

SAFETY DATA SHEET

Cevimeline Hydrochloride

DATE INITIAL PREPARATION: January 25, 1994

DATE LAST REVISED: March 30, 2015

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT IDENTIFIER:

Product name: Cevimeline Hydrochloride

RELEVANT IDENTIFIED USES OF SUBSTANCE OR MIXTURE:

Product use: This material is used to manufacture Cevimeline Hydrochloride 30 mg capsules and EVOXAC® 30 mg Capsules (formulation) and prohibited for any other use.

SUPPLIER

Company: Daiichi Sankyo, Inc.

Address: 2 Hilton Court

Parsippany, NJ 07054

Phone Number: 877- 437-7763

Emergency Phone Number: 877- 437-7763

COMMENTS: To the best of our knowledge, this Safety Data Sheet conforms to the requirements of U.S. Occupational Safety and Health Administration (OSHA) Title 29 Code of Federal Regulations Section 1910.1200 (29 CFR 1910.120).

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW



Signal word: Danger

Hazard Statements: H301 Toxic if swallowed.

H361 Suspected of damaging fertility or the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

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Precautionary statements

Safety measures: refer to "7. Handling and Storage," "8. Exposure Controls/Personal Protection"

- P201 Obtain special instructions before use
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash hands thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P281 Use personal protective equipment as required.

First-aid measures: refer to "4. First-Aid Measures," "5. Fire-Fighting Measures"

- P201+310 IF SWALLOWED: immediately call a POISON CENTER or doctor/physician.
 P308+313 IF exposure or concerned: Get medical advice/attention.
 P330 Rinse mouth.

Handling and storage: refer to "7. Handling and Storage"

- P405 Store locked up.

Disposal considerations: refer to "13. Disposal Considerations"

- P501 Dispose of contents/container to governmental and local regulations.

NFPA RATINGS

Health	2
Fire	0
Reactivity	0
Personal Protection	X

Key:
 0=Insignificant
 1=Slight
 2=Moderate
 3=High
 4=Extreme
 X=Determined by User

HMIS RATINGS

Health	2
Fire	0
Reactivity	0
Personal Protection	X

TARGET ORGANS: None

POTENTIAL HEALTH EFFECTS/SYMPTOMS OF EXPOSURE

EYE CONTACT: No data available.

SKIN CONTACT: No data available.

INGESTION: Harmful if swallowed.

INHALATION: Prolonged or repeated inhalation of dust may cause irritation in some individuals.

COMMENTS: For detailed toxicological information see Section 11.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Synonyms	Wt %	CAS #
Cevimeline Hydrochloride	cis-2-methylspiro [1,3-oxathiolane-5,3'-quinuclidine] monohydrochloride hemihydrates; cis-2-methylspiro[1-azabicyclo[2,2,2]octane-3,5;-[1,3]oxathiolane] hydrochloride, hydrate (2:1)	>98.00%	153504-70-2

4. FIRST AID MEASURES

EYES: Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

SKIN: Wash exposed area with soap and water. Get medical advice if irritation develops.

INGESTION: Immediately call a POISON CENTER or doctor/physician.

INHALATION: Move to fresh air. Get medical attention for any breathing difficulty.

5. FIRE FIGHTING MEASURES**FIRE FIGHTING PROCEDURES**

FIRE FIGHTING EQUIPMENT: Wear full protective clothing and breathing equipment for high intensity fire or potential explosion conditions. Use of limited water spray on a smoldering fire can release explosive hydrogen.

EXTINGUISHING MEDIA: Dry chemical, foam or carbon dioxide.

HAZARDOUS DECOMPOSITION PRODUCTS: Release of toxic fumes by heating and burning. Take precautions to avoid dust explosion

6. ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS:**

Remove all sources of ignition.

Ventilate of leak or spill.

Wear appropriate personal protective equipment.

SPILL: Pick up spill for recovery or disposal and place in a closed container. Do not release into the environment.

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METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP: Clean up spills in a manner that does not disperse dust into the air. Use non sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING:

- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Do not breathe dust.
- Wear protective gloves/protective clothing.
- Handle this chemical in work areas with adequate local exhaust ventilation.

STORAGE:

- Keep in a tightly closed container, stored in a cool, dry, ventilated area.
- Protect against physical damage.
- Separate from acids and oxidizing materials.
- Inner bags of this material may be hazardous when empty since they retain product residues.
- Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE GUIDELINES

Chemical	ACGIH (TLV®)	NIOSH (REL)	OSHA (PEL)
Cevimeline hydrochloride	N.E.	N.E.	N.E.
N.E. = not established			

ENGINEERING CONTROLS:

- A system of local and/or general exhaust is recommended.

PERSONAL PROTECTIVE EQUIPMENT

- EYES AND FACE:** Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.
- SKIN:** Gloves and laboratory coat, apron or coveralls.
- RESPIRATORY:** A half face-piece particulate respirator (NIOSH type N95 or better filters) is recommended.

If respirators are used the respiratory protection program needs to meet requirements of 29 CFR 1910.134 (or equivalent in countries other than the United States).

