Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Methadone Hydrochloride
Product Use:	Treatment of Opioid Addiction
Manufacturer's Name:	VistaPharm, Inc.
Address:	7265 Ulmerton Road Largo, FL 33771
Phone Number:	727-530-1633

In Case of Emergency Call National Poison Control: 800-222-1222

2. HAZARDS IDENTIFICATION

Emergency Overview

Odorless, white crystalline powder may be harmful if swallowed or inhaled. Dust may cause irritation of the eyes and respiratory tract. Avoid contact with skin and eyes. Do not breathe dust or fumes. Overexposure to this material may produce sedation and drowsiness which can result in the impairment of mental and physical abilities which are required to perform hazardous tasks such as operating a motor vehicle or machinery. May cause physical dependence (Habit forming drug).

Potential Health Effects:

Relevant Routes of Exposure:

Inhalation, ingestion, eye contact, skin contact.

Acute Effects:

General: Based on clinical use of this material, symptoms of overexposure may include drowsiness, lightheadedness, sedation, sweating, disorientation, agitation, visual disturbances, ataxia (muscular incoordination), lethargy, malaise, nausea, vomiting, respiratory distress, miosis, euphoria, constipation urinary retention, flushing of the face and rapid heart rate. In cases of severe overdoses: decreased temperature, depressed respiration, decreased blood pressure, sometimes shock, euphoria, stupor, pupils constricted, diminished reflexes to absent and pulmonary edema.

Ingestion: See General effects.

Eyes: Dust may cause irritation. Also see General effects.

Skin: Repeated or prolonged contact may cause a skin irritation or allergic skin reactions.

Chronic Effects:

Repeated overexposure can lead to a "Tolerance" or an addiction (dependence) to the effects of this compound. Abrupt cessation of exposure, after development of a tolerance or an addiction to this drug, can cause withdrawal symptoms, including delirium, convulsions and

possibly death.

Reproductive Effects: Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. The placental transfer of this material in humans has been documented. May cause respiratory depression in the fetus. Since this material has been shown to be excreted in breast milk, nursing mothers should exercise caution regarding exposure. Neonates from mothers treated with methadone have shown withdrawal symptoms.

Target organs: Ocular, respiratory, dermal, gastrointestinal (GI), cardiovascular and central nervous (CNS), hepatic systems, reproductive.

Medical Conditions Aggravated by Exposure: Individuals taking, central nervous systems depressants (alcohol, narcotics, hypnotics), monoamine oxidase inhibitors, hepatic or renal function impairment, hypothyroidism, Addison's disease, asthma, prostate hypertrophy or urethral restrictions, hypersensitivity to this material and a history of drug abuse should exercise caution when working with this material.

3. HAZARDOUS COMPONENT INFORMATION

Hazardous Ingredients	CASRN	Wt. %
Methadone Hydrochloride	1095-90-5	98.5+

Chemical Name: 6-(dimethylamino)-4,4-diphenyl- 3-heptanone,hydrochloride

Synonyms: Adanon hydrochloride, Althose hydrochloride, Amidone hydrochloride, Diaminon hydrochloride, Diasone hydrochloride, Dolophine.

Chemical Formula: $C_{21}H_{27}NO \bullet HCl$

4. FIRST AID MEASURES

First Aid Procedures:

Eye : Wash eyes with large amounts of water for at least 15 minutes. Get medical attention.

Skin: Remove contaminated clothing and shoes. Wash skin with soap and large amounts of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.

Inhalation: Remove to fresh air. If not breathing give artificial respiration. Get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Note to Physician: Death can result from accidental ingestion. The treatment methadone poisonings is similar to the treatment of a heroin overdose. Naloxone intravenous infusion has been used to treat severe overexposure. The adverse effects of this compound can be delayed up to 5 hours after exposure. Observe the patient for a sufficient length of time before

discharging.

5. FIRE AND EXPLOSION HAZARD

Unusual Fire and Explosion Hazards: None known.

Fire Fighting Procedures: NIOSH approved positive pressure, self-contained breathing apparatus and full protective turn-out gear. Evacuate personnel to an area upwind to avoid smoke and vapors. Remove containers of this material if it can be done safely. Use water to keep fire exposed containers cool. Protective clothing and equipment must be decontaminated if contact with the material or vapors have occurred.

Extinguishing Media: All common extinguishing media are suitable.

Conditions to Avoid: Not determined.

Hazardous Combustion Products: May produce irritating and toxic smoke and fumes. The composition of the combustion products have not been determined.

Flash Point: Not determined.

Flammability Limits: **Lower:** Not determined **Upper:** Not determined

Autoignition Temperature: Not determined.

6. ACCIDENTAL RELEASE MEASURES

Pre-Entry Spill Procedure: Shut off source of spill if it is safe to do so.
Eliminate sources of ignition.
Review Section 3 – Hazards Identification and Section B – Exposure Control/Personal Protection before proceeding with the clean up.

