



SAFETY DATA SHEET

Section 1: Identification	
Material	Acetaminophen Injection
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	No additional information available
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Acetaminophen	103-90-2
Mannitol	69-65-8
L-Cysteine hydrochloride Monohydrate	7048-04-6
Disodium hydrogen phosphate dihydrate	10028-24-7
Sodium hydroxide	1310-73-2
Hydrochloric acid	7647-01-0
Water for Injection	7732-18-5
Section 4: First-Aid Measures	
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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.
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	None
Section 6: Accidental Release Measures	
Environmental precautions	Prevent entry to sewers and public waters



For containment	Stop the flow of material, if this is without risk.
Methods for cleaning up	Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.
Section 7: Handling and Storage	
Precautions for safe handling	Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Storage conditions	Acetaminophen injection should be stored at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. For single-dose only. The product should be used within 6 hours after opening. Do not refrigerate or freeze. Discard unused portion.
Section 8: Exposure Controls/Personal Protection	
Appropriate engineering controls	Local exhaust and general ventilation must be adequate to meet exposure standards
Hand protection	No protection is ordinarily required under normal conditions of use
Eye protection	Wear safety glasses or goggles
Skin and body protection	Wear suitable working clothes
Respiratory protection	No protection is ordinarily required under normal conditions of use
Section 9: Physical and Chemical Properties	
Physical Form	Solution
Colour	Clear, colorless solution
Description	Acetaminophen Injection is a sterile, clear, colorless solution supplied in a 100 mL glass vial containing 1000 mg acetaminophen (10 mg/mL) in cartons of 24 vials. Carton of 24 Single-Dose Vials N DC 31722-205-24
Section 10: Stability and Reactivity	
Reactivity	No additional information available
Chemical stability	The product is stable at normal handling and storage conditions.

Section 11: Toxicological Information

Acute toxicity : Not classified

Water (7732-18-5)

LD50 oral rat	> 90 ml/kg
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Mannitol (69-65-8)

LD50 oral rat	13500 mg/kg
ATE US (oral)	13500 mg/kg

Acetaminophen (103-90-2)

ATE US (oral)	500 mg/kg body weight
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Hydrochloric acid (7647-01-0)

LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h

Sodium hydroxide (1310-73-2)

LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Skin corrosion/irritation : Not classified
 Serious eye damage/irritation : Not classified
 Respiratory or skin sensitization : Not classified
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified

Hydrochloric acid (7647-01-0)

IARC group : 3 - Not classifiable
 Reproductive toxicity : Not classified
 STOT-single exposure : Not classified
 STOT-repeated exposure : Not classified
 Aspiration hazard : Not classified



Section 12: Ecological Information

Toxicity

Sodium hydroxide (1310-73-2)

LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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Persistence and degradability : No additional information available

Bioaccumulative potential : No additional information available

Mobility in soil : No additional information available

Other adverse effects : No additional information available

Section 13: Disposal Considerations

Waste treatment methods

Product/Packaging disposal recommendations:

Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 14: Transport Information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

Section 15: Regulatory Information

US Federal regulations

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Mannitol (69-65-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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US State regulations

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Section 16: Other Information

Issue Date: 30-01-2023

Version: 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Aspiro Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Aspiro Pharma Private Limited reserves the right to revise this SDS.