1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Bismuth Subnitrate Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Specific target organ toxicity - repeated exposure : Category 1 (Central nervous system)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms : 
Signal word : Danger
Hazard statements : H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects.
Precautionary statements : Prevention:
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention if you feel unwell.
P391 Collect spillage.

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

**Other hazards which do not result in classification**
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture**: Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>1304-85-4</td>
<td>&gt;= 60 - &lt; 70</td>
<td>1-97</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 2.5 - &lt; 10</td>
<td>1-561</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td>3-540, 9-1805</td>
</tr>
</tbody>
</table>

### 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.

### 5. FIREFIGHTING 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 firefighters
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling
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, vapours 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.

Avoidance of contact: Oxidizing agents

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.

Storage

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

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/Personal Protection

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Petrolatum</td>
<td>8009-03-8</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>4 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>OEL-C</td>
<td>25 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>
Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.

<table>
<thead>
<tr>
<th>Substance</th>
<th>ID</th>
<th>TWA (Inhalable fraction and vapor)</th>
<th>ACGLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>2 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**

**Hand protection**: Combined particulates and organic vapour type

**Material**: Chemical-resistant gloves

**Remarks**: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Eye protection**: Wear the following personal protective equipment:

**Skin and body protection**: Skin should be washed after contact.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state**: paste

**Colour**: white

**Odour**: Petroleum

**Odour Threshold**: No data available

**Melting point/freezing point**: No data available

**Boiling point, initial boiling point and boiling range**: No data available

**Flammability (solid, gas)**: Not classified as a flammability hazard

**Flammability (liquids)**: No data available

**Lower explosion limit and upper explosion limit / flammability limit**

**Upper explosion limit / Upper flammability limit**: No data available

**Lower explosion limit / Lower flammability limit**: No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td></td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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.

11. TOXICOLOGICAL INFORMATION

- **Information on likely routes of exposure**: Skin contact, Ingestion, Eye contact
Acute toxicity
Not classified based on available information.

**Product:**

**Acute oral toxicity**
- Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

**Acute inhalation toxicity**
- Acute toxicity estimate: > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method

**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

**Petrolatum:**

**Acute oral toxicity**
- LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
  - Remarks: Based on data from similar materials

**Acute dermal toxicity**
- LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity
  - Remarks: Based on data from similar materials

