US - OSHA SAFETY DATA SHEET

Issue Date 24-Jul-2019 **Revision Date** 24-Jul-2019 **Version** 1

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

Product identifier

Product Name Nalmefene Hydrochloride Injection

Other means of identification

Synonyms None known.

Recommended use of the chemical and restrictions on use

Recommended Use Pharmaceutical.
Uses Advised Against Not available.

Details of the supplier of the safety data sheet

Supplier
Purdue Pharmaceuticals L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 726-7535

Emergency telephone number

24 Hour Emergency Phone Number Chemtrec
Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical Hazards
Not classified.

OSHA Regulatory Status
This chemical has biological/pharmaceutical effects on animal or human bodily functions or systems, but does not reach the criteria of any specific GHS classification label. Therefore, it is considered hazardous by “other hazards” but not classified. (29 CFR 1910.1200; Revision 3)

Label elements

Emergency Overview

Appearance Clear and colorless solution **Physical State** Liquid. **Odor** None

Hazards not otherwise classified (HNOC)

This chemical has biological/pharmaceutical effects on animal or human bodily functions or systems.

Other information

- Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%
Nalmefene Hydrochloride	58895-64-0	<1
Sodium chloride	7440-23-5	<1
Hydrochloric acid	7647-01-0	<1
Purified Water, USP	7732-18-5	>99

4. FIRST AID MEASURES

First aid measures

Eye Contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately wash exposed area with soap and water. Obtain medical attention if skin reaction occurs.

Inhalation Immediately move exposed subject to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms Nalmefene hydrochloride adverse effects include decreased appetite, disturbed sleep, libido decrease, dizziness, headache, nausea, tachycardia, palpitations, vomiting, dry mouth, and fatigue.

Indication of any immediate medical attention and special treatment needed

Note to Physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media Not available.

Specific hazards arising from the chemical
Not available.

Hazardous Combustion Products Not available.

Explosion data
Sensitivity to Mechanical Impact Not available.
Sensitivity to Static Discharge Not available.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear appropriate personal protective equipment (see Section 8). Keep unnecessary personnel away. Ensure adequate ventilation, especially in confined areas.

Environmental Precautions

Environmental precautions Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13).

Methods for Cleaning Up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines The final product solution is not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommendations for manufacturing or other situations where exposure may occur during addition stages of individual ingredients.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydrochloric acid 7647-01-0	Ceiling: 2 ppm	Ceiling: 5 ppm Ceiling: 7 mg/m^3	IDLH: 50 ppm Ceiling: 5 ppm Ceiling: 7 mg/m^3

Appropriate engineering controls

Engineering Controls None required for normal handling of packaged product. The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/Face Protection In laboratory, medical or industrial settings, safety glasses with side shields are highly 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.

Skin and Body Protection In laboratory, medical or industrial settings, double gloves, lab coat, apron, and sleeve covers are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hoods or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory Protection Not required for normal handling of packed product. 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 the 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 indicated by OSHA Standard 29 CFR 1910.134.

General Hygiene Considerations 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.		
Appearance	Clear and colorless solution	**Odor**	None
Color	Colorless.	**Odor Threshold**	Not available.

Property	Values	Remarks • Method
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point/boiling range	Not available.	
Flash point	Not available.	

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability Limit in Air	
Upper flammability limit:	Not available.
Lower flammability limit:	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive Properties	Not available.
Oxidizing Properties	Not available.

Other information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Not available.

Chemical stability
Not available.

Possibility of Hazardous Reactions
Not available.

Hazardous Polymerization
Not available.

Conditions to Avoid
Not available.

Incompatible Materials
Not available.

Hazardous Decomposition Products
Not available.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute Toxicity No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Hydrochloric acid 7647-01-0	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h	-
Purified Water, USP 7732-18-5	> 90 mL/kg (Rat)	-	-	-

Information on toxicological effects

Symptoms Nalmefene hydrochloride adverse effects include decreased appetite, disturbed sleep, libido decrease, dizziness, headache, nausea, tachycardia, palpitations, vomiting, dry mouth, and fatigue.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

Skin Corrosion/Irritation No data available.
Serious Eye Damage/Eye Irritation No data available.
Sensitization No data available.
Germ Cell Mutagenicity Nalmefene did not have mutagenic activity in the Ames test with five bacterial strains or the mouse lymphoma assay. Clastogenic activity was not observed in the mouse micronucleus test or in the cytogenic bone marrow assay in rats. However, nalmefene did exhibit a weak but significant clastogenic activity in the human lymphocyte metaphase assay in the absence but not in the presence of exogenous metabolic activation.
Carcinogenicity Not available.

Chemical Name	ACGIH	IARC	NTP	OSHA
Hydrochloric acid 7647-01-0		Group 3		

Legend
Reproductive Toxicity Oral administration of nalmefene up to 1200 mg/m2/day did not affect fertility, reproductive performance, and offspring survival in rats. Reproduction studies have been performed in rats (up to 1200 mg/m2/day) and rabbits (up to 2400 mg/m2/day) by oral administration of nalmefene and in rabbits by intravenous administration up to 96 mg/m2/day (114 times the human dose). There was no evidence of impaired fertility or harm to the fetus. Nalmefene and its metabolites were secreted into rat milk, reaching concentrations approximately three times those in plasma at one hour and decreasing to about half the corresponding plasma concentrations by 24 hours following bolus administration.
STOT - Single Exposure Single dose of nalmefene hydrochloride (oral) at 500 mg/kg in mice caused somnolence, tremor, convulsions and death.
STOT - Repeated Exposure Nalmefene is an orally available opioid receptor antagonist that has been shown to suppress appetite in humans, but its effects on chronic food intake and body weight remain unclear. Here, /investigators/ report that chronic (21-day) oral administration of nalmefene at 2 or 10 mg/kg/day in diet-induced obese mice led to significant increases (9-11%) in cumulative food intake. Mice in the nalmefene-treated groups also gained body weight at a rate faster than the control. Body composition analysis showed that the extra body weight gains in the treated animals were mostly due to increased fat accumulation.
Other adverse effects No data available.
Aspiration Hazard No data available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity
The following values are calculated based on chapter 3.1 of the GHS document:
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12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Hydrochloric acid 7647-01-0		282: 96 h Gambusia affinis mg/L LC50 static		

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not send down the drain or flush down the toilet.
Contaminated Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.
US EPA Waste Number	Not available.
California Hazardous Waste Codes	Not available.

This product does not contain substances that are listed with the State of California as hazardous waste.

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not determined.

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical Name	CAS No.	Weight-%	SARA 313 - Threshold Values %
Hydrochloric acid - 7647-01-0	7647-01-0	QS	1.0

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium chloride 7440-23-5	10 lb			X
Hydrochloric acid 7647-01-0	5000 lb			X

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium chloride 7440-23-5	10 lb		RQ 10 lb final RQ RQ 4.54 kg final RQ
Hydrochloric acid 7647-01-0	5000 lb	5000 lb	RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations

California Proposition 65

No component is on the Prop 65 list.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sodium chloride 7440-23-5	X	X	X
Hydrochloric acid 7647-01-0	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	24-Jul-2019
Revision Date	24-Jul-2019
Revision Note	This is the first version of this SDS.

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

End of Safety Data Sheet