SAFETY DATA SHEET

Prochlorperazine Edisylate Injection, USP

WEST-WARD PHARMACEUTICALS

Section 1. Identification

GHS product identifier : Prochlorperazine Edisylate Injection, USP

Synonyms : Prochlorperazine Edisylate Injection, USP (NOVAPLUS)

Product code : NDC 0641-6135-25

Chemical family : Antipsychotic. Antiemetic.

Product type : Regulated prescription drug.

Container information : 2 mL (10 mg) Dosette® vials

Identified uses : Pharmaceuticals.

Supplier's details : West-Ward Pharmaceuticals Corp.
465 Industrial Way West
Eatontown NJ 07724 USA

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Hazards not otherwise classified (HNOC) : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Prochlorperazine Edisylate Injection, USP (NOVAPLUS)

CAS number/other identifiers

CAS number : Not applicable.

Product code : NDC 0641-6135-25

Ingredient name	%	CAS number
Benzyl alcohol	0.3 - 1	100-51-6
Water	90 - 100	7732-18-5
Ethane-1,2-disulphonic acid, compound with 2-chloro-10-[3-(4-methylpiperazin-1-yl)propyl]-10H-phenothiazine (1:1)	0.3 - 1	1257-78-9
Butanedioic acid, 2,3-dihydroxy- (2R,3R)-, sodium salt, hydrate (1:2:2)	1 - 3	6106-24-7
Phosphoric acid, monosodium salt, monohydrate	0.3 - 1	10049-21-5
1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	0 - 0.1	128-44-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Section 4. First aid measures

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
phosphorus oxides
metal oxide/oxides

Special protective actions for fire-fighters : No special measures are required.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Benzyl alcohol	**AIHA WEEL (United States, 10/2011).** TWA: 10 ppm 8 hours.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Aqueous solution.]

Color : Colorless.

Odor : Not available.

Odor threshold : Not available.

pH : 4.2 to 6.2

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Acids. bases. Oxidizing agents.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Benzyl alcohol	LD50 Dermal LD50 Oral	Rabbit Rat	2000 mg/kg 1230 mg/kg	- -

Irritation/Corrosion

Section 11. Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
Benzyl alcohol	Skin - Mild irritant Skin - Moderate irritant Skin - Moderate irritant	Man Pig Rabbit	- - -	48 hours 16 mg 100 % 24 hours 100 mg	- - -

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Phosphoric acid, monosodium salt, monohydrate	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Section 11. Toxicological information

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral Inhalation (vapors)	26252.2 mg/kg 1101.1 mg/L

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Benzyl alcohol	Acute LC50 460000 µg/L Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Benzyl alcohol	0.87	-	low

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 4(a) proposed test rules**: 1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Section 15. Regulatory information

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Butanedioic acid, 2,3-dihydroxy- (2R,3R)-, sodium salt, hydrate (1:2:2)	≥1 - ≤3	No.	No.	No.	Yes.	No.
Benzyl alcohol	≥1 - ≤3	No.	No.	No.	Yes.	No.
Phosphoric acid, monosodium salt, monohydrate	≥1 - ≤3	No.	No.	No.	Yes.	No.

SARA 313

No products were found.

State regulations

Massachusetts : The following components are listed: Benzyl alcohol

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Benzyl alcohol

California Prop. 65

No products were found.

Section 16. Other information

History

Date of issue mm/dd/yyyy : 02/15/2016

Version : 1

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

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Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.