


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | BACLOFEN, USP |
| PRODUCT CODE | 3209 |
| 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) Acute Toxicity - Dermal (Category 3) Toxic to Reproduction (Category 2) Sensitization - Skin (Category 1) Specific Target Organ Toxicity - Single Exposure (Category 3) - (Narcotic effects) Acute Aquatic Toxicity (Category 2) |
| PICTOGRAM |  |
| SIGNAL WORD | Danger |
| HAZARD STATEMENT(S) | Toxic if swallowed. Toxic in contact with skin. Irritating to eyes, skin and respiratory system. Suspected of damaging fertility or the unborn child. May cause an allergic skin reaction. May cause drowsiness or dizziness. Toxic to aquatic life. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Not Applicable |

PRECAUTIONARY STATEMENT(S)

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| Prevention | <p>Wash thoroughly after handling.</p> <p>Do not eat, drink or smoke when using this product.</p> <p>Do not handle until all safety precautions have been read and understood.</p> <p>Avoid breathing dust, fume, gas, mist, vapors, spray.</p> <p>Contaminated work clothing must not be allowed out of the workplace.</p> <p>Obtain, read and follow all special instructions before use.</p> <p>Wear protective gloves, protective clothing, eye and face protection and hearing protection.</p> <p>Use only outdoors or in a well-ventilated area.</p> <p>Avoid release to the environment.</p> |
| Response | <p>IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.</p> <p>IF ON SKIN (HAIR): Wash with plenty of water; Immediately call a poison center or medical professional. Take off immediately all contaminated clothing and wash it before reuse.</p> <p>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.</p> <p>IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell.</p> <p>IF EXPOSED OR CONCERNED: Get medical advice.</p> |
| Storage | <p>Store locked up.</p> <p>Store in a well-ventilated place.</p> <p>Keep container tightly closed.</p> |
| Disposal | <p>Dispose of contents and/or container in accordance with local regulations.</p> |

HMS CLASSIFICATION

| | | | |
|----------------------|---|----------------------------|---|
| Health Hazard | 3 | Flammability | 1 |
| Reactivity | 0 | Personal Protection | G |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME | Butanoic acid, 4-amino-3-(4-chlorophenyl)- | | | | | | | | |
|-----------------------------|--|---------------|-------------|-----------|-------------|----------|-----------|-----------|-----|
| BOTANICAL NAME | Not applicable | | | | | | | | |
| SYNONYM | Not applicable | | | | | | | | |
| CHEMICAL FORMULA | C ₁₀ H ₁₂ ClNO ₂ | | | | | | | | |
| CHEMICAL FAMILY | Benzene derivative | | | | | | | | |
| CAS NUMBER | 1134-47-0 | | | | | | | | |
| ALTERNATE CAS NUMBER | Not applicable | | | | | | | | |
| MOLECULAR WEIGHT | 213.6628 | | | | | | | | |
| COMPOSITION | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #008000; color: white;"> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>BACLOFEN</td> <td>1134-47-0</td> <td>214-486-9</td> <td>100</td> </tr> </tbody> </table> | CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | BACLOFEN | 1134-47-0 | 214-486-9 | 100 |
| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | | | | | | |
| BACLOFEN | 1134-47-0 | 214-486-9 | 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 | <p>Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.</p> |
| IN CASE OF SKIN CONTACT | <p>Wash with soap & water for 15 minutes. If irritation persists seek medical aid.</p> |
| IF SWALLOWED | <p>Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.</p> |

| | |
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| 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

| | |
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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, 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

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| 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

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|-------------------------------|---|
| 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. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable. |

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: BACLOFEN CAS #: 1134-47-0

| | 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

NOTES

 USP: ELV: Industrial use: TWA: 0.4 mg/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White to off-white, crystalline powder. Is odorless or practically so.

SOLUBILITY

Slightly soluble in water; very slightly soluble in methanol; insoluble in chloroform; practically insoluble in acetone. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.

