


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | ISOPROPYL MYRISTATE, NF |
| PRODUCT CODE | 0906 |
| 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 Toxicity - Dermal (Category 5) Acute Toxicity - Oral (Category 4) Acute Toxicity - Inhalation (Category 5) Skin Irritation (Category 3) Eye Irritation (Category 2B) Chronic Aquatic Toxicity (Category 3) |
| PICTOGRAM |  |
| SIGNAL WORD | Warning |
| HAZARD STATEMENT(S) | May be harmful if in contact with skin. Causes mild skin irritation. Causes eye irritation. May cause an allergic reaction Harmful if swallowed. May be harmful if inhaled. Harmful to aquatic life with long lasting effects. |
| 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. Do not eat, drink or smoke when using this product. Avoid release to the environment. | | |
| | Response | 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: Immediately call a poison center. Get medical help. Rinse mouth. IF INHALED: Get medical help. IF SKIN IRRITATION OCCURS: Get medical help. | | |
| | Storage | Not applicable | | |
| | Disposal | Dispose of contents/container in accordance with local regulations. | | |
| HMS CLASSIFICATION | Health Hazard | 1 | Flammability | 1 |
| | Reactivity | 0 | Personal Protection | B |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME | Tetradecanoic acid, 1-methylethyl ester | | | | | | | | |
|-----------------------------|---|---------------|-------------|-----------|-------------|---------------------|----------|-----------|-----|
| BOTANICAL NAME | Not applicable | | | | | | | | |
| SYNONYM | Myristic acid, isopropyl alcohol ester; Isopropyl tetradecanoate | | | | | | | | |
| CHEMICAL FORMULA | C ₁₇ H ₃₄ O ₂ | | | | | | | | |
| CHEMICAL FAMILY | Linear aliphatic derivative; fatty acid ester | | | | | | | | |
| CAS NUMBER | 110-27-0 | | | | | | | | |
| ALTERNATE CAS NUMBER | Not applicable | | | | | | | | |
| MOLECULAR WEIGHT | 270.4536 | | | | | | | | |
| COMPOSITION | <table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>ISOPROPYL MYRISTATE</td> <td>110-27-0</td> <td>203-751-4</td> <td>100</td> </tr> </tbody> </table> | CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | ISOPROPYL MYRISTATE | 110-27-0 | 203-751-4 | 100 |
| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | | | | | | |
| ISOPROPYL MYRISTATE | 110-27-0 | 203-751-4 | 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

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| 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 breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers.

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.

The freezing point of Isopropyl Myristate, NF is 13.3 °C (56 °F). Product is not affected by cycling between freezing and thawing conditions as long as label directions are followed.

Product can be left at room temperature or in a controlled-temperature water bath to thaw. Gently stir or tumble the container to ensure it is homogenous.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: ISOPROPYL MYRISTATE CAS #: 110-27-0

| | 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

Liquid

DESCRIPTION

Clear, practically colorless, oily liquid. Is practically odorless and congeals at about 5°C.

SOLUBILITY

Freely soluble in 90% alcohol; insoluble in water, in glycerin, and in propylene glycol. Miscible with most organic solvents and with fixed oils.

ODOR

Practically odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

225 °C, 437 °F

BOILING POINT

 192.6°C,
378.68°F (20
mmHg)

DECOMPOSITION TEMPERATURE

Not available

| | | | | | |
|-------------------------------------|---------------|---|---------------|---|----------------------------------|
| EVAPORATION RATE | Not available | EXPLOSIVE LIMIT | Not available | FLASH POINT | 153.5°C, 308.3°F (closed cup) |
| log P (OCTANOL-WATER) | 7.17 (20°C) | LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) | 0.5 % | MELTING/FREEZING POINT | 13.34 °C, 56.012 °F |
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | 6.5 - 7.5 (5%) |
| RELATIVE DENSITY (WATER = 1) | 0.853 | SPECIFIC GRAVITY | 0.846 - 0.854 | UPPER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available |
| VAPOR DENSITY (AIR = 1) | 9.4 | 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

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|--|--|
| REACTIVITY | Not established |
| CHEMICAL STABILITY | Stable under recommended storage conditions |
| INCOMPATIBLE MATERIALS | Strong oxidants, acids, bases. Hard paraffin. |
| 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): 2000 Dermal: Rabbit LD50: (mg/kg): 5000 Inhalation: Rat: LC50: (mg/L/4hr): 5.3 |
| SKIN CORROSION/IRRITATION | Causes mild irritation 100 mg Irritancy test (Draize): Result: Irritant.: Species: Guinea pig: Organ: Skin.: Severity: Moderate. 426 mg Irritancy test (Draize): Result: Irritant.: Species: Rabbit: Organ: Skin.: Severity: Mild. 85 mg Irritancy test (Draize): Result: Irritant.: Species: Human: Organ: Skin.: Severity: Mild. |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Causes eye irritation. Irritancy test (Draize): 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.
 Guinea Pig: Skin: Skin sensitization; Magnusson & Kligman sensitization test: Result: Non-sensitizing.
 Guinea pig: Skin: Maximization test: Result: Non-sensitizing.
 Human: Skin: Patch test: Result: Non-sensitizing.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA ISOPROPYL MYRISTATE is not listed.
NTP ISOPROPYL MYRISTATE is not listed.
IARC ISOPROPYL MYRISTATE 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

Based on available data, the classification criteria are not met.
 < 850 mg/kg Carcinogenicity study
 Result: Benign skin tumors.
 Species: Mouse
 Test Duration: 110 weeks

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
 500 - 2000 mg/kg/day Reproductivity study
 Result: No developmental toxicity was observed.
 Species: Rat

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

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
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. Abdominal pain. Defatting of the skin. Dry skin. Red, scaly skin.

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. Causes mild skin irritation. Sensitivity reactions have been reported.
Eyes Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): > 100
 LC50: 96 Hr: Fish: (mg/L): 8400
 EC50: 72 Hr: Algae (or other aqua plants): (mg/L): 100

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

LogPow: 7.17 (20°C)

MOBILITY IN SOIL

Water Solubility: 0.050 mg/L (25°C)

OTHER ADVERSE EFFECTS

 Henry's Law Constant: 9.26E-03atm-m³/mole (25°C)

Not available

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.

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 | |
| ISOPROPYL MYRISTATE, 110-27-0 | 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 |
|----------------------------------|-------------------------------------|--------------------------|--|---------------------|--|---|
| ISOPROPYL MYRISTATE, 110-27-0 | 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 |
|-------------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| ISOPROPYL MYRISTATE, 110-27-0 | 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
ABBREVIATIONS AND ACRONYMS

Available upon request

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** – 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

03/2023

SUPERSEDES

03/2022

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.