


SAFETY DATA SHEET

Section 1: Identification	
Section 1, Identification	
Product	Ketorolac Tromethamine Injection USP
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-842-25 (15mg/mL) (1mL vial) 70512-843-25 (30mg/mL) (1mL vial)
Section 2: Hazard(s) Identification	
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Classification of the Substance or Mixture	
GHS – Classification	Reproductive Toxicity: Category 1A Specific target organ systemic toxicity (repeated exposure): Category 2
Label Elements	
Signal Word	Danger
Hazard Statements	H360D – may damage the unborn child H373 – may cause damage to organs through prolonged or repeated exposure
Precautionary Statements	P201 – obtain special instructions before use P202 – do not handle until all safety precautions have been read and understood P260 – do not breathe dust/fume/gas/mist/vapors/spray P280 – wear protective gloves/protective clothing/eye protection/face protection P308 + P313 – IF exposed or concerned: get medical attention/advise P314 – get medical attention/advise if you feel unwell P405 – store locked up P501 – dispose of contents/container in accordance with all local and national regulations
	
Other Hazards Note	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/Information on Ingredients

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Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ethanol	64-17-5	200-578-6	Flam. Liq. 2 (H225)	7 – 12
Ketorolac tromethamine	74103-07-4	Not listed	Acute Tox. 3 (H301) STOT RE 2 (H373) Repr. 1A (H360D)	1.5 – 3.0
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr. 1A (H314)	Adjust to pH
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr. 1A (314) Acute Tox. 3 (H331)	Adjust to pH
Sodium chloride	7647-14-5	231-598-3	Not listed	0.4 – 0.7
Water for injection	7732-18-5	231-791-2	Not listed	Qs to 100%

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16.

Section 4: First-Aid Measures

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Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects Of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions	None known
Aggravated by Exposure	
Indication of the Immediate Medical Attention and Special Treatment Needed	
Notes to Physician	None

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Special Hazards Arising from the Substance or Mixture	
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire/Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment,

Including self-contained breathing apparatus.

Section 6: Accidental Release Measures

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Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean-up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage

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Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific End Use(s): Pharmaceutical product used as non-steroidal, anti-inflammatory drug (NSAID)

Section 8: Exposure Controls / Personal Protection

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Control Parameters

Refer to available public information for specific member-state Occupational Exposure Limits.

Ketorolac Tromethamine

Caplin OEL TWA-8Hr: 30 µg/m³

Ethanol

ACGHI Threshold Limit Value (STEL) 1000 ppm

Australia TWA 1000 ppm

Australia OEL – MAKs 1000 ppm

1900 mg/m³

Belgium OEL – TWA 1000 ppm

1907 mg/m³

Bulgaria OEL - TWA 1000.0 mg/m³

Czech Republic OEL - TWA 1000 mg/m³

Denmark OEL - TWA 1000 ppm

1900 mg/m³

Estonia OEL - TWA 500 ppm

1000 mg/m³

Finland OEL - TWA 1000 ppm

France OEL - TWA	1900 mg/m ³ 1000 ppm
Germany - TRGS 900 - TWAs	1900 mg/m ³ 500 ppm
Germany (DFG) – MAK	960 mg/m ³ 500 ppm
Greece OEL – TWA	960 mg/m ³ 1000 ppm
Hungary OEL – TWA	1900 mg/m ³
Latvia OEL – TWA	1900 mg/m ³
Lithuania OEL – TWA	260 mg/m ³
Netherlands OEL – TWA	500 ppm
OSHA – Final PELs – TWAs	1000 mg/m ³ 260 mg/m ³
Poland OEL – TWA	1000 ppm
Portugal OEL – TWA	1900 mg/m ³
Romania OEL – TWA	1000 ppm
Russia OEL – TWA	1900 mg/m ³
Slovakia OEL – TWA	1000 mg/m ³
Slovenia OEL – TWA	500 ppm
Sweden OEL – TWA	960 mg/m ³
Switzerland OEL – TWAs	1000 ppm
Vietnam OEL – TWAs	1900 mg/m ³ 500 ppm 1000 mg/m ³

