SAFETY DATA SHEET

1. Identification

Product identifier	**Eslicarbazepine Acetate Peak ID Mixture**	
Other means of identification		
Catalog number	1249520	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Customer Service	301-881-0666
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	Reproductive toxicity	Category 1
	Specific target organ toxicity, single exposure	Category 2 (nervous system)
	Specific target organ toxicity, repeated exposure	Category 2 (liver)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements

Signal word	Danger
Hazard statement	May damage fertility or the unborn child. May cause damage to organs (nervous system). May cause damage to organs (liver) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Eslicarbazepine Acetate		236395-14-5	97.63
Carbamazepine		298-46-4	0.79
10-Acetoxycarbamazepine		952740-00-0	0.65
Eslicarbazepine		104746-04-5	0.42
Oxcarbazepine		28721-07-5	0.42
Related Impurities		No Data	0.09

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation Move 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.

Most important symptoms/effects, acute and delayed Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

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. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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 Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP materials, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities
Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Components	Type	Value
Carbamazepine (CAS 298-46-4)	TWA	0.2 mg/m3

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection
Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other
Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection
Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Handling practices in this SDS are recommendations for laboratory use of USP materials. Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

Appearance
Appearance descriptions are general information and not specific to any USP lot.

Physical state
Solid.

Form
Powder.

Color
White.

Odor
Not available.

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

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.

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.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical and toxicological characteristics	Dibenzazepine anticonvulsants: Gastrointestinal disturbances. Hypersensitivity reactions. Central nervous system effects. Blurred vision. Seizures. Cardiovascular effects. Suicidal thoughts. Weakness. Headache. Tremor.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Carbamazepine (CAS 298-46-4)		
Acute		
Dermal		
LD50	Rabbit	2680 mg/kg
Inhalation		
LC50	Rat	> 2160 mg/m3, 4 h
Oral		
LD50	Mouse	529 mg/kg
	Rabbit	2680 mg/kg
	Rat	1957 mg/kg

Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.

Local effects

Carbamazepine	Eye irritation Result: Irritant. Species: Rabbit Severity: Mild. Skin irritation Result: Non-irritant. Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Eslicarbazepine Acetate	Ames test Result: Negative.
Oxcarbazepine	Ames test Result: Positive in one of five bacterial strains.
Carbamazepine	Dominant lethal test Result: Negative. Species: Mouse
Oxcarbazepine	Micronucleus test Result: Negative. Mutagenicity: Chinese hamster ovary cells without activation Result: Increased chromosome aberrations and polyploidy. Mutagenicity: v79 Chinese hamster cells Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

Oxcarbazepine	>= 25 mg/kg/day Carcinogenicity Result: Increased hepatocellular carcinomas in females. Species: Rat >= 70 mg/kg/day Carcinogenicity Result: Increased hepatocellular adenomas. Species: Mouse
Carbamazepine	25 - 250 mg/kg/day Carcinogenicity Result: Dose-related increased incidence of hepatocellular tumors in females and benign interstitial cell adenomas in the testes of males. Species: Rat Test Duration: 2 years
Oxcarbazepine	250 mg/kg/day Carcinogenicity Result: Increased benign testicular interstitial cell tumors in males. Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child. Therapeutic use of anticonvulsant drugs during the first trimester of pregnancy has been associated with increased risk of fetal malformations.

Reproductivity

Oxcarbazepine	1000 mg/kg Reproductivity, Administered during gestation. Result: Embryofetal death; decreased fetal weight. Species: Rat 1100 mg/kg/day Reproductivity, Administered during gestation. Result: Increased malformations. Species: Mouse
Eslicarbazepine Acetate	150 - 650 mg/kg/day Developmental Result: Fetal malformations observed at all doses. Species: Mouse

Reproductivity

Oxcarbazepine	150 Reproductivity, Administered during gestation. Result: Reduction in body weight and altered behavior in offspring. Species: Rat
Carbamazepine	1500 mg/kg/day Reproductivity, Skeletal and soft tissue defects in offspring. Result: Positive Species: Mouse
	250 - 650 mg/kg Reproductivity, Offspring showed kinked ribs at the low dose and other anomalies, including cleft palate, at the high dose. Result: Positive Species: Rat
Oxcarbazepine	300 mg/kg Reproductivity, Administered during gestation. Result: Increased birth defects. Species: Rat
Eslicarbazepine Acetate	40 - 320 mg/kg/day Developmental Result: Increased incidences of skeletal variations at mid and high doses. Species: Rabbit
	65 - 250 mg/kg/day Developmental Result: Embryolethality observed at all doses. Species: Rat

Specific target organ toxicity - single exposure May cause damage to organs (nervous system).

Specific target organ toxicity - repeated exposure May cause damage to organs (liver) through prolonged or repeated exposure.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Carbamazepine (CAS 298-46-4)			
Aquatic			
Crustacea	EC50	Ceriodaphnia dubia	71 mg/l
		Daphnia	92 mg/l, 24 hours
Fish	LC50	Zebra danio (Danio rerio)	43 mg/l, 96 hours
			13.3 mg/l

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Carbamazepine	1.76 2.45

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. 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.

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 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 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.

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

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

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

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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.

US state regulations

California Proposition 65

WARNING: This product can expose you to Carbamazepine, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Carbamazepine (CAS 298-46-4) Listed: January 29, 1999

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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 09-05-2019

Revision date 09-17-2024

Version # 02

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