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9. PHYSICAL AND CHEMICAL PROPERTIES**APPEARANCE****PHYSICAL STATE:** Crystalline powder**COLOR:** White to off-white or pale yellow**ODOR:** Slightly characteristic odor**ODOR THRESHOLD:** Not Available**pH:** 5.1~5.3 (1% solution)**MELTING or FREEZING POINT:** Approximately 203.3~203.3°C**INITIAL BOILING POINT:** Not Available**BOILING RANGE:** Not Available**FLASH POINT:** Not flammable**EVAPORATION RATE:** Not Available**FLAMMABILITY:** Not Available**UPPER EXPLOSIVE LIMIT:** Not Available**LOWER EXPLOSIVE LIMIT:** Not Available**VAPOR PRESSURE:** Not Available**VAPOR DENSITY:** Not Available**RELATIVE DENSITY:** Not Available**SOLUBILITY:** Easy to extremely dissolve in water

Easy to dissolve in methanol and ethanol (99.5)

Easy to dissolve in acetonitrile a little.

PARTITION COEFFICIENT:**n-octanol/water;** acidic area (pH2~6): There is not the distribution of the organic solution (0-0.29).

Weak basic area (pH8): There is the distribution of the organic solution a little (2.3).

Basic area (pH 10~12): There is many distribution of the organic solution (50~∞).

AUTO-IGNITION TEMPERATURE: Not Available**DECOMPOSITION TEMPERATURE:** Not Available**VISCOSITY:** Not Available**10. STABILITY AND REACTIVITY****CHEMICAL STABILITY:** Stable for 5 years under ordinary conditions of storage.**REACTIVITY:** Not available.**POSSIBILITY OF HAZARDOUS REACTIONS:** Not available.**CONDITIONS TO AVOID:** Strong humidity and water.**INCOMPATIBLE MATERIALS:** Strong oxidizers.**HAZARDOUS DECOMPOSITION PRODUCTS:** Can form hydrochloric acid and sulfur dioxide when burned

11. TOXICOLOGICAL INFORMATION**ACUTE EFFECTS**

EYES:	Not Available.
INHALATION TC_{Lo}:	Not Available.
DERMAL LD₅₀:	Not Available.
ORAL LD₅₀:	Rat (Male): 122.2 mg/kg.
	Rat (Female): 108.5 mg/kg
	Mouse (Male): 139.2 mg/kg
	Mouse (Female): 167.3 mg/kg

POTENTIAL HEALTH EFFECTS/SYMPTOMS OF EXPOSURE

EYE CONTACT: No data available.

SKIN CONTACT: No data available.

INGESTION: May cause salivation, lachrymation, sweating, nausea or stomachache. When a large amount of swallowing, tremors or convulsions occur.

SUBACUTE TOXICITY:

Oral Rat NOEL: 18 mg/kg (Male/Female)

Oral Dog NOEL: 3 mg/kg (Male/Female)

CHRONIC TOXICITY:

Oral Rat NOEL: 6 mg/kg (Male/Female)

Oral Dog NOEL: 3 mg/kg (Male/Female)

CARCINOGENICITY:

None (mouse, rat)

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

REPRODUCTIVE/TERATOGENIC EFFECTS:

Rat female (the 7th day from 17th day of pregnancy):

60mg/kg/day (Female/fetus)

Rabbit female (the 6th day from the 18th day of pregnancy):

45 mg/kg/day (Female/fetus)

Rat female (the 17th day from 20th day of pregnancy):

45 mg/kg/day (Female), 12 mg/kg/day (next generation)

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MUTAGENICITY:None [*S.typhimurium*(TA100, TA1535, TA98, TA1537) and *E.coli* (WP2uvrA)].**GENOTOXICITY:**

Not Available

12. ECOTOXICOLOGICAL INFORMATION**AQUATIC TOXICITY****Toxicity for fish:** LC₅₀ (48h) 119ppm (*Killifish*)**Toxicity for algae:** Not available.**Toxicity for daphnia:** Not available.**PERSISTENCE AND DEGRADABILITY**

Not available.

BIOACCUMULATIVE POTENTIAL

Not available.

MOBILITY IN SOIL

Not available.

OTHER ADVERSE EFFECTS

Not available.

13. DISPOSAL CONSIDERATIONS

Dispose of container and unused contents in accordance with federal, state and local requirements.

14. TRANSPORT INFORMATION

UN Proper Shipping Name	Medicine, Solid, Toxic, N.O.S. (Cevimeline Hydrochloride)
UN Class	Not available
UN Number	3249
UN Packaging Group	III
Transport Hazard Class	6.1
Environmental Hazards	None
Transport in Bulk	Not available
Special Precautions	Not available

15. REGULATORY INFORMATION

This material is approved by FDA as an active pharmaceutical ingredient for Cevimeline Hydrochloride 30 mg capsules and EVOXAC® 30 mg Capsules. Comply with governmental and local regulations.

International inventories:

EINECS Status: On the inventory, or in compliance with the act.

AICS Status: On the inventory, or in compliance with the act.

DSL Status: On the inventory, or in compliance with the act.

ENCS (JP) Status: On the inventory, or in compliance with the act.

KECI (KR) Status: On the inventory, or in compliance with the act.

PICCS (PH) Status: On the inventory, or in compliance with the act.

IECSC (CN) Status: On the inventory, or in compliance with the act.

16. OTHER INFORMATION**Product Use:**

This material is limited to use of manufacturing Cevimeline Hydrochloride 30 mg capsules and EVOXAC® 30 mg Capsules (formulation) and prohibited for any other use.

Last revised: March 30, 2015

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