


## SECTION 1: PRODUCT IDENTIFICATION

<b>PRODUCT NAME</b>	<b>DICLOFENAC SODIUM, USP</b>
<b>PRODUCT CODE</b>	<b>2683</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> 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 <b>MEDISCA Pharmaceutique Inc.</b> 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 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
<b>USES</b>	Analgesic; Anti-inflammatory; Antipyretic (NSAID)

## SECTION 2: HAZARDS IDENTIFICATION

<b>GHS CLASSIFICATION</b>	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)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	<b>Danger</b>
<b>HAZARD STATEMENT(S)</b>	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.
<b>AUSTRALIA-ONLY HAZARDS</b>	Repeated exposure may cause skin dryness or cracking.
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b> 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.

**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.

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

## HMIS CLASSIFICATION

<b>Health Hazard</b>	3	<b>Flammability</b>	0
<b>Reactivity</b>	0	<b>Personal Protection</b>	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<sub>14</sub>H<sub>10</sub>Cl<sub>2</sub>NNaO<sub>2</sub>

**CAS NUMBER** 15307-79-6

**ALTERNATE CAS NUMBER** Not applicable

**MOLECULAR WEIGHT** 318.1

### COMPOSITION

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
DICLOFENAC SODIUM	15307-79-6	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** Chemical family: Phenylacetic acid derivative.

## 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, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, 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/m<sup>3</sup>.

**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/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE</b>	Solid				
<b>DESCRIPTION</b>	White to off-white, hygroscopic, crystalline powder.				
<b>SOLUBILITY</b>	Freely soluble in methanol; soluble in ethanol; sparingly soluble in water; practically insoluble in chloroform and in ether.				
<b>ODOR</b>	Odorless				
<b>FLAMMABILITY</b>	May be combustible at high temperature				
<b>ODOR THRESHOLD</b>	Not available	<b>pH</b>	7.0 - 8.5 (1%)	<b>MELTING POINT</b>	(283 - 285)°C, (541.4-545)°F
<b>BOILING POINT</b>	Not available	<b>FREEZING POINT</b>	(283 - 285)°C, (541.4-545)°F	<b>FLASH POINT</b>	Not available
<b>SPECIFIC GRAVITY</b>	0.3 - 0.7	<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available
<b>UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>VAPOR PRESSURE</b>	< 0.0000001 kPa (25°C)
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>log P (OCTANOL-WATER)</b>	0.7
<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available	<b>VISCOSITY</b>	Not available

**NOTES**

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

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>STABILITY</b>	Stable under recommended storage conditions
<b>MATERIALS TO AVOID</b>	Strong oxidants, strong bases and acid chlorine materials.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	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 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**

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
<b>AUSTRALIA</b>	
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.