**IN CASE OF EMERGENCY CALL:**
National Poison Control 800-222-1222

# Material Safety Data Sheet

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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|---|---|
| Product Name: | Oxycodone HLC Oral Solution, USP |
| CAS No: | 124-90-3 |
| Chemical Name: | 14-hydroxydihydrocodeinone |
| Chemical Formula: | $C_{18}H_{21}NO_4$ •HCl |
| Molecular Weight: | 351.83 |
| Product Use: | Relief of moderate to moderately severe pain |

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| Manufacturer's Name: | VistaPharm, Inc. |
| Address: | 7265 Ulmerton Road<br>Largo, FL 33771 |

## 2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Oxycodone Hydrochloride (5mg/5mL) active ingredient

Please refer to current package insert for other components.

## 3. HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid solution administered orally.
Raspberry containing 5 mg of Oxycodone.

Odor: No data available.

WARNING: Oxycodone Hydrochloride is an opioid analgesic.
May be harmful if swallowed.
Accidental ingestion of large amounts may be fatal.

Primary Route of Entry: Ingestion

Potential Health Effects:

Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.

Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness.

Skin Contact: Not expected to be a hazard t the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.

Ingestion: May be harmful in ingested. Can cause respiratory depression, nausea, vomiting, sedation and dizziness.

Effects of Overexposure: The potential for exposure is reduced in finished pharmaceutical form. Overexposure may cause respiratory depression, extreme somnolence progressing toward stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and constricted pupils. Severe overexposure can cause apnea, circulatory collapse, cardiac arrest and death.

Target Organs: Central nervous system.

**4. FIRST AID MEASURES**

Eye Exposure: Any material that contacts the eye should be washed out immediately with water. Obtain medical attention if symptoms persist.

Skin Exposure: Wash affected area with soap and water. Remove contaminated clothing and shoes immediately. Obtain medical attention if symptoms occur.

Inhalation: Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Obtain medical attention immediately.

Ingestion: Call a physician or poison control center immediately.

**5. FIRE AND EXPLOSION HAZARD**

Flash Point: Not determined.

Extinguishing Media: Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area.

Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen chloride.

**6. ACCIDENTAL RELEASE MEASURES**

If Material is Spilled or Released: Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

**7. HANDLING AND STORAGE**

Handling: Observe good industrial hygiene practices.

Storage: Store at 20° and 25°C (68° to 77°F). Keep container closed tightly and protect from light. Store away from foodstuffs. Store according to DEA regulations.

**8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**

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| OSHA Exposure Limits: | None |
| Engineering Controls: | Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions. |
| Respiratory Protection: | Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions. |
| Personal Protection: | Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves. |
| Recommended Facilities: | Eye wash, washing facilities |

**9. PHYSICAL AND CHEMICAL PROPERTIES**

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| Appearance and Odor: | Red liquid solution. |
| Melting Point (deg. C): | Not determined. |
| Boiling Point (deg. C): | Not determined. |
| Solubility: | Soluble |
| pH: | Not determined. |

**10. STABILITY AND REACTIVITY**

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| Chemical Stability: | Yes |
| Conditions to Avoid: | Excessive heat or cold, light |
| Incompatibility: | Oxidizing agents, alkalis |
| Hazardous Decomposition: | Oxides of carbon, oxides of nitrogen, hydrogen chloride |
| Hazardous Polymerization: | No |

**11. TOXICOLOGICAL INFORMATION**

Acute Toxicity:

Active Ingredient:

Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

**12. ECOLOGICAL INFORMATION**

Environmental Effects : Not determined.

**13. WASTE DISPOSAL INFORMATION**

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| Waste Disposal Considerations: | Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witness destruction of the product beyond reclamation. Disposal by incineration is recommended. |
| At Home: | Discard away from children’s reach. |

**14. TRANSPORTATION INFORMATION**

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

**15. REGULATORY INFORMATION**

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| DEA: | Oxycodone Hydrochloride Solution CII is a DEA Schedule II controlled substance. |
| FDA: | Oxycodone Hydrochloride Solution CII is currently an unapproved prescription medication. This product is rated as grandfathered. |
| Inventory Status: | The 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.<br>This material is not listed on the DSL Inventory but is exempt. |

**16. DISCLAIMER**

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for it particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: June 2009

**SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION**