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Section 1. Identification

GHS product identifier : Neostigmine Methylsulfate Injection, USP

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: cholinesterase inhibition

Area of application: Professional applications.

Supplier's details: Meitheal Pharmaceuticals, Inc.

8700 W. Bryn Mawr, Suite600S

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)

f

: 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication

Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available

for employees and other users of this product.

Classification of the substance or mixture

: Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention: Not applicable.Response: Not applicable.Storage: Not applicable.



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Section 2. Hazards identification

Disposal : Not applicable.

Hazards not otherwise : None known.

classified

Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of : Not available.

identification

Ingredient name	Other names	%	CAS number
water	-	≥90	7732-18-5
phenol	-	<1	108-95-2
acetic acid	-	≤0.3	64-19-7
sodium hydroxide	-	≤0.3	1310-73-2
nitrogen	-	≤0.3	7727-37-9
neostigmine metilsulfate	-	≤0.1	51-60-5
Acetic acid, sodium salt, hydrate (1:1:3)	-	≤0.1	6131-90-4

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 as hazardous to health 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. Get medical attention if irritation

occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get

medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and

shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.



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Section 4. First aid measures

Over-exposure signs/symptoms

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

Unsuitable extinguishing

media

: Do not use water jet.

Specific hazards arising from the chemical

Hazardous thermal

decomposition products

: In a fire or if heated, a pressure increase will occur and the container may burst.

: Decomposition products may include the following materials: carbon dioxide

: Use an extinguishing agent suitable for the surrounding fire.

carbon monoxide

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.



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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. 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 nonemergency 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. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. 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 (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

Advice on general occupational hygiene

- : Put on appropriate personal protective equipment (see Section 8).
- ; 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.

including any incompatibilities

Conditions for safe storage, : 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. 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.



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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
water phenol acetic acid	None. ACGIH TLV (United States, 3/2019). Absorbed through skin. TWA: 5 ppm 8 hours. TWA: 19 mg/m³ 8 hours. NIOSH REL (United States, 10/2016). Absorbed through skin. TWA: 5 ppm 10 hours. TWA: 19 mg/m³ 10 hours. CEIL: 15.6 ppm 15 minutes. CEIL: 60 mg/m³ 15 minutes.
	NIOSH REL (United States, 10/2016). TWA: 10 ppm 10 hours. TWA: 25 mg/m³ 10 hours. STEL: 15 ppm 15 minutes. STEL: 37 mg/m³ 15 minutes. OSHA PEL (United States, 5/2018). TWA: 10 ppm 8 hours. TWA: 25 mg/m³ 8 hours.
sodium hydroxide	ACGIH TLV (United States, 3/2019). C: 2 mg/m³ NIOSH REL (United States, 10/2016). CEIL: 2 mg/m³
nitrogen	OSHA PEL (United States, 5/2018). TWA: 2 mg/m³ 8 hours. ACGIH TLV (United States, 3/2019). Oxygen Depletion [Asphyxiant]. None.
neostigmine metilsulfate Acetic acid, sodium salt, hydrate (1:1:3)	None.

Appropriate engineering controls

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.



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Section 8. Exposure controls/personal protection

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: safety glasses with sideshields.

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.

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

Appearance

Physical state : Liquid. [Clear.] Color : Colorless. Odor : Not available. **Odor threshold** : Not available. pН 5 to 6.5 **Melting point** : Not available. **Boiling point** : Not available. : Not available. Flash point : Not available. **Evaporation rate**



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Section 9. Physical and chemical properties

Flammability (solid, gas)

Lower and upper explosive

(flammable) limits

: Not applicable. : Not available.

: Not available. Vapor pressure Vapor density : Not available. : 1 [Water = 1] **Relative density** : 1 g/cm³ **Density Solubility** : Not available. : Notavailable.

Solubility in water Partition coefficient: n-

octanol/water

: Not available.

