SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Bismuth Subnitrate (with Mineral Oil) Formulation

Version 5.1 Revision Date: 12/06/2023 SDS Number: 5060473-00012 Date of last issue: 12/04/2023 Date of first issue: 10/17/2019

SECTION 1. IDENTIFICATION

Product name: Bismuth Subnitrate (with Mineral Oil) Formulation
Other means of identification: Shutout (A011866) CEPRALOCK (89964)

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

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:
P260 Do not breathe dust, fume, gas, mist, vapors or spray.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Bismuth hydroxide nitrate oxide</td>
<td>1304-85-4</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td></td>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>29.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>9740-28-9</td>
<td>4.8</td>
</tr>
</tbody>
</table>

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 (CO2)
 Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Nitrogen oxides (NOx)
 Metal oxides
 Carbon oxides
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. 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. 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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 breathe dust, fume, gas, mist, vapors or spray. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

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.

**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
- **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 size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: None.
Hazardous decomposition products: No hazardous decomposition products are known.

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

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
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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
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
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**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

**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

Carcinogenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
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<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 Months</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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

#### White mineral oil (petroleum):
- **Effects on fertility**
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative

#### Fatty acids, C14-26, aluminum salts:
- **Effects on fertility**
  - Test Type: Combined repeated dose toxicity study with the 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
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
Application Route: Ingestion
Exposure time: 42 Days
Remarks: Based on data from similar materials

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 aquatic invertebrates:**
  - EL50 (Daphnia magna (Water flea)): > 137 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants:**
  - EL50 (Pseudokirchneriella subcapitata (green algae)): > 137 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 (Onchorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants:**
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- **Toxicity to fish (Chronic toxicity):**
  - NOEC (Onchorhynchus mykiss (rainbow trout)): 1,000 mg/l
  - Exposure time: 28 d
- **Toxicity to daphnia and other:**
  - NOEC (Daphnia magna (Water flea)): 1,000 mg/l
aquatic invertebrates (Chronic toxicity)  Exposure time: 21 d

Persistence and degradability

Components:
White mineral oil (petroleum):
Biodegradability:  Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Fatty acids, C14-26, aluminum salts:
Biodegradability:  Result: Readily biodegradable.
Biodegradation: 81.2 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:
Fatty acids, C14-26, aluminum salts:
Partition coefficient: n-octanol/water:  log Pow: > 7
Remarks: Calculation

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
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
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IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
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

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
DSL : not determined
IECSC : not determined
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HMIS® IV:

HEALTH 3

FLAMMABILITY 1

PHYSICAL HAZARD 0

Flammability

Instability

Health

Special hazard

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 Standardisation; DOT - Department of Transportation; DSL - Domestic Substances 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 Organisation for Standardization; KECI - Korea Existing Chemi-
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

US / Z8