1. Identification

Product identifier: Recuvyra

Other means of identification:

- Item Code: CA4232
- Synonyms: Propanamide, N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-

Recommended use: Pharmaceutical

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name: Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)
Email: lilly_msds@lilly.com

Emergency Telephone Numbers:
Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards

- Flammable liquids

Health hazards

- Acute toxicity, oral
- Acute toxicity, dermal
- Acute toxicity, inhalation
- Serious eye damage/eye irritation
- Specific target organ toxicity, single exposure

OSHA defined hazards

- Not classified.

Label elements

Signal word: Danger

Hazard statement

- H225: Highly flammable liquid and vapor.
- H300: Fatal if swallowed.
- H310: Fatal in contact with skin.
- H330: Fatal if inhaled.
- H319: Causes serious eye irritation.
- H336: May cause drowsiness or dizziness.

Precautionary statement

Prevention

- P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- P233: Keep container tightly closed.
- P240: Ground/bond container and receiving equipment.
- P260: Do not breathe mist or vapor.
- P262: Do not get in eyes, on skin, or on clothing.
- P264: Wash hands thoroughly after handling.
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P284: Wear respiratory protection.
Response
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 P305 + P351 + P338 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P310 If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 + P337 + P313 Immediately call a POISON CENTER or doctor/physician.
P321 Specific treatment (see this label).
P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td></td>
<td>67-63-0</td>
<td>90</td>
</tr>
<tr>
<td>Fentanyl Base</td>
<td></td>
<td>437-38-7</td>
<td>5</td>
</tr>
<tr>
<td>Other components below reportable levels</td>
<td></td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation
Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.

Skin contact
Wash off immediately with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention immediately.

Eye contact
Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.

Ingestion
If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.

Most important symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed
Symptoms may be delayed. Fentanyl is a narcotic and dependency may occur with prolonged exposure.

For treatment of an acute overdose, administration of a specific narcotic antagonist such as naloxone may be used. Because this product is a narcotic, continued medical monitoring is required. If overdose occurs, all components must be treated. Due to the dermal release formulation, significant skin absorption is possible and raises the concern for extended medical monitoring. After an acute overdosage, the fentanyl component can cause respiratory and central nervous system depression ultimately resulting in death. Attention should be focused on establishing an adequate airway and assisted ventilation with oxygen. Gastrointestinal decontamination is not recommended routinely and should only be used on a case by case basis. Opioid antagonists such as naloxone will reverse respiratory depression from opioid overdose, but should not be administered in the absence of clinically significant respiratory or circulatory depression. In patients who are physically dependent on any opioid, an opioid antagonist may precipitate an acute opioid withdrawal syndrome. Significant exposure including ingestion, inhalation, or dermal should be monitored for 16-24 hours.

General information
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). NOT FOR HUMAN USE!

5. Fire-fighting measures

Suitable extinguishing media
Water. Carbon dioxide (CO2). Dry chemical.
6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up
Small Spillages:
Use absorbent/adsorbent material to solidify liquids. Do not vacuum. Remove sources of ignition. Collect in a non-combustible container for prompt disposal.

Large Spillages:
Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Because this is a controlled substance, special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations.

Avoid inhalation of vapors/spray and contact with skin and eyes. Wash hands thoroughly after handling. Avoid heat, sparks, open flames and other ignition sources. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities
Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Avoid contact with oxidizing agents. Avoid moisture. Do not store in open or unlabelled containers. Keep container tightly closed.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Lilly (LEG) Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl Base (CAS 437-38-7)</td>
<td>STEG (15min)</td>
<td>1.3 ug/m3</td>
<td>(Skin designation)</td>
</tr>
<tr>
<td></td>
<td>TWA (12hrs)</td>
<td>0.1 ug/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (8hrs)</td>
<td>0.15 ug/m3</td>
<td></td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>US. ACGIH Threshold Limit Values Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td>STEL</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
</tr>
</tbody>
</table>

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td>PEL</td>
<td>980 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>400 ppm</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>US. NIOSH: Pocket Guide to Chemical Hazards Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td>STEL</td>
<td>1225 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>980 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>400 ppm</td>
</tr>
</tbody>
</table>
Biological limit values

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Determinant</th>
<th>Specimen</th>
<th>Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td>40 mg/l</td>
<td>Acetone</td>
<td>Urine</td>
<td>*</td>
</tr>
</tbody>
</table>

* - For sampling details, please see the source document.

