## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>DICLOFENAC SODIUM, USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>2683</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia PTY LTD</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
</tbody>
</table>

## SECTION 2: HAZARDS IDENTIFICATION

| GHS CLASSIFICATION                  | Acute Toxicity - Oral (Category 3) |
|                                    | Acute Toxicity - Dermal (Category 4) |
|                                    | Skin Irritation (Category 2) |
|                                    | Eye Irritation (Category 2A) |
|                                    | Toxic to Reproduction (Category 2) |
|                                    | Specific Target Organ Toxicity - Repeated Exposure (Category 1) |
|                                    | Acute Aquatic Toxicity (Category 3) |

<table>
<thead>
<tr>
<th>PICTOGRAM</th>
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<tbody>
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<td>![Hazard Symbols]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SIGNAL WORD</th>
<th>Danger</th>
</tr>
</thead>
</table>

| HAZARD STATEMENT(S)                | Toxic if swallowed. |
|                                    | Harmful in contact with skin. |
|                                    | Causes skin and serious eye irritation. |
|                                    | Suspected of damaging fertility or the unborn child. |
|                                    | Causes damage to organs (cardiovascular system, gastrointestinal tract, liver, renal system) through prolonged or repeated exposure. |
|                                    | Harmful to aquatic life. |

| AUSTRALIA-ONLY HAZARDS             | Repeated exposure may cause skin dryness or cracking. |

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<thead>
<tr>
<th>PRECAUTIONARY STATEMENT(S)</th>
<th>Prevention</th>
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<tr>
<td></td>
<td>Wash thoroughly after handling.</td>
</tr>
<tr>
<td></td>
<td>Do not eat, drink or smoke when using this product.</td>
</tr>
<tr>
<td></td>
<td>Obtain special instructions before use.</td>
</tr>
<tr>
<td></td>
<td>Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td></td>
<td>Wear protective gloves, protective clothing, eye protection, face protection.</td>
</tr>
<tr>
<td></td>
<td>Do not breathe dust/fume/gas/mist/ vapors/spray.</td>
</tr>
<tr>
<td></td>
<td>Avoid release to the environment.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF ON SKIN (HAIR): Wash with plenty of water. Call a poison center or medical professional.
Take off immediately all 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.
Get medical advice/attention if you feel unwell.

Response

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.

Get medical advice/attention if you feel unwell.

Storage

Store locked up.

Disposal

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

HMIS CLASSIFICATION

Health Hazard 3 Flammability 0 Reactivity 0 Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
2-[(2,6-dichlorophenyl)amino]-, monosodium salt

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C₁₄H₁₀Cl₂N₂NaO₂

CAS NUMBER
15307-79-6

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
318.1

COMPOSITION

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

Diclofenac, a phenylacetic acid derivative, is an NSAID (nonsteroidal anti-inflammatory drug).

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
No unusual fire or explosion hazards noted.

Dust explosion properties:
Minimum ignition energy (MIE) - dust cloud: > 1000 mJ

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, light-resistant containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: DICLOFENAC SODIUM    CAS #: 15307-79-6

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

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.
SAFETY DATA SHEET

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. Fume hood, eye wash station, and safety shower.

NOTES

USP Exposure Limit - Industrial Use:
TWA: 0.5 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White to off-white, hygroscopic, crystalline powder.

SOLUBILITY
Freely soluble in methanol; soluble in ethanol; sparingly soluble in water; practically insoluble in chloroform and in ether.

ODOR
Odorless

FLAMMABILITY
May be combustible at high temperature

ODOR THRESHOLD
Not available

PH
7.0 - 8.5 (1%)

MELTING POINT
(283 - 285)°C, (541.4-545)°F

BOILING POINT
Not available

FREEZING POINT
Not available

FLASH POINT
Not available

SPECIFIC GRAVITY
0.3 - 0.7

EVAPORATION RATE
Not available

EXPLOSIVE LIMIT
Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

VAPOR PRESSURE
< 0.0000001 kPa (25°C)

VAPOR DENSITY
(AIR = 1)
Not available

RELATIVE DENSITY
(WATER = 1)
Not available

log P
(OCTANOL-WATER)
0.7

AUTO-IGNITION TEMPERATURE
Not available

DECOMPOSITION TEMPERATURE
Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY
Not established

STABILITY
Stable under recommended storage conditions

MATERIALS TO AVOID
Strong oxidants, strong bases and acid chlorine materials.

