Section 1. Identification

GHS product identifier : Busulfan Injection

Other means of identification : Not available.

Product type : Liquid.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Pharmaceuticals. (For intended use only.)
Observe technical data sheet/instructions for use.
Specific Treatments: Cancer

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

Telephone: 224-443-4617
www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture :

H332	ACUTE TOXICITY (inhalation) - Category 4
H320	EYE IRRITATION - Category 2B
H350	CARCINOGENICITY - Category 1B
H360	TOXIC TO REPRODUCTION - Category 1B
H362	TOXIC TO REPRODUCTION - Effects on or via lactation
H336	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
H373	SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 67%

GHS label elements

Section 2. Hazards identification

Hazard pictograms :

Signal word : Danger

Hazard statements :
H320 - Causes eye irritation.
H332 - Harmful if inhaled.
H336 - May cause drowsiness or dizziness.
H350 - May cause cancer.
H360 - May damage fertility or the unborn child.
H362 - May cause harm to breast-fed children.
H373 - May cause damage to organs through prolonged or repeated exposure. (liver)

Precautionary statements

Prevention :
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing and eye or face protection.
P271 - Use only outdoors or in a well-ventilated area.
P260 - Do not breathe vapor.
P263 - Avoid contact during pregnancy or while nursing.
P270 - Do not eat, drink or smoke when using this product.
P264 - Wash thoroughly after handling.

Response :
P308 + P313 - IF exposed or concerned: Get medical advice or attention.
P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation persists: Get medical advice or attention.

Storage :
P405 - Store locked up.
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

Disposal :
P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

Section 3. Composition/information on ingredients

Ingredient name	Other names	%	Identifiers
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-Ethane-1,2-diol, ethoxylated	-	≥50 - ≤75	CAS: 25322-68-3
N,N-dimethylacetamide	-	≥25 - ≤35	CAS: 127-19-5
busulfan	-	<1	CAS: 55-98-1

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

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

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. Continue to rinse for at least 10 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes eye irritation.

Inhalation : Harmful if inhaled. Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.

Section 4. First aid measures

Skin contact : No known significant effects or critical hazards.

Ingestion : Can cause central nervous system (CNS) depression.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use dry chemical, CO_2, alcohol-resistant foam or water spray (fog).

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

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. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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.

Section 6. Accidental release measures

Large spill : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. 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.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid contact during pregnancy or while nursing. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe vapor or mist. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

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. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). 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. Store locked up. 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. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated N,N-dimethylacetamide	**OARS WEEL (United States, 4/2022)** TWA 8 hours: 10 mg/m³. **ACGIH TLV (United States, 1/2024)** A3. Absorbed through skin. TWA 8 hours: 10 ppm. TWA 8 hours: 36 mg/m³. **NIOSH REL (United States, 10/2020)** Absorbed through skin. TWA 10 hours: 10 ppm.

Section 8. Exposure controls/personal protection

busulfan	TWA 10 hours: 35 mg/m³. **OSHA PEL (United States, 5/2018)** Absorbed through skin. TWA 8 hours: 10 ppm. TWA 8 hours: 35 mg/m³. **CAL OSHA PEL (United States, 5/2018)** Absorbed through skin. TWA 8 hours: 35 mg/m³. TWA 8 hours: 10 ppm. None.

Appropriate engineering controls : Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

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: chemical splash goggles.

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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

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.

Section 8. Exposure controls/personal protection

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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Liquid. [Clear.]

Color : Colorless.

Odor : Ammonia. [Slight]

Odor threshold : Not available.

pH : Not available.

Melting point : Not available.

Boiling point or initial boiling point and boiling range : Not available.

Flash point :

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
N,N-dimethylacetamide				64	147.2	ISO 13736

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Vapor pressure :

Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
N,N-dimethylacetamide	1.50013	0.2				

Relative vapor density : Not available.

Relative density : Not available.

Density : 1.024 to 1.087 g/cm³ [25°C (77°F)]

Solubility(ies) : Not available.

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

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	360	680	

Decomposition temperature : Not available.

Section 9. Physical and chemical properties

SADT : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Other information

Physical/chemical properties comments : No additional information.

Section 10. Stability and reactivity

Reactivity : Keep away from the following materials to prevent strong exothermic reactions: Carbon tetrachloride, Hexachlorocyclohexane. Reacts violently in presence of iron.

Chemical stability : The product is stable.

