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Section 1. Identification

GHS product identifier	:	Bleomycin for Injection	
Chemical name	:	Bleomycin, sulfate (salt)	
Other means of identification	:	: bleomycin sulfate; Bleomycin, sulfate; 3-[[2-[2-[[2-[[4-[[2-[[6-amino-2-[3-amino-1-[(2,3-diamino-3-oxopropyl)amino]-3-oxopropyl]-5-methylpyrimidine-4-carbonyl]amino]-3-[(2R,3S,4S,5S,6S)-3-[(2R,3S,4S,5R,6R)-4-carbamoyloxy-3,5-dihydroxy-6-(hydroxymethyl) oxan-2-yl]oxy-4,5-dihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-3-(3H-imidazol-4-yl) propanoyl]amino]-3-hydroxy-2-methylpentanoyl]amino]-3-hydroxybutanoyl]amino]ethyl] -1,3-thiazol-4-yl]1,3-thiazole-4-carbonyl]amino]propyl-dimethylsulfanium, hydrogen sulfate	
Product type	1	Powder.	
Relevant identified uses of th	<u>e s</u>	substance or mixture and uses advised against	
Product use	-	Pharmaceuticals. (For intended use only.) Observe technical data sheet/instructions for use. Specific Treatments: Anti-bacterial agent/Antineoplastic agents.	
Area of application	1	Professional applications.	
Supplier's details	:	Meitheal Pharmaceuticals, Inc. 8700 W. Bryn Mawr, Suite 600S Chicago, IL 60631 Telephone: 224-443-4617 www.meithealpharma.com	
e-mail address of person responsible for this SDS	:	info@meithealpharma.com	
Emergency telephone number (with hours of operation)	:	844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)	

Section 2. Hazards identification

OSHA/HCS status		: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	
Classification of the substance or mixture	: H340 H351 H361	COMBUSTIBLE DUSTS GERM CELL MUTAGENICITY - Category 1B CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION - Category 2	

GHS label elements



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Section 2. Hazards identification

Hazard pictograms



Signal word	: Danger
Hazard statements	 H340 - May cause genetic defects. H351 - Suspected of causing cancer. H361 - Suspected of damaging fertility or the unborn child. May form combustible dust concentrations in air.
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.
Response	: P308 + P313 - IF exposed or concerned: Get medical advice or attention.
Storage	: P405 - Store locked up.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Substance
Chemical name	: Bleomycin, sulfate (salt)
Other means of identification	: bleomycin sulfate; Bleomycin, sulfate; 3-[[2-[2-[[2-[[2-[[4-[[2-[[6-amino-2-[3-amino-1-[(2,3-diamino-3-oxopropyl)amino]-3-oxopropyl]-5-methylpyrimidine-4-carbonyl]amino]-3-[(2R,3S,4S,5S,6S)-3-[(2R,3S,4S,5R,6R)-4-carbamoyloxy-3,5-dihydroxy-6-(hydroxymethyl) oxan-2-yl]oxy-4,5-dihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-3-(3H-imidazol-4-yl) propanoyl]amino]-3-hydroxy-2-methylpentanoyl]amino]-3-hydroxybutanoyl]amino]ethyl] -1,3-thiazol-4-yl]1,3-thiazole-4-carbonyl]amino]propyl-dimethylsulfanium, hydrogen sulfate

CAS number/other identifiers

CAS number	: 9041-93-4			
Ingredient name		Other names	%	Identifiers
Bleomycin, sulfate (salt)		-	100	CAS: 9041-93-4

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.



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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 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 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. 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 effe	<u>cts</u>	
Eye contact	: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.	
Inhalation	: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.	
Skin contact	: No known significant effects or critical hazards.	
Ingestion	: No known significant effects or critical hazards.	
<u>Over-exposure signs/sym</u>	<u>otoms</u>	
Eye contact	: Adverse symptoms may include the following: irritation redness	
Inhalation	: Adverse symptoms may include the following: respiratory tract irritation coughing reduced fetal weight increase in fetal deaths skeletal malformations	



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Section 4. First aid measures

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 med	dical 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.

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See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media	
Suitable extinguishing media	: Use dry chemical powder.
Unsuitable extinguishing media	: Do not use water jet.
Specific hazards arising from the chemical	: May form explosible dust-air mixture if dispersed.
Hazardous thermal decomposition products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides sodium 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. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
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.



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Section 6. Accidental release measures

Personal precautions, protect	ive 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. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions Methods and materials for con	: 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).
Small spill	: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.
Large spill	: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

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 exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. 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. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.



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Section 7. Handling and storage

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 a segregated and approved area. 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. Eliminate all ignition sources. Separate from oxidizing materials. 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 lin	<u>iits</u>	
Ingredient name	Exposure limits	
Bleomycin, sulfate (salt)	None.	
Appropriate engineering controls	: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.	
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 meas	res	
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: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.	

