

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	DICLOFENAC SODIUM, USP
PRODUCT CODE	2683
SUPPLIER	<p>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</p> <p>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</p> <p>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</p>
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Analgesic; Anti-inflammatory; Antipyretic (NSAID)

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) - (cardiovascular system, gastrointestinal tract, liver) Acute Aquatic Toxicity (Category 3)
PICTOGRAM	
SIGNAL WORD	Danger
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.
PRECAUTIONARY STATEMENT(S)	<p>Prevention</p> <p>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. Do not breathe dust/fume/gas/mist/ vapors/spray. Avoid release to the environment.</p>

	Response	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.		
	Storage	Store locked up.		
HMIS CLASSIFICATION	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	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	C ₁₄ H ₁₀ Cl ₂ NNaO ₂								
CAS NUMBER	15307-79-6								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	318.1								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>DICLOFENAC SODIUM</td> <td>15307-79-6</td> <td>100</td> </tr> </tbody> </table>			CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	DICLOFENAC SODIUM	15307-79-6	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT							
DICLOFENAC SODIUM	15307-79-6	100							
NOTES	<p>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.</p> <p>Chemical family: Phenylacetic acid derivative.</p>								

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. 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 unlabelled 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, light-resistant containers. Keep in dry place.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	TWA	Ceiling	STEL	REL	IDLH	Remarks
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: 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	(283 - 285)°C, (541.4-545)°F	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	VISCOSITY	Not available

NOTES

The physical data presented above are typical values and should not be construed as a specification.

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

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 53
Dermal: Rabbit LD50: (mg/kg): 2000
Inhalation: Rat: LC50: (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

Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Due to lack of data the classification is not possible.
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.

GERM CELL MUTAGENICITY

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
Proposition 65 cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

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

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.
Reversible 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

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

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Causes damage to organs (cardiovascular system, gastrointestinal tract, liver, renal system) through prolonged or repeated exposure.

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE

Symptoms related to the physical, chemical, and toxicological characteristics:
 Irritant effects. Swelling of extremities. Yellow eyes and/or skin. Lethargy. Right upper quadrant tenderness. For nonsteroidal anti-inflammatory drugs (NSAIDs): Nausea. Vomiting. Diarrhea. Constipation. Heartburn. Stomach pain. Black or tarry stools. Bleeding or bruising. Swelling. Sores, ulcers, or white spots on lips or mouth. Sweating. Bluish-colored skin. Insomnia. Mood, mental or behavioral changes. Confusion. Dizziness. Drowsiness. Headache. Itching. Weight gain. Vision, speech, or walking problems. Ringing in ears. Trouble breathing. Tremors.

Delayed and immediate effects of exposure:
 Fluid retention. Liver damage.
 For nonsteroidal anti-inflammatory drugs (NSAIDs): Gastrointestinal ulceration or bleeding. Hypertension. Kidney impairment. Blood disorders. Cardiovascular thrombotic events. Stroke. Central nervous system effects. Coma.

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

Medical conditions aggravated by exposure:
 Porphyria. Systemic lupus erythematosus.
 For nonsteroidal anti-inflammatory drugs (NSAIDs): Asthma. Aspirin allergy. Active alcoholism. Anemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or gastrointestinal bleeding. Hypertension. Stomatitis.

POTENTIAL HEALTH EFFECTS

Inhalation	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion	Toxic if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 70

LC50: 96 Hr: Fish: (mg/L): 130.6 - 214

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

The product is potentially degradable.

BIOACCUMULATIVE POTENTIAL

Log Pow: 0.7. Bioaccumulative potential is weak.

MOBILITY IN SOIL

Soluble in water. Water solubility: 2430 mg/L (25°C).

OTHER ADVERSE EFFECTS

Not available

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

UNITED STATES & CANADA

UN PROPER SHIPPING NAME

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS	6.1
PACKING GROUP	III

AUSTRALIA

UN PROPER SHIPPING NAME TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER 2811

CLASS 6.1

PACKING GROUP III

HAZCHEM 2X

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable



SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
DICLOFENAC SODIUM 15307-79-6	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
DICLOFENAC SODIUM 15307-79-6	N/L	Listed as Schedule 4*	N/L

NOTES

*Listed as the base

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

07/2018

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.