SAFETY DATA SHEETS

This SDS packet was issued with item:

078071823

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078156076

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071259555

MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

MSD
Avenida 16 de Septiembre No. 301
Xaltocan, Xochimilco Mexico 16090 MEXICO, D.F.

MATERIAL SAFETY DATA SHEET

*Merck Animal Health urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.****

SECTION1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Imidocarb Dipropionate Injectable Solution**

SYNONYM(S): Imidocarb Dipropionate Injectable Solution
Carbesia
Carbesia B.
Imizol

MSDS NUMBER: SP000787

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Clear, Pale amber
Solution
Odor unknown
May be irritating to skin, eyes, or mucous membranes.
May cause effects to:
nervous system
liver
kidney

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

Imidocarb dipropionate is a cholinesterase inhibitor. Signs of acute toxicity may include blurred vision, weakness, nausea, vomiting, abdominal cramps, loose stool, salivation, sweating, pin-point pupils, tremors, and convulsions.

Acute effects of workers exposed to propionic acid included mild to moderate skin burns and mild eye redness. No chronic or cumulative effects are known from industrial exposures. Propionic acid is an irritant to skin, eyes, and mucous membranes and concentrated solutions can cause local damage. Breathing propionic acid can irritate the nose, throat and lungs causing coughing wheezing and shortness of breath. Overexposure to this material may cause blurred vision, corneal burns, skin burns, abdominal pain, headache, nausea, vomiting, and asthma-like allergies.

LISTED CARCINOGENS

Not listed as a carcinogen by OSHA, IARC, NTP or ACGIH.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

The formulation may contain propionic acid for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	EU CLASSIFICATION	PERCENT
Imidocarb Dipropionate	55750-06-6	259-791-8	Xn;R22	12.1
Propionic Acid	79-09-4	201-176-3	C; R34	< 10

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 15 for EU hazard classification symbols and risk and safety phrases.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SECTION 5. FIRE FIGHTING MEASURES

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Water, carbon dioxide (CO2), foam, or dry chemical.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Keep personnel away from the clean-up area. Wear appropriate personal protective equipment as specified in Section 8.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store between 2 and 25 deg C. Do not freeze.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Propionic Acid	79-09-4	10 ppm	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Solution
COLOR: Clear, Pale amber
ODOR: Odor unknown
pH: 4.5
BOILING POINT / RANGE: 100 deg C (212 deg F)
FREEZING POINT: 0 deg C (32 deg F)
SOLUBILITY:

Water: Soluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Water-reactive materials. Oxidizers.

HAZARDOUS POLYMERIZATION PRODUCTS / REACTIONS:
Does not occur.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon monoxide (CO). Carbon dioxide (CO2).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture.

ACUTE TOXICITY DATA

SKIN:
Propionic acid: Dermal LD50: 495-500 mg/kg (rabbit)
The application of 495 mg to rabbit skin produced a severe response. In a rabbit skin irritation test, tissue necrosis was observed after the application of 10 mg of undiluted propionic acid for 24 hours.

EYE:
Propionic acid produced severe corneal damage in the eyes of rabbits.

ORAL:
Imidocarb dipropionate: Oral LD50: 454-1251 mg/kg (rat); 646-723 mg/kg (mice)
Rats and mice treated with a single oral dose of imidocarb dipropionate exhibited signs that were generally consistent with anticholinesterase activity and included lethargy, salivation, lacrimation, ataxia, tremors and convulsions.

Propionic acid: Oral LD50: 2600-5160 mg/kg (rat); 5100 mg/kg (mouse)

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Repeat dose toxicity studies for imidocarb dipropionate were conducted in rats, dogs, and primates. Rats were administered imidocarb dipropionate orally for three months at dose levels of 125, 250, 750 and 1500 mg/kg/day. Mortality was observed in all animals in the high dose group. Pathological changes, such as cloudy swelling, were observed in the livers of rats administered 125 and 250 mg/kg/day. No histopathology was carried out at higher doses and no NOEL was established. In a dietary study, rats were treated at doses as high as 415 and 554 mg/kg/day in males and females, respectively. Body weight gain was reduced in male and female rats at the high dose. No effects on hematology, clinical chemistry, urinalysis or brain cholinesterase were observed. In the high dose at termination, mild bile stasis in the liver was observed. The NOEL for reduced body weight gain and liver toxicity was 75 and 101 mg/kg/day in males and females, respectively.

