

SAFETY DATA SHEET
ACETAMINOPHEN INJECTION 1000 MG/100 ML (10 MG/ML)



Caplin Steriles Limited

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name : Acetaminophen Injection 1000 mg/100 mL (10 mg/mL)
(Caplin Steriles Ltd.)

Chemical Family : 4-aminophenol

Synonyms : Paracetamol; A-Acetamidophenol; N-(4-hydroxyphenyl)acetamide

Manufacturer or supplier's details : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai,
Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District),
Pin Code: 601 201, Tamil Nadu (State), INDIA.

Details of the Supplier of the Safety Data Sheet :

Emergency Telephone Number : +91-4467901901/02/03

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical product used for the management of mild to moderate
pain the management of moderate to severe pain with adjunctive opioid
analgesics the reduction of fever.

Restrictions on use : Not applicable

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS -Classification : Acute Oral Toxicity. Category 4

Label elements



Signal word

Warning

Hazard statements

Harmful if swallowed

Precautionary Statements

Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
IF SWALLAOWED: Call a POISON CENTER or doctor /
physician if you feel unwell. Dispose of contents/container in
accordance with local, state, Federal and provincial regulations.

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Other Hazards



Occupational exposure to acetaminophen may occur through inhalation and dermal contact with this compound at workplaces where acetaminophen is produced or used.

Note

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 INGREDIENT

Hazardous

Ingredient	CAS Number	GHS Classification	%
Acetaminophen	103-90-2	Acute Tox. 4 (Oral), H302	1
Mannitol	69-65-8	Not classified	3.76
Cysteine	52-90-4	Eye Irrit. 2A, H319	<1
Hydrochloric Acid/ or sodium hydroxide	7647-01-0/1310-73-1	Skin Corr. 1, H314 Eye Dam. 1, H318	Adjust to pH
Water for injection	7732-18-5	Not classified	Quantity Sufficient

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

Description of First Aid Measures

Eye Contact:

Eye Exposure: No eye exposure is expected with this formulation under normal conditions of use. If eye exposure occurs, flush eyes with large volumes of water for 15 min. Get medical attention.

Skin Contact:

Wash contaminated area with soap and water for 15 min. Get medical attention if irritation is noted

Ingestion:

No ingestion exposure is expected with this formulation under normal conditions of use. If ingested, do not induce vomiting unless directed to do so by medical personnel. In cases where large amounts have been ingested, contact a Physician or Poison Control Center immediately. Acetyl cysteine is known to significantly reduce the risk of serious

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	hepatotoxicity, especially if taken less than eight hours after ingestion of the overdose.
Inhalation:	No inhalation exposure is expected with this formulation under normal conditions of use. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Contact a physician immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects of Exposure:	None
Medical Conditions Aggravated by Exposure:	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	
Notes to Physician:	None

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media:

Suitable extinguishing media Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media None.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: 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 molecule weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Fire / Explosion Hazards: Fine particles (such as 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

Personal precautions, protective equipment and emergency procedures Evacuate area and keep unnecessary and unprotected personal from entering the spill area. Avoid personal contact and berating vapors or mists. Use proper personal I protective equipment as listed in (see Section 8).

Environmental Precautions Avoid runoff into storm sewers, ditches , and waterways.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Stop the flow of material, if this is without risk. Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

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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

Precautions for Safe Handling

Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store at 20° to 25°C (68° to 77°F).

Specific end use(s):

Pharmaceutical

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters

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

Water (7732-18-5)	Not applicable
D-Mannitol (69-65-8)	Not applicable
Acetaminophen (103-90-2)	Not applicable
L-Cysteine hydrochloride monohydrate (7048-04-6)	Not applicable
Phosphoric acid, disodium salt, dihydrate (10028-24-7)	Not applicable

Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
OSHA	OSHA PEL (Ceiling) [ppm]	5 ppm
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
NIOSH	NIOSH REL (Ceiling) [ppm]	5 ppm

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL ((TWA) (mg/m ³)	2 mg/m ³
IDLH	US IDLH (mg/m ³)	10 mg/m ³
NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³

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Exposure Controls

Engineering Controls:	Local exhaust and general ventilation must be adequate to meet exposure standards 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.
Personal protective equipment	
Hands:	No protection is ordinarily required under normal conditions of use.
Eyes:	Wear safety glasses or goggles.
Skin:	Wear suitable working clothes.
Respiratory protection:	No protection is ordinarily required under normal conditions of use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance: Liquid. When properly stored, Is a clear colorless solution.

pH: 5.0 to 6.2

Melting point/freezing point: 28 °F (- 2 °C)

Initial boiling point and boiling range: Approx. to water

Evaporation rate: Approx. to water

Vapor pressure: Approx. to water

Relative density: 1.015 g/L

Solubility: Miscible with water in any proportion

Partition coefficient: n-octanol/water: 0.46 (logP, Acetaminophen)

Decomposition Temperature(°C):

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:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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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:	No data available
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides, and sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effect

For acetaminophen (active ingredient), see RTECS Number AE4200000.

Acute Toxicity Acetaminophen:

Oral – Rat LD50: >4000 mg/kg

Oral – Rabbit LD50: 3000 mg/kg

Oral – Mouse LD50: 900 – 1200 mg/kg

Oral – Dog LD50: 200 mg/kg

Oral – Guinea Pig LD50: 3500 mg/kg

Oral – Cat LD50: 120 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

Information is currently not available on the environmental impact of Acetaminophen. Handle in a manner to prevent spills or releases to the environment. Tests run according to the OECD Guide–line 302 B "Inherent biodegradability: Modified Zahn–Wellens Test" showed a 99% aerobic and anaerobic degradation of acetaminophen inoculated with industrial activated sludge after 5 days.

SECTION 13: DISPOSAL CONSIDERATIONS

Incineration in an approved incinerator is recommended. Refer to local, state and federal disposal guidelines.

SECTION 14: TRANSPORT INFORMATION

None of the components of acetaminophen is a DOT hazardous material.

Not Regulated by DOT, IATA/ICAO, or IMDG.

SECTION 15: REGULATORY INFORMATION

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR Part 173) are not applicable.

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SECTION 16: OTHER INFORMATION

Use of this product should be through or under the direction of a physician. This SDS does not address the therapeutic use of this material. The version of the MSDS dated 04 JAN 2012 was updated to bring the format in line with the recommendations of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The document has been renamed to “SDS” and content has been moved and added throughout

SDS creation date	:	Sep 10, 2024
SDS Revision date	:	NA
Version #	:	00
Disclaimer:		The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Caplin steriles assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product

---End of Safety Data Sheet---