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

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; dermatological applications.

SECTION 2: HAZARDS IDENTIFICATION

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

PICTOGRAM:

SIGNAL WORD: Danger

HAZARD STATEMENT(S):
Cytotoxic! Extremely hazardous to all tissues.
Harmful if swallowed.
May be harmful if in contact with skin.
May damage fertility or the unborn child.
Suspected of causing cancer
Causes skin irritation.
Causes serious eye irritation.
Very toxic to aquatic life with long lasting effects.

AUSTRALIA-ONLY HAZARDS: Not Available.

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.
SAFETY DATA SHEET

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 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 advice/attention.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

COLLECT SPILLAGE

Response

Storage
Store locked up.

Disposal
Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

<table>
<thead>
<tr>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Reactivity</th>
<th>Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>K</td>
</tr>
</tbody>
</table>

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
Tretinoin

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>
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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.

NOTES
Chemical family: Retinoid.

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 at any time there is skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water for 15 minutes. The worker should not scrape or abrade the skin by using a scrub brush as this could increase exposure. It is always recommended to seek a medical evaluation by a physician.

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
Refer to section 11

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Not applicable
SAFETY DATA SHEET

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, 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. The use of chemical inactivates is not recommended as they may create a hazardous by-product. All contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner.

CLEANUP PROCEDURE
A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Cytotoxic! Extremely hazardous to all tissues. Avoid all contact. 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.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: TRETINOIN (Retinoic Acid)</th>
<th>CAS #: 302-79-4</th>
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<tbody>
<tr>
<td><strong>OSHA PEL</strong></td>
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<tr>
<td><strong>ACGIH TLV</strong></td>
<td>N/L</td>
</tr>
<tr>
<td><strong>NIOSH</strong></td>
<td>N/L</td>
</tr>
<tr>
<td><strong>AIHA WEEL</strong></td>
<td>N/L</td>
</tr>
<tr>
<td><strong>Safe Work Australia HSIS</strong></td>
<td>N/L</td>
</tr>
<tr>
<td><strong>HSE</strong></td>
<td>N/L</td>
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</table>

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

N/L = Not Listed

EXPOSURE GUIDELINES
Cytotoxic: There are no exposure limits set for cytotoxic drugs. Exposure must be kept to a minimum.
PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Chemical splash goggles, and if necessary, full-face protection. 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:** Protective gloves made of vinyl or nitrile rubber. Gloves should be changed frequently, or immediately if punctured, cut, or torn. It is also recommended that workers wear two pairs at a time for additional protection. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. A moisture resistant, long sleeved gown with elastic cuffs. To prevent the spread of medication, protective clothing should not be worn outside of the preparation area. **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. In cases where there is a possibility of the medication becoming airborne, a powered air purifying respirator is recommended.

SPECIFIC ENGINEERING CONTROLS

The following engineering controls should be put in place where cytotoxic medications are being used:

- A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs.
- The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication.
- Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location.
- Puncture proof containers for the disposal of needles, syringes and vials must be provided.
- Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

NOTES

Additional controls

Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should be completely prohibited in the preparation area.

USP: ELV: Industrial use: TWA: 0.001 mg/m³

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th><strong>PHYSICAL STATE</strong></th>
<th>Solid</th>
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</thead>
<tbody>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>Yellow to light-orange crystalline powder.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Slightly soluble in alcohol, in chloroform, and in methanol; insoluble in water.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
</tbody>
</table>

