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

Material Name: Oxycodone Hydrochloride Tablets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>OXECTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>None</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as, opioid analgesic</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

- **Short Term:** Active ingredient may be harmful if swallowed.
- **Known Clinical Effects:** 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. Additionally symptoms of dependence/withdrawal may occur.

EU Classification

- **EU Indication of danger:** Not classified


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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone hydrochloride</td>
<td>124-90-3</td>
<td>204-717-1</td>
<td>Xn;R22</td>
<td>1.0-1.5</td>
</tr>
<tr>
<td>Polyethylene oxide NF</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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>%</th>
</tr>
</thead>
<tbody>
<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></td>
<td></td>
<td>418-260-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-786-1</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 and CLP/GHS abbreviations 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.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Fire / Explosion Hazards: Not applicable

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). 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.

Storage Conditions:
Store as directed by product packaging.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Polyethylene oxide NF
Austria OEL - MAKs
Germany - TRGS 900 - TWAs
Germany (DFG) - MAK
Slovenia OEL - TWA
Slovenia OEL - TWA

1000 mg/m³
1000 mg/m³
1000 mg/m³
1000 mg/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: 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 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: Tablet

Molecular Formula: Mixture

Color: White

Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

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

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)

**Oxycodone hydrochloride**

Mouse Oral LD50 482 mg/kg

**Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

**Sodium lauryl sulfate**

Rat Oral LD50 1288 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)

**Polyethylene oxide NF**

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild
11. TOXICOLOGICAL INFORMATION

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)

Oxycodone hydrochloride
28 Day(s)  Rat  Oral  4 mg/kg/day  NOAEL  Central nervous system
3 Month(s)  Dog  Oral  1 mg/kg/day  NOAEL  Central Nervous System

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

Oxycodone hydrochloride
Fertility and Embryonic Development  Rat  Oral  8 mg/kg/day  NOAEL  Negative, Not teratogenic
Fertility and Embryonic Development  Rabbit  Oral  125 mg/kg/day  NOAEL  Negative, Not Teratogenic
Reproductive & Fertility  Rat  Oral  2 mg/kg/day  NOAEL  Neonatal toxicity

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

Oxycodone hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vitro Chromosome Aberration  Not specified  Positive
In Vivo Micronucleus  Not specified  Negative

Sodium lauryl sulfate
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Carcinogen Status:
Not listed as a carcinogen by IARC, NTP or US OSHA.

Crosповидони
IARC:
Group 3 (Not Classifiable)

Colloidal silicon dioxide
IARC:
Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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
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

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b  toxic materials

Oxycodone hydrochloride
U.S. Drug Enforcement Administration: Schedule II
Australia (AICS): Present
EU EINECS/ELINCS List: 204-717-1

Polyethylene oxide NF
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present

Microcrystalline cellulose
15. REGULATORY INFORMATION

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

**Crovtpidone**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4
  418-260-2

**Sodium lauryl sulfate**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 205-788-1

**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**

R22 - Harmful if swallowed.

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

**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