ODOR

Practically odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

 364°C, 687.2°F
(760mmHg)

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

174°C, 345.2°F

| | | | | | |
|---|---------------|--|---------------------------|--|-----------------------------------|
| log P (OCTANOL-WATER) | - 0.96 | LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | (206 - 208)°C, (402.8-406.4)°F |
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | Not available |
| 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 | < 0.0000001 kPa (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 oxidizing agents. Nitric acid. |
| 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

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| ACUTE TOXICITY | Oral: Rat: LD50: (mg/kg): 145 Dermal: Rabbit: LD50: (mg/kg): 290 Dermal: Rat LD50: (mg/kg): 115 Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| SKIN CORROSION/IRRITATION | Based on available data, the classification criteria are not met. Causes irritation. |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Based on available data, the classification criteria are not met. Causes irritation. |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | May cause an allergic skin reaction. Allergic reactions have been reported in literature following the therapeutic use of a related material. Suspected skin sensitizer: CAESAR skin sensitization model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability) |
| GERM CELL MUTAGENICITY | Due to lack of data the classification is not possible. |
| CARCINOGENICITY | OSHA BACLOFEN is not listed. NTP BACLOFEN is not listed. IARC BACLOFEN is not evaluated. |

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| ADDITIONAL CARCINOGENICITY INFORMATION | <p>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.</p> <p>Based on available data, the classification criteria are not met.</p> <p>< 500 mg/kg/day Carcinogenicity study; Result: No evidence of carcinogenicity.; Species: Rat; Test Duration: 2 years.</p> <p>Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity; ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (moderate reliability)</p> |
| REPRODUCTIVE TOXICITY | <p>May damage fertility or the unborn child. May cause congenital malformation in the fetus. Presumed human reproductive toxicant.</p> <p>Species: Rat : 12.5 mg/kg/day Reproductivity study; Result: No increase in birth defects.</p> <p>Species: Mouse :15 mg/kg/day Reproductivity study; Result: No increase in birth defects</p> <p>Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability)</p> |
| SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE | Narcotic effects. |
| 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 | <p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Prolonged or repeated ingestion may cause weight loss. Prolonged or repeated inhalation may affect the bone marrow (changes in bone marrow).</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics: Central nervous system effects. Ringing in ears. Fainting. Visual disturbances. Urinary problems. Muscle pain. Chest pain. Numbness of extremities. Stuffy nose. Difficulty sleeping. Gastrointestinal disturbances.</p> |
| POTENTIAL HEALTH EFFECTS | <p>Inhalation Harmful if inhaled. Causes respiratory tract irritation. May cause drowsiness and dizziness.</p> <p>Ingestion Toxic if swallowed.</p> <p>Skin Toxic in contact with skin. Causes skin irritation. May cause an allergic skin reaction.</p> <p>Eyes Causes eye irritation.</p> |
| NOTES | Pharmacologically active material. Occupational exposure may cause physiological effects. |

SECTION 12: ECOLOGICAL INFORMATION

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| ECOTOXICITY | <p>EC50: 48 Hr: Crustacea: Daphnia Magna (mg/L): 4.42*</p> <p>LC50: 96 Hr: Fish: (mg/L): 9.64**</p> <p>LC50: 96 Hr: Fish: Fathead Minnow (mg/L): 82.45***</p> <p>EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p> |
| PERSISTENCE AND DEGRADABILITY | Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is Possible NON Readily Biodegradable (moderate reliability);The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable |
| BIOACCUMULATIVE POTENTIAL | Low: LogPow: - 0.96 |

MOBILITY IN SOIL

Slightly soluble in water.
 Water Solubility: 2090 mg/L (25°C)
 Vapor Pressure: 2.36E-09mm Hg (25°C)
 Henry's Law Constant: 5.94E-12atm·m³/mole (25°C)

OTHER ADVERSE EFFECTS

Suspected hazardous to the aquatic environment.

NOTES

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

*VEGA (Q)SAR platform prediction (moderate reliability).

**Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (moderate reliability).

*** (EPA) in VEGA (Q)SAR platform prediction (moderate reliability).

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

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 Part 372.65 | EPA 40 CFR Part 355 | | Pennsylvania | Right-to-know | | California Prop 65 |
|---------------------|--------------------------|-------------------------------------|---------------------|------------|--------------|---------------|---------------|--------------------|
| | | | Appendix A | Appendix B | | New Jersey | Massachusetts | |
| BACLOFEN 1134-47-0 | 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 Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|---------------------|-------------------------------|-----------------------|---|------------------|------------------------------------|-----------------------------------|
| BACLOFEN 1134-47-0 | N/L | Listed as Schedule 4 | N/L | Listed | 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 |
|---------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| BACLOFEN 1134-47-0 | 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

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

01/2025

SUPERSEDES

02/2023

 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.