: Not available. **Auto-ignition temperature** : Notavailable. **Decomposition temperature SADT** : Not available. **Viscosity** : Not available. : Not available. Flow time (ISO 2431)

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

: The product is stable. **Chemical stability**

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 : No specific data.

: Reactive or incompatible with the following materials: oxidizing materials. **Incompatible materials**

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	Result	Species	Dose	Exposure
phenol	LC50 Inhalation Dusts and mists	Rat	316 mg/m³	4 hours
	LD50 Dermal LD50 Dermal	Rabbit Rat	630 mg/kg 669 mg/kg	-
	LD50 Oral	Rat	317 mg/kg	<u>-</u> .
acetic acid	LC50 Inhalation Vapor LD50 Dermal	Rat Rabbit	11000 mg/m³ 1060 mg/kg	4 hours
	LD50 Oral	Rat	3310 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
phenol	Eyes - Mild irritant	Rabbit	/-	0.5 minutes 5	-
				mg	
	Eyes - Severe irritant	Rabbit	-	5 mg	-
	Skin - Mild irritant	Rabbit	-	100 mg	-
	Skin - Severe irritant	Rabbit	-	535 mg	-
acetic acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5	-
		1		mg	
	Skin - Mild irritant	Rabbit	-	24 hours 50	-
				mg	
	Skin - Severe irritant	Rabbit	-	525 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50	-
				ug	
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1	-
				mg	
	Skin - Severe irritant	Rabbit	-	24 hours 500	-
				mg	

Sensitization

Not available.

Mutagenicity

Conclusion/Summary: Not available.

Carcinogenicity

Conclusion/Summary: Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
phenol	-	3	-

Reproductive toxicity

Conclusion/Summary: Not available.



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Section 11. Toxicological information

Teratogenicity

Conclusion/Summary: Not available.

Specific target organ toxicity (single exposure)

Name		Route of exposure	Target organs
sodium hydroxide	Category 3		Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	1 3 3 7	Route of exposure	Target organs
phenol	Category 2		kidneys, liver, nervous system

Aspiration hazard

Not available.

Information on the likely : Not available. routes of exposure

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

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

Short term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.



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Section 11. Toxicological information

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.
 Fertility effects : No known significant effects or critical hazards.

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/ I)
phenol	317	630	N/A	N/A	0.316
acetic acid	3310	1060	N/A	11	N/A
neostigmine metilsulfate	100	5	N/A	0.05	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
phenol	Acute EC50 61.1 μg/l Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute EC50 36 mg/l Marine water	Algae - Hormosira banksii - Gamete	72 hours
	Acute EC50 94 mg/l Fresh water	Aquatic plants - Lemna aequinoctialis	96 hours
	Acute EC50 4200 μg/l Fresh water Acute LC50 800 μg/l Marine water	Daphnia - Daphnia magna Crustaceans - Archaeomysis kokuboi - Juvenile (Fledgling, Hatchling, Weanling)	48 hours 48 hours
	Acute LC50 1555 μg/l Fresh water Chronic NOEC 16 μg/l Marine water	Fish - Cirrhinus mrigala - Larvae Algae - Hormosira banksii - Gamete	96 hours 72 hours
acetic acid	Chronic NOEC 1.5 mg/l Fresh water Chronic NOEC 118 μg/l Fresh water Acute EC50 73400 μg/l Fresh water Acute EC50 65000 μg/l Fresh water	Daphnia - Daphnia magna Fish - Oncorhynchus mykiss Algae - Navicula seminulum Daphnia - Daphnia magna - Neonate	21 days 90 days 96 hours 48 hours



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Section 12. Ecological information

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	Acute LC50 32 mg/l Marine water	Crustaceans - Artemia salina	48 hours
	Acute LC50 75000 μg/l Fresh water	Fish - Lepomis macrochirus	96 hours
sodium hydroxide	Acute EC50 40.38 mg/l Fresh water	Crustaceans - Ceriodaphnia	48 hours
		dubia - Neonate	
	Acute LC50 125 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours

Conclusion/Summary: Not available.

