



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

|                                                           |                                          |                                     |
|-----------------------------------------------------------|------------------------------------------|-------------------------------------|
| <b>SDS Title:</b><br>Busulfan Injection Safety Data Sheet | <b>SDS Number:</b><br>SDS-000030         | <b>Page Number:</b><br>Page 1 of 19 |
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## 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.  
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Telephone: 224-443-4617  
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**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                                         |
| H319 | EYE IRRITATION - Category 2A                                                     |
| 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

|                                                           |                                          |                                     |
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## Section 2. Hazards identification

### Hazard pictograms

:



### Signal word

: Danger

### Hazard statements

: H319 - Causes serious 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 and 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.

### Hazards identified when used

: No known significant effects or critical hazards.

## Section 3. Composition/information on ingredients

### Substance/mixture

: Mixture

### Other means of identification

: Not available.

|                                                           |                                          |                                     |
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## Section 3. Composition/information on ingredients

| Ingredient name                                                                                                                | Synonyms                      | %                                                                 | Identifiers                                      |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------|--------------------------------------------------|
| Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -hydroxy-Ethane-1,2-diol, ethoxylated<br>N,N-dimethylacetamide<br>busulfan | polyethylene glycol<br>-<br>- | $\geq 60 - \leq 80$<br>$\geq 15 - \leq 40$<br>$\geq 0.1 - \leq 1$ | CAS: 25322-68-3<br>CAS: 127-19-5<br>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 serious eye irritation.
- Inhalation** : Harmful if inhaled. Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.

|                                                           |                                          |                                     |
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## 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:  
pain or 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)

|                                                           |                                          |                                     |
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## Section 5. Fire-fighting measures

### Extinguishing media

**Suitable extinguishing media** : Use dry chemical, CO<sub>2</sub>, 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. Do not breathe vapor. 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. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

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## 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

| <b>Ingredient name</b>                                                                             | <b>Exposure limits</b>                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated<br>N,N-dimethylacetamide | <b>OARS WEEL (United States, 6/2025)</b><br>TWA 8 hours: 10 mg/m <sup>3</sup> .<br><b>ACGIH TLV (United States, 1/2025)</b> A3. Absorbed through skin.<br>TWA 8 hours: 10 ppm.<br>TWA 8 hours: 36 mg/m <sup>3</sup> .<br><b>NIOSH REL (United States, 10/2020)</b> Absorbed through skin.<br>TWA 10 hours: 10 ppm. |

|                                                           |                                          |                                     |
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## Section 8. Exposure controls/personal protection

|          |                                                                                                                                                                                                                                                                                                                                    |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| busulfan | <p>TWA 10 hours: 35 mg/m<sup>3</sup>.<br/> <b>OSHA PEL (United States, 5/2018)</b> Absorbed through skin.<br/> TWA 8 hours: 10 ppm.<br/> TWA 8 hours: 35 mg/m<sup>3</sup>.<br/> <b>CAL OSHA PEL (United States, 1/2025)</b> Absorbed through skin.<br/> TWA 8 hours: 35 mg/m<sup>3</sup>.<br/> TWA 8 hours: 10 ppm.<br/> None.</p> |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Biological exposure indices

| Ingredient name       | Exposure indices                                                                                                                                      |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| N,N-dimethylacetamide | <b>ACGIH BEI (United States, 1/2025)</b><br>BEI: 30 mg/g creatinine, N-methylacetamide [in urine].<br>Sampling time: end of shift at end of workweek. |

### 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.

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## Section 8. Exposure controls/personal protection

- 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

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/cm<sup>3</sup> [25°C (77°F)]
- Solubility(ies)** : Not available.

|                                                           |                                          |                                     |
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## Section 9. Physical and chemical properties

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

|                                    |                                                                           |           |           |               |
|------------------------------------|---------------------------------------------------------------------------|-----------|-----------|---------------|
| <b>Auto-ignition temperature</b> : | <b>Ingredient name</b>                                                    | <b>°C</b> | <b>°F</b> | <b>Method</b> |
|                                    | Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated | 360       | 680       |               |

