

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Oxycodone and Acetaminophen Tablets USP, 5mg/325mg CII</b>
<b>Other means of identification</b>	
<b>Product code</b>	5mg/325mg round, white tablet, debossed with product identification "54 543" on one side, and score on the other.
<b>Recommended use</b>	For relief of moderate to moderately severe pain
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company name</b>	Boehringer Ingelheim Roxane Inc.
<b>Address</b>	1809 Wilson Road Columbus, Ohio 43228
<b>Telephone</b>	(614) 276-4000
<b>Emergency phone number</b>	(614) 276-4000

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	Warning
<b>Hazard statement</b>	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials. Protect from moisture. Store at 20 – 25 °C (68 - 77°F).
<b>Disposal</b>	Incineration of waste at an approved USEPA incinerator is recommended.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

## 3. Composition/information on ingredients

<b>Substances</b>			
<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Acetaminophen		103-90-2	325mg
Oxycodone Hydrochloride		124-90-3	5mg

**Composition comments** Refer to Physician's Desk Reference for common components present at <1%

## 4. First-aid measures

<b>Inhalation</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

<b>Most important symptoms/effects, acute and delayed</b>	The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating
<b>Indication of immediate medical attention and special treatment needed</b>	In the case of overdose, the primary management should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>5. Fire-fighting measures</b>	
<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
<b>Methods and materials for containment and cleaning up</b>	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
<b>Conditions for safe storage, including any incompatibilities</b>	Store at 20 – 25 °C (68 - 77°F). Protect from moisture. Keep locked up and out of the reach of children. Dispense in a tight, light-resistant container as defined in the USP/NF. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	PEL	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m <sup>3</sup>	Respirable particles.
		10 mg/m <sup>3</sup>	Inhalable particles.

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection</b>	
<b>Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
<b>Respiratory protection</b>	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	White.
<b>Odor</b>	None.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Slightly soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available.

<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.
<b>Eye contact</b>	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.
<b>Ingestion</b>	Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics**  
The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating

### Information on toxicological effects

**Acute toxicity** May be harmful if swallowed in large quantities.

Components	Species	Test Results
Acetaminophen (CAS 103-90-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Dust may irritate the eyes.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>	This product is not expected to be mutagenic.	
<b>Carcinogenicity</b>	Animal studies to evaluate the carcinogenic potential have not been performed.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Acetaminophen (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>Reproductive toxicity</b>	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. This product passes into breast milk. Breast-feeding is not advised in mothers being treated.	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.	
<b>Aspiration hazard</b>	Due to the physical form of the product it is not an aspiration hazard.	

**Further information** See package insert.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous.

Components	Species	Test Results
Acetaminophen (CAS 103-90-2)		
<b>Aquatic</b>		
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 6.1 - 14 mg/l, 48 hours
Fish	LC50	Fathead minnow ( <i>Pimephales promelas</i> ) 814 mg/l, 96 hours

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** Product components are soluble in water and will slowly dissolve and disperse.

**Other adverse effects** None.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**US federal regulations** This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

DEA: Oxycodone and Acetaminophen Tablets USP, 5mg/325 mg are a DEA scheduled II controlled substance.

FDA: Oxycodone and Acetaminophen Tablets USP, 5mg/325mg, CII are an approved prescription medication.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

Drug Enforcement Administration (DEA): This product is a Schedule II Controlled Substance (21 CFR 1308.14)

**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 08-May-2015**Revision date** -**Version #** 01**References** 1) Oxycodone and Acetaminophen Tablets USP, 5mg/325mg, CII, Package Insert, Roxane Laboratories, Inc. , Columbus, Ohio.

2) PDR – Physicians Desk Reference.

3) Ariel Webinsight. Regulatory and ChemExpert Database.

**Disclaimer**

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