SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Indomethacin for Injection**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	March 01, 2011
SDS Revision Date:	June 03, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Acute Oral Toxicity. Category 2.
Respiratory sensitisation. category 1.
Skin Sensitization. category 1.
Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Fatal if swallowed.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.
Specific treatment (see ... on this label).
Rinse mouth.
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
DANGER! Toxic. This product is intended for therapeutic use only when prescribed by a physician.
Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

Potential Health Effects: Tumorigen Drug Mutagen Reproductive Effector Human

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms:
Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Occupational exposure has not been fully investigated.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Indomethacin	53-86-1	1 mg/vial
Dibasic Sodium Phosphate, Anhydrous	7558-79-4	0.41 mg/vial
Monobasic Sodium Phosphate, Monohydrate	10049-21-5	0.29 mg/vial
Hydrochloric Acid, NF	7647-01-0	mg /vial pH adjustment
Sodium Hydroxide, NF	1310-73-2	=< 0.24 mg/vial
Water for Injection	7732-18-5	- Negligible -

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). Protect from light. Store container in carton until contents have been used.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ingredient	Guideline OSHA	Guideline ACGIH	Quebec Canada	Ontario Canada	Alberta Canada
Indomethacin	Not established.	Not established.	Not established.	Not established.	Not established.
Dibasic Sodium Phosphate, Anhydrous	Not established.	Not established.	Not established.	Not established.	Not established.
Monobasic Sodium Phosphate, Monohydrate	Not established.	Not established.	Not established.	Not established.	Not established.
Hydrochloric Acid, NF	Not established.	Not established.	VEMP-ceiling./Peak.: 5 ppm	OEL-CEV: 2 ppm	OEL-ceiling./Peak: 5 ppm
Water for Injection	Not established.	Not established.	Not established.	Not established.	Not established.

Ingredient	British Columbia Canada
Indomethacin	Not established.
Dibasic Sodium Phosphate, Anhydrous	Not established.
Monobasic Sodium Phosphate, Monohydrate	Not established.
Hydrochloric Acid, NF	OEL-ceiling./Peak.: 2 ppm
Water for Injection	Not established.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Powder or plug.
Color:	White to yellow
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	6.0 - 7.5
Molecular Formula:	Mixture
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from air and light.

SECTION 11 : TOXICOLOGICAL INFORMATION

Indomethacin :

RTECS Number:	NL3500000
Ingestion:	Oral - Rat LD50: 2420 ug/kg [Gastrointestinal - Ulceration or bleeding from stomach] Oral - Rat LD50: 17 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 11841 ug/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 21 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 13 mg/kg [Details of toxic effects not reported other than lethal dose value] Intramuscular - Rat LD50: 26300 ug/kg [Details of toxic effects not reported other than lethal dose value]

Dibasic Sodium Phosphate, Anhydrous :

RTECS Number:	WC4500000
Eye:	Eye - Rabbit Standard Draize test.: 500 mg/24H (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Ingestion:	Oral - Rat LD50: 17000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Monobasic Sodium Phosphate, Monohydrate :

Ingestion:	Oral - Rat LD50: 8290 mg/kg

Hydrochloric Acid, NF :

Inhalation:	Inhalation - Rat LC50: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] (RTECS)

Sodium Hydroxide, NF :

RTECS Number:	WB4900000
Eye:	Eye - Rabbit Standard Draize test.: 400 ug Eye - Rabbit Standard Draize test.: 50 ug/24H (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H
Ingestion:	Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Medicine, solid, toxic, n.o.s. (Indomethacin for Injection)
DOT UN Number:	UN3249
DOT Hazard Class:	6.1
DOT Packing Group:	II
DOT Exemption:	Limited Quantity

SECTION 15 : REGULATORY INFORMATION

Canada WHMIS:	Controlled - Class: D2B Toxic

Dibasic Sodium Phosphate, Anhydrous :

TSCA Inventory Status:	Listed
EINECS Number:	231-448-7
Canada DSL:	Listed

Hydrochloric Acid, NF :

Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

Sodium Hydroxide, NF :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3
HMIS Fire Hazard:	1
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	March 01, 2011
SDS Revision Date:	June 03, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Updated the Section 14 - Transportation section for the Exemption description (from the former 'ORM-D' exemption, which is no longer used by DOT, to the 'Limited Quantity' exemption). Revised the HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

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