

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Acetaminophen Injection (freeflex®)
Distributor 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: October 20, 2020
SDS Revision Date: February 12, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: Warning.
GHS Class: Acute Oral Toxicity. Category 4.
Hazard Statements: Harmful if swallowed.
Precautionary Statements: Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
Emergency Overview: 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: Occupational exposure has not been fully investigated.
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.
Acetaminophen	103-90-2	1 %	
Mannitol	69-65-8	3.76 %	
Cysteine	52-90-4	<1 %	
Hydrochloric acid and/or Sodium hydroxide	7647-01-0/ 1310-73-1	As needed %	
Water for Injection	7732-18-5	Quantity Sufficient	

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.

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:	Use mechanical handling equipment. Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Carefully sweep up and collect. Collect in a suitable container and dispose as hazardous waste according to section 13. Wash the contaminated surface with water.

SECTION 7 : HANDLING and STORAGE

Handling:	Provide adequate ventilation. Use protective equipment as referred to in section 8. Avoid inhalation of dust. Use work methods which minimize dust production. Avoid contact with eyes and skin.
Storage:	Store in tightly closed original container in a dry, cool and well-ventilated place. Protect against direct sunlight.
Work Practices:	Do not eat, drink or smoke during work. Good personal hygiene is necessary. Wash hands and contaminated areas with water and soap before leaving the work site. Wash contaminated clothing before reuse.
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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	white.
Odor:	None.
Boiling Point:	Not established.
Melting Point:	Not determined.
Density:	1.29 g/cm ³
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	5.5 - 6.5 (In aqueous solution)
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:	Risk of dust explosion: Dust may form explosive mixtures with air. Keep away from heat /sparks /open flames /hot surfaces. No smoking.
Incompatible Materials:	Keep away from: Acids. Water. Amides.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	May cause irritation when ingested
Acute Effects:	Eye, skin, and respiratory irritation may occur.
Ingestion:	Oral - LD50 - 338 mg/kg (mouse)
Chronic Effects:	None known.

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.
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SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

SECTION 16 : ADDITIONAL INFORMATION

<u>HMIS Ratings:</u>	
HMIS Health Hazard:	1
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

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SDS Revision Notes: Overall SDS review - no changes.

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