


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	APOMORPHINE HYDROCHLORIDE, USP/EP
PRODUCT CODE	1764
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
USES	Manufacturing and Compounding

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Specific Target Organ Toxicity - Single Exposure (Category 3) - narcotic effects Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	May be harmful if swallowed. Harmful if inhaled or in contact with skin. May cause drowsiness or dizziness. Toxic to aquatic life. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable
PRECAUTIONARY STATEMENT(S)	Prevention Avoid breathing dust/fume/gas/mist/ vapors/spray. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.

Response	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.			
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.			
Disposal	Dispose of contents and/or container in accordance with local regulations.			
HMIS CLASSIFICATION	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	4H-Dibenzo[de,g]quinoline-10,11-diol, 5,6,6a,7-tetrahydro-6-methyl-, hydrochloride, hemihydrate,(R)-
BOTANICAL NAME	Not applicable
SYNONYM	6aβ-Aporphine-10, 11-diol hydrochloride hemihydrate
CHEMICAL FORMULA	C ₁₇ H ₁₇ NO ₂ •HCl•½H ₂ O
CAS NUMBER	41372-20-7 (hemihydrate)
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	312.79 (hemihydrate)

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
APOMORPHINE HCl	41372-20-7 (hemihydrate)	206-243-0	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES Chemical family: Morphinan derivative.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
SYMPTOMS AND EFFECTS	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable.
FLAMMABLE PROPERTIES	May be combustible at high temperature.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE
EXTINGUISHING MEDIA**

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND
PRECAUTIONS FOR FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture. Short term excursions up to 40°C are acceptable.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: APOMORPHINE HCl CAS #: 41372-20-7 (hemihydrate)

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
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N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: Industrial: TWA 0.1 mg/m³

Manufacturer in house exposure limit: 0.1 mg/m³ (8 hour TWA)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Minute, white or grayish-white, glistening crystals or white powder. Is odorless. It gradually acquires a green color on exposure to light and air.

SOLUBILITY

Sparingly soluble in water and in alcohol; soluble in water at 80°; very slightly soluble in chloroform and in ether; practically insoluble in toluene.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

225°C, 437°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

195°C, 383°F
(Decomposition at 225°C, 437°F)

ODOR THRESHOLD

Not available

OXIDIZING PROPERTY

Not available

pH

4 - 5 (1%)

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY (AIR = 1)

Not available

VAPOR PRESSURE

Not available

VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions. It gradually acquires a green color on exposure to light and air.
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Bases. Tannins.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 2000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Based on available data, the classification criteria are not met. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met. Suspected mutagen: CAESAR Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (good reliability); ISS Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability); KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (good reliability); SARPY Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (good reliability)
CARCINOGENICITY	OSHA APOMORPHINE HYDROCHLORIDE is not listed. NTP APOMORPHINE HYDROCHLORIDE is not listed. IARC APOMORPHINE HYDROCHLORIDE is not evaluated. California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
ADDITIONAL CARCINOGENICITY INFORMATION	Based on available data, the classification criteria are not met. Suspected carcinogen: CAESAR Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (moderate reliability); ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (moderate reliability).
REPRODUCTIVE TOXICITY	Due to lack of data the classification is not possible.
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 HAZARDS	Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

Symptoms related to the physical, chemical, and toxicological characteristics:
Opioid analgesics: Dizziness. Drowsiness. Weakness. Restlessness. Euphoria. Depression. Agitation. Confusion. Hallucinations. Slurred speech. Nausea. Vomiting. Constipation. Decreased or difficult urination. Sweating. Flushing. Itching. Rash. Cold and clammy skin. Difficulty breathing. Loss of consciousness. Pinpoint pupils. Muscle rigidity. Convulsions. Seizures.

Delayed and immediate effects of exposure:

Opioid analgesics: Low blood pressure. Slow or irregular heart rate. Hypothermia. Tolerance. Dependence. Coma. Heart attack. Death.

Chronic effects: Tolerance.

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

Medical conditions aggravated by exposure:

Opioid analgesics: Liver impairment. Kidney impairment. Hypothyroidism. Seizure disorders. Asthma. Respiratory disorders. Heart arrhythmia. Alcoholism. History of drug abuse or dependence. Gallbladder disorders. Inflammatory bowel disease. Urinary disorders. Low blood pressure. Gastrointestinal obstruction. Adrenal gland problems. Sickle cell disease. Addison's disease. Concurrent use of monoamine oxidase inhibitors (MAOIs).

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion	May be harmful if swallowed. Ingestion may cause nausea/vomiting.
Skin	May be harmful if in contact with skin. May cause an allergic skin reaction.
Eyes	Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.

SECTION 12: ECOLOGICAL INFORMATION**TOXICITY**

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): < 1*
LC50: 96 Hr: Fish: (mg/L): 4.73*
EC50: 96 Hr: Green Algae: (mg/L): 1.42*

PERSISTENCE AND DEGRADABILITY

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

Not available.

MOBILITY IN SOIL

Sparingly soluble in water: 20 g/L

OTHER ADVERSE EFFECTS

Suspected hazardous to the aquatic environment: Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform predicts that the chemical is Toxic-2 (between 1 and 10 mg/L) (moderate reliability).

This product is not intended to be released into the environment.

NOTES

*Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UN PROPER SHIPPING NAME**

Not dangerous good

UN NUMBER Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

AUSTRALIA

HAZCHEM Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE Not Listed

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
APOMORPHINE HCl 41372-20-7 (hemihydrate)	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
APOMORPHINE HCl 41372-20-7 (hemihydrate)	N/L	Listed as Schedule 4*	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	EC 649/2012	EC 2012/118
APOMORPHINE HCl 41372-20-7 (hemihydrate)	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

NOTES *Listed as the base

SECTION 16: OTHER INFORMATION
REFERENCES Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2021

SUPERSEDES

06/2019

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.