Sodium Hydroxide

ACGIH Ceiling Threshold Limit	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL – MAKs	2 mg/m ³
Bulgaria OEL – TWA	2.0 mg/m ³
Czech Republic OEL – TWA	1 mg/m ³
Estonia OEL – TWA	1 mg/m ³
France OEL – TWA	2 mg/m ³
Greece OEL – TWA	2 mg/m ³
Hungary OEL – TWA	2 mg/m ³
Japan – Oels – Ceilings	2 mg/m ³
Latvia OEL – TWA	2 mg/m ³
OSHA – Final PELs – TWAs	0.5 mg/m ³
Poland OEL – TWA	2 mg/m ³
Slovakia OEL – TWA	0.5 mg/m ³
Slovenia OEL – TWA	2 mg/m ³
Sweden OEL – TWAs	2 mg/m ³ 1 mg/m ³

Switzerland OEL – TWAs	2 mg/m ³
Sodium Chloride	
Latvia OEL – TWA	5 mg/m ³
Lithuania OEL – TWA	5 mg/m ³
Hydrochloric Acid	
ACGIH Ceiling Threshold Limit	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL – MAKs	5 ppm
	8 mg/m ³
Belgium OEL – TWA	5 ppm
	8 mg/m ³
Bulgaria OEL – TWA	5 ppm
	8 mg/m ³
Cyprus OEL – TWA	5 ppm
	8 mg/m ³
Czech Republic OEL – TWA	8 mg/m ³
Estonia OEL – TWA	5 ppm
	8 mg/m ³
Germany – TRGS 900 - TWAs	2 ppm
	3.0 mg/m ³
Greece OEL – TWA	5 ppm
	7 mg/m ³
Hungary OEL – TWA	8 mg/m ³
Ireland OEL – TWA	5 ppm
	8 mg/m ³
Italy OEL – TWA	5 ppm
	8 mg/m ³
Japan – Oels – Ceilings	2 ppm
	3.0 mg/m ³
Latvia OEL – TWA	5 ppm
	8 mg/m ³
Lithuania OEL – TWA	5 ppm
	8 mg/m ³
Luxembourg OEL – TWA	5 ppm
	8 mg/m ³
Malta OEL – TWA	5 ppm
	8 mg/m ³
Netherlands OEL – TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL – TWA	5 ppm
	8 mg/m ³
Romania OEL – TWA	5 ppm
	8 mg/m ³
Slovakia OEL – TWA	5 ppm
	8 mg/m ³

Slovenia OEL – TWA	5 ppm
	8 mg/m ³
Spain OEL – TWA	5 ppm
	7.6 mg/m ³
Switzerland OEL – TWAs	2 ppm
	3.0 mg/m ³
Vietnam OEL – TWAs	5 mg/m ³

Sodium Chloride

Caplin Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Band (OEB):

Exposure Controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory Protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Section 9, Physical and Chemical Properties

Information on Basic Physical and Chemical Properties

Physical State	Solution
Color	Clear to light yellow
Odor Threshold	No data available
Molecular Weight	Mixture

Odor	Alcohol slight
Molecular Formula	Mixture
Solvent Solubility	No data available
Water Solubility	No data available
pH	6.9 – 7.9
Melting/Freezing Point (C°)	No data available
Boiling Point (C°)	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
Ketorolac tromethamine	No data available
Ethanol	No data available
Water for injection	No data available
Hydrochloric acid	No data available
Sodium hydroxide	No data available
Decomposition Temperature (C°)	No data available
Evaporation Rate (Gram/s)	No data available
Vapor Pressure (kPa)	No data available
Vapor Density (g/mL)	No data available
Relative Density	No data available
Specific Gravity	0.991
Viscosity	No data available
Flammability	
Autoignition Temperature (Solid) (C°)	No data available
Flammability (Solids)	No data available
Flash Point Liquid (C°)	55 (ethanol)
Upper Explosive Limits (Liquid) (% by Vol.)	No data available
Lower Explosive Limits (Liquid) (% by Vol.)	No data available
Polymerization	Will not occur
Section 10: Stability and Reactivity	
Section 10, Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions of use
Possibility of Hazardous Reactions	
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products	No data available
Section 11: Toxicological Information	
Section 11, Toxicological Information	
Information on Toxicological Effect	
General Information	The information included in this section describes the potential hazards of the individual ingredients.
Short Term	Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class

Known Clinical Effects may develop allergic reactions. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Clinical use of this drug has caused headache, dizziness, blurred vision, ringing of the ears, skin rash, itching, swelling, and liver effects.

