SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: HYDROCORTISONE, USP/EP (Micronized)
PRODUCT CODE: 0009
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

MEDISCA UK Limited
Tel.: 0800.029.4641
33 St. James's Square, London, United Kingdom SW1Y 4JS

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

USES:
Glucocorticoid; anti-inflammatory (Hormone)

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
Eye Irritation (Category 2B)
Toxic to Reproduction (Category 2)
Sensitization - Respiratory (Category 1)
Sensitization - Skin (Category 1)
Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (endocrine system)

PICTOGRAM:

SIGNAL WORD: Danger

HAZARD STATEMENT(S):
Causes eye irritation.
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS:
Repeated exposure may cause skin dryness or cracking.
PRECAUTIONARY STATEMENT(S) Prevention
Avoid breathing dust, fume, gas, mist, vapors, and spray.
In case of inadequate ventilation wear respiratory protection.
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.
Contaminated work clothing must not be allowed out of the workplace.

Response
IF EXPOSED OR CONCERNED: Get medical advice/attention.
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional.
IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or medical professional.

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>
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<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>G</td>
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</table>

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
Pregn-4-ene-3, 20-dione,11,17,21-trihydroxy-, (11beta)-

BOTANICAL NAME
Not applicable

SYNONYM
Cortisol

CHEMICAL FORMULA
C₂₁H₃₀O₅

CAS NUMBER
50-23-7

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
362.463

COMPOSITION
<table>
<thead>
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<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
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<td>HYDROCORTISONE</td>
<td>50-23-7</td>
<td>200-020-1</td>
<td>100</td>
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</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: Corticosteroid.

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

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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. Preserve in well-closed containers. Store at controlled room temperature. Protected from light.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: HYDROCORTISONE  CAS #: 50-23-7

<table>
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<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>-</td>
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<td>-</td>
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<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
<td>N/L</td>
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Last Revision: 06/2019

HYDROCORTISONE, USP/EP (Micronized)
# SAFETY DATA SHEET

<table>
<thead>
<tr>
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<th>Safe Work Australia HSIS</th>
<th>HSE</th>
<th>GESTIS</th>
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<tbody>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed

## EXPOSITION 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.

## NOTES
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Manufacturer - OEL TWA-8 Hr: 100 µg/m³, Skin
USP: ELV: Industrial: TWA: 0.02 mg/m³

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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<tr>
<th>Physical State</th>
<th>Solid</th>
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<tbody>
<tr>
<td>Description</td>
<td>White to practically white odorless crystalline powder.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Very slightly soluble in water and ether; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Flammability</td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td>Auto-ignition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>215°C, 419°F</td>
</tr>
<tr>
<td>Evaporation Rate</td>
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<tr>
<td>Explosive Limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
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<tr>
<td>Log P (OCTANOL-WATER)</td>
<td>3.7 (20°C)</td>
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<tr>
<td>Lower Flammable/ Explosive Limit(S)</td>
<td>Not available</td>
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<tr>
<td>Melting/Freezing Point</td>
<td>(217 - 220)°C, (422.6-428)°F</td>
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<tr>
<td>Oxidizing Property</td>
<td>Not available</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
<td>pH</td>
<td>7.5 - 8.5</td>
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<tr>
<td>Relative Density (WATER = 1)</td>
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</tr>
<tr>
<td>Specific Gravity</td>
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</tr>
<tr>
<td>Upper Flammable/ Explosive Limit(S)</td>
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<tr>
<td>Vapour Density (AIR = 1)</td>
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<tr>
<td>Vapour Pressure</td>
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<tr>
<td>Viscosity</td>
<td>Not available</td>
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</table>

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**: Alkalis and strong acids. Strong oxidizing agents.
- **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. Protect from light