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
### SAFETY DATA SHEET

#### SECTION 11: TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY

- **Oral:** Rat: LD50: (mg/kg): 53
- **Dermal:** Rabbit: LD50: (mg/kg): 2000
- **Inhalation:** Rat: LD50: (mg/L/4hr): Not available

#### SKIN CORROSION/IRRITATION

Causes skin irritation. Self-limiting skin reactions such as rash or pruritus may occur in patients given diclofenac. More serious skin reactions attributed to diclofenac include bullous dermatitis and erythema multiforme.

#### SERIOUS EYE DAMAGE/EYE IRRITATION

Causes serious eye irritation.

Ocular diclofenac and related drugs have been implicated in reports of corneal toxicity. Ulceration of the conjunctiva or cornea, corneal or scleral melts, and perforations have been reported in patients using diclofenac eye drops, particularly after cataract surgery. Keratitis and perforations were also reported with ketorolac eye drops, although less frequently.

#### RESPIRATORY OR SKIN SENSITIZATION

A formulation containing this material showed no evidence of skin sensitization when tested in humans.

There have been reports of allergic reactions and contact dermatitis following therapeutic exposure to this material.

Cross sensitivity: Persons sensitive to aspirin or any of the nonsteroidal anti-inflammatory agents may be sensitive to this material also.

#### GERM CELL MUTAGENICITY

- **Ames test:** Negative.
- **Chromosome aberration test in Chinese hamsters:** Negative.
- **Dominant lethal test in mice:** Negative.
- **In vivo sister chromatid exchange:** No change in sister chromatid exchange rate in lymphocytes from humans dosed with this material for 14 days.
- **Male germinal epithelial chromosome test in mice:** Negative.
- **Mouse lymphoma test:** Negative.
- **Nucleus anomaly test in Chinese hamsters:** Negative.

Based on available data, the classification criteria are not met.

#### CARCINOGENICITY

- **OSHA**
  - DICLOFENAC SODIUM is not listed.
- **NTP**
  - DICLOFENAC SODIUM is not listed.
- **IARC**
  - DICLOFENAC SODIUM is not evaluated.
- **California**
  - This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm. (Proposition 65)

#### ADDITIONAL CARCINOGENICITY INFORMATION

- **Carcinogenicity study:** Rat: 0.25 - 2 mg/kg administered orally to female rats for 2 years: Increased incidence of benign mammary tumors.
- **Carcinogenicity study:** Mouse: 0.3 mg/kg/day administered orally to male mice for 2 years: No evidence of oncogenic potential.
- **Carcinogenicity study:** Mouse: 1 mg/kg/day administered orally to female mice for 2 years: No evidence of oncogenic potential.
- **Carcinogenicity study:** Rat: 2 mg/kg/day administered orally for 2 years: No evidence of carcinogenic potential.

Based on available data, the classification criteria are not met.
SAFETY DATA SHEET

REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child. Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates.