**Decomposition temperature** : Not available.

**SADT** : Not available.

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

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## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

##### **Product/ingredient name**

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated

N,N-dimethylacetamide

##### **Result**

###### **Rat - Female - Oral - LD50**

>2000 mg/kg

###### **Rat - Male, Female - Dermal - LD50**

>2000 mg/kg

###### **Rat - Oral - LD50**

4300 mg/kg

###### **Rabbit - Dermal - LD50**

2240 mg/kg

###### **Rat - Inhalation - LC50 Vapor**

2475 ppm [1 hours]

OECD [Acute Oral toxicity - Acute Toxic Class Method]

OECD [Acute Dermal Toxicity]

Toxic effects: Skin After topical exposure - Primary irritation

Toxic effects: Gross Metabolite Changes - Weight loss or decreased weight gain

##### **Conclusion/Summary [Product]**

: Not available.

### Skin corrosion/irritation

##### **Product/ingredient name**

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated

N,N-dimethylacetamide

##### **Result**

###### **Rabbit - Skin - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

###### **Rabbit - Skin - Mild irritant**

Amount/concentration applied: 500 mg

###### **Rabbit - Skin - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

###### **Rabbit - Skin - Mild irritant**

Amount/concentration applied: 500 mg

###### **Rabbit - Skin - Mild irritant**

Amount/concentration applied: 500 mg

###### **Rabbit - Skin - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 10 mg

##### **Conclusion/Summary [Product]**

: Not available.

### Serious eye damage/eye irritation

##### **Product/ingredient name**

##### **Result**



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Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated

### **Rabbit - Eyes - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

### **Rabbit - Eyes - Mild irritant**

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

### **Rabbit - Eyes - Mild irritant**

Amount/concentration applied: 500 mg

### **Rabbit - Eyes - Mild irritant**

Amount/concentration applied: 100  $\mu$ L

N,N-dimethylacetamide

### **Rabbit - Eyes - Mild irritant**

Amount/concentration applied: 100 mg

**Conclusion/Summary [Product]**

: Not available.

### Respiratory corrosion/irritation

**Conclusion/Summary [Product]**

: Not available.

### Respiratory or skin sensitization

#### **Skin**

**Conclusion/Summary [Product]**

: Not available.

#### **Respiratory**

**Conclusion/Summary [Product]**

: Not available.

### Germ cell mutagenicity

**Conclusion/Summary [Product]**

: Not available.

### Carcinogenicity

**Conclusion/Summary [Product]**

: Not available.

### Classification

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

|                                                           |                                          |                                      |
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### Reproductive toxicity

**Conclusion/Summary [Product]** : Not available.

### Specific target organ toxicity (single exposure)

**Product/ingredient name**

N,N-dimethylacetamide

**Result**

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)  
(Narcotic effects) - Category 3

### Specific target organ toxicity (repeated exposure)

**Product/ingredient name**

N,N-dimethylacetamide

**Result**

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)  
(liver) - Category 2

### 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 serious 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:  
pain or 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



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## Section 11. Toxicological information

- Skin contact** : skeletal malformations  
: 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.

**Potential delayed effects** : Not available.

#### Long term exposure

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

### Potential chronic health effects

**Conclusion/Summary [Product]** : Not available.

- 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), $\alpha$ -hydro- $\omega$ -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                                 |

|                                                           |                                          |                                      |
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## Section 11. Toxicological information

## Section 12. Ecological information

### Toxicity

#### Product/ingredient name

Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated

#### Result

##### Acute - LC50 - Fresh water

Fish - Atlantic salmon - *Salmo salar* - Parr

Size: 8.2 to 11.7 cm; Weight: 5.1 to 14.1 g

>1000 mg/l [96 hours]

##### Acute - EC50 - Fresh water

Daphnia - *Daphnia magna*

>100 mg/l [48 hours]

Effect: Mortality

OECD [Daphnia sp. Acute Immobilization Test and Reproduction Test]

#### Conclusion/Summary [Product]

: Not available.

