

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Bismuth Subnitrate (with Mineral Oil) Formulation

Version 7.3      Revision Date: 05/09/2026      SDS Number: 5060473-00018      Date of last issue: 01/21/2026  
Date of first issue: 10/17/2019

### SECTION 1. IDENTIFICATION

Product name : Bismuth Subnitrate (with Mineral Oil) Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

#### Hazards for the product as supplied

Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure

#### Other hazards

None known.

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**  
P314 Get medical attention if you feel unwell.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Bismuth hydroxide nitrate oxide	1304-85-4*	>= 60 - <= 80	TSC
White mineral oil (petroleum)	8042-47-5*	>= 10 - <= 30	TSC
Fatty acids, C14-26, aluminum salts	97404-28-9*	>= 3 - <= 7	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

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- |  |   |   |
|--|---|---|
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                  | : | Nitrogen oxides (NOx)<br>Metal oxides<br>Carbon oxides  |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

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### SECTION 7. HANDLING AND STORAGE

- |                         |   |   |
|-------------------------|---|---|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.   |
| Local/Total ventilation | : | Use only with adequate ventilation.   |
| Advice on safe handling | : | Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment |

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Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Mist)	5 mg/m <sup>3</sup>	NIOSH REL
		ST (Mist)	10 mg/m <sup>3</sup>	NIOSH REL
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection  
Material : Chemical-resistant gloves

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Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	ointment
Color	:	White to light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available

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Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-  
tions : None known.

Conditions to avoid : None known.

Incompatible materials : None.

Hazardous decomposition  
products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

#### **Bismuth hydroxide nitrate oxide:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

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Acute inhalation toxicity : LC50 (Rat): > 5.07 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
Remarks: Based on data from similar materials

### White mineral oil (petroleum):

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### Fatty acids, C14-26, aluminum salts:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Bismuth hydroxide nitrate oxide:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439

Result : No skin irritation

#### White mineral oil (petroleum):

Species : Rabbit  
Result : No skin irritation

#### Fatty acids, C14-26, aluminum salts:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431

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Remarks : Based on data from similar materials

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials

Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### **Bismuth hydroxide nitrate oxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

#### **White mineral oil (petroleum):**

Species : Rabbit  
Result : No eye irritation

#### **Fatty acids, C14-26, aluminum salts:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

### Respiratory or skin sensitization

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **Bismuth hydroxide nitrate oxide:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

#### **White mineral oil (petroleum):**

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

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### Fatty acids, C14-26, aluminum salts:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Bismuth hydroxide nitrate oxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

#### White mineral oil (petroleum):

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

#### Fatty acids, C14-26, aluminum salts:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

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### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **White mineral oil (petroleum):**

Species : Rat  
Application Route : Ingestion  
Exposure time : 24 Months  
Result : negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Bismuth hydroxide nitrate oxide:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

#### **White mineral oil (petroleum):**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Fatty acids, C14-26, aluminum salts:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

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reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

### Components:

#### Bismuth hydroxide nitrate oxide:

Target Organs

: Central nervous system

Assessment

: Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### White mineral oil (petroleum):

Species

: Rat

LOAEL

: 160 mg/kg

Application Route

: Ingestion

Exposure time

: 90 Days

Species

: Rat

LOAEL

: >= 1 mg/l

Application Route

: inhalation (dust/mist/fume)

Exposure time

: 4 Weeks

Method

: OECD Test Guideline 412

#### Fatty acids, C14-26, aluminum salts:

Species

: Rat

: >= 1000 mg/kg

Application Route

: Ingestion

Exposure time

: 42 Days

Remarks

: Based on data from similar materials

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### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Bismuth hydroxide nitrate oxide:**

Ingestion : Target Organs: Blood  
Symptoms: Methaemoglobinemia  
Target Organs: Central nervous system  
Symptoms: Neurological disorders

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Bismuth hydroxide nitrate oxide:**

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 137 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 137 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EL50 (Pseudokirchneriella subcapitata (green algae)): > 137  
plants : mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201

NOELR (Pseudokirchneriella subcapitata (green algae)): >  
137 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201

#### **White mineral oil (petroleum):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): 100



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If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

##### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

##### Domestic regulation

##### 49 CFR

Not regulated as a dangerous good

##### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

Bismuth hydroxide nitrate oxide	1304-85-4
White mineral oil (petroleum)	8042-47-5
Fatty acids, C14-26, aluminum salts	97404-28-9

##### California List of Hazardous Substances

White mineral oil (petroleum)	8042-47-5
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### California Permissible Exposure Limits for Chemical Contaminants

White mineral oil (petroleum)

8042-47-5

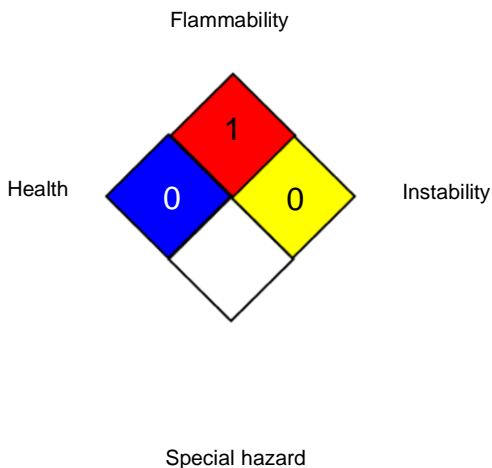
The ingredients of this product are reported in the following inventories:

AICS : not determined  
CA. DSL : not determined  
CN IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV / CED:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday  
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Sub-

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stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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