SAFETY DATA SHEET

Bismuth Subnitrate (with Mineral Oil) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Bismuth Subnitrate (with Mineral Oil) Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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/ spray. 
P264 Wash skin thoroughly after handling. 
P270 Do not eat, drink or smoke when using this product. 
Response: 
P314 Get medical advice/ attention if you feel unwell. 
Disposal: 
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
SAFETY DATA SHEET

Bismuth Subnitrate (with Mineral Oil) Formulation

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>1304-85-4</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>&gt;= 1 - &lt; 5</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 fire fighting: 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: In the event of fire, wear self-contained breathing apparatus.
for fire-fighters

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 | Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
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. |
| 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 |
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:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
## Appearance
: Paste

## 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)

<table>
<thead>
<tr>
<th>Water solubility</th>
<th>: No data available</th>
</tr>
</thead>
</table>

## Partition coefficient: n-octanol/water
: Not applicable

## Autoignition temperature
: No data available

## Decomposition temperature
: No data available

## Viscosity

<table>
<thead>
<tr>
<th>Viscosity, kinematic</th>
<th>: Not applicable</th>
</tr>
</thead>
</table>

## Explosive properties
: Not explosive

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

## Molecular weight
: No data available
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Bismuth Subnitrate (with Mineral Oil) Formulation

Version 2.0    Revision Date: 10.10.2020    SDS Number: 5060469-00003    Date of last issue: 23.03.2020

Date of first issue: 17.10.2019

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: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
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

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

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         |

SAFETY DATA SHEET

Bismuth Subnitrate (with Mineral Oil) Formula-
tion

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

Genotoxicity in vitro:
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
Exposure time: 24 Months
Result: negative

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
SAFETY DATA SHEET

Bismuth Subnitrate (with Mineral Oil) Formula-
tion

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
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
SAFETY DATA SHEET

Bismuth Subnitrate (with Mineral Oil) Formula-
tion

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 (Oncorhynchus 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 (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) :
NOEC (Daphnia magna (Water flea)): 1,000 mg/l
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.
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

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

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico, Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE- PPT : Time weighted average limit value

AICL - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System


Revision Date : 10.10.2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8