### Persistence and degradability

#### Product/ingredient name

Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated

#### Result

##### Aerobic - 4 mg/l

74.85% [28 days] - Readily

OECD [Ready Biodegradability - Closed Bottle Test]

#### Conclusion/Summary [Product]

: Not available.

| Product/ingredient name                                                                    | Aquatic half-life | Photolysis | Biodegradability |
|--------------------------------------------------------------------------------------------|-------------------|------------|------------------|
| Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated | -                 | -          | Readily          |
| N,N-dimethylacetamide                                                                      | -                 | -          | Readily          |

### Bioaccumulative potential

| Product/ingredient name                                                                    | LogP <sub>ow</sub> | BCF | Potential |
|--------------------------------------------------------------------------------------------|--------------------|-----|-----------|
| Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -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

: Not available.

|                                                           |                                          |                                      |
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## Section 12. Ecological information

### 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

|                                   | <b>DOT Classification</b> | <b>IMDG</b>    | <b>IATA</b>    |
|-----------------------------------|---------------------------|----------------|----------------|
| <b>UN number</b>                  | Not regulated.            | Not regulated. | Not regulated. |
| <b>UN proper shipping name</b>    | -                         | -              | -              |
| <b>Transport hazard class(es)</b> | -                         | -              | -              |
| <b>Packing group</b>              | -                         | -              | -              |
| <b>Environmental hazards</b>      | 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.



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## 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.

### TSCA 12(b) - Chemical export notification

Not applicable.

**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

**Classification** : ACUTE TOXICITY (inhalation) - Category 4  
EYE IRRITATION - Category 2A  
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), $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated | $\geq 60$ - $\leq 80$ | EYE IRRITATION - Category 2B                                                                                                                                                                                                                                          |
| N,N-dimethylacetamide                                                                      | $\geq 15$ - $\leq 40$ | FLAMMABLE LIQUIDS - Category 4<br>ACUTE TOXICITY (inhalation) - Category 4<br>EYE IRRITATION - Category 2A<br>CARCINOGENICITY - Category 2<br>TOXIC TO REPRODUCTION - Category 1B<br>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3 |

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|                                                           |                                          |                                      |
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## Section 15. Regulatory information

|          |           |                                                                                                                                                                                                                                                                                                                                                                |
|----------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| busulfan | ≥0.1 - ≤1 | SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2<br>ACUTE TOXICITY (oral) - Category 3<br>ACUTE TOXICITY (dermal) - Category 2<br>ACUTE TOXICITY (inhalation) - Category 2<br>GERM CELL MUTAGENICITY - Category 2<br>CARCINOGENICITY - Category 1B<br>TOXIC TO REPRODUCTION - Category 2<br>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](http://www.P65Warnings.ca.gov).

| <b>Ingredient name</b>            | <b>No significant risk level</b> | <b>Maximum acceptable dosage level</b> |
|-----------------------------------|----------------------------------|----------------------------------------|
| 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.

|                                                    |                                   |                               |
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## 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

| Classification                                                                   | Justification      |
|----------------------------------------------------------------------------------|--------------------|
| ACUTE TOXICITY (inhalation) - Category 4                                         | Calculation method |
| EYE IRRITATION - Category 2A                                                     | 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 | : 08/04/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Date of previous issue         | : 07/30/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Version                        | : 5.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prepared by                    | : Sphera Solutions                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Key to abbreviations           | : ATE = Acute Toxicity Estimate<br>BCF = Bioconcentration Factor<br>GHS = Globally Harmonized System of Classification and Labelling of Chemicals<br>IATA = International Air Transport Association<br>IBC = Intermediate Bulk Container<br>IMDG = International Maritime Dangerous Goods<br>IMO = International Maritime Organization<br>LogPow = logarithm of the octanol/water partition coefficient<br>MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as |



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## Section 16. Other information

modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available

SGG = Segregation Group

TDG = Transportation of Dangerous Goods

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

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