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

Product Identifier

Material Name: AVINZA (Morphine Sulfate) Extended Release Capusles
Trade Name: AVINZA
Chemical Family: Opiod

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

Intended Use: Pharmaceutical active used as opioid analgesic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 1B
Effects on or via lactation

EU Classification:
EU Indication of danger: Harmful
Toxic to reproduction, Category 2
Mutagenic: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risk of irreversible effects.

Label Elements

Signal Word: Danger
Hazard Statements:
H302 - Harmful if swallowed
H360D - May damage the unborn child
H362 - May cause harm to breast-fed children
H341 - Suspected of causing genetic defects
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
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

Other Hazards
Australian Hazard Classification (NOHSC):

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sugar</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>64-31-3</td>
<td>200-582-8</td>
<td>Xn;R22</td>
<td>Acute Tox. 4,H302; Repr. 1B,H360D; Lact.,H362; Muta. 2,H341</td>
<td>30, 45, 60, 75, 90, or 120mg***</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonio methacrylate coploymer</td>
<td>33434-24-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Fumaric acid</td>
<td>110-17-8</td>
<td>203-743-0</td>
<td>Xi; R36</td>
<td>Eye Irrit. 2A (H319)</td>
<td>*</td>
</tr>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
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.
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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Not applicable

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect 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 thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Sugar
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 6.0 mg/m³
  3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
  2 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
  0.8 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Capsule

Color: Various According to product specification

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)

Talc (non-asbestiform)

No data available

Hard gelatin capsules
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability:</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
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</table>

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Information on Toxicological Effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information:</td>
<td>The information included in this section describes the potential hazards of the individual ingredients.</td>
</tr>
<tr>
<td>Short Term:</td>
<td>Dust may cause irritation if tablets are crushed or broken</td>
</tr>
<tr>
<td>Long Term:</td>
<td>Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.</td>
</tr>
<tr>
<td>Known Clinical Effects:</td>
<td>Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.</td>
</tr>
</tbody>
</table>

Acute Toxicity: (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

**Talc (non-asbestiform)**
- Rat Oral LD50 > 1600 mg/kg

**Povidone**
- Rat Oral LD50 100 g/kg

**Morphine Sulfate**
- Rat Oral LD50 461 mg/kg
- Rat Para-periosteal LD50 70mg/kg
- Rat Intraperitoneal LD50 235mg/kg
- Mouse Oral LD50 600mg/kg
- Mouse Intravenous LD50 156mg/kg

**Sodium lauryl sulfate**
- Rat Oral LD50 1288 mg/kg

**Sugar**
- Rat Oral LD50 29700 mg/kg
- Mouse Oral LD50 14000mg/kg

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

**Fumaric acid**
- Eye Irritation Rabbit Moderate
- Skin 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

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

**Morphine Sulfate**
- 18 Week(s) Rat Oral60 g/kg LOAEL Lungs
- 15 Day(s) Rat Subcutaneous 3144 mg/kg LOAEL Kidney, Ureter, Bladder
- 9 Week(s) Rat Subcutaneous 3150 mg/kg LOAEL

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

**Morphine Sulfate**
- Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Hamster Subcutaneous 35 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Mouse Oral 200 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Rat Subcutaneous 35 mg/kg LOAEL Fetotoxicity

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

Morphine Sulfate
11. TOXICOLOGICAL INFORMATION

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

Sodium lauryl sulfate
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

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

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

Canada - WHMIS: Classifications
WHMIS hazard class:
D1b  toxic materials
D2a  very toxic materials

Ammonio methacrylate coploymer
  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

Sodium lauryl sulfate
  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

Povidone
  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

Fumaric acid
  CERCLA/SARA 313 Emission reporting  Not Listed
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
    5000 lb
    2270 kg
  California Proposition 65  Not Listed
  Inventory - United States TSCA - Sect. 8(b)  Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Present</td>
<td>203-743-0</td>
</tr>
<tr>
<td>Hard gelatin capsules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
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</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-334-9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>U.S. Drug Enforcement Administration:</td>
<td>Schedule II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
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<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-582-8</td>
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<tr>
<th>Substance</th>
<th>California Proposition 65</th>
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</thead>
<tbody>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td>238-877-9</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
- Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
- Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Toxic to Reproduction: Category 2  
Xn - Harmful  
Mutagenic: Category 3

- R22 - Harmful if swallowed.  
- R61 - May cause harm to the unborn child.  
- R64 - May cause harm to breastfed babies.  
- R68 - Possible risks of irreversible effects.

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

Material Name: AVINZA (Morphine Sulfate) Extended Release Capsules
Revision date: 06-Mar-2015

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 06-Mar-2015
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet