

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Diluent for Romidepsin for Injection**
Product Use/Restriction: Diluent for Romidepsin
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: May 24, 2013
SDS Revision Date: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Flammable Liquid. Category 2.
Eye Irritation. Category 2.

Hazard Statements: Highly flammable liquid and vapor.
Causes serious eye irritation.

Precautionary Statements: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
Keep container tightly closed.
Ground/Bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Wash hands thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
In case of fire: Use dry chemical, carbon dioxide to extinguish small fires. Use water for large fires.
Store in a well-ventilated place. Keep cool.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: Flammable. CNS effects, and liver effects. Direct contact may cause irritation.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation.

Carcinogenicity: None of the constituents are listed by U.S. OSHA, NTP, or IARC as a carcinogen.

Target Organs: Liver, nervous system.

Aggravation of Pre-Existing Conditions: Pre-existing skin and respiratory conditions.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|------------------|---------|--------------------|-----------|
| Propylene Glycol | 57-55-6 | 80 % | 200-338-0 |
| Ethyl Alcohol | 64-17-5 | 20 % | 200-578-6 |

SECTION 4 : FIRST AID MEASURES

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| Eye Contact: | Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention. |
| Skin Contact: | Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists. |
| Inhalation: | If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention. |
| Ingestion: | If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. |
| Other First Aid: | For Adverse Event Information, please call (800) 551-7176. |

SECTION 5 : FIRE FIGHTING MEASURES

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| Flammable Properties: | Flammable. |
| Flash Point: | 75 °F (24 °C) |
| Flash Point Method: | Not reported. |
| Auto Ignition Temperature: | Not established. |
| Lower Flammable/Explosive Limit: | Not established. |
| Upper Flammable/Explosive Limit: | Not established. |
| Fire Fighting Instructions: | Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water. |
| Extinguishing Media: | Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Protective Equipment: | As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Hazardous Combustion Byproducts: | Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion. |

SECTION 6 : ACCIDENTAL RELEASE MEASURES

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| Personal Precautions: | Avoid contact with eyes and skin. |
| Methods for containment: | Contain spill using inert absorbent material. |
| Methods for cleanup: | Wipe up with adsorbent material (e.g. cloth, fleece). Rinse absorbent material thoroughly with water before disposing of it. Do not place soaked material in a closed container. |

SECTION 7 : HANDLING and STORAGE

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| Handling: | Use with adequate ventilation. Avoid breathing vapor and contact with eyes, skin and clothing. Do not take internally. |
| Storage: | Store in a cool, dry, well ventilated area away from sources of heat and incompatible materials. Keep container tightly closed when not in use. |
| Hygiene Practices: | Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist. |

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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| Engineering Controls: | General ventilation is sufficient if this product is being used in a controlled art studio setting for its sole intended photo-shooting purpose for the Marketing Catalog. NOTE: This product demo is a dummy for product catalog photo-shooting only; thus it is not a real pharmaceutical injectable product. It is not intended for real parenteral (injection) purposes. |
| Eye/Face Protection: | Chemical splash goggles. Wear a face shield also when splash hazard exist. |
| Skin Protection Description: | Protective laboratory coat, apron, or disposable garment recommended. |
| Hand Protection Description: | Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended. |
| Respiratory Protection: | No special protective equipment required. |
| Other Protective: | Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment. |

EXPOSURE GUIDELINES

Ethyl Alcohol:

Guideline ACGIH: TLV-TWA: 1000 ppm
Guideline OSHA: PEL-TWA: 1000 ppm
Guideline NIOSH: REL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State: Liquid solution.
Color: Clear
Boiling Point: 74-80 °C
Melting Point: Not established.
Specific Gravity: <1
Solubility: Insoluble in water.
Vapor Density: Not established.
Vapor Pressure: 5.3kPa @ 20 °C
Percent Volatile: Not established.
pH: Not established.
Molecular Formula: Mixture
Molecular Weight: Mixture
Flash Point: 75 °F (24 °C)
Flash Point Method: Not reported.
Auto Ignition Temperature: Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.
Hazardous Polymerization: Not reported.
Conditions to Avoid: Protect from light, heat, and freezing.
Incompatible Materials: Avoid contact with strong oxidizing agents.
Special Decomposition Products: Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 11 : TOXICOLOGICAL INFORMATION

Propylene Glycol:

RTECS Number: TY2000000
Eye: Eye - Rabbit Standard Draize test.: 100 mg [mild]
Eye - Rabbit Standard Draize test.: 500 mg/24H [mild]
Skin: Administration onto the skin - Rabbit : 20800 mg/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit : 20800 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression]
Administration onto the skin - Human : 10 pph [Skin and Appendages - Dermatitis, allergic (After topical exposure)]
Administration onto the skin - Mouse : 1284800 mg/kg/2Y (Intermittent) [Skin and Appendages - Tumors]
Administration onto the skin - Human : 5 mg/kg/7D (Intermittent) [Skin and Appendages - Primary irritation (After topical exposure)]
Administration onto the skin - Human : 4.5 mg/kg/3D (Intermittent) [Skin and Appendages - Primary irritation (After topical exposure)]
Administration onto the skin - : 0.03 mL/kg/22D (Intermittent) [Skin and Appendages - Cutaneous sensitization, experimental (After topical exposure)]
Administration onto the skin - Human : 10 pph/48H (Continuous) [Skin and Appendages - Dermatitis, allergic (After topical exposure)]
Administration onto the skin - Human : 500 mg/7D
Administration onto the skin - Human : 104 mg/3D (Intermittent)
Administration onto the skin - : 10 %/2D
Administration onto the skin - : 30 %/96H (Continuous)
Administration onto the skin - : 30 %/96H
Ingestion: Oral - Mouse LD50: 22 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 20300 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression]
Oral - Rat LD50: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]

Ethyl Alcohol:

RTECS Number: KQ6300000
Eye: Eye - Rabbit Rinsed with water.: 100 mg/4S
Skin: Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Open irritation test: 400 mg
Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H

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| Inhalation: | Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 39 gm/m3/4H [Details of toxic effects not reported other than lethal dose value] |
| Ingestion: | Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value] |
| Carcinogenicity: | Studies considered equivocal. |
| Mutagenicity: | Mixed results reported. |
| Reproductive Toxicity: | No studies identified. |
| Teratogenicity: | Birth defects reported after oral ingestion. |
| Chronic Effects: | CNS depression and liver effects. |

SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity: | No ecotoxicity data was found for the product. |
| Environmental Stability: | No environmental information found for this product. |

SECTION 13 : DISPOSAL CONSIDERATIONS

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| Waste Disposal: | Dispose of in accordance with Local, State, Federal and Provincial regulations. |
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SECTION 14 : TRANSPORT INFORMATION

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| DOT Shipping Name: | Not Regulated. |
| DOT UN Number: | Not Regulated. |
| DOT Exemption: | ORM-D Consumer Commodity. |

SECTION 15 : REGULATORY INFORMATION

Propylene Glycol:

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| TSCA Inventory Status: | Listed |
| Canada DSL: | Listed |
| EC Number: | 200-338-0 |

Ethyl Alcohol:

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| TSCA Inventory Status: | Listed |
| EINECS Number: | 200-578-6 |
| Canada DSL: | Listed |
| EC Number: | 200-578-6 |

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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| HMIS Health Hazard: | 2 |
| HMIS Fire Hazard: | 3 |
| HMIS Reactivity: | 1 |
| HMIS Personal Protection: | X |

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|---------------------------|---------------|
| SDS Creation Date: | May 24, 2013 |
| SDS Revision Date: | June 01, 2015 |

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