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

Material Name: Flurbiprofen Tablets

Trade Name: ANSAID®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. HAZARDS IDENTIFICATION

Appearance: Blue film-coated tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause allergic skin reaction.
Suspected of damaging the unborn child.

Additional Hazard Information:

Short Term: May be harmful if absorbed through the skin.
Animal studies indicate that this material may cause adverse effects on the gastrointestinal system and kidneys. Animal studies have shown a potential to cause adverse effects on the fetus. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Long Term: Ingestion of this material may cause effects similar to those seen in clinical use including gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

Known Clinical Effects:

EU Indication of danger:
Toxic to Reproduction; Category 3
Irritant
Harmful

EU Hazard Symbols:

EU Risk Phrases:
R22 - Harmful if swallowed.
R43 - May cause sensitization by skin contact.
R63 - Possible risk of harm to the unborn child.
Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td>225-827-6</td>
<td>T;R25</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R21</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R43</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat3;R63</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. 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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
MATERIAL SAFETY DATA SHEET

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

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

General 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).

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
France OEL - TWA = 10 mg/m³ VME
Ireland OEL - TWAs = 10 mg/m³ TWA
= 4 mg/m³ TWA
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

Colloidal silicon dioxide
Australia TWA = 2 mg/m³ TWA
Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
Ireland OEL - TWAs = 2.4 mg/m³ TWA
= 6 mg/m³ TWA
OSHA - Final PELs - Table Z-3 Mineral D: (80)(% SiO2) mg/m³ TWA
= 20 mppcf TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Sweden OEL - TWAs = 5 mg/m³ LLV

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Flurbiprofen
Pfizer Occupational Exposure Band (OEB):

OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

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:

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Film-coated tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Blue</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Magnesium stearate

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50</td>
<td>&gt; 2000 mg/m³</td>
</tr>
</tbody>
</table>

Flurbiprofen

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>117 mg/kg</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD 50</td>
<td>500 mg/kg</td>
</tr>
</tbody>
</table>
Lactose
Rat Oral LD50 > 10 g/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)

**Flurbiprofen**
Skin Irritation Guinea Pig Minimal
Skin Sensitization - GPMT Guinea Pig Moderate
Photosensitization Guinea Pig Negative

**Microcrystalline cellulose**
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

**Flurbiprofen**
- 14 Day(s) Monkey Oral 100 mg/day LOAEL Kidney
- 3 Month(s) Rat Oral 2 mg/kg/day LOAEL Gastrointestinal system, Kidney
- 80 Week(s) Mouse Oral 5 mg/kg LOAEL Gastrointestinal system
- 80 Week(s) Mouse Oral 12 mg/kg LOAEL Kidney

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Flurbiprofen**
- Fertility and Embryonic Development Rat Intravenous 10 mg/kg Fetotoxicity, Not teratogenic
- Fertility and Embryonic Development Rabbit Intravenous 80 mg/kg Maternal Toxicity, Not Teratogenic

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

**Flurbiprofen**
- Unscheduled DNA Synthesis Negative
  - *In Vivo* Micronucleus Negative

**Flurbiprofen**
- 80 Week(s) Mouse Oral, in feed 12 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: See below

Colloidal silicon dioxide
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3
Irritant
Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.
R43 - May cause sensitization by skin contact.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
May cause allergic skin reaction.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B
Flurbiprofen

California Proposition 65: developmental toxicity, initial date 8/20/99
female reproductive toxicity, initial date 8/20/99

Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
EU EINECS/ELINCS List: 225-827-6

Lactose

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-559-2

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present
EU EINECS/ELINCS List: 232-674-9

Carnauba wax

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 232-399-4

Crocarmellose sodium

Australia (AICS): Present

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 231-545-4
EEC No. 418-260-2

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R21 - Harmful in contact with skin.
R25 - Toxic if swallowed.
R43 - May cause sensitization by skin contact.
R63 - Possible risk of harm to the unborn child.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety
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End of Safety Data Sheet