Appropriate engineering controls
Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth. Use explosion-proof ventilation equipment.

Individual protection measures, such as personal protective equipment

**Eye/face protection**
Wear goggles/face shield.

**Skin protection**

**Hand protection**
Wear nitrile gloves. Nitrile prevents breakthrough of continuous exposure to solution for 8 hours. Latex gloves may be used, but studies report that latex prevents breakthrough for 30 minutes only.

**Other**
Chemical-resistant gloves and impermeable body covering to minimize skin contact.

**Respiratory protection**
Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.

**Thermal hazards**
None known.

General hygiene considerations
NOT INTENDED FOR HUMAN USE.
Use good industrial hygiene practices in handling this material. In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

Because this is a controlled substance, special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

9. Physical and chemical properties

**Appearance**
Liquid

**Physical state**
Liquid.

**Form**
Liquid.

**Color**
Colorless

**Odor**
Alcohol-like

**Odor threshold**
No data available.

**pH**
No data available.

**Melting point/freezing point**
No data available.

**Initial boiling point and boiling range**
No data available.

**Flash point**
59.0 °F (15.0 °C)

**Evaporation rate**
No data available.

**Flammability (solid, gas)**
Highly flammable liquid and vapor.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%) temperature**
No data available.

**Flammability limit - upper (%)**
No data available.

**Explosive limit - lower (%)**
2% (V)

**Explosive limit - upper (%)**
12% (V)

**Vapor pressure**
No data available.

**Vapor density**
No data available.

**Relative density**
No data available.

**Solubility(ies)**

**Solubility (water)**
No data available.

**Partition coefficient (n-octanol/water)**
No data available.
Auto-ignition temperature: No data available.
Decomposition temperature: No data available.
Viscosity: No data available.

Other information:
- Density: No data available.
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Percent volatile: No data available.
- VOC (Weight %): No data available.

10. Stability and reactivity

Reactivity: Not available.
Chemical stability: Material is stable under normal conditions.
Possibility of hazardous reactions: Hazardous polymerization does not occur.
Conditions to avoid: Heat.
Incompatible materials: Strong oxidizing agents.
Hazardous decomposition products: Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity: May be fatal if inhaled, absorbed through skin, or swallowed.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl Base (CAS 437-38-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>18 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>12800 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>19000 ppm, 8 hours</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>5045 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Rabbit: Causes mild skin irritation. (Isopropyl Alcohol)

No data available for remaining ingredient(s).

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Rabbit: Causes eye irritation. (Isopropyl Alcohol)

Respiratory or skin sensitization

Respiratory sensitization: Due to lack of data the classification is not possible.

Skin sensitization: Due to lack of data the classification is not possible.

Germ cell mutagenicity: In vitro and in vivo tests did not show mutagenic effects. (Fentanyl Base)

Negative in in vitro genetic toxicity assays. (Isopropyl Alcohol)

Carcinogenicity: Due to lack of data the classification is not possible.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity: Impaired fertility and embryocidal effects were reported in rats administered intravenous doses (equivalent to 0.3 times the human dose) for 12 days. No teratogenic effects reported. (Fentanyl Base)

No data available for remaining ingredient(s).

Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure
Narcotic effects. May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

Aspiration hazard
No aspiration toxicity classification.

Chronic effects
This information is not available.

12. Ecological information

Ecotoxicity
No data available.

