

1. Identification

Product identifier	Aspartame	
Other means of identification		
Catalog number	1043706	
Chemical name	L-Phenylalanine, N-L-alpha-aspartyl-, 1-methyl ester	
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		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
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	Not classified.
OSHA hazard(s)	Not classified.
Label elements	
Hazard symbol	No symbol.
Signal word	Not available.
Hazard statement	Not available.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Aspartame		22839-47-0	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed	Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	Treatment of overdose treatment should be symptomatic and supportive and may include the following: Gastric decontamination is unlikely to be necessary unless very large amounts (greater than 10 grams) have been ingested. Single ingestions of less than 10 grams are unlikely to produce symptoms unless the person has phenylketonuria. Up to 100 mg/kg aspartame has been ingested without toxic effects. Administer activated charcoal as a slurry. In phenylketonurics, treat seizures with intravenous diazepam or lorazepam. Consider phenobarbital if seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. [Meditext 2006]
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	
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
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.
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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Off-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	5.3 (0.8% solution in water)
Melting point/freezing point	474.8 - 482 °F (246 - 250 °C) (also reported as 190 °C and 196 °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 (%)	11 %
Flammability limit - upper (%)	3 %
Explosive limit - lower (%)	3 %
Explosive limit - upper (%)	17.5 %
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Sparingly soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Dipeptide ester.
Molecular formula	C ₁₄ H ₁₈ N ₂ O ₅
Molecular weight	294.3
Solubility (other)	Slightly soluble in alcohol; practically insoluble in dichloromethane and in hexane.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	NO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
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 Gastrointestinal disturbances. Headache. Fever. Dizziness. Hives. Inflammation of eyes, lips, or skin. Swelling.

Medical conditions aggravated by exposure Phenylketonuria (PKU).

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

Product	Species	Test Results
----------------	----------------	---------------------

Aspartame (CAS 22839-47-0)

Oral

LD50

Mouse

> 10 g/kg

Rat

> 10 g/kg

> 4 g/kg

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 Due to lack of data the classification is not possible.

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.

Mutagenicity

Dominant lethal test
Result: Negative.
Species: Rodent

Carcinogenicity

Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. Aspartame was approved as an artificial sweetener by the FDA in 1981, after numerous tests showed that it did not cause cancer or other adverse effects in laboratory animals.

In 1996, a report suggested that an increase in the number of people with brain tumors between 1975 and 1992 might be associated with the introduction and use of the sweetener in the U.S. However, an analysis of National Cancer Institute statistics showed that the overall incidence of brain and central nervous system cancers began to rise in 1973, 8 years before the approval of aspartame.

In 2005, a long-term carcinogenicity study found that aspartame caused cancer at 20 mg/kg when administered with feed to Sprague-Dawley rats over their natural lifetime. The European Food and Safety Authority and the FDA concluded in 2006 that this study did not provide a scientific basis for reconsidering the safety of aspartame's use in foods, due to all the available data to date, and issues in the 2005 study, including the high background incidence of chronic inflammatory disease in the rats, no clear dose-response relationship of the nerve tumors and exposure, and other major concerns.

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

Reproductivity

14 - 1614 mg/kg/day Reproductivity study
Result: Perinatal exposure by pregnant rats did not affect reflex development, morphological development, or spatial memory in the offspring.
Species: Rat

500 - 4000 mg/kg/day Reproductivity study
Result: No physical or functional developmental problems in the offspring.
Species: Mouse

500 mg/kg Reproductivity study
Result: Disruption of odor-associative learning in 15 day old offspring.
Species: Guinea pig

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

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

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).
Persistence and degradability No data is available on the degradability of this product.
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 available.
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 a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.
All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

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.

International Inventories

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

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

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 07-01-2006

Revision date 03-18-2015

Version # 02

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.

Disclaimer USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information This document has undergone significant changes and should be reviewed in its entirety.