



Safety Data Sheet

Section 1. Identification

Common / Trade Name: Buprenorphine and Naloxone Sublingual Film

Recommended use: Pharmaceutical industry: Dosage form.
Therapeutic category: For treatment of opioid dependence.

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended Restrictions: : No other uses are advised.

Supplier: : Ingenus Pharmaceuticals, LLC
4901 Vineland Road, Suite 260
Orlando, FL 32811
Telephone: 407-354-5365
Fax: 407-264-6632

Emergency phone: : 1-877-748-1970 (IMIC)
Monday-Friday (0900 - 1700)

Section 2. Hazards Identification

Classification of the substance or mixture: : SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms:



Signal word: : Warning

Hazard statements: : H336 - May cause drowsiness and dizziness.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

General: : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention: : Use only outdoors or in a well-ventilated area. Do not breathe dust.

Response: : Get medical attention if you feel unwell. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

Storage: : Store locked up.

Disposal: : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified: : None known.

Section 3. Composition/Information on Ingredients

Name	CAS #	%
Buprenorphine hydrochloride	53152-21-9	10 - 30
Naloxone hydrochloride	51481-60-8	3 - 7
All other components are either non-hazardous or the concentrations are below the regulatory threshold limits of Hazard Communication standard 29 CFR 1910.1200, and the European Directive 91/155/EEC, and 93/112/EC of Schedule I.		

Chemical name : Not available.

Synonyms : Not available.

Chemical family : Not available.

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

Eye contact : Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin contact : Flush with copious amounts of water. Seek medical attention if irritation persist

Inhalation : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Potential acute and delayed health effects : Refer to Sec. 11

Section 5. Fire Fighting Measures

Specific hazard arising from the chemical : During fire, gases hazardous to health may be formed.

Suitable extinguishing media and special protective equipment for firefighters : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use selfcontained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Methods and materials for containment and cleaning up : Cordon off spill area as needed. Assess hazard levels (contact Safety Department if required). Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.

Protective equipment and personal precautions : Personnel involved in clean up should wear appropriate personal protective equipment (refer to section 8) to avoid exposure.

Section 7. Handling and Storage

Precautions for safe handling : Handle in an environment with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory protection. Avoid inhalation, skin and eye contact. Wash hands thoroughly after handling.

Conditions for safe storage : Store as directed by product packaging/manufacture's requirements.

Section 8. Exposure Controls/Personal Protection

Engineering Controls : Airborne exposure to this material should be mitigated using engineering controls such as mechanical ventilation, dilution and process enclosure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Local exhaust ventilation (e.g. fume hoods or other vented enclosures) is recommended, particularly for crushing, grinding or other activities prone to generating dust or aerosols.

Personal Protection : **For Manufacturing Environments:**

Skin: Covering uniform

Respiratory: Where respiratory protection has been deemed necessary use an approved air purifying respirator with appropriate cartridges. Contact your local safety professional for specific requirements.

Hand: Nitrile or other chemically compatible gloves.

Eye: Safety glasses

For all other environments (Laboratories, hospitals, pharmacies, etc.):

Skin: Lab coat

Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding, breakage, generation of aerosols or for spill cleaning, an approved respirator may be required. Contact your local safety professional for specific requirements.

Hand: Nitrile or other chemically compatible gloves.

Eye: Safety glasses

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Sublingual film.

pH : Not available.

Melting point/Freezing point : Not available.

Boiling point : Not available.

Volatility : Not available.

Specific gravity : Not available.

Evaporation rate : Not available.

Vapor density : Not available.

Relative density : Not available.

Vapor pressure : Not available.

Odor : Not available.

Odor threshold : Not applicable.

Conditions of instability : No additional remark.

Decomposition temperature : Not available.

Partition Coefficient: : Not available.

Viscosity : Not available.

Flash points : Not available.

Flammable limits : Not available.

Autoignition temperature : Not available.

Continued on Next Page

Revision date: 08/04/2023

Flammability : Emits toxic fumes under fire conditions.

Solubility : Not available.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable.

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Not available.

Section 11. Toxicological Information

Information on the likely routes of exposure : As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.

Toxicity data : Buprenorphine hydrochloride:
LD50: >1 gram/kg (oral-rat)
LD50: 800 mg/kg (oral-mouse)

Naloxone hydrochloride:
LD50: >1000 mg/kg (oral-rat)
LD40: >1000 mg/kg (oral-mouse)

Delayed and immediate effects and also chronic effects from short and long term exposure : Buprenorphine hydrochloride:
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. No evidence of carcinogenicity was observed in animal studies.
Reproductive and Developmental Effects: Based on experimental animal studies, buprenorphine exposure during pregnancy is not expected to increase the risk of adverse outcomes at birth but might produce later behavioral changes. As with other opioids, a neonatal abstinence syndrome can occur.
Mutagenicity: No evidence of mutagenicity was observed in animal studies.

Naloxone hydrochloride:
Carcinogenicity: In 26 weeks oral carcinogenicity study in trans gender mice and 2 years oral carcinogenicity study in rats, no tumorigenicity was reported.

Teratogenicity: Based on experimental animal studies, use of naloxone during pregnancy is not expected to increase the risk of congenital anomalies.

Mutagenicity: Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study. Overall, the weight of evidence from these tests indicates that naloxone does not pose a genotoxic risk to human.

Remark

No additional remarks.

Symptoms related to the physical, chemical and toxicological characteristics : Common side effects of buprenorphine and naloxone sublingual film include: nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, swollen and/or painful tongue, the inside of mouth (more red than normal, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heart beat (palpitations), decrease in sleep (insomnia), blurred vision, back pain, fainting, dizziness, sleepiness

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

Section 15. Regulatory Information

Canada Regulations : Not listed on the Domestic Substances List (DSL).

Other Regulations : Not available.

Section 16. Other Information

Revision date: 08/04/2023

Notice to Reader

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