


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CETYL ALCOHOL, NF
PRODUCT CODE	0618
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	Skin Irritation (Category 2) Eye Irritation (Category 2B) Acute Toxicity - Oral (Category 5) Acute Toxicity - Dermal (Category 5)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	Causes skin irritation. Causes eye irritation. May be harmful if swallowed. May be harmful if in contact with skin. May cause long lasting harmful effects to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable
PRECAUTIONARY STATEMENT(S)	Prevention Wash hands thoroughly after handling. Do not touch eyes. Wear protective gloves. Avoid release to the environment.

Response IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help.
IF SWALLOWED: Get medical help.
IF ON SKIN: Get medical help.

Storage Not applicable

Disposal Dispose of contents/container to in accordance with local regulation.

HMIS CLASSIFICATION

Health Hazard 1

Flammability 1

Reactivity 0

Personal Protection D

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 1-Hexadecanol
BOTANICAL NAME Not applicable
SYNONYM Palmityl alcohol; 1-hexadecyl alcohol
CHEMICAL FORMULA C₁₆H₃₄O
CHEMICAL FAMILY Linear aliphatic derivatives
CAS NUMBER 36653-82-4
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT 242.44

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
CETYL ALCOHOL	36653-82-4	253-149-0	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, CO₂ or water spray. **Large fire:** dry chemical, CO₂, 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.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CETYL ALCOHOL CAS #: 36653-82-4

	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

NOTES

GESTIS: Germany (ACS)
 LV (8 Hr)* - 20 ppm ; 200 mg/m³
 LV (15 Min)* - 20 ppm ; 200 mg/m³
 *Inhalable aerosol and vapour

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Unctuous, white flakes, granules, cubes, or castings. Has a faint characteristic odor.

SOLUBILITY

Insoluble in water; soluble in alcohol and in ether, the solubility increasing with an increase in temperature.

ODOR

Faint characteristic odor

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

251°C, 483.8°F

BOILING POINT

> 248.89°C,
480°F

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

113°C, 235.4°F
c.c.

log P (OCTANOL-WATER)

6.7 (20°C)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

1 %

MELTING/FREEZING POINT

(45-50)°C,
(113-122)°F

PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.8187 (50°C)	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	8 %
VAPOR DENSITY (AIR = 1)	8.36	VAPOR PRESSURE	< 0.0000001 kPa (30°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
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Strong mineral acids.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Reactive with oxidizing agents, acids.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 2000 Dermal: Rabbit LD50: (mg/kg): > 2600 Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Causes skin irritation. Local effects 100 mg/kg/day, Irritancy test; Result: Irritant; Species: Rabbit; Organ: Skin; Severity: Severe. 0.2%, Irritancy test; Result: Irritant; Species: Human; Organ: Skin; Severity: Severe 75 mg/3D-I, Irritancy test; Result: Irritant; Species: Human; Organ: Skin; Severity: Mild.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation. Local effects 82 mg/kg Irritancy test; Result: Irritant.; Species: Rabbit; Organ: Eye; Severity: Mild.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Maximization test; Result: Non-sensitizing.; Species: Guinea pig Maximization test; Result: Non-sensitizing.; Species: Human Hypersensitivity reactions have occasionally occurred.
GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met.
CARCINOGENICITY	OSHA CETYL ALCOHOL is not listed. NTP CETYL ALCOHOL is not listed.

ADDITIONAL CARCINOGENICITY INFORMATION	IARC CETYL ALCOHOL is not evaluated.
REPRODUCTIVE TOXICITY	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. Due to lack of data the classification is not possible.
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 HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eyes EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available Symptoms related to the physical, chemical, and toxicological characteristics: Diarrhea. Nausea. Vomiting. May affect cardiovascular system, respiration and behaviour/central nervous system (tremor, ataxia). Hypersensitivity reactions have occasionally occurred.
POTENTIAL HEALTH EFFECTS	Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Ingestion May be harmful if swallowed. If ingested, may cause hypermotility and diarrhoea. Skin May be harmful if absorbed through skin. Causes skin irritation. Skin inflammation is characterized by itching, scaling, reddening, or occasionally, blistering. Eyes Causes 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	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
BIOACCUMULATIVE POTENTIAL	High: Log Pow: 6.7 (20°C)
MOBILITY IN SOIL	Insoluble in water
OTHER ADVERSE EFFECTS	May cause long lasting harmful effects to aquatic life. This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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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		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
CETYL ALCOHOL 36653-82-4	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
CETYL ALCOHOL 36653-82-4	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
CETYL ALCOHOL 36653-82-4	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 Abstract 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** – Istituto 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

02/2023

SUPERSEDES

11/2022

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.