1. Identification

Product identifier: Apomorphine Hydrochloride

Other means of identification:
- Catalog number: 1041008
- Chemical name: 4H-Dibenzo[de,g]quinoline-10,11-diol, 5,6,6a,7-tetrahydro-6-methyl-, hydrochloride, hemihydrate, (R)-

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790
- Telephone: RS Technical Services, USA 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Acute toxicity, oral: Category 3
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

OSHA hazard(s): Not classified.

Label elements

- Signal word: Danger
- Hazard statement: Toxic if swallowed. May cause drowsiness or dizziness.
- Precautionary statement:
  - Prevention: Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
  - Response: If inhaled: Remove person to fresh air and keep comfortable for breathing. Rinse mouth. Call a poison center/doctor/medical professional.
  - Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

- Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apomorphine Hydrochloride</td>
<td></td>
<td></td>
<td>41372-20-7</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

**Inhalation**
Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Most important symptoms/effects, acute and delayed**
Narcotic effects.

**Indication of immediate medical attention and special treatment needed**
Treatment for opioid overdose should be symptomatic and supportive and may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. Administer oxygen and assist ventilation for respiratory depression. Protect airway with orotracheal intubation. Naloxone reverses coma and respiratory depression. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. Treat seizures with intravenous benzodiazepines; propofol or barbiturates may be administered if seizures persist. Treat hypotension with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis and hemoperfusion are not recommended. Treat excessive emesis with domperidone.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Exposure limit values**

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apomorphine Hydrochloride (CAS 41372-20-7)</td>
<td>TWA</td>
<td>0.1 mg/m3</td>
</tr>
</tbody>
</table>

Material name: Apomorphine Hydrochloride

4758  Version #: 02  Revision date: 07-26-2013  Issue date: 12-17-2010
Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
Small, white or slightly yellow to greenish-gray crystals or powder.

Physical state
Solid.

Form
Crystalline powder.

Odor
Odorless.

Odor threshold
Not available.

pH
4 (1% concentration)

Melting point/freezing point
500 °F (260 °C) ; also reported as 195 °C

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility in water
Sparingly soluble.

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

 Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Morphinan derivative.

Molecular formula
C17H17NO2 . HCl . 1/2H2O
Molecular weight
312.79
Solubility (other)
Sparingly soluble in ethanol; slightly soluble in chloroform and in ether.

10. Stability and reactivity
Reactivity
No reactivity hazards known.
Chemical stability
Material is stable under normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.
Conditions to avoid
None known.
Incompatible materials
Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. HCl.

11. Toxicological information
Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Toxic if swallowed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Chronic effects
Tolerance.

Cross sensitivity
Persons sensitive to morphine or its derivatives may be sensitive to this material also.

Medical conditions aggravated by exposure

Acute toxicity
Product
Test Results

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apomorphine Hydrochloride (CAS 41372-20-7)</td>
<td>Mouse</td>
<td>Oral LD50 300 mg/kg, (base) &lt; 2000 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
</tbody>
</table>

Mutagenicity
Ames test (S. typhimurium) Result: Positive
In vitro chromosome aberration assay
Result: Clastogenic results in human lymphocytes, mouse lymphoma cells, and Chinese hamster lung cells.
In vitro mouse lymphoma assay
Result: Positive
In vivo micronucleus assay
Result: Negative
Species: Mouse

Carcinogenicity
Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity
Due to lack of data the classification is not possible.
Reproductivity
- 0.4 mg/kg/day Fertility study (males)
  Result: No effect on reproductive endpoints.
- Species: Dog
- 2 mg/kg/day Fertility study (males)
  Result: No effect on reproductive endpoints.
- Species: Rat

Specific target organ toxicity - single exposure
Narcotic effects.

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

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

12. Ecological information

Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
- UN number: UN2811
- UN proper shipping name: Toxic solid, organic, n.o.s. (Apomorphine Hydrochloride)
- Transport hazard class(es): 6.1
- Subsidiary class(es): Not available.
- Packing group: III

IATA
- UN number: UN2811
- UN proper shipping name: Toxic solid, organic, n.o.s. (Apomorphine Hydrochloride)
- Transport hazard class(es): 6.1
- Subsidiary class(es): -
- Packaging group: III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.
15. Regulatory information

US federal regulations  CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories  Immediate Hazard - Yes
                   Delayed Hazard - No
                   Fire Hazard - No
                   Pressure Hazard - No
                   Reactivity Hazard - No

SARA 302 Extremely hazardous substance  No
SARA 311/312 Hazardous chemical  No

Other federal regulations  Safe Drinking Water Act (SDWA)  Not regulated.
                          Food and Drug Administration (FDA)  Not regulated.

US state regulations  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>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</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)

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

Issue date  12-17-2010
Revision date  07-26-2013
Version #  02
Further information  Not available.
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Revision Information  This document has undergone significant changes and should be reviewed in its entirety.