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl Base (CAS 437-38-7)</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>Activated sewage sludge inoculum</td>
</tr>
<tr>
<td>NOEC</td>
<td>Activated sewage sludge inoculum</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>EbC50</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
<tr>
<td>ErC50</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>NOEC</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Fish</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>Danio rerio</td>
</tr>
<tr>
<td>LC50</td>
<td>Danio rerio</td>
</tr>
<tr>
<td>NOEC</td>
<td>Danio rerio</td>
</tr>
<tr>
<td>Isopropyl Alcohol (CAS 67-63-0)</td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Bluegill (Lepomis macrochirus)</td>
</tr>
</tbody>
</table>

Persistence and degradability
The product is not expected to be biodegradable.

Bioaccumulative potential
The product is not bioaccumulating.

Partition coefficient n-octanol / water (log Kow)
Fentanyl Base 4.05
Isopropyl Alcohol 0.05

Mobility in soil
No data available.

Other adverse effects
Not available.

Ecotoxicological Properties

Drinking Water
Components
Fentanyl Base 0.0044 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms
Components
Fentanyl Base 0.0056 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms
Components
Fentanyl Base 427 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations
Disposal instructions
Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.
14. Transport information

**DOT**

- **UN number**: UN1986
- **UN proper shipping name**: Alcohols, flammable, toxic, n.o.s. (Isopropyl Alcohol, Fentanyl Base)
- **Transport hazard class(es)**:
  - Class: 3
  - Subsidiary risk: 6.1
  - Label(s): 3, 6.1
- **Packing group**: II
- **Special precautions for user**: Read safety instructions, SDS and emergency procedures before handling.
- **Special provisions**: IB2, T7, TP2, TP13
- **Packaging exceptions**: 150
- **Packaging non bulk**: 202
- **Packaging bulk**: 243

**IATA**

- **UN number**: UN1986
- **UN proper shipping name**: Alcohols, flammable, toxic, n.o.s. (Isopropyl Alcohol, Fentanyl Base)
- **Transport hazard class(es)**:
  - Class: 3
  - Subsidiary risk: 6.1
- **Packing group**: II
- **Environmental hazards**: No.
- **ERG Code**: 3HP
- **Special precautions for user**: Read safety instructions, SDS and emergency procedures before handling.
- **Other information**:
  - Passenger and cargo aircraft: Allowed.
  - Cargo aircraft only: Allowed.

**IMDG**

- **UN number**: UN1986
- **UN proper shipping name**: Alcohols, flammable, toxic, n.o.s. (Isopropyl Alcohol, Fentanyl Base)
- **Transport hazard class(es)**:
  - Class: 3
  - Subsidiary risk: 6.1
- **Packing group**: II
- **Environmental hazards**: No.
- **EmS**: F-E, S-D
- **Special precautions for user**: Read safety instructions, SDS and emergency procedures before handling.
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**: Not available.
15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Isopropyl Alcohol (CAS 67-63-0) Listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Hazard - Yes</td>
</tr>
<tr>
<td>Delayed Hazard - No</td>
</tr>
<tr>
<td>Fire Hazard - Yes</td>
</tr>
<tr>
<td>Pressure Hazard - No</td>
</tr>
<tr>
<td>Reactivity Hazard - No</td>
</tr>
</tbody>
</table>

SARA 313 (TRI reporting)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>% by wt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol</td>
<td>67-63-0</td>
<td>90</td>
</tr>
</tbody>
</table>

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))
Isopropyl Alcohol (CAS 67-63-0)

US. Massachusetts RTK - Substance List
Isopropyl Alcohol (CAS 67-63-0)

US. New Jersey Worker and Community Right-to-Know Act
Isopropyl Alcohol (CAS 67-63-0)

US. Pennsylvania Worker and Community Right-to-Know Law
Isopropyl Alcohol (CAS 67-63-0)

US. Rhode Island RTK
Isopropyl Alcohol (CAS 67-63-0)

US. California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.
International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date               05-19-2015
Version #                 01
Lilly Lab Code
Health: 3
Fire: 3
Reactivity: 0
Special 1: P

List of abbreviations
LEG = Lilly Exposure Guideline
STEG: Short Term Exposure Guideline

Disclaimer
As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441

Revision Information
Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: Safety Phrases
HazReg Data: North America
GHS: Classification