Skin protection



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Section 8. Exposure controls/personal protection

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Hand protection	: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
Body protection	 Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	 Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
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	: Solid. [Lyophilized/Powder.]
Color	: White to off-white. Colorless to light yellow. [Reconstitution solution]
Odor	: Odorless.
Odor threshold	: Not available.
рН	: 4.5 to 6
Melting point	: 71°C (159.8°F)
Boiling point or initial boiling point and boiling range	: Not available.
Flash point	: Not applicable.
Evaporation rate	: Not available.
Flammability	: Not available.
Lower and upper explosion limit/flammability limit	: Not applicable.
Vapor pressure	: Not available.
Relative vapor density	: Not applicable.
Relative density	: Not available.
Density	: Not available.



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Section 9. Physical and chemical properties

Solubility(ies)	1	Media	Result
		cold water	Soluble
		hot water	Soluble
Miscible with water	:	Yes.	
Partition coefficient: n- octanol/water	:	Not available.	
Auto-ignition temperature	1	Not applicable.	
Decomposition temperature	1	Not available.	
SADT	1	Not available.	
Viscosity	:	Dynamic (room temperatur Kinematic (room temperatu Kinematic (40°C (104°F)): N	ure): Not available.
Flow time (ISO 2431)	1	Not available.	
Particle characteristics			
Median particle size	:	Not available.	
Other information		(
Physical/chemical properties comments	:	No additional information.	

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
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 the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation. Extremes of temperature and direct sunlight.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials Reactive or incompatible with the following materials: acids, alkalis and moisture.
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

Not available.

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mu	Itad	aen	icit	v
_	_		_	-

Conclusion/Summary	: No	ot available.		0
Carcinogenicity				
Conclusion/Summary	: No	ot available.		
Classification				
Product/ingredient name		OSHA	IARC	NTP
Bleomycin, sulfate (salt)		-	2B	-
Reproductive toxicity		C.	$\overline{\mathcal{O}}_{1}$	
Conclusion/Summary	: No	ot available.		
<u>Teratogenicity</u>				
Conclusion/Summary	: No	ot available.		
Specific target organ toxicit	y (sin	<u>gle exposure)</u>		

Not available.

Specific target organ toxicity (repeated exposure) Not available.

Aspiration hazard

Not available.

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

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routes of exposure
Potential acute health effects
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Eye contact: Exposure to airborne concentrations above statutory or recommended exposure limits
may cause irritation of the eyes.Inhalation: Exposure to airborne concentrations above statutory or recommended exposure limits
may cause irritation of the nose, throat and lungs.Skin contact: No known significant effects or critical hazards.Ingestion: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics



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Section 11. Toxicological information

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Eye contact	: Adverse symptoms may include the following: irritation redness
Inhalation	: Adverse symptoms may include the following: respiratory tract irritation coughing reduced fetal weight increase in fetal deaths skeletal malformations
Skin contact	: Adverse symptoms may include the following: reduced fetal weight increase in fetal deaths skeletal malformations
Ingestion	: Adverse symptoms may include the following: reduced fetal weight increase in fetal deaths skeletal malformations

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

Delayed and initiadate energy	to and also enrolle encets non-short and long term exposure
<u>Short term exposure</u>	
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 eff	<u>ects</u>
General	: Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.
Carcinogenicity	: Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.
Mutagenicity	: May cause genetic defects.
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.

Numerical measures of toxicity

Acute toxicity estimates

N/A



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Section 12. Ecological information

Toxicity

Conclusion/Summary : Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

Section 13. Disposal considerations

Dis	posal	met	hods
	posu	met	1045

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-



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Environmental	No.	No.	No.
hazards			

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 : Not available. to IMO instruments

Section 15. Regulatory information

U.S. Federal regulations	: TSCA 8(a) CDR Exempt/Partial exemption: Not determined
	United States inventory (TSCA 8b): Not determined.
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	: COMBUSTIBLE DUSTS GERM CELL MUTAGENICITY - Category 1B CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION - Category 2
Composition/information	on ingredients



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Section 15. Regulatory information

Name	%	Classification
Bleomycin, sulfate (salt)	100	COMBUSTIBLE DUSTS GERM CELL MUTAGENICITY - Category 1B CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION - Category 2

SARA 313

Not applicable.

State regulations Massachusetts

: This material is not listed.

New York New Jersey : This material is not listed.

: This material is not listed.

: This material is not listed.

Pennsylvania

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

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

Health	*	0
Flammability		3
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.



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Section 16. Other information

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
COMBUSTIBLE DUSTS GERM CELL MUTAGENICI CARCINOGENICITY - Cate TOXIC TO REPRODUCTIC	gory 2		On basis of test data Expert judgment Expert judgment Expert judgment
History Date of issue/Date of revision Date of previous issue	: 07/25/2024 : 08/03/2022	Č,	
Version Prepared by	: 4.0 : Sphera Solutions		
Key to abbreviations	8-hr shift BCF = Bioconcentration GHS = Globally Harmon IATA = International Air T IBC = International Ma LogPow = Iogarithm of th MARPOL = International modified by the Protocol N/A = Not available UN = United Nations	mum peak above the a Factor ized System of Classifi Transport Association Container ritime Dangerous Good ne octanol/water partitio Convention for the Pre of 1978. ("Marpol" = m	on coefficient evention of Pollution From Ships, 1973 as narine pollution)
References	: HCS (U.S.A.)- Hazard C International transport re		rd

Indicates information that has changed from previously issued version.

Notice to reader

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

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.