SAFETY DATA SHEET

Issuing Date: 17-Jul-2020 **Revision Date:** 22-Oct-2021

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
SDS Number: BXU555490
Product Name: Acetaminophen Injection 10 mg/mL

Other means of identification
Product Code(s): EZPE-8821
Synonyms: None

Recommended use of the chemical and restrictions on use
Product Use: Analgesic.
Product Type: Regulated Prescription Drug
Uses advised against No information available

Details of the supplier of the safety data sheet
BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368
Emergency telephone number
Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity (single exposure)	Category 1

Label Elements

Emergency Overview

Danger

Hazard Statements
Causes damage to organs



Precautionary Statements - Prevention
Do not breathe dust/fume/gas/mist/vapors/spray
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements -
Response

Specific treatment (see supplemental first aid instructions on this label)
IF exposed: Call a POISON CENTER or doctor/physician

Precautionary Statements - Storage
Store locked up

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)
Other Information
• Causes mild skin irritation
Unknown Acute Toxicity 4.85 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%
Paracetamol	103-90-2	1
Mannitol	69-65-8	2-5
Cysteine Hydrochloride monohydrate	7048-04-6	<0.1
Dibasic Sodium Phosphate	7558-79-4	<0.1
Water	7732-18-5	>90

4. FIRST AID MEASURES

Description of first aid measures

General Advice Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact: In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
No information available.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical
No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions
See Section 12 for environmental precautions.

Methods and material for containment and cleaning up
Methods for Containment:
If emergency personnel are unavailable, contain spilled material.
Methods for cleaning up:
For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical measures/precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Do not refrigerate. Do not freeze.

Incompatible materials: Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Paracetamol 103-90-2	None	None	None	None	None	None
Mannitol 69-65-8	None	None	None	None	None	None
Cysteine Hydrochloride monohydrate 7048-04-6	None	None	None	None	None	None
Dibasic Sodium Phosphate 7558-79-4	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Individual protection measures, such as personal protective equipment

Eye protection	No special technical protective measures are necessary Safety glasses with side-shields are recommended for laboratory and manufacturing use.
Hand protection	Use chemical resistant, impervious gloves.
Skin and body protection	Work uniform or laboratory coat.
Respiratory protection	No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Aqueous solution.
Color:	Clear, Colorless.
Odor:	No information available
Odor Threshold:	No information available
pH:	5.7-6.3
Melting point / melting range:	No information available
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammable limits in air-upper (%):	No information available
Flammable limits in air-lower (%):	No information available
Vapor pressure:	No information available
Vapor density	No information available
Density:	No information available
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other information

10. STABILITY AND REACTIVITY

Reactivity
No data available

Chemical stability
Stable under recommended storage conditions

Possibility of hazardous reactions
None under normal use conditions

Conditions to Avoid
Do not refrigerate. Do not freeze.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

Carbon oxides. Nitrogen oxides (nox).

11. TOXICOLOGICAL INFORMATION

Chemical Name	Inhalation LC50	Dermal LD50	Oral LD50
Paracetamol 103-90-2	-	-	= 1944 mg/kg (Rat)
Mannitol 69-65-8	-	-	= 13500 mg/kg (Rat)
Cysteine Hydrochloride monohydrate 7048-04-6	-	-	-
Dibasic Sodium Phosphate 7558-79-4	-	-	= 17 g/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: May cause eye irritation.

Skin contact: May cause skin irritation.

Ingestion: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Anemia. Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice).

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not mutagenic in ames test.

Carcinogenic effects: Not classified.

Chemical Name	ACGIH	IARC	NTP	OSHA
Paracetamol 103-90-2	-	Group 3	-	-
Mannitol 69-65-8	-	-	-	-
Cysteine Hydrochloride monohydrate 7048-04-6	-	-	-	-
Dibasic Sodium Phosphate 7558-79-4	-	-	-	-
Water	-	-	-	-

7732-18-5				

Reproductive toxicity: May impair fertility based on animal data. May be fetotoxic based on animal data.

STOT - single exposure: Liver. Kidney.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 4.85 % of the mixture consists of ingredient(s) of unknown toxicity

12. ECOLOGICAL INFORMATION

Chemical Name	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Paracetamol 103-90-2	6.1 - 14 mg/L EC50 48 h	814 mg/L LC50 Pimephales promelas 96 h	None.	None.
Mannitol 69-65-8	None.	None.	None.	None.
Cysteine Hydrochloride monohydrate 7048-04-6	None.	None.	None.	None.
Dibasic Sodium Phosphate 7558-79-4	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity
No information available
3.8854 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability
No information available.

Bioaccumulative potential
Bioaccumulative potential

Mobility in soil
No information available

Other adverse effects
No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products In accordance with local and national regulations

Contaminated Packaging In accordance with local and national regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

Environmental hazard Not applicable
Special Provisions None

15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Chemical Name	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Paracetamol 103-90-2	1	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol 69-65-8	2-5	Not Listed	Not Listed	Not Listed	Not Listed
Cysteine Hydrochloride monohydrate 7048-04-6	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Dibasic Sodium Phosphate 7558-79-4	<0.1	Not Listed	5000 lb 2270 kg	Not Listed	Not Listed
Water 7732-18-5	>90	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Chemical Name	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Paracetamol 103-90-2	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol 69-65-8	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Cysteine Hydrochloride monohydrate 7048-04-6	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Dibasic Sodium Phosphate 7558-79-4	Not Listed	Not Listed	Not Listed	Not Listed	Present	Present	Present
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
None

Additional information:
Not Available.

Prepared by:	Baxter Research & Development
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End of Safety Data Sheet