Clean Up and Containment: Scoop or shovel spilled material into suitable labeled containers with a tight fitting lid.
Secure the drum cover and remove the container to a safe holding area.
Check area for residual material and repeat clean up if detected.

Environmental Concerns: None known.

Treatment and Disposal: Decontaminate or dispose of all protective clothing and equipment.
See Section 13 – Disposal Recommendations for disposal information.

Reporting Requirements: The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for release of this material.

Report all releases which are likely to endanger the public health, harm the environment, or cause complaint to the appropriate State and Local officials.

7. HANDLING AND STORAGE

General Measures: Store at room temperature, in airtight containers and protect from light.
Do not generate dust or exposure to ignition sources.
Keep away from heat, sparks, and flames.

Materials or Conditions to Avoid: Contact with oxidizing agents.
Elevated temperatures.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

General Hygienic Practices: Do not get on eyes, skin or clothing.
Do not breath dust or fumes
Wash thoroughly after handling.

Recommended Exposure Limits: None established.

Personal Protective Equipment:

Eyewear: Chemical goggles.

Skin: Gloves are required if there is a potential for skin contact. A plastic or rubber glove which provides a physical barrier to the powder is required. Use disposable spun polyolefin (e.g. Tyvek) coveralls or equivalent to protect against contact. Consult the glove and clothing manufacturer, supplier and/or industrial hygienist for further information.

Respiratory Protection: Respiratory protection is required whenever air contamination (dust, mist or vapors) is generated by the process. A NIOSH approved high-efficiency toxic dust/mist/fume respirator is recommended.

Work Practices and Engineering Controls: General room ventilation is adequate unless the process generates dust or fumes.
Work clothing should be removed in a change room on site and laundered professionally.
Employees should shower and change into street clothes before leaving the facility.
Prevent the accumulation of dust in the work area by thorough periodic cleaning of the area.

Protective Measures During Repair and Maintenance: No special measures are required. Follow the recommendation for personal protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Crystalline.
Color:	White.
Odor:	Odorless.
Taste:	Bitter.
pH:	4.5 to 6.5
Volatile (Wt or Vol.), %:	<0.1 Wt.
Moisture Content, (Wt.) %:	<0.3.
Solubility in Water:	Soluble (12g/100ml).
Solubility-other solvents:	Soluble in ethyl alcohol, chloroform. Practically insoluble in ether and glycerol.
Specific Gravity/Bulk Density:	Not determined.
Vapor Pressure:	Not determined.
Vapor Density (air = 1):	Not determined.
Evaporation Rate (butyl acetate = 1):	<1
Boiling Point:	Not determined.
Melting Point:	233 - 236° C.

10. STABILITY AND REACTIVITY

General Stability Considerations: Stable at room temperature.

Incompatible Materials: Oxidizing agents.

Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: Oral – rat LD_{50} – 30 mg/kg; Oral – mouse LD_{50} = 124 mg/kg; Intravenous – rat LD_{50} = 92 mg/kg; Intravenous – mouse LD_{50} = 16 mg/kg; Subcutaneous – mouse LD_{50} = 16 mg/kg; Subcutaneous – monkey LDL_0 = 10 mg/kg; Subcutaneous – guinea pig LD_{50} = 54 mg/kg.

Reproductive/Teratogenicity Effects: Studies in laboratory animals have shown that this compound is fetotoxic and affects the viability, grown and development of the newborn.

Mutagenicity/Genotoxicity Information: This compound was mutagenic in an E. Coli DNA repair assay, in the mouse dominant lethal test, and in a mouse intraperitoneal cytogenetic assay and produced positive response in a microorganism mutation assay.

12. ECOLOGICAL INFORMATION

Environmental Effects : Not determined.

Ecotoxicity: No data available.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Method: Dispose of material, liners, and containers in a manner approved for U.S. Drug Enforcement Agency Schedule II controlled substances and in accordance with all applicable federal, state and local environmental regulations.

14. TRANSPORTATION INFORMATION

U.S. DOT: Shipping Name: Toxic solids, organic, n. o. s. (6-(dimethylamino)-4,4-diphenyl- 3-heptanone,hydrochloride)
UN NO: UN 2811
Hazard Class: 6.1
Packing group: II
Hazard Label: "Harmful – Stowe Away From Foodstuffs" or Poison"

IATA: Shipping Name: Toxic solids, organic, n. o. s. (6-(dimethylamino)-4,4-diphenyl- 3-heptanone,hydrochloride)
UN NO: UN 2811
Hazard Class: 6.1
Packing group: II
Hazard Label: Toxic

IMO: See IATA requirements.

15. REGULATORY INFORMATION

SARA TITLE III : Section 302. Not listed.
Section 313. Not listed.
CERCLA Hazardous Substance: Not listed.
RCRA Hazardous Substance: Not listed.
California Prop. 65 List: Not listed.
Massachusetts Substance List: Not listed.
New Jersey Right to Know Hazardous Substance List: Not listed.
Pennsylvania Hazardous Substance List: Not listed.
Canadian WHMIS List: Not listed.

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: May 2015

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION