

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Busulfan Injection

Product Code: 0517-0920-01

Synonyms: Busulfan Injectable

1.2. Intended Use of the Product

Use of the Substance/Mixture: An alkylating agent for the treatment of cancer dissolved in N,N-dimethylacetamide and Polyethylene Glycol 400. The product is intended for dilution with 0.9% sodium chloride injection or 5% dextrose injection prior to intravenous infusion.

1.3. Name, Address, and Telephone of the Responsible Party

Company

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Flam. Liq. 4 H227

Acute Tox. 4 (Oral) H302

Muta. 1B H340

Carc. 1A H350

Repr. 1A H360

STOT SE 3 H335

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H227 - Combustible liquid.
 H302 - Harmful if swallowed.
 H335 - May cause respiratory irritation.
 H340 - May cause genetic defects.
 H350 - May cause cancer.
 H360 - May damage fertility or the unborn child.

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P210 - Keep away from extremely high or low temperatures, ignition sources, and incompatible materials. - No smoking.
 P261 - Avoid breathing vapors, mist, or spray.
 P264 - Wash hands, forearms, and other exposed areas with soap and water thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.
 P271 - Use only outdoors or in a well-ventilated area.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.

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P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P312 - Call a poison center or doctor if you feel unwell.

P330 - Rinse mouth.

P370+P378 - In case of fire: Use appropriate media (see section 5) to extinguish.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P403+P235 - Store in a well-ventilated place. Keep cool.

P405 - Store locked up.

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

2.3. Other Hazards

This product should be handled by technically qualified individuals knowledgeable in the handling of potent pharmaceutical products. Overexposure may cause effects on the hematological system (anemia and decreased platelets) with symptoms of increased risk of bleeding and tiredness. The active ingredient is considered a potential reproductive toxicant (affects fertility), a potential teratogen and developmental toxicant (affects the developing fetus and causes birth defects), and a potential carcinogen (causes cancer). Avoid all skin contact, eye contact, and inhalation. Refer to patient insert for more information.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Polyethylene glycol	(CAS No) 25322-68-3	67	STOT SE 3, H335
Dimethylacetamide	(CAS No) 127-19-5	33	Flam. Liq. 4, H227 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation: vapour), H332 Repr. 1B, H360
Busulfan	(CAS No) 55-98-1	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation: dust, mist), H330 Muta. 1B, H340 Carc. 1A, H350 Repr. 1A, H360 STOT RE 1, H372

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: First, take proper precautions to ensure your own safety before attempting rescue (e.g. wear appropriate respiratory protective equipment, use the buddy system), then remove the exposed person to fresh air. Keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Wash affected areas with soap and water. Get immediate medical advice/attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Harmful if swallowed. May be harmful in contact with skin. May cause respiratory irritation. Causes damage to organs through prolonged or repeated exposure. May cause genetic defects. May cause cancer. May damage fertility. May damage the unborn child. Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

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Symptoms/Injuries After Skin Contact: This material may cause adverse health effects. This material may be absorbed through the skin and eyes.

Symptoms/Injuries After Eye Contact: May cause eye irritation. May be absorbed through the eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects.

Chronic Symptoms: May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Repeated or prolonged exposure may damage:

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible liquid.

Explosion Hazard: May form flammable or explosive vapor-air mixture.

Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: No smoking. Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing. Do not handle until all safety precautions have been read and understood. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: As an immediate precautionary measure, isolate spill or leak area in all directions. Ventilate area. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Handle empty containers with care because residual vapors are flammable.

Precautions for Safe Handling: Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing. Do not breathe mist, vapors, spray. Use only outdoors or in a well-ventilated area. Do not handle until all safety precautions have been read and understood.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Take action to prevent static discharges. Ground and bond container and receiving equipment. Use explosion-proof electrical, ventilating, and lighting equipment.

Storage Conditions: Store in a dry, cool, well-ventilated place. Keep/Store away from ignition sources, direct sunlight, extremely high or low temperatures and incompatible materials.