SECTION 11: TOXICOLOGICAL INFORMATION

- **ACUTE TOXICITY**: Oral: Rat: LD50: (mg/kg): 5000; Dermal: Rabbit LD50: (mg/kg): Not available; Inhalation: Rat: LC50: (mg/L/4hr): Not available
- **SKIN CORROSION/IRRITATION**: Due to lack of data the classification is not possible.
- **SERIOUS EYE DAMAGE/EYE IRRITATION**: Causes eye irritation. Local effects; Eye irritation study; Result: Minimal irritation.; Species: Rabbit
- **RESPIRATORY SENSITIZATION**: Due to lack of data the classification is not possible.
- **SKIN SENSITIZATION**: Decrease in the formation of antibodies and immunocompetent lymphocytes, inhibition of inflammatory response. There have been occasional reports of hypersensitivity reactions, and sometimes anaphylaxis, caused by corticosteroids. Reactions have occurred with any route, although the topical route is mainly involved. Due to lack of data the classification is not possible.
- **GERM CELL MUTAGENICITY**: Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
- **CARCINOGENICITY**: OSHA HYDROCORTISONE is not listed. NTP HYDROCORTISONE is not listed. IARC HYDROCORTISONE 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**: Due to lack of data the classification is not possible.
- **REPRODUCTIVE TOXICITY**: Suspected of damaging fertility or the unborn child. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.
- **SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**: Based on available data, the classification criteria are not met.
- **SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**: Causes damage to organs (endocrine system) through prolonged or repeated exposure.
- **ASPIRATION HAZARDS**: Based on available data, the classification criteria are not met.
SIGN AND SYMPTOMS OF EXPOSURE
Symptoms related to the physical, chemical, and toxicological characteristics:
Mineralocorticoid effects: Swelling, Confusion, Lightheadedness, Nausea, Vomiting, Numbness.
Tremors. Glucocorticoid effects: Bone fractures, Back pain, Joint pain or stiffness, Weakness, Increased appetite, Infection, Delayed wound healing, Thinning skin, Bruising, Purple lines on skin, Increased hair growth.
Acne, Redistribution of body fat, Menstrual irregularities, Impotence, Headache, Increased sweating, Eye pain, Change in vision, Mental or behavioral changes. Withdrawal effects: Fever, Muscle pain, Joint pain, Malaise.
Delayed and immediate effects of exposure:
Corticosteroids: Fluid and electrolyte imbalance, Cushing’s syndrome, Adrenal suppression, Immune system depression, Withdrawal.

Cross sensitivity:
Persons sensitive to one corticosteroid may be sensitive to this material also.
Medical conditions aggravated by exposure:
Corticosteroids: Heart disease, High blood pressure, Diabetes, Epilepsy, Glaucoma, Hypothyroidism, Osteoporosis, Peptic ulcer, Systemic fungal infection, Mental disorders, Impaired liver or kidney function.

POTENTIAL HEALTH EFFECTS
Inhalation
May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion
May be harmful if swallowed. Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, muscle cramps, weakness, nervousness, restlessness, trouble sleeping.

Skin
May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.

Eyes
Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): > 100
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Biodegradation: > 80

MOBILITY IN SOIL
Water solubility: 320 mg/L (25°C)
Henry’s Law Constant: 5.77E-08 atm·m³/mole (25°C)

OTHER ADVERSE EFFECTS
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

UN PROPER SHIPPING NAME
Not dangerous good

UN NUMBER
Not applicable

CLASS
Not applicable

PACKING GROUP
Not applicable
SAFETY DATA SHEET

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

<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 Appendix A</th>
<th>EPA 40 CFR Part 355 Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
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<tbody>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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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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<tbody>
<tr>
<td>HYDROCORTISONE 50-23-7</td>
<td>N/L</td>
<td>Listed as Schedule 3</td>
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N/L = Not Listed

EU REGULATIONS

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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request
<table>
<thead>
<tr>
<th>ABBREVIATIONS AND ACRONYMS</th>
<th>Definition</th>
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</table>

| LAST REVISION             | 06/2019 |
| SUPERSEDES                | 06/2019 |

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

<table>
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<tr>
<th>DISCLAIMER</th>
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</thead>
</table>
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.

<table>
<thead>
<tr>
<th>SUPPLEMENTARY INFORMATION</th>
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For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.