Imidocarb dipropionate was administered orally (capsules) to beagle dogs for three months at doses of 5, 20, or 80 mg/kg/day. All males and 2 of 4 females at the high dose died or were euthanized. Signs of toxicity at the high dose included recumbency, salivation muscle fasciculation, ataxia and splayed legs. Eosinophilia and increased liver enzymes were also observed at the high dose. Similar but less severe effects were noted at 20 mg/kg/day. Kidney, thyroid and adrenal weight increases were observed at the high dose. Pathology changes observed in the mid and high dose groups included alterations in the kidney and liver. A NOEL was not determined based on minor changes in hematology and clinical chemistry values and hepatocellular changes observed at the low dose level.

Five primates were administered 5 mg/kg imidocarb dipropionate orally by stomach tube daily for 30 days. All animals survived. Apart from minor biological variations, there were no important changes noted.

In a combined chronic toxicity/carcinogenicity study rats were administered imidocarb dipropionate in the diet at dose levels of 15, 60 and 240 mg/kg/day for 104 weeks. Only 9 of 65 males survived in the high dose group at study termination. Animals at the high dose level exhibited emaciation, reduced body weight gain and food consumption, anemia, and liver and kidney effects. The mid and high dose group animals exhibited cystic distension of the renal tubules and glomeruli, and mineralization of the renal medulla [NOEL for chronic toxicity: 15 mg/kg/day].

Rats, mice, and hamsters fed diets containing 4 percent propionic acid for 7 days showed evidence of damage and cellular proliferation in the epithelium of the forestomach. The administration of propionic acid in the diet had no effect after 9 days; however, it induced a five- to six-fold increase in cell perliferation in the midregion of the rat forestomach after 27 days of treatment. Rats fed calcium propionate at 1 percent in the diet for 4 weeks (about 750 mg of propionic acid kg/day) followed by 3 percent for 3 weeks showed no change in weight gain compared with controls.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
In a multigeneration study, rats were treated with imidocarb dipropionate at dose levels as high as 135 mg/kg/day. Maternal body weights were reduced at the high dose. The number of live births was reduced at the high dose following the first mating of the F0 generation and there was an increase in the number of dead or missing fetuses. A similar trend was evident following the first mating of the F1 generation [NOEL: 45 mg/kg/day].

Imidocarb dipropionate was evaluated in rat teratogenicity studies at dose levels of 47, 138 and 760 mg/kg (dietary)and 19, 76, and 304 mg/kg (gavage). No evidence of teratogenicity was observed in either study. In rabbits administered 20, 60 or 180 mg/kg of imidocarb dipropionate all animals administered the high dose and most animals treated at 60 mg/kg died. No evidence of teratogenicity was observed at any dose level [NOEL for maternal and fetal toxicity: 20 mg/kg/day].

Calcium propionate, the calcium salt form of propionic acid, did not have an effect on maternal or fetal survival. There was no increase in the number of fetal abnormalities observed when it was fed to pregnant mice and rats (as high as 300 mg/kg/day for 10 days), hamsters (as high as 400 mg/kg/day for 5 days), or rabbits (as high as 400 mg/kg/day for 13 days).

MUTAGENICITY / GENOTOXICITY:
Imidocarb dipropionate was negative in the in vitro S. typhimurium assay and in the in vitro assay for gene mutation in mouse lymphoma cells. It was also negative in three in vivo assays including the cytogenetics assay, the mouse micronucleus assay and the dominant lethal assay. Three chromosomal aberration assays were carried out in human peripheral blood lymphocytes. The first study was negative, the second study was positive with metabolic activation. The third study was designed to test for aneuplody and tested the ability of imidocarb dipropionate to induce micronuclei in human peripheral lymphocytes. No increase in micronuclei was observed. Slides from a single interim dose level (the only level examined) confirmed the induction of polyploidy at this dose level (895.5 ug/mL).

Propionic acid was negative in the following tests: a Salmonella microsome mutagenicity test (Ames), a sister chromatid exchange test in vitro, and in a micronucleus test in vivo. Propionic acid was also negative in mutagenicity assays using Salmonella typhimurium or Saccharomyces cerevisiae with or without mammalian liver preparation.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

In a combined chronic toxicity/carcinogenicity study rats were administered imidocarb dipropionate in the diet at dose levels of 15, 60 and 240 mg/kg/day for 104 weeks. Only 9 of 65 males survived in the high dose group at study termination. The high dose group exhibited an increase in the incidence of multiple fibroadenomas of the mammary gland in females and multiple subcutaneous fibromas in males. The significance of these findings was considered doubtful due to the excessive toxicity observed at this dose level, poor survival, and inadequate histopathology. There were no significant increases in any types of malignant tumors.