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Incompatible Products: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 2 - 8 °C (35.6 - 46.4 °F)

7.3. Specific End Use(s)

An alkylating agent for the treatment of cancer dissolved in N,N-dimethylacetamide and Polyethylene Glycol 400. The product is intended for dilution with 0.9% sodium chloride injection or 5% dextrose injection prior to intravenous infusion.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Dimethylacetamide (127-19-5)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm
USA ACGIH	ACGIH chemical category	Skin - potential significant contribution to overall exposure by the cutaneous route, Not Classifiable as a Human Carcinogen
USA ACGIH	Biological Exposure Indices (BEI)	30 mg/g Kreatinin Parameter: N-Methylacetamide - Medium: urine - Sampling time: end of shift at end of workweek
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	35 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
USA IDLH	US IDLH (ppm)	300 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	35 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm
USA OSHA	Limit value category (OSHA)	prevent or reduce skin absorption
Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³ (MW>200, aerosol)

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when flammable gases or vapors may be released. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Gas detectors should be used when toxic gases may be released.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear
Odor	: Odorless
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available

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Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: 1.07 (Water = 1)
Solubility	: Water: Water Soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Reacts violently with strong oxidizers. Increased risk of fire or explosion.
- 10.2. Chemical Stability:** Combustible liquid. May form flammable or explosive vapor-air mixture.
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, heat, hot surfaces, sparks, open flames, incompatible materials, and other ignition sources.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂). Nitrogen oxides. Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

Busulfan Injection	
ATE (Oral)	1,656.38 mg/kg body weight
Dimethylacetamide (127-19-5)	
LD50 Oral Rat	4263 mg/kg
LD50 Dermal Rabbit	2240 mg/kg
LC50 Inhalation Rat	8.81 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	4.41 mg/l/4h
LC50 Inhalation Rat	2.5 mg/l/4h
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 ml/kg
Busulfan (55-98-1)	
LD50 Oral Rat	19 mg/kg
ATE (Dermal)	50.00 mg/kg body weight
ATE (Dust/Mist)	0.05 mg/l/4h

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: May cause cancer.

Busulfan (55-98-1)	
IARC group	1
National Toxicology Program (NTP) Status	Known Human Carcinogens.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

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Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: This material may cause adverse health effects. This material may be absorbed through the skin and eyes.

Symptoms/Injuries After Eye Contact: May cause eye irritation. May be absorbed through the eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects.

Chronic Symptoms: May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Repeated or prolonged exposure may damage:

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Dimethylacetamide (127-19-5)

EC50 Daphnia 1 > 500 mg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability

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Persistence and Degradability Not established.

12.3. Bioaccumulative Potential

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Bioaccumulative Potential Not established.

Dimethylacetamide (127-19-5)

Log Pow 0.8

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Fire hazard Immediate (acute) health hazard Delayed (chronic) health hazard
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Dimethylacetamide (127-19-5)

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

Polyethylene glycol (25322-68-3)

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

EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e., Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C))
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15.2. US State Regulations

Dimethylacetamide (127-19-5)

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U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	WARNING: This product contains chemicals known to the State of California to cause (Male) reproductive harm.
Busulfan (55-98-1)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
Dimethylacetamide (127-19-5)	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List	
Busulfan (55-98-1)	
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Special Hazardous Substances U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date	: 01/10/2019
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal) Category 2
Acute Tox. 2 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation: vapor)	Acute toxicity (inhalation: vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 1A	Carcinogenicity Category 1A
Flam. Liq. 4	Flammable liquids Category 4
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1A	Reproductive toxicity Category 1A
Repr. 1B	Reproductive toxicity Category 1B
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H301	Toxic if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
H312	Harmful in contact with skin
H330	Fatal if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure

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Refer to American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall American Regent, Inc., its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if American Regent, Inc. has been advised of the possibility of such damages.

SDS US (GHS HazCom)