Persistence and degradability

Product/ingredient name	Test	Result	Dose		Inoculum
phenol	301C Ready Biodegradability - Modified MITI Test (I)	85 % - 14 days	-		-
Product/ingredient name	Aquatic half-life	Photolysis		Biodeg	radability
phenol acetic acid	-			Inheren Readily	

Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
water phenol acetic acid nitrogen Acetic acid, sodium salt, hydrate (1:1:3)	-1.38 1.47 -0.17 0.67 -4.22	- 647 3.16 -	low high low low

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

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



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Section 13. Disposal considerations

safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and

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	-	-	-
Environmental hazards	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 : 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 Water Act (CWA) 307: phenol

Clean Water Act (CWA) 311: phenol; acetic acid; sodium hydroxide

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Listed

Clean Air Act Section 602

: Notlisted

Class I Substances

: Notlisted

Clean Air Act Section 602

Class II Substances



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Section 15. Regulatory information

DEA List I Chemicals

: Notlisted

(Precursor Chemicals)

DEA List II Chemicals

: Notlisted

(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

			SARA 302 TPQ		SARA 304 RQ	
Name	%	EHS	(lbs)	(gallons)	(lbs)	(gallons)
phenol	<1	Yes.	500 / 10000	-	1000	-

SARA 304 RQ : 222222.2 lbs / 100888.9 kg [26652 gal / 100888.9 L]

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
phenol	<1	ACUTE TOXICITY (oral) - Category 4
		ACUTE TOXICITY (dermal) - Category 3
	. 64	ACUTE TOXICITY (inhalation) - Category 2
		SKIN CORROSION - Category 1B
		SERIOUS EYE DAMAGE - Category 1
		GERM CELL MUTAGENICITY - Category 2
		SPECIFIC TARGET ORGAN TOXICITY (REPEATED
		EXPOSURE) - Category 2
		HNOC - Corrosive to digestive tract
acetic acid	≤0.3	FLAMMABLE LIQUIDS - Category 3
		ACUTE TOXICITY (dermal) - Category 4
		ACUTE TOXICITY (inhalation) - Category 4
		SKIN CORROSION - Category 1A
		SERIOUS EYE DAMAGE - Category 1
		HNOC - Corrosive to digestive tract [severe]
sodium hydroxide	≤0.3	CORROSIVE TO METALS - Category 1
		SKIN CORROSION - Category 1A
		SERIOUS EYE DAMAGE - Category 1
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
		(Respiratory tract irritation) - Category 3
		HNOC - Corrosive to digestive tract [severe]
nitrogen	≤0.3	GASES UNDER PRESSURE - Compressed gas
		SIMPLE ASPHYXIANTS
neostigmine metilsulfate	≤0.1	ACUTE TOXICITY (oral) - Category 3
		ACUTE TOXICITY (dermal) - Category 1
	10.4	ACUTE TOXICITY (inhalation) - Category 1
Acetic acid, sodium salt, hydrate (1:1:3)	≤0.1	COMBUSTIBLE DUSTS

SARA 313



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Not applicable.

State regulations

Massachusetts: None of the components are listed.New York: None of the components are listed.New Jersey: None of the components are listed.Pennsylvania: None of the components are listed.

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)

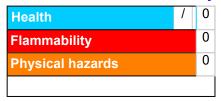
Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

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



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.)



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Section 16. Other information



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

Date of issue/Date of

revision

Date of previous issue

: No previous validation

Version : 1.0

Prepared by

: Sphera Solutions

Key to abbreviations

: ATE = Acute Toxicity Estimate

AMP = Acceptable maximum peak above the acceptable ceiling concentration for an

8-hr shift

: 07/15/2020

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

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

N/A = Not available
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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Section 16. Other information

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.