| **ODOR THRESHOLD** | Not available |
| **pH** | 8.2 |
| **MELTING POINT** | (178-184 °C, (352.4-363.2)°F |
| **BOILING POINT** | Not available |
| **FREEZING POINT** | (178-184 °C, (352.4-363.2)°F |
| **FLASH POINT** | Not available |
| **EVAPORATION RATE** | Not available |
| **EXPLOSIVE LIMIT** | Not available |
| **UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)** | Not available |
| **LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)** | Not available |
| **VAPOR PRESSURE** | 2.42E-07 mm Hg |
| **VAPOR DENSITY (AIR = 1)** | Not available |
| **RELATIVE DENSITY (WATER = 1)** | Not available |
| **log P (OCTANOL-WATER)** | 6.3 (20°C) |
### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>REACTIVITY</th>
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</tr>
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<tbody>
<tr>
<td>STABILITY</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>MATERIALS TO AVOID</td>
<td>Strong oxidants</td>
</tr>
<tr>
<td>HAZARDOUS DECOMPOSITION PRODUCTS</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td>HAZARDOUS POLYMERIZATION</td>
<td>Will not occur</td>
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<tr>
<td>POSSIBILITY OF HAZARDOUS REACTION</td>
<td>Not established</td>
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<tr>
<td>CONDITIONS TO AVOID</td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### SECTION 11: TOXICOLOGICAL INFORMATION

| ACUTE TOXICITY | Oral: Rat: LD50: (mg/kg): 2000  
Dermal: Rabbit LD50: (mg/kg): >2500  
Inhalation: Rat: LC50: (mg/L/4hr): Not available |
|----------------|------------------------------------------------|
| SKIN CORROSION/IRRITATION | Causes skin irritation.  
525 mg Irritation test; Result: Irritant; Species: Human; Organ: Skin; Severity: Mild |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Causes serious eye irritation. |
| RESPIRATORY OR SKIN SENSITIZATION | Due to lack of data the classification is not possible. |
| GERM CELL MUTAGENICITY | Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in exposed workers. |
| CARCINOGENICITY | OSHA: TRETINOIN (Retinoic Acid) is not listed.  
NTP: TRETINOIN (Retinoic Acid) is not listed.  
IARC: TRETINOIN (Retinoic Acid) is not evaluated.  
California Proposition 65: 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 | Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause cancer. However, many cytotoxic drugs are known to be: Genotoxic, Carcinogenic, Mutagenic.  
30 mg/kg/day Carcinogenicity test  
Result: Increased rate of adenomas and carcinomas.  
Species: Mouse |
SAFETY DATA SHEET

**REPRODUCTIVE TOXICITY**
Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility.

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

Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); DART database in the Toolbox reports that this substance as Known developmental potential.

**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

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

**POTENTIAL HEALTH EFFECTS**
- **Inhalation**: May be harmful if inhaled. May cause respiratory tract irritation.
- **Ingestion**: Harmful if swallowed.
- **Skin**: 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.
- **Eyes**: Causes serious eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**
- **EC50: 48 Hr:** Crustacea: Daphnia magna: (mg/L): 0.1 - 3.1
- **LC50: 96 Hr:** Fish: (mg/L): 0.2 - 4.6
- **EC50: 72 or 96Hr:** Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**
Biodegradability: 50 - 60 %

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
### BIOACCUMULATIVE POTENTIAL

Log Pow: 6.3 (20°C)

Suspected bioaccumulative: EpiSuite data included in the Toolbox contain at least one experimental log Kow value equal to or higher than 4.5; The Danish QSAR database contains information indicating that the substance is predicted as bioaccumulative (BCF > 2000 L/kg)

### MOBILITY IN SOIL

Insoluble in water. Water Solubility: 0.126 mg/L (25°C)

Vapor Pressure: 2.42E-07 mm Hg (25°C)

Henry's Law Constant: 9.50E-06 atm-m³/mole (25°C)

### OTHER ADVERSE EFFECTS

Suspected hazardous to the aquatic environment

This product is not intended to be released into the environment

### SECTION 13: DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL**

Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labelled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the government regulations for hazardous waste disposal. Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to government regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.

### 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

Last Revision: 06/2018

TRETINOIN, USP (Retinoic Acid)
SAFETY DATA SHEET

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

<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>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/L</td>
<td>N/L</td>
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</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>
<td>N/L</td>
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### 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
06/2018

#### SUPERSEDES
11/2015

#### 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.