SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	**ASPARTAME, NF**
PRODUCT CODE	**3098**
SUPPLIER	**MEDISCA Inc.** Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 **MEDISCA Pharmaceutique Inc.** Tel.: 1.800.665.6334 | Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 **MEDISCA Australia PTY LTD** Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.
PICTOGRAM	Not Applicable
SIGNAL WORD	Not applicable
HAZARD STATEMENT(S)	Not applicable
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)

Prevention	Not applicable
Response	Not applicable
Storage	Not applicable
Disposal	Not applicable

HMIS CLASSIFICATION

Health Hazard	0	**Flammability**	0
Reactivity	0	**Personal Protection**	A

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	(3S)-3-amino-3-{[(2S)-1-methoxy-1-oxo-3-phenylpropan-2-yl]carbamoyl}propanoic acid
BOTANICAL NAME	Not applicable
SYNONYM	L-Phenylalanine; N-L-alpha-aspartyl-; 1-methyl ester
CHEMICAL FORMULA	$C_{14}H_{18}N_2O_5$
CHEMICAL FAMILY	Dipeptide ester
CAS NUMBER	22839-47-0
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	294.3052

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ASPARTAME	22839-47-0	245-261-3	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	In a small quantities this product does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous. Upper/lower flammability or explosive limits: Flammability limit - lower (%): 11 % Flammability limit - upper (%): 3 % Explosive limit - lower (%): 3 % Explosive limit - upper (%): 17.5 %
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	**Small fire:** dry chemical, CO_2 or water spray. **Large fire:** dry chemical, CO_2, alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.
Store between 15 - 30°C and 35 - 60 % relative humidity.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ASPARTAME CAS #: 22839-47-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available
PELs are 8-hour TWAs = Limit value - Eight hours
Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES	Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.
PERSONAL PROTECTIVE EQUIPMENT	**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.
SPECIFIC ENGINEERING CONTROLS	Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.
BIOLOGICAL MONITORING	Not available
CONTROL BANDING	Not available
NOTES	Particles otherwise not classified ACGIH TLV: 10 mg/m³ (inhalable) 8-hour TWA 3 mg/m³ (respirable) 8-hour TWA This product is not likely to present an airborne exposure concern under normal use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid
DESCRIPTION	White, odorless, crystalline powder.
SOLUBILITY	Sparingly soluble in water; slightly soluble in alcohol.
ODOR	Odorless
FLAMMABILITY	May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	**BOILING POINT**	Not available	**DECOMPOSITION TEMPERATURE**	Not available
EVAPORATION RATE	Not available	**EXPLOSIVE LIMIT**	Not available	**FLASH POINT**	Not available
log P (OCTANOL-WATER)	0.070	**LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	11 %	**MELTING/FREEZING POINT**	(246-250)°C, (474.8-482)°F
PARTICLE CHARACTERISTICS	Not available	**OXIDIZING PROPERTY**	Not available	**pH**	5.3 (0.8%)
RELATIVE DENSITY (WATER = 1)	Not available	**SPECIFIC GRAVITY**	Not available	**UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	3 %
VAPOR DENSITY (AIR = 1)	Not available	**VAPOR PRESSURE**	< 0.0000001 kPa (25°C)	**VISCOSITY**	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions. In the presence of moisture aspartame hydrolyses to form aspartylphenylalanine and a diketopiperazine derivative, with a resulting loss of sweetness.
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBLITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 5000 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available	
SKIN CORROSION/IRRITATION	Due to lack of data classification is not possible.	
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data classification is not possible.	
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.	
SKIN SENSITIZATION	Due to lack of data classification is not possible. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer(moderate reliability).	
GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met. Suspected mutagen: equivocal mutagenicity data according to ISSSTY Dominant lethal test. Result: Negative. Species: Rodent	
CARCINOGENICITY	**OSHA**	ASPARTAME is not listed.
	NTP	ASPARTAME is not listed.
	IARC	ASPARTAME is not evaluated.
	California Proposition	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Due to lack of data the classification is not possible.
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. 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 classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Due to lack of data classification is not possible.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	ROUTES OF EXPOSURE: Oral EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available 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).
POTENTIAL HEALTH EFFECTS	**Inhalation**: May be harmful if inhaled. May cause respiratory tract irritation. **Ingestion**: May be harmful if swallowed. No significant adverse health effects are expected to develop if only small amounts, (less than a mouthful) are swallowed. Mild gastrointestinal side effects including diarrhea have been reported. **Skin**: May be harmful if absorbed through skin. May cause skin irritation. May cause sensitisation dermatitis. **Eyes**: May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is NON Readily Biodegradable (moderate reliability). The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
BIOACCUMULATIVE POTENTIAL	Log Pow: 0.070
MOBILITY IN SOIL	Sparingly soluble in water. Henry's Law Constant: 2.53E-18 atm-m3/mole (25°C)
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment

NOTES	Suspected hazardous to the aquatic environment: Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform predicts that the chemical is Toxic2 (between 1 and 10 mg/l) (good reliability)

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

HAZCHEM	Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusett	California Prop 65
ASPARTAME 22839-47-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ASPARTAME 22839-47-0	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ASPARTAME 22839-47-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT	Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES	Available upon request
ABBREVIATIONS AND ACRONYMS	**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Instituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System
LAST REVISION	01/2023
SUPERSEDES	04/2021
	For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com
DISCLAIMER	This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.
SUPPLEMENTARY INFORMATION	For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.