

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name

- **Opium tincture**

Product Code

- NDC 0187-4203-04; NDC 0187-4203-16; NDC 42998-0203-01; NDC 42998-0203-02

Relevant identified uses of the substance or mixture and uses advised against

Recommended use

- For the treatment of diarrhea.

Restrictions on use

- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer

- Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer

- 1-800-535-5053 - US - Infotrac

Manufacturer

- +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS

- Specific Target Organ Toxicity Single Exposure 3: Narcotic Effects
Flammable Liquids 3

Label elements

UN GHS

WARNING



- Hazard statements** • Flammable liquid and vapour
May cause drowsiness or dizziness

Precautionary statements

- Prevention** • Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
Keep container tightly closed.

Use personal protective equipment as required.

Response • Call a POISON CENTER or doctor/physician if you feel unwell.

In case of fire, use carbon dioxide, dry chemical powder, appropriate foam or water fog extinguishing media.

Storage/Disposal • Store in a well-ventilated place. Keep cool.

Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Ethanol	CAS:64-17-5 EINECS:200-578-6	15% TO 20%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1B; Repr. 1B
Morphine	CAS:57-27-2 EINECS:200-320-2	8.7%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 70%	UN GHS: Classification criteria not met

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- Symptoms of toxicity are those of morphine and alcohol, such as nausea, vomiting, miosis, cool and clammy skin, respiratory and CNS depression, bradycardia, hypotension, and skeletal muscle flaccidity. Noncardiogenic pulmonary edema may develop after opioid overdose and monitoring of heart filling pressure may be helpful. Ethanol has been demonstrated to cause hypoglycemia in children or adults with limited glycogen stores. In severe overdosage, apnea, circulatory collapse, cardiac arrest, and death may occur.

Indication of any immediate medical attention and special treatment needed

Antidotes

- Initial management of opioid overdose should emphasize establishment of a secure airway and support of ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, blood glucose, etc. Naloxone antagonizes most effects of opioids. Protect the airway as naloxone may induce vomiting. Since naloxone has a shorter duration of action than opioids, repeated doses may be needed. In patients who abuse opioids chronically, a withdrawal syndrome may be manifest on administration of naloxone. This may include yawning, tearing, restlessness, sweating, dilated pupils, piloerection, vomiting, diarrhea, and abdominal cramps. This syndrome usually abates quickly as the effect of naloxone dissipates. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Since opium tincture can delay gastric emptying, evacuation of the stomach may be beneficial. Safeguard the patient's airway when employing gastric emptying or charcoal. Monitor for and treat hypoglycemia.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
 - LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

- Firefighting Procedures**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- Contains flammable liquid.

- Hazardous Combustion Products**
- No data available

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.

- Emergency Procedures**
- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep unauthorized personnel away. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

- Keep away from fire - No Smoking. Keep away from heat and sparks.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed and store in upright position. Solution is flammable, keep away from heat or flame. Store at a controlled room temperature: 15-25C (59-77F).

Section 8 - Exposure Controls/Personal Protection**Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Ethanol (64-17-5)	TWAs	Not established	1000 ppm TWA _{EV} ; 1880 mg/m ³ TWA _{EV}	1000 ppm TWA; 1900 mg/m ³ TWA	1000 ppm TWA; 1900 mg/m ³ TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established

Exposure Control Notations**ACGIH**

- Ethanol (64-17-5): **Carcinogens:** (A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans)

Exposure controls**Engineering Measures/Controls**

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment**Respiratory**

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear protective gloves .

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways,

and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Not relevant
Color	Clear, reddish brown.	Odor	Mild alcohol odor.
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Heat, direct sunlight.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Morphine (8.7%)	57-27-2	Acute Toxicity: Ingestion/Oral-Rat LD50 • 335 mg/kg
Ethanol (15% TO 20%)	64-17-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7060 mg/kg; <i>Lungs, Thorax, or Respiration:</i> Other changes

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 3: Narcotic Effects
STOT-RE	UN GHS • Classification criteria not met

Target Organs

- Central nervous system

Potential Health Effects**Inhalation****Acute (Immediate)**

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available

Skin**Acute (Immediate)**

- May cause mild irritation.

Chronic (Delayed)

- No data available

Eye**Acute (Immediate)**

- May cause irritation.

Chronic (Delayed)

- No data available

Ingestion**Acute (Immediate)**

- May cause gastrointestinal disturbances including nausea and vomiting.

Chronic (Delayed)

- No data available

Carcinogenic Effects			
	CAS	IARC	NTP
Ethanol	64-17-5	Group 1-Carcinogenic	Evidence of Carcinogenicity

Other information

- Controlled Substance – Opium Tincture, USP (Deodorized), is a Schedule II drug. Addiction can result from opium usage. Opium preparations should be given in the smallest effective dose and as infrequently as possible to minimize the development of tolerance and physical dependence.

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user

- No data available

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

- No data available

Other information

- DOT** • See DOT Part 173.150(g): Exception. For volumes greater than 8 fluid ounces to 16 fluid ounces the company name and the words "Contains Ethyl Alcohol" are marked on the package.

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ethanol	64-17-5	Yes	Yes	Yes
Morphine	57-27-2	Yes	Yes	No

Canada

Labor

Canada - WHMIS - Classifications of Substances

- | | | |
|------------|---------|------------|
| • Ethanol | 64-17-5 | B2, D2B |
| • Morphine | 57-27-2 | Not Listed |

Canada - WHMIS - Ingredient Disclosure List

- | | | |
|------------|---------|------------|
| • Ethanol | 64-17-5 | 0.1 % |
| • Morphine | 57-27-2 | Not Listed |

Europe

Other**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Ethanol	64-17-5	F; R11
• Morphine	57-27-2	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Ethanol	64-17-5	F R:11 S:(2)-7-16
• Morphine	57-27-2	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Ethanol	64-17-5	S:(2)-7-16
• Morphine	57-27-2	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Ethanol	64-17-5	carcinogen, 4/29/2011 (in alcoholic beverages)
• Morphine	57-27-2	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Ethanol	64-17-5	developmental toxicity, 10/1/1987 (in alcoholic beverages)
• Morphine	57-27-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Ethanol	64-17-5	Not Listed
• Morphine	57-27-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Ethanol	64-17-5	Not Listed
• Morphine	57-27-2	Not Listed

Section 16 - Other Information**Revision Date**

- 08/January/2016

Last Revision Date

- 08/January/2016

Preparation Date

- 08/January/2016

Disclaimer/Statement of Liability

- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.