SAFETY DATA SHEET

1. Identification

Product identifier **Codeine Sulfate Tablets USP, CII**

Other means of identification

Product code 15 mg tablet, debossed with product identification “54 613” on one side, and "15" on the other., 30 mg tablet, debossed with product identification “54 783” on one side, and "30" on the other., 60 mg tablet, debossed with product identification “54 412” on one side, and "60" on the other.

Recommended use Pain relief

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name Hikma Pharmaceuticals USA Inc.

Address 1809 Wilson Road
Columbus, Ohio 43228

Telephone (614) 276-4000

Emergency phone number CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887 24/7

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Reproductive toxicity (the unborn child)	Category 1A
Specific target organ toxicity, repeated exposure	Category 1

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Warning

Hazard statement This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials. Protect from light. Protect from moisture. Store at controlled room temperature at 15-30 ºC (59-86ºF).

Disposal Incineration of waste at an approved USEPA incinerator is recommended.

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

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate		630-08-0	15mg - 60mg

Composition comments Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating
Indication of immediate medical attention and special treatment needed	In the case of overdose, the primary management should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store away from incompatible materials (see Section 10 of the SDS). Store at controlled room temperature at 15-30 ºC (59-86ºF). Protect from moisture. Protect from light. Keep locked up and out of the reach of children. Dispense in well-closed container as defined in the USP/NF

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value
Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)	PEL	55 mg/m3 50 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)	TWA	25 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)	Ceiling	229 mg/m3
		200 ppm
	TWA	40 mg/m3
		35 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)	3.5 %	Carboxyhemoglobin	Hemoglobin in blood	*
	20 ppm	Carbon monoxide	End-exhaled air	*

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

Appropriate engineering controls Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection For consumer use, no unusual precautions are necessary.

Other None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Round, white, biconvex tablets

Physical state Solid.

Form Tablet.

Color	White.
Odor	None.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Molecular formula	C25H43NO18
Molecular weight	645.6

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.
Skin contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	The most common symptoms include: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, and sweating

Information on toxicological effects

Acute toxicity	May be harmful if swallowed in large quantities.
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Dust may irritate the eyes.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	This product is not expected to be mutagenic.
Carcinogenicity	There is no evidence of carcinogenic effects for this product.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	May cause adverse reproductive effects - such as birth defects, miscarriages, or infertility based on animal data. Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Nursing mothers: The risk of infant exposure to codeine and morphine through breast milk should be weighed against the benefits of breastfeeding for both the mother and the baby.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Further information	See package insert.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	None.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. 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

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

DEA: Codeine Sulfate CII is a DEA scheduled II controlled substance.

FDA: Codeine Sulfate CII is an approved prescription medication.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-m ethyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

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.

Drug Enforcement Administration (DEA): This product is a Schedule II Controlled Substance (21 CFR 1308.14)

US state regulations

US. Massachusetts RTK - Substance List

Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)

US. New Jersey Worker and Community Right-to-Know Act

Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)

US. Pennsylvania Worker and Community Right-to-Know Law

Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Morphinan-6-ol,7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-(5α,6 α)-, sulfate (2:1) (salt), trihydrate (CAS 630-08-0)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies 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

Revision date	15-October-2018
Version #	2
References	1) Codeine Sulfate Tablets USP, Package Insert, Hikma Pharmaceuticals USA Inc., Columbus, Ohio 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.
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