Reproductivity and development study: Rat: 10 mg/kg/day: Maternally toxic; fetotoxic; not teratogenic.
Reproductivity and development study: Rabbit: 10 mg/kg/day: administered orally: Maternally toxic; fetotoxic; not teratogenic.
Reproductivity and development study: Mouse: 20 mg/kg/day: Maternally toxic; fetotoxic; not teratogenic.
Reproductivity and development study: Rat: 4 mg/kg/day: No impairment of fertility.
Reversable infertility has been reported in women on long-term NSAIDs. Prostaglandins are considered to be involved in the processes of ovulation and it is thought that NSAIDs may compromise ovulation via inhibition of cyclo-oxygenase-2 (COX-2). Women trying to become pregnant may need to avoid treatment with NSAIDs. Diclofenac is distributed into breast milk although the BNF and some licensed product information consider the amount to be too small to be harmful to breast-fed infants.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Causes damage to organs (cardiovascular system, gastrointestinal tract, liver, renal system) through prolonged or repeated exposure.
Women: TDLo: Intramuscular: 9 mg/kg/1 week: Blood: normocytic anemia. Kidney, ureter, and bladder: changes in tubules including acute renal failure, acute tubular necrosis.
Women: TDLo: Intramuscular: 15 mg/kg/5 days: Kidney, ureter, and bladder: changes in tubules including acute renal failure, acute tubular necrosis. Gastrointestinal: hypermotility, diarrhea and other changes
Women: TDLo: Oral: 30 mg/kg/10 days: Gastrointestinal: nausea or vomiting
Women: TDLo: Oral 183 mg/kg/26 weeks: Liver: jaundice, other or unclassified, hepatitis, fibrous (cirrhosis, post-necrotic scarring).
Women: TDLo: Oral: 270 mg/kg/90 days: Blood: changes in erythrocyte (rbc) count. Gastrointestinal: other changes, ulceration or bleeding from large intestine.
Women: TDLo: Oral: 300 mg/kg/17 weeks: Liver: liver function tests impaired.
Women: TDLo: Oral: 2190 mg/kg/2 years: Gastrointestinal: hypermotility, diarrhea.
Women: TDLo: unreported administration route: 364 mg/kg/26 weeks: Kidney, ureter, and bladder: urine volume decreased, interstitial nephritis and proteinuris.

ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.
Cross sensitivity: Persons sensitive to aspirin or any of the nonsteroidal anti-inflammatory agents may be sensitive to this material also.

POTENTIAL HEALTH EFFECTS

Inhalation                 Harmful if inhaled. May cause respiratory tract irritation.
Ingestion                 Toxic if swallowed.
### SECTION 12: ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOXICITY</strong></td>
<td></td>
</tr>
<tr>
<td>EC50: 48 Hr: Daphnia magna: (mg/L):</td>
<td>70</td>
</tr>
<tr>
<td>LC50: 96 Hr: Fish: (mg/L):</td>
<td>130.6 - 214</td>
</tr>
<tr>
<td>IC50: 72 Hr: Algae: (mg/L):</td>
<td>Not available</td>
</tr>
<tr>
<td><strong>PERSISTENCE AND DEGRADABILITY</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The product is potentially degradable.</td>
</tr>
<tr>
<td><strong>BIOACCUMULATIVE POTENTIAL</strong></td>
<td>Log Pow: 0.7. Bioaccumulative potential is weak.</td>
</tr>
<tr>
<td><strong>MOBILITY IN SOIL</strong></td>
<td>Water solubility: 2430 mg/L (25°C).</td>
</tr>
<tr>
<td><strong>OTHER ADVERSE EFFECTS</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>This product is not intended to be released into the environment</td>
</tr>
</tbody>
</table>

### 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**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
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<tbody>
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<tr>
<td>UN NUMBER</td>
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<tr>
<td>CLASS</td>
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<tr>
<td>PACKING GROUP</td>
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</table>

**AUSTRALIA**

<table>
<thead>
<tr>
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<td>PACKING GROUP</td>
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<td>HAZCHEM</td>
<td>2X</td>
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<tr>
<td>ENVIRONMENTAL HAZARDS</td>
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<tr>
<td>SPECIAL SHIPPING INFORMATION</td>
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</table>

### SECTION 15: REGULATORY INFORMATION

Last Revision: 11/2015
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>
</tr>
</thead>
<tbody>
<tr>
<td>DICLOFENAC SODIUM 15307-79-6</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
<td>Not Listed</td>
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</tbody>
</table>

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.