Rats fed high levels of propionic acid (4 percent) in the diet developed forestomach neoplasia, due to sustained high levels of cellular proliferation. The persistent damage to cells of the forestomach and associated proliferative responses are common factors in rodent tumorigenesis. The relevance to humans has not been determined.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Propionic acid: 96-hour LC50 (fathead minnow): 4740 mg/L
Propionic acid: 24-hour LC50 (daphnid): 130 mg/L

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Propionic Acid	X

EUROPEAN UNION REGULATIONS:

Caution - substance not fully tested.

Based on available data, this material or product does not require labelling according to the EC directives.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:	Global Safety & the Environment Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889
MERCK SDS HELPLINE:	+1 (908) 473-3371 (Worldwide) Monday to Friday, 9am to 5pm (US Eastern Time)
MSDS CREATION DATE:	05-Sep-1998
SUPERSEDES DATE:	25-Mar-2010
SIGNIFICANT CHANGES (LAM SUBFORMAT):	New regional format, New Language (Latin-American Spanish), OEB

SAFETY DATA SHEET

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

Product Identifier

Material Name: Naloxone Hydrochloride Injection, USP (Hospira Inc.)

Trade Name: Naloxone Hydrochloride Injection
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
Chemtrec (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Naloxone hydrochloride	357-08-4	206-611-0	Not Listed	0.04

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

Naloxone hydrochloride

Pfizer OEL TWA-8 Hr:	200 µg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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 (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Color: Colorless
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.0-6.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
HYDROCHLORIC ACID
No data available
SODIUM CHLORIDE
No data available
Methylparaben
No data available
Propylparaben
No data available
Water for Injection
No data available
Naloxone hydrochloride
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, sweating, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), shortness of breath (dyspnea), increased heart rate (tachycardia), irritability, anxiety, inability to concentrate, lack of appetite.

Acute Toxicity: (Species, Route, End Point, Dose)

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

Naloxone hydrochloride
Rat Oral LD50 > 1000 mg/kg
Mouse Oral LD50 > 1000mg/kg
Rat Intravenous LD50 107mg/kg
Mouse Intravenous LD50 90mg/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)

SODIUM CHLORIDE
Skin Irritation Rabbit Mild

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild

HYDROCHLORIC ACID
30 Day(s)

Naloxone hydrochloride

3 Month(s)	Rat	Oral	2.13 mg/kg/day	NOAEL	None identified
3 Month(s)	Dog	Oral	0.68 mg/kg/day	NOAEL	None identified
9 Month(s)	Dog	Oral	75 mg/kg/day	NOAEL	Brain, Pituitary, Thymus, Central Nervous System
30 Day(s)	Monkey	Subcutaneous	60 mg/kg/day	LOAEL	Central Nervous System
2 Year(s)	Rat	Oral	4 mg/kg/day	LOAEL	Gastrointestinal system, Female reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

HYDROCHLORIC ACID
Fertility and Embryonic Development

Naloxone hydrochloride

Embryo / Fetal Development	Rat	No route specified	8 times human dose	NOAEL	Not teratogenic
Embryo / Fetal Development	Mouse	No route specified	4 times human dose	NOAEL	Not Teratogenic
Fertility and Embryonic Development	Rat	Oral	200 mg/kg/day	NOAEL	Paternal toxicity
Fertility and Embryonic Development	Rat	Oral	200 mg/kg/day	NOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	800 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rabbit	Oral	400 mg/kg/day	NOAEL	No effects at maximum dose

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

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Naloxone hydrochloride
Bacterial Mutagenicity (Ames) Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Mammalian Cell Mutagenicity HGPRT Hamster Negative
In Vivo Chromosome Aberration Rat Bone Marrow Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Naloxone hydrochloride

26 Week(s)	Mouse	Oral	200 mg/kg/day	NOAEL	Not carcinogenic
52 Week(s)	Rat	Oral	25 mg/kg/day	LOAEL	Not carcinogenic
2 Year(s)	Rat	Oral	100 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

HYDROCHLORIC ACID

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Naloxone hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	206-611-0

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	30-Jul-2019
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this 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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Naloxone Hydrochloride Injection, USP (Hospira Inc.)

