

SECTION 1: Identification

1.1. Identification

Product name : BUPRENORPHINE and NALOXONE Sublingual Film

1.2. Recommended use and restrictions on use

Recommended use : Pharmaceuticals
 Restrictions on use : No additional information available

1.3. Supplier

Dr. Reddy's Laboratories
 107 College Rd E
 Princeton, New Jersey 08540 - USA
 T (609) 375-9900

1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Reproductive toxicity, Category 2	H361	Suspected of damaging fertility or the unborn child
Specific target organ toxicity — Repeated exposure, Category 2	H373	May cause damage to organs through prolonged or repeated exposure

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US)	: Warning
Hazard statements (GHS-US)	: H361 - Suspected of damaging fertility or the unborn child H373 - May cause damage to organs through prolonged or repeated exposure
Precautionary statements (GHS-US)	: P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P260 - Do not breathe dust, fume P280 - Wear protective gloves P308+P313 - If exposed or concerned: Get medical advice/attention P314 - Get medical advice/attention if you feel unwell P405 - Store locked up P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Buprenorphine Hydrochloride	(CAS No) 53152-21-9	3.5 - 6	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Eye Irrit. 2, H319 Repr. 2, H361 STOT RE 2, H373
Naloxone Hydrochloride Dihydrate	(CAS No) 51481-60-8	1 - 2	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Gently wash with plenty of soap and water. Wash contaminated clothing before reuse.
First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water.
First-aid measures after ingestion : Call a POISON CENTER or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/injuries : Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None known.

5.2. Specific hazards arising from the chemical

- Fire hazard : No particular fire or explosion hazard.
Reactivity : No dangerous reactions known.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Cool adjacent structures and containers with water spray to protect and prevent ignition.
Protection during firefighting : Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing. Do not breathe dust.

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.2.
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Refer to section 8.2.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Contain and collect as any solid.
Methods for cleaning up : Sweep or shovel spills into appropriate container for disposal.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with skin, eyes and clothing. Avoid creating or spreading dust. Do not breathe dust.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash your hands immediately after handling this product, and once again before leaving the workplace.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container closed when not in use. Keep only in original container.
- Incompatible products : Direct sunlight.
- Storage area : Store in a dark area. Store in a dry place.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Buprenorphine Hydrochloride (53152-21-9)
Not applicable

Naloxone Hydrochloride Dihydrate (51481-60-8)
Not applicable

8.2. Appropriate engineering controls

- Appropriate engineering controls : Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Ensure good ventilation of the work station.
- Environmental exposure controls : Prevent leakage or spillage.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear suitable gloves resistant to chemical penetration

Eye protection:

In case of dust production: protective goggles

Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. In case of inadequate ventilation wear respiratory protection. Disposable half mask

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Solid
- Colour : Orange
- Odour : odourless
- Odour threshold : No data available
- pH : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Relative evaporation rate (butylacetate=1) : No data available
- Flammability (solid, gas) : No data available
- Vapour pressure : No data available

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Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

Direct sunlight.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Likely routes of exposure	: Skin and eye contact; Inhalation; Ingestion
Acute toxicity	: Not classified

Buprenorphine Hydrochloride (53152-21-9)	
LD50 oral rat	1000 mg/kg
ATE US (oral)	1000.000 mg/kg bodyweight
ATE US (gases)	4500.000 ppmv/4h
ATE US (vapours)	11.000 mg/l/4h
ATE US (dust,mist)	1.500 mg/l/4h

Naloxone Hydrochloride Dihydrate (51481-60-8)	
LD50 oral rat	> 1000 mg/kg
ATE US (oral)	500.000 mg/kg bodyweight

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Buprenorphine Hydrochloride (53152-21-9)	
NOAEL (chronic, oral, animal/male, 2 years)	> 56 mg/kg bodyweight
Additional information	No carcinogenic effect

Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified

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Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No ecotoxicological data about this product are known.

12.2. Persistence and degradability

BUPRENORPHINE and NALOXONE Sublingual Film	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

BUPRENORPHINE and NALOXONE Sublingual Film	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

BUPRENORPHINE and NALOXONE Sublingual Film	
Ecology - soil	Not established.

12.5. Other adverse effects

Other information : No additional information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT
Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

Buprenorphine Hydrochloride (53152-21-9)	
EPA TSCA Regulatory Flag	Exempt from TSCA : Pharmaceutical/drug substance
Naloxone Hydrochloride Dihydrate (51481-60-8)	
EPA TSCA Regulatory Flag	Exempt from TSCA : Pharmaceutical/drug substance

15.2. International regulations

CANADA

Buprenorphine Hydrochloride (53152-21-9)	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	
Naloxone Hydrochloride Dihydrate (51481-60-8)	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	

EU-Regulations

No additional information available

National regulations

No additional information available

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15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources : ACGIH (American Conference of Government Industrial Hygienists).
European Chemicals Agency (ECHA) C&L Inventory database. Accessed at <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>.
Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition.
National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition.
OSHA 29CFR 1910.1200 Hazard Communication Standard.
TSCA Chemical Substance Inventory. Accessed at <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>.

Other information : None.

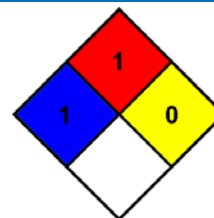
Full text of H-statements:

H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

Abbreviations and acronyms:

	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	EC50: Environmental Concentration associated with a response by 50% of the test population.
	GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).
	LD50: Lethal Dose for 50% of the test population
	OSHA: Occupational Safety & Health Administration

NFPA health hazard : 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA fire hazard : 1 - Materials that must be preheated before ignition can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product