


SECTION 1: PRODUCT IDENTIFICATION

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|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PRODUCT NAME | OXYTRIPTAN (L-5-Hydroxytryptophan) |
| PRODUCT CODE | 0719 |
| 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 - Oral (Category 3) |
| PICTOGRAM |  |
| SIGNAL WORD | Danger |
| HAZARD STATEMENT(S) | Toxic if swallowed. Causes skin irritation. Causes serious eye irritation. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Repeated exposure may cause skin dryness or cracking. |
| PRECAUTIONARY STATEMENT(S) | Prevention Wash hands thoroughly after handling. Do not touch eyes. Do not eat, drink or smoke when using this product. Wear eye protection, face protection and protective gloves. Response IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation occurs, get medical help. 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. |

| | | | |
|---------------------|----------------------|----------------------------------------------------------------------------|------------------------------|
| HMIS CLASSIFICATION | Storage | Store locked up. | |
| | Disposal | Dispose of contents and/or container in accordance with local regulations. | |
| | Health Hazard | 2 | Flammability 1 |
| | Reactivity | 0 | Personal Protection G |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME | (2S)-2-amino-3-(5-hydroxy-1H-indol-3-yl)propanoic acid. | | | | | | | | |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------|-----------|-------------|-------------|-----------|-----------|-----|
| BOTANICAL NAME | Not applicable | | | | | | | | |
| SYNONYM | Oxatriptan; 5-Hydroxy-L-tryptophan; 5-HTP | | | | | | | | |
| CHEMICAL FORMULA | C ₁₁ H ₁₂ N ₂ O ₃ | | | | | | | | |
| CHEMICAL FAMILY | Not available | | | | | | | | |
| CAS NUMBER | 4350-09-8 | | | | | | | | |
| ALTERNATE CAS NUMBER | Not applicable | | | | | | | | |
| MOLECULAR WEIGHT | 220.2268 | | | | | | | | |
| 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>OXYTRIPATAN</td> <td>4350-09-8</td> <td>224-411-1</td> <td>100</td> </tr> </tbody> </table> | CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | OXYTRIPATAN | 4350-09-8 | 224-411-1 | 100 |
| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | | | | | | |
| OXYTRIPATAN | 4350-09-8 | 224-411-1 | 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.

NOTES Oxatriptan is the L form of 5-hydroxytryptophan, a precursor of serotonin.

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 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: OXYTRIPTAN CAS #: 4350-09-8

| | 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/m ³ |
| 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. When the risk evaluation foresees the need to use respirator devices with assisted ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU). Powders are divided in three categories : 2a (inert powder with TLV= 10 mg/m ³) - P1 filter 2b (hazards powders with TLV = 0,1-10 mg/m ³ (excluding asbestos) - P2 filter 2c (toxic powders with TLV < 0,1 mg/m ³ (asbestos, carcinogens, bacteria, viruses, enzymes, spores, etc) - P3 filter |
| BIOLOGICAL MONITORING | Not available |
| CONTROL BANDING | Not available |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | | | | |
|----------------------------------|-----------------------------------------------------------|-------------------------------------------|---------------------------------|----------------------------------|----------------------|
| PHYSICAL STATE | Solid | | | | |
| DESCRIPTION | White to off-white hygroscopic powder. | | | | |
| SOLUBILITY | Slightly soluble in water, insoluble in organic solvents. | | | | |
| ODOR | Not available | | | | |
| FLAMMABILITY | May be combustible at high temperature | | | | |
| AUTO-IGNITION TEMPERATURE | Not available | BOILING POINT | 520.6°C, 969.08°F (760 mmHg) | DECOMPOSITION TEMPERATURE | Not available |
| EVAPORATION RATE | Not available | EXPLOSIVE LIMIT | Not available | FLASH POINT | 268.7°C, 515.66°F |
| log P (OCTANOL-WATER) | -1.70 | LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | 270°C, 518°F |
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | 4.0 - 6.0 |

| | | | | | |
|-------------------------------------|---------------|-------------------------|----------------------|-------------------------------------------|---------------|
| RELATIVE DENSITY (WATER = 1) | Not available | SPECIFIC GRAVITY | Not available | UPPER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available |
| VAPOR DENSITY (AIR = 1) | Not available | VAPOR PRESSURE | 1.15e-11 mmHg (25°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

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|------------------------------------------|--------------------------------------------------------------------------------------------|
| REACTIVITY | Not established. |
| CHEMICAL STABILITY | Stable under recommended storage conditions. |
| INCOMPATIBLE MATERIALS | 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. Hygroscopic - Avoid exposure to moisture. |

SECTION 11: TOXICOLOGICAL INFORMATION

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|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ACUTE TOXICITY | Oral: Rat: LD50: (mg/kg): 243 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| SKIN CORROSION/IRRITATION | Based on available data, the classification criteria are not met. Causes skin irritation (pH 4.0-6.0). |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Based on available data, the classification criteria are not met. Causes serious eye irritation (pH 4.0-6.0). |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | Due to lack of data the classification is not possible |
| GERM CELL MUTAGENICITY | Based on available data, the classification criteria are not met. |
| CARCINOGENICITY | OSHA OXYTRIPTAN is not listed. NTP OXYTRIPTAN is not listed. IARC OXYTRIPTAN 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. |
| REPRODUCTIVE TOXICITY | Based on available data, the classification criteria are not met. Suspected toxic for reproduction: 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 | Based on available data, the classification criteria are not met. | | | | | | | | |
| 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 Not expected to present a significant hazard under anticipated conditions of normal use. | | | | | | | | |
| POTENTIAL HEALTH EFFECTS | <table border="0"> <tr> <td style="vertical-align: top;">Inhalation</td> <td>May be harmful if inhaled. May cause respiratory tract irritation.</td> </tr> <tr> <td style="vertical-align: top;">Ingestion</td> <td>Toxic if swallowed. Possible abdominal and stomach pain.</td> </tr> <tr> <td style="vertical-align: top;">Skin</td> <td>May be harmful if absorbed through skin. Causes skin irritation</td> </tr> <tr> <td style="vertical-align: top;">Eyes</td> <td>Causes serious eye irritation.</td> </tr> </table> | Inhalation | May be harmful if inhaled. May cause respiratory tract irritation. | Ingestion | Toxic if swallowed. Possible abdominal and stomach pain. | Skin | May be harmful if absorbed through skin. Causes skin irritation | Eyes | Causes serious eye irritation. |
| Inhalation | May be harmful if inhaled. May cause respiratory tract irritation. | | | | | | | | |
| Ingestion | Toxic if swallowed. Possible abdominal and stomach pain. | | | | | | | | |
| Skin | May be harmful if absorbed through skin. Causes skin irritation | | | | | | | | |
| Eyes | Causes serious 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 | Not available. |
| BIOACCUMULATIVE POTENTIAL | Log Pow: -1.70. BCF: 1 at pH 5.5 and 7.4 (predicted). |
| MOBILITY IN SOIL | Water solubility: 40g/l in warm water, 10g/l in cold water. |
| OTHER ADVERSE EFFECTS | Not available. This product is not intended to be released into the environment. |

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 14: TRANSPORT INFORMATION

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|--------------------------------|------------------------------|
| UN PROPER SHIPPING NAME | TOXIC SOLID, ORGANIC, N.O.S. |
| UN NUMBER | 2811 |
| CLASS | 6.1 |
| PACKING GROUP | III |

AUSTRALIA

HAZCHEM 2X

**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 Appendix A Appendix B | | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|----------------------|--------------------------|-------------------------|-------------------------------------------|-----|--------------|--------------------------|---------------|--------------------|
| OXYTRIPTAN 4350-09-8 | 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 |
|----------------------|-------------------------------|-----------------------|----------------------------------|------------------|------------------------------------|-----------------------------------|
| OXYTRIPTAN 4350-09-8 | 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 |
|----------------------|------------------|-----------------|--------------|-------------|--------------|-----------------------------------------|------------|
| OXYTRIPTAN 4350-09-8 | 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 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

07/2023

SUPERSEDES

02/2021

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.