Acute Toxicity: (Species, Route End Point, Dose)

Sodium Chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Ketorolac tromethamine

Rat	Oral	LD50	189 mg/kg
Mouse	Oral	LD50	293 mg/kg

Ethanol

Mouse	Oral	LD50	3,450 g/m ³
Rat	Oral	LD50	7,050 mg/kg
Mouse	Inhalation	LC50	4h 39 g/m ³
Rat	Inhalation	LC50	10h 20,000 ppm

Sodium hydroxide

Mouse	IP	LD50	40mg/kg
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Irritation/Sensitization: (Study Type, Species, Severity)

Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Ethanol

Eye Irritation	Rabbit	Severe
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Hydrochloric acid

Skin Irritation	Severe
Eye Irritation	Severe

Sodium hydroxide

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Reproduction and Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ketorolac tromethamine

Reproductive & Fertility – Females	Rat	Oral	16mg/kg/day	NOAEL	Negative
Reproductive & Fertility – Males		Oral	9mg/kg/day	NOAEL	Negative
Prenatal & Postnatal Development	Rabbit	Oral	3.6mg/kg/day	NOAEL	Negative
Prenatal & Postnatal Development	Rat	Oral	10mg/kg/day	NOAEL	Negative

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ketorolac tromethamine

Bacterial Mutagenicity (Ames)	<i>Salmonella, E.coli</i>	Negative
Unscheduled DNA Synthesis	Not specified	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ketorolac tromethamine

24 Month(s)	Rat	Oral	5mg/kg/day	NOAEL	Not carcinogenic
18 Month(s)	Mouse	Oral	2mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status

Carcinogenicity of the mixture has not been determined. Alcohol is listed as IARC. The IARC monograph examining the carcinogenic potential of ethanol only alcoholic beverages. See below.

Ethanol IARC	Group 1 (Carcinogenic to Humans)
Hydrochloric Acid IARC	Group 3 (not Classifiable)

Section 12: Ecological Information

Section 12, Ecological Information

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol

Fathead Minnow	NPDES	LC50	24 hours	11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout)	NPDES	LC50	96 hours	12,900 mg/L
Pimephales promelas (Fathead Minnow)	NPDES	LC50	96 hours	14,200 mg/L

Persistence and Degradability No data available

Bio-accumulative Potential No data available

Mobility in Soil No data available

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Waste Treatment Methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

Section 14, Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, UEADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Section 15, Regulatory Information

Safety, Health and Environmental

Regulations/Legislation Specific for the Substance or Mixture

Ketorolac tromethamine

CERCLA/SARA 313 Emission Reporting	Not listed
California Proposition 65	Not listed
Australia (AICS)	Not listed
Standard for the Uniform Scheduling for Drugs and Poisons	Schedule 4
EU EINECS/ELINCS List	Not listed

Ethanol

CERCLA/SARA 313 Emission Reporting	Not listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages Developmental toxicity 10/1/1987 in alcoholic beverages
Inventory – United States TSCA – Sect. 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	200-578-6

Sodium Chloride

CERCLA/SARA 313 Emission Reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect. 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	231-598-3

Sodium Hydroxide

CERCLA/SARA 313 Emission Reporting	Not listed
CERCLA/SARA Hazardous Substances and Their Reportable Quantities	1000 lb 454 kg
California Proposition 65	Not listed
Inventory – United States TSCA – Sect. 8(b)	Present
Australia (AICS)	Present
Standard for the Uniform Scheduling For Drugs and Poisons	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Water for Injection

CERCLA/SARA 313 Emission Reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect. 8(b)	Present
Australia (AICS)	Present
REACH – Annex IV – Exemptions from the Obligations of Register	Present
EU EINECS/ELINCS List	200-578-6

Hydrochloric Acid

CERCLA/SARA 313 Emission Reporting	1.0%
CERCLA/SARA Hazardous Substances and their Reportable Quantities	5000 lb 2270 kg
CERCLA/SARA – Section 302 Extremely Hazardous TPQs	500 lb
California Proposition 65	Not listed
Inventory – United States TSCA – Sect. 8(b)	Present
Australia (AICS)	Present
Standard for the Uniform Scheduling For Drugs and Poisons	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Section 16: Other Information

Section 16, Other Information

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Reproductive toxicity-Cat.1A; H360D - May damage the unborn child Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.