

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 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 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	Manufacturing and Compounding
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	
HMS CLASSIFICATION	Health Hazard	1	Flammability 1
	Reactivity	0	Personal Protection B

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

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.
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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 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/m ³	ppm	mg/m ³				
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.

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
POSSIBILITY 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): Not available

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 1.4×10^{-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 2.09×10^{-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 1.4×10^{-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 2.09×10^{-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		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
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

