SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: **Romidepsin for Injection**

Other means of identification:

Recommended use of the chemical and restrictions on use:

Product Use/Restriction: Antineoplastic.

Chemical manufacturer address and telephone number:

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

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:

Signal Word: DANGER!

GHS Class:
Skin Sensitizer, Category 1.
Acute Toxicity Oral, Category 3.
Germ cell mutagenicity, Category 2.

Hazard Statements:
H301 - Toxic if swallowed.
H317 - May cause an allergic skin reaction.
H341 - Suspected of causing genetic defects.

Precautionary Statements:
P264: Wash {hands} thoroughly after handling.
P261: Avoid breathing {dust/fume/gas/mist/vapours/spray}.
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
P362+364: Take off contaminated clothing and wash it before reuse.
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P281: Use personal protective equipment as required.
P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P330: Rinse mouth.
P302+352: IF ON SKIN: Wash with plenty of soap and water.
P333+313: If skin irritation or rash occurs, seek medical advice/attention.
P308+313: IF exposed or concerned: Get medical attention/advice.
P391: Collect spillage
P501 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Hazards not otherwise classified that have been identified during the classification process:

Emergency Overview: Material may be irritating to the mucous membranes and upper respiratory tract.

Route of Exposure: Inhalation Ingestion Skin Absorption. Injection.

Signs/Symptoms: The most commonly observed adverse effects in clinical trials with romidespsin were hematotoxicity (anemia, neutropenia, thrombocytopenia), gastrointestinal toxicity (nausea, vomiting, constipation, diarrhea), infection, fatigue, lethargy, asthenia, and transient liver enzyme abnormalities. Other frequently occurring effects included anorexia, clinical chemistry abnormalities, fever, taste alteration, and ECG abnormalities without clinically significant sequelae. There are no adequate and well-controlled studies of romidepsin in pregnant women. However, based on its mechanism of action and the embryocidal/developmental effects seen in rats, it is reasonable to predict that romidepsin may cause fetal harm when administered to pregnant women.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Romidepsin	128517-07-7	10 mg/vial	

SECTION 4 : FIRST AID MEASURES

Description of necessary measures:

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.

Most important symptoms/effects, acute and delayed:

Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable 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.

Specific hazards arising from the chemical:

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.

Special protective equipment and precautions for fire-fighters:

Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
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.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.

Environmental precautions:

Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].

Specific end use(s):

Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Appropriate engineering controls:

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

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 personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
General Hygiene Considerations:	Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Lyophilized powder.
Color:	Off-white.
Boiling Point:	Not established.
Melting Point:	272.2°C
Solubility:	0.3 mg/l (VERY SLIGHTLY SOLUBLE) FREELY SOLUBLE IN DIMETHYLFORMAMIDE (249 mg/ml); SOLUBLE IN CHLOROFORM (26.5 mg/ml); SPARINGLY SOLUBLE IN DEHYDRATED ALCOHOL (23.5 mg/ml) AND ACETONE (22.4 mg/ml)
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	540.71
Flash Point:	Not established.
Flash Point Method:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization:	Not reported.

Incompatible Materials:

Incompatible Materials:	May react with strong oxidizing agents (peroxides, permanganates, nitric acid, etc.).

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Romidepsin :

Ingestion:	LD50 Rat Oral 55 mg/kg
Mutagenicity:	Romidepsin was negative in the Ames bacterial mutagenicity assay and an in vivo rat micronucleus test. It was very weakly positive in a mouse lymphoma forward mutation assay. The data suggest that romidepsin is not genotoxic in standard short-term screening assays. However, it is expected to cause epigenetic changes resulting in altered gene expression and cytotoxicity.
Reproductive Toxicity:	In repeat-dose toxicity studies, testicular lesions which persisted for two weeks post-dosing were seen in male mice (dose not specified). In dogs, doses >1 mg/kg/day caused hypospermia in the testes and epididymides as well as degeneration of seminiferous tubules. Minimal-to-severe ovarian atrophy with a decrease in follicular activity was seen in female rats (dose not specified); atrophic changes were also observed in the uterus.
Teratogenicity:	Maternal and developmental toxicity was observed in embryo-fetal developmental toxicity studies with rats administered IV romidepsin doses of 0.1, 0.2, and 0.5 mg/kg/day (0.6, 1.2 and 3.0 mg/m2, respectively) during organogenesis. Maternal findings included adverse clinical signs and dose-dependent reductions in body weight gain and feed consumption or body weight at ³0.1 mg/kg/day (³0.6 mg/m2). Gravid uterine weight was also reduced. Adverse developmental findings included early resorptions, reduced fetal body weights, increased incidences of rotated hindlimbs and folded retina, delayed ossifications and supernumerary thoracic ribs at doses ³0.2 mg/kg/day (³1.2 mg/m2).
Other Toxicological Information:	LD50 Intravenous Rat 2.6-3.6 mg/kg (males), 3.6-5.1 mg/kg (females)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:

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

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Medicine, solid, toxic, n.o.s.
DOT UN Number:	UN3249
DOT Hazard Class:	6.1
DOT Packing Group:	III

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Romidepsin :

TSCA Inventory Status:	Exempt.
Canada DSL:	Not listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

Health Hazard	**3***
Fire Hazard	**0**
Reactivity	**0**
Personal Protection	**X**

* **Chronic Health Effects**

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