Trade Name: Naloxone Hydrochloride Injection
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
Chemtrec (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Naloxone hydrochloride	357-08-4	206-611-0	Not Listed	0.04

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

Naloxone hydrochloride

Pfizer OEL TWA-8 Hr:	200 µg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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 (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Color: Colorless
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.0-6.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
HYDROCHLORIC ACID
No data available
SODIUM CHLORIDE
No data available
Methylparaben
No data available
Propylparaben
No data available
Water for Injection
No data available
Naloxone hydrochloride
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include headache, sweating, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), shortness of breath (dyspnea), increased heart rate (tachycardia), irritability, anxiety, inability to concentrate, lack of appetite.

Acute Toxicity: (Species, Route, End Point, Dose)

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

Naloxone hydrochloride
Rat Oral LD50 > 1000 mg/kg
Mouse Oral LD50 > 1000mg/kg
Rat Intravenous LD50 107mg/kg
Mouse Intravenous LD50 90mg/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)

SODIUM CHLORIDE
Skin Irritation Rabbit Mild

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild

HYDROCHLORIC ACID
30 Day(s)

Naloxone hydrochloride

3 Month(s)	Rat	Oral	2.13 mg/kg/day	NOAEL	None identified
3 Month(s)	Dog	Oral	0.68 mg/kg/day	NOAEL	None identified
9 Month(s)	Dog	Oral	75 mg/kg/day	NOAEL	Brain, Pituitary, Thymus, Central Nervous System
30 Day(s)	Monkey	Subcutaneous	60 mg/kg/day	LOAEL	Central Nervous System
2 Year(s)	Rat	Oral	4 mg/kg/day	LOAEL	Gastrointestinal system, Female reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

HYDROCHLORIC ACID
Fertility and Embryonic Development

Naloxone hydrochloride

Embryo / Fetal Development	Rat	No route specified	8 times human dose	NOAEL	Not teratogenic
Embryo / Fetal Development	Mouse	No route specified	4 times human dose	NOAEL	Not Teratogenic
Fertility and Embryonic Development	Rat	Oral	200 mg/kg/day	NOAEL	Paternal toxicity
Fertility and Embryonic Development	Rat	Oral	200 mg/kg/day	NOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	800 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rabbit	Oral	400 mg/kg/day	NOAEL	No effects at maximum dose

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

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Naloxone hydrochloride
Bacterial Mutagenicity (Ames) Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Mammalian Cell Mutagenicity HGPRT Hamster Negative
In Vivo Chromosome Aberration Rat Bone Marrow Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Naloxone hydrochloride

26 Week(s)	Mouse	Oral	200 mg/kg/day	NOAEL	Not carcinogenic
52 Week(s)	Rat	Oral	25 mg/kg/day	LOAEL	Not carcinogenic
2 Year(s)	Rat	Oral	100 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

HYDROCHLORIC ACID

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Naloxone hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	206-611-0

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	30-Jul-2019 Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this 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

SAFETY DATA SHEET

Imidocarb Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/15/2018
3.0	08/30/2018	632255-00006	Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name : Imidocarb Injection Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - single exposure (Oral) : Category 1 (Central nervous system)

Specific target organ systemic toxicity - repeated exposure (Oral) : Category 1 (Liver, Kidney)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.
H370 Causes damage to organs (Central nervous system) if swallowed.
H372 Causes damage to organs (Liver, Kidney) through prolonged or repeated exposure if swallowed.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P307 + P311 IF exposed: Call a POISON CENTER or doctor/ physician.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Imidocarb	27885-92-3	>= 10 - < 20
Propionic acid	79-09-4	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed	:	Suspected of damaging the unborn child. Causes damage to organs if swallowed. Causes damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Avoid inhalation of vapor or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame-ters / Permissible concentration	Basis
Imidocarb	27885-92-3	TWA	50 µg/m3 (OEB 3)	Internal
		Wipe limit	500 µg/100 cm²	Internal
Propionic acid	79-09-4	TWA	10 ppm	ACGIH

		TWA	10 ppm 30 mg/m³	NIOSH REL
		ST	15 ppm 45 mg/m³	NIOSH REL

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.

