

1. Identification

Product identifier	Rivastigmine Tartrate	
Other means of identification		
Catalog number	1604858	
Chemical name	Carbamic acid, ethylmethyl-, 3-((1S)-1-(dimethylamino)ethyl)phenyl ester, (2R,3R)-2,3-dihydroxybutanedioate (1:1)	
Synonym(s)	Rivastigmine hydrogen tartrate	
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		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	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

Note	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
		
Signal word	Danger	
Hazard statement	Fatal if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	
Other hazards which do not result in classification	None known.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Rivastigmine Tartrate	Rivastigmine hydrogen tartrate	129101-54-8	100

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	Rinse mouth. Call a physician or poison control center immediately. 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

Gastrointestinal disturbances. Central nervous system effects..

Indication of immediate medical attention and special treatment needed

Overdose treatment should be symptomatic and supportive and may include the following:

1. Do NOT induce vomiting.
2. Administer activated charcoal as a slurry.
3. Administer atropine for cholinergic effects, such as bradycardia, bronchorrhea, and bronchospasm.
4. For bronchospasm, administer albuterol. For severe cardiovascular or bronchoconstrictor responses, administer epinephrine.
5. For acute lung injury, maintain ventilation and oxygenation and evaluate with frequent arterial blood gas or pulse oximetry monitoring. Early use of PEEP and mechanical ventilation may be needed.
6. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
7. Infuse isotonic fluid for hypotension. If hypotension persists, administer dopamine or norepinephrine.
8. For severe nausea or vomiting, administer antiemetics.
9. Dialysis (hemodialysis, peritoneal dialysis, or hemofiltration) would NOT be clinically indicated due to the short half-life of rivastigmine. [Meditext 2008 and PDR 2008]

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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.

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.

Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

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

Industrial Use Material

	Type	Value
Rivastigmine Tartrate (CAS 129101-54-8)	TWA	0.01 mg/m ³

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

White to off-white powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless or weak odor.

Odor threshold

Not available.

pH

3.5 (10 grams/liter)

Melting point/freezing point

251.6 - 267.8 °F (122 - 131 °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	Soluble.
Partition coefficient (n-octanol/water)	2.4 = log Pow (22 °C; OECD 107)
Auto-ignition temperature	698 °F (370 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Carbamate derivative.
Dust explosion properties	
Minimum ignition energy (MIE) - dust cloud	3 - 10 mJ (Mike3i test)
Molecular formula	C14H22N2O2 . C4H6O6
Molecular weight	400.43
Solubility (other)	Freely soluble in methanol; soluble in dichloromethane, ethanol, and acetonitrile; slightly soluble in octanol; and very slightly soluble in ethyl acetate.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Oxidizing agents. Acids. Bases.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Fatal if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics Nausea. Vomiting. Diarrhea. Constipation. Cramps. Bloating. Gas. Indigestion. Loss of appetite. Weight loss. Headache. Weakness. Drowsiness. Dizziness. Fainting. Depression. Confusion. Hallucinations. Insomnia. Sweating. Runny nose. General feeling of discomfort or illness.

Delayed and immediate effects of exposure Low blood pressure. Slow heartbeat.

Cross sensitivity Persons sensitive to carbamate derivatives may be sensitive to this material also.

Medical conditions aggravated by exposure Cardiac conduction disorders. History of seizures. Metabolic disorders. Urinary tract obstruction. Gastrointestinal tract obstruction. Peptic ulcer. Parkinson's disease.

Acute toxicity Fatal if swallowed.

Product	Species	Test Results
Rivastigmine Tartrate (CAS 129101-54-8)		
Acute		
Oral		
LD50	Rat	13 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Local effects		
Eye irritation test		
Result: Not irritating.		
Species: Rabbit		

Local effects

Skin irritation test
 Result: Not irritating.
 Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Based on available data, the classification criteria are not met.

Skin sensitization
 Skin sensitization test
 Result: Not sensitizing.
 Species: Guinea pig
 Skin sensitization test
 Result: Not sensitizing.
 Species: Mouse

Germ cell mutagenicity Due to lack of data the classification is not possible.
 Data from germ cell mutagenicity tests were not found.

Mutagenicity
 Ames test
 Result: Negative.
 Chromosomal aberration tests in Chinese hamster lung cells
 and human lymphocytes
 Result: Positive.
 HGPRT test in V79 Chinese hamster cells
 Result: Negative.
 In vivo mouse micronucleus test
 Result: Negative.
 Unscheduled DNA synthesis test in rat hepatocytes
 Result: Negative.

Carcinogenicity Based on available data, the classification criteria are not met.
 This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

1.1 mg/kg/day Carcinogenicity test, administered as base.
 Result: Not carcinogenic.
 Species: Rat
 1.6 mg/kg/day Carcinogenicity test, administered as base.
 Result: Not carcinogenic.
 Species: Mouse

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductivity
 1.1 mg/kg/day Reproductivity study, administered as base.
 Result: No adverse effects on fertility or reproductive
 performance.
 Species: Rat
 2.3 mg/kg/day Reproductivity study, administered during
 pregnancy as base.
 Result: No increase in birth defects.
 Species: Rabbit
 2.3 mg/kg/day Reproductivity study, administered during
 pregnancy as base.
 Result: No increase in birth defects. Slightly decreased
 fetal/pup weights at maternally toxic doses.
 Species: Rat

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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

12. Ecological information**Ecotoxicity**

Product	Species	Test Results
Rivastigmine Tartrate (CAS 129101-54-8)		
Acute		
Other	IC50 Pseudokirchnerella subcapitata	43 mg/l, 72 hours

Product	Species	Test Results
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 1.4 mg/l, 48 hours
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>) Rainbow Trout 31.8 mg/l, 96 hours > 100 mg/l, 96 hours

Persistence and degradability	Not readily degradable.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

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	Not available.
Hazardous waste code	Not regulated.
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

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Rivastigmine Tartrate)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Rivastigmine Tartrate)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

DOT; IATA



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 - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

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.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	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
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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 06-24-2009

Revision date 09-15-2015

Version # 03

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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Revision Information

First-aid measures: Most important symptoms/effects, acute and delayed
Physical & Chemical Properties: Multiple Properties
Toxicological information: Symptoms related to the physical, chemical, and toxicological characteristics
Transport Information: Material Transportation Information
GHS: Classification