SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: TRETINOIN, USP (Retinoic Acid)
PRODUCT CODE: 0001
SUPPLIER:
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
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

USES:
Keratolytic; antineoplastic.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
Acute Toxicity - Oral (Category 4)
Acute Toxicity - Dermal (Category 5)
Toxic to Reproduction (Category 1A)
Skin Irritation (Category 2)
Chronic Aquatic Toxicity (Category 1)

PICTOGRAM:

SIGNAL WORD:
Warning

HAZARD STATEMENT(S):
Harmful if swallowed.
May be harmful if in contact with skin.
Causes skin irritation.
Causes serious eye irritation.
Suspected of damaging fertility or the unborn child.
Very toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENT(S):
Prevention
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye protection, face protection.
Avoid release to the environment.

Response
IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
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 EXPOSED OR CONCERNED: Get medical advice/attention.
Collect spillage.
SAFETY DATA SHEET

Section 3: Composition/Information on Ingredients

**Chemical Name:** Tretinoin (Retinoic Acid)

**Botanical Name:** Not applicable

**Synonym:** Vitamin A acid, all-trans-Retinoic acid

**Chemical Formula:** C₂₀H₂₈O₂

**CAS Number:** 302-79-4

**Alternate CAS Number:** Not applicable

**Molecular Weight:** 300.44

**Composition:**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>% by Weight</th>
</tr>
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<tbody>
<tr>
<td>Tretinoin (Retinoic Acid)</td>
<td>302-79-4</td>
<td>100</td>
</tr>
</tbody>
</table>

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.

**Symptoms and Effects:**
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.

**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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: TRETINOIN (Retinoic Acid) CAS #: 302-79-4

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<td>OSHA PEL</td>
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<td>N/L</td>
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<td>ACGIH TLV</td>
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<td>N/L</td>
<td>N/L</td>
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<td>NIOSH</td>
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<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>HSE</td>
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<td>N/L</td>
<td>-</td>
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<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits.

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.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES

USP: TWA: 0.001 mg/m3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid
SAFETY DATA SHEET

Description: Yellow to light-orange crystalline powder.

Solubility: Slightly soluble in alcohol, in chloroform, and in methanol; insoluble in water.

Odor: Not available.

Flammability: May be combustible at high temperature

Odor Threshold: Not available

Boiling Point: Not available

Freezing Point: Not available

Specific Gravity: Not available

Upper Flammable/Explosive Limit(s): Not available

Lower Flammable/Explosive Limit(s): Not available

Vapor Density (Air = 1): Not available

Relative Density (Water = 1): Not available

Auto-Ignition Temperature: 265 °C, 509 °F

Decomposition Temperature: Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not established

Stability: Stable under recommended storage conditions

Materials to Avoid: Strong oxidants

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: 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): > 2500

Inhalation: Rat: LD50: (mg/L/4hr): Not available

Skin Corrosion/Irritation: 525 mg Irritation test

Result: Irritant.

Species: Human

Organ: Skin

Severity: Mild

Serious Eye Damage/Eye Irritation: Due to lack of data the classification is not possible.
SAFETY DATA SHEET

RESPIRATORY OR SKIN SENSITIZATION
Due to lack of data the classification is not possible.

GERM CELL MUTAGENICITY
Due to lack of data the classification is not possible.

CARCINOGENICITY

<table>
<thead>
<tr>
<th>Source</th>
<th>Classification</th>
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<tbody>
<tr>
<td>OSHA</td>
<td>TRETINOIN (Retinoic Acid) is not listed.</td>
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<tr>
<td>NTP</td>
<td>TRETINOIN (Retinoic Acid) is not listed.</td>
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<tr>
<td>IARC</td>
<td>TRETINOIN (Retinoic Acid) is not evaluated.</td>
</tr>
<tr>
<td>California</td>
<td>Proposition 65</td>
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</tbody>
</table>

This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: TRETINOIN (Retinoic Acid).

ADDITIONAL CARCINOGENICITY INFORMATION

- 30 mg/kg/day Carcinogenicity test
- Result: Increased rate of adenomas and carcinomas.
- Species: Mouse

REPRODUCTIVE TOXICITY
May damage fertility or the unborn child. This material has caused adverse fetal effects in animal studies.

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
Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Symptoms related to the physical, chemical, and toxicological characteristics
- Rash
- Fever
- Weakness
- Fatigue
- Fast heartbeat
- Irregular breathing
- Shortness of breath
- Dry eyes
- Dry mouth
- Dry skin
- Bone pain
- Nausea
- Vomiting
- Mouth sores
- Itching
- Sweating
- Visual disturbances
- Hearing problems
- Hair loss
- Loss of appetite
- Flushing
- Abdominal pain
- Dizziness
- Depression

Delayed and immediate effects of exposure
- High blood pressure
- Low blood pressure
- Blood disorders
- Liver damage
- Spleen disorders
- Cross sensitivity: Persons sensitive to acitretin, etretinate, isotretinoin, or other retinoids may be sensitive to tretinoin also.

Medical conditions aggravated by exposure
- Skin disorders
- Acute promyelocytic leukemia
- Leukocytosis
- Respiratory disorders

SIGNS AND SYMPTOMS OF EXPOSURE

- May be harmful if inhaled. May cause respiratory tract irritation.
- May be harmful if swallowed.
- May be harmful if absorbed through skin. Causes skin irritation. Topical application may cause transitory stinging and a feeling of warmth, and in normal use it produces some erythema, dryness, pruritus, and peeling similar to that of mild sunburn. Sensitive individuals may experience oedema, blistering, and crusting of the skin. Excessive application can cause severe erythema, peeling, and discomfort. Photosensitivity may occur. Temporary hypopigmentation and hyperpigmentation have been reported.
- Causes serious eye irritation

SECTION 12: ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>TOXICITY</th>
<th>LC50: 96 Hr: Fish: (mg/L): 0.2 - 4.6</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>IC50: 72 Hr: Algae: (mg/L): Not available</td>
</tr>
<tr>
<td></td>
<td>EC50: 48 Hr: Daphnia magna: (mg/L): 0.1 - 3.1</td>
</tr>
</tbody>
</table>

PERSISTENCE AND DEGRADABILITY
- Biodegradability: 50 - 60 %

BIOACCUMULATIVE POTENTIAL
Log Pow: 6.3 (20°C)

MOBILITY IN SOIL
- Insoluble in water
- Henry's Law Constant: 9.50E-06 atm-m3/mole (25°C)
SAFETY DATA SHEET

OTHER ADVERSE EFFECTS

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life.

This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

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

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
UN NUMBER: 3077
CLASS: 9
PACKING GROUP: III

AUSTRALIA

UN PROPER SHIPPING NAME: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
UN NUMBER: 3077
CLASS: 9
PACKING GROUP: III
HAZCHEM: 2Z

ENVIRONMENTAL HAZARDS

Not applicable

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRETINOIN (Retinoic Acid) 302-79-4</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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<tr>
<td>TRETINOIN (Retinoic Acid) 302-79-4</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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</tr>
</tbody>
</table>

Last Revision: 11/2015
SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION
11/2015

SUPERSEDES
04/2015

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.