When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	clear
Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	4.5
Melting point/freezing point	:	212 °F / 100 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Imidocarb:

Acute oral toxicity	:	LD50 (Rat): 1,216 - 1,652 mg/kg LD50 (Mouse): 544 - 702 mg/kg LD50 (Rabbit): 317 mg/kg

Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Rat): 32.7 mg/kg Application Route: Intravenous LD50 (Mouse): 22.3 mg/kg Application Route: Intravenous

Propionic acid:

Acute oral toxicity	:	LD50 (Rat): 3,455.1 mg/kg
Acute dermal toxicity	:	LD50 (Rat): 3,235 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Imidocarb:

Remarks	:	No data available

Propionic acid:

Species	:	Rabbit
Result	:	Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Imidocarb:

Remarks	:	No data available

Propionic acid:

Species	:	Rabbit
Result	:	Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Imidocarb:

Remarks	:	No data available

Propionic acid:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Imidocarb:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Chromosome aberration test in vitro Result: equivocal
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Oral Result: negative Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: negative

Propionic acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Chinese hamster Application Route: Intraperitoneal injection Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Imidocarb:

Species	:	Rat
Application Route	:	Oral

Exposure time	:	104 weeks
LOAEL	:	240 mg/kg body weight
Result	:	negative
Target Organs	:	Mammary gland
Remarks	:	The mechanism or mode of action may not be relevant in humans.

Propionic acid:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Imidocarb:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: LOAEL: 135 mg/kg body weight Result: Adverse neonatal effects. Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 45 mg/kg body weight
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 76 mg/kg body weight Result: Effects on fetal development., No teratogenic effects. Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 19 mg/kg body weight Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight

Result: No effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Propionic acid:

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

Components:

Imidocarb:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

Propionic acid:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Causes damage to organs (Liver, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Imidocarb:

Target Organs : Liver, Kidney
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Imidocarb:

Species : Rat
LOAEL : 125 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver

Species : Rat
NOAEL : 76 mg/kg
LOAEL : 415 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver

Species : Dog

LOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Liver, Kidney
Symptoms	:	muscle twitching, Salivation, recumbency, ataxia, splayed legs

Species	:	Rat
NOAEL	:	15 mg/kg
LOAEL	:	60 mg/kg
Application Route	:	Oral
Exposure time	:	104 Weeks
Target Organs	:	Liver, Kidney, Blood

Species	:	Monkey
NOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	30 Days
Remarks	:	No significant adverse effects were reported

Propionic acid:

Species	:	Rat
NOAEL	:	50000 ppm
Application Route	:	Ingestion
Exposure time	:	90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Imidocarb:

Inhalation	:	Target Organs: Central nervous system Symptoms: Salivation, muscle twitching, Tremors, Lachrymation, ataxia, lethargy Remarks: Based on Animal Evidence

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propionic acid:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 85.3 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 22.7 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 48.7 mg/l Exposure time: 72 h

Persistence and degradability

Components:

Propionic acid:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 93 % Exposure time: 20 d

Bioaccumulative potential

Components:

Imidocarb:

Partition coefficient: n-octanol/water	:	log Pow: 3.88

Propionic acid:

Partition coefficient: n-octanol/water	:	log Pow: 0.33

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Propionic acid	79-09-4	5000	166666

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water	7732-18-5
Imidocarb	27885-92-3
Propionic acid	79-09-4

California Prop. 65
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California List of Hazardous Substances

Propionic acid	79-09-4

California Permissible Exposure Limits for Chemical Contaminants

Propionic acid	79-09-4

The ingredients of this product are reported in the following inventories:

AICS : not determined

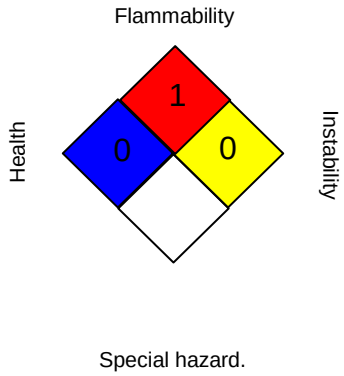
DSL : not determined

IECSC : not determined

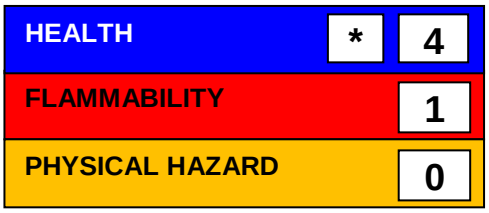
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-

tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	08/30/2018

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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