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

Conditions to avoid : Avoid high temperatures. Avoid inhalation of vapor, spray or mist.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials and alkalis.
Iron

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

Section 11. Toxicological information

Product/ingredient name	Result	Species	Dose	Exposure
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
	LD50 Oral	Rat - Female	>2000 mg/kg	-
N,N-dimethylacetamide	LC50 Inhalation Vapor	Rat	2475 ppm	1 hours
	LD50 Dermal	Rabbit	2240 mg/kg	-
	LD50 Oral	Rat	4300 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Mild irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	500 mg	-
N,N-dimethylacetamide	Eyes - Mild irritant	Rabbit	-	100 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 10 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
N,N-dimethylacetamide	-	2B	-
busulfan	-	1	Known to be a human carcinogen.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
N,N-dimethylacetamide	Category 3	-	Narcotic effects

Specific target organ toxicity (repeated exposure)

Section 11. Toxicological information

Name	Category	Route of exposure	Target organs
N,N-dimethylacetamide	Category 2	-	liver

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact : Causes eye irritation.

Inhalation : Harmful if inhaled. Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.

Skin contact : No known significant effects or critical hazards.

Ingestion : Can cause central nervous system (CNS) depression.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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

Short term exposure

Potential immediate effects : Not available.

Section 11. Toxicological information

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : May cause damage to organs through prolonged or repeated exposure.

Carcinogenicity : May cause cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : May damage fertility or the unborn child.
May cause harm to breast-fed children.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Busulfan Injection	2918.1	2422.2	N/A	11.2	N/A
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	2500	2500	N/A	N/A	N/A
N,N-dimethylacetamide	4300	2240	N/A	11	N/A
busulfan	100	50	N/A	0.5	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	Acute EC50 >100 mg/l Fresh water	Daphnia - *Daphnia magna*	48 hours
	Acute LC50 >1000000 µg/l Fresh water	Fish - *Salmo salar* - Parr	96 hours

Conclusion/Summary : Not available.

Persistence and degradability

Section 12. Ecological information

Product/ingredient name	Test	Result	Dose	Inoculum
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	OECD 301D Ready Biodegradability - Closed Bottle Test	74.85 % - Readily - 28 days	4 mg/l	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	-	-	Readily
N,N-dimethylacetamide	-	-	Readily

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	0.2	3.2	Low
N,N-dimethylacetamide	-0.77	-	Low
busulfan	-0.52	-	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 at all times 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. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. 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 Classification	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

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 IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) PAIR**: N,N-dimethylacetamide

TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): All components are active or exempted.

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

Section 15. Regulatory information

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : ACUTE TOXICITY (inhalation) - Category 4
EYE IRRITATION - Category 2B
CARCINOGENICITY - Category 1B
TOXIC TO REPRODUCTION - Category 1B
TOXIC TO REPRODUCTION - Effects on or via lactation
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

Composition/information on ingredients

Name	%	Classification
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	≥50 - ≤75	EYE IRRITATION - Category 2B
N,N-dimethylacetamide	≥25 - ≤35	FLAMMABLE LIQUIDS - Category 4 ACUTE TOXICITY (inhalation) - Category 4 EYE IRRITATION - Category 2B CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION - Category 1B SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2
busulfan	<1	ACUTE TOXICITY (oral) - Category 3 ACUTE TOXICITY (dermal) - Category 2 ACUTE TOXICITY (inhalation) - Category 2 GERM CELL MUTAGENICITY - Category 2 CARCINOGENICITY - Category 1B TOXIC TO REPRODUCTION - Category 2 TOXIC TO REPRODUCTION - Effects on or via lactation

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: DIMETHYL ACETAMIDE

New York : None of the components are listed.

New Jersey : The following components are listed: DIMETHYL ACETAMIDE

Pennsylvania : The following components are listed: ACETAMIDE, N,N-DIMETHYL-

California Prop. 65

⚠ **WARNING**: This product can expose you to chemicals including N, N-Dimethylacetamide and 1,4-Butanediol dimethanesulfonate, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Section 15. Regulatory information

Ingredient name	No significant risk level	Maximum acceptable dosage level
N, N-Dimethylacetamide	-	-
1,4-Butanediol dimethanesulfonate	-	-

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	4
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)

Procedure used to derive the classification

Section 16. Other information

Classification	Justification
ACUTE TOXICITY (inhalation) - Category 4	Calculation method
EYE IRRITATION - Category 2B	Calculation method
CARCINOGENICITY - Category 1B	Calculation method
TOXIC TO REPRODUCTION - Category 1B	Calculation method
TOXIC TO REPRODUCTION - Effects on or via lactation	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method

History

Date of issue/Date of revision : 08/22/2024

Date of previous issue : 09/09/2022

Version : 3.0

Prepared by : Sphera Solutions

Key to abbreviations :
ATE = Acute Toxicity Estimate
AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift
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)
N/A = Not available
UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
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.