SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	**ASCORBYL PALMITATE, NF**
PRODUCT CODE	**0908**
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	Acute Aquatic Toxicity (Category 3)	
PICTOGRAM	Not Applicable	
SIGNAL WORD	Not applicable	
HAZARD STATEMENT(S)	Harmful to aquatic life.	
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable	
PRECAUTIONARY STATEMENT(S)	**Prevention**	Avoid release to the environment.
	Response	Not applicable
	Storage	Not applicable
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard	0	**Flammability**	1
Reactivity	0	**Personal Protection**	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	L-Ascorbic acid, 6-hexadecanoate
BOTANICAL NAME	Not applicable

SYNONYM	L-Ascorbic acid 6-palmitate; Vitamin C Palmitate
CHEMICAL FORMULA	$C_{22}H_{38}O_7$
CHEMICAL FAMILY	Carboxylic acid derivative.
CAS NUMBER	137-66-6
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	414.5352

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ASCORBYL PALMITATE	137-66-6	205-305-4	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	Not applicable
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

Preserve in tight containers, protected from light, in a dry place.

Store at 2° - 8°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ASCORBYL PALMITATE CAS #: 137-66-6

	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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid
DESCRIPTION	White to yellowish white powder, having a characteristic odor.
SOLUBILITY	Very slightly soluble in water and in vegetable oils; soluble in alcohol.
ODOR	Characteristic odor
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**	>93.3 °C, >199.9 °F (Closed Cup)
log P (OCTANOL-WATER)	Not available	**LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available	**MELTING/FREEZING POINT**	(107 - 117)°C, (224.6-242.6)°F
PARTICLE CHARACTERISTICS	Not available	**OXIDIZING PROPERTY**	Not available	**pH**	Not available
RELATIVE DENSITY (WATER = 1)	Not available	**SPECIFIC GRAVITY**	Not available	**UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available
VAPOR DENSITY (AIR = 1)	Not available	**VAPOR PRESSURE**	Not available	**VISCOSITY**	Not available

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

NOTES

0.15-0.25 g/cm3 (bulk density)
0.40-0.50 g/cm3 (tapped density)

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide 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): Not available Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available	
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. 10 % Irritancy test; Result: Non-irritant; Species: Rabbit; Organ: Skin (intact)	
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met.	
RESPIRATORY SENSITIZATION	Due to lack of data, the classification is not possible.	
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Human exposure studies of 119 subjects were enrolled in a modified Draize assay for skin sensitization potential, the study concluded that under the conditions of this study, that 1-5% ascorbyl palmitate was not sensitizing.	
GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met.	
CARCINOGENICITY	**OSHA**	ASCORBYL PALMITATE is not listed.
	NTP	ASCORBYL PALMITATE is not listed.
	IARC	ASCORBYL PALMITATE is not evaluated.
	California Proposition 65	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	Based on available data, the classification criteria are not met. Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity.	
REPRODUCTIVE TOXICITY	Based on available data, the classification criteria are not met.	
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 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: Nausea. Vomiting. Stomach cramps. Diarrhea. Flushing. Headache. Increased urination. Ascorbyl palmitate used as a chemical preservative in food for human consumption is generally recognized as safe when used in accordance with good manufacturing practice. Ascorbyl palmitate used as a chemical preservative in animal drugs, feeds, and related products is generally recognized as safe when used in accordance with good manufacturing or feeding practice.	
POTENTIAL HEALTH EFFECTS	**Inhalation**	May be harmful if inhaled. May cause respiratory tract irritation.
	Ingestion	May be harmful if swallowed.
	Skin	May be harmful if absorbed through skin. May cause skin irritation
	Eyes	May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): 51 mg/L (Rainbow trout) EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	TERRESTRIAL FATE: Based on a classification scheme(1), an estimated Koc value of 450(SRC), determined from a structure estimation method(2), indicates that ascorbyl palmitate is expected to have moderate mobility in soil(SRC). Volatilization of ascorbyl palmitate from moist soil surfaces is not expected to be an important fate process(SRC) given an estimated Henry's Law constant of 1.4X10-7 atm-cu m/mole(SRC), using a fragment constant estimation method(3). Ascorbyl palmitate is not expected to volatilize from dry soil surfaces(SRC) based upon an estimated vapor pressure of 2.09X10-15 mm Hg at 25 deg C(SRC), determined from a fragment constant method(4). Biodegradation data in soil were not available(SRC, 2010).
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment
NOTES	AQUATIC FATE: Based on a classification scheme(1), an estimated Koc value of 450(SRC), determined from a structure estimation method(2), indicates that ascorbyl palmitate is expected to adsorb to suspended solids and sediment(SRC). Volatilization from water surfaces is not expected(3) based upon an estimated Henry's Law constant of 1.4X10-7 atm-cu m/mole(SRC), developed using a fragment constant estimation method(4). According to a classification scheme(5), an estimated BCF of 180(SRC), from an estimated log Kow of 6.0(6) and a regression-derived equation(2), suggests the potential for bioconcentration in aquatic organisms is high, provided the compound is not metabolized by the organism(SRC). Biodegradation data in water were not available(SRC, 2010). ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere(1), ascorbyl palmitate, which has an estimated vapor pressure of 2.09X10-15 mm Hg at 25 deg C(SRC), determined from a fragment constant method(2), is expected to exist solely in the particulate phase in the ambient atmosphere. Particulate-phase ascorbyl palmitate may be removed from the air by wet or dry deposition(SRC). Ascorbyl palmitate does not contain chromophores that absorb at wavelengths >290 nm(3), and therefore is not expected to be susceptible to direct photolysis by sunlight(SRC).

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 Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Right-to-know Pennsylvania	Right-to-know New Jersey	Right-to-know Massachusetts	California Prop 65
ASCORBYL PALMITATE 137-66-6	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 Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ASCORBYL PALMITATE 137-66-6	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
ASCORBYL PALMITATE 137-66-6	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 07/2025

SUPERSEDES 10/2023

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.