TWA-8 Hr:	3000µg/m <sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

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. Engineering controls should be used as the primary means to control exposures.

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 6 of 14  
Version: 3.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets or Caplets	<b>Color:</b>	Pinkish brown
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Titanium dioxide</b>	No data available		
<b>Colloidal silicon dioxide</b>	No data available		
<b>Croscarmellose sodium</b>	No data available		
<b>Methylparaben</b>	No data available		
<b>Microcrystalline cellulose</b>	No data available		
<b>Pharmaceutical glaze</b>	No data available		
<b>Pharmaceutical ink</b>	No data available		
<b>Povidone</b>	No data available		
<b>Propylparaben</b>	No data available		
<b>Sodium benzoate</b>	No data available		
<b>Sodium lauryl sulfate</b>			

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 7 of 14  
Version: 3.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Stearic acid**

No data available

**Ibuprofen**

No data available

**Synthetic iron oxide**

No data available

**Sucrose**

No data available

**Beeswax**

No data available

**Acetylated monoglycerides**

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.

**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. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Acute overdosage and/or chronic abuse of ibuprofen may cause kidney effects.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the 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. Drowsiness, fatigue, or headache are also possible. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 8 of 14  
Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

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

##### **Titanium dioxide**

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

##### **Microcrystalline cellulose**

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

##### **Povidone**

Rat Oral LD50 100 g/kg

##### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

##### **Sodium benzoate**

Rat Oral LD50 4,070 mg/kg  
Mouse Oral LD50 1600mg/kg

##### **Sodium lauryl sulfate**

Rat Oral LD50 1288 mg/kg

##### **Stearic acid**

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

##### **Ibuprofen**

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

##### **Sucrose**

Rat Oral LD50 29.7 g/kg

#### **Acute Toxicity Comments:**

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

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

##### **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



## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 9 of 14  
Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

Skin Sensitization - LLNA Mouse Negative

#### Stearic acid

Skin Irritation Rabbit Moderate

Eye Irritation Rabbit Mild

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

##### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

##### Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

##### 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

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

##### Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

##### 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)

##### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### Stearic acid

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative

Unscheduled DNA Synthesis *E. coli* Negative

##### Ibuprofen

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 10 of 14  
Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

#### Stearic acid

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

**Carcinogen Status:** 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

#### Povidone

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

#### Toxicity:

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

#### 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.

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 11 of 14  
Version: 3.0

### 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

#### Acetylated monoglycerides

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

#### Croscarmellose sodium

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

#### Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

#### 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 glaze

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

#### Povidone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 12 of 14  
Version: 3.0

**15. REGULATORY INFORMATION**

Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Propylparaben</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7
<b>Sodium benzoate</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	208-534-8
<b>Sodium lauryl sulfate</b>	
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
<b>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>Stearic acid</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	200-313-4
<b>Sucrose</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	200-334-9
<b>Synthetic iron oxide</b>	

## SAFETY DATA SHEET

Material Name: Advil Tablets/Caplets  
Revision date: 09-Apr-2018

Page 13 of 14  
Version: 3.0

### 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
EU EINECS/ELINCS List	215-570-8

#### 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

#### 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

#### Pharmaceutical ink

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

#### Beeswax

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	232-383-7

### 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. Publicly available toxicity information.

**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

## SAFETY DATA SHEET

**Material Name: Advil Tablets/Caplets**  
**Revision date: 09-Apr-2018**

**Page 14 of 14**  
**Version: 3.0**

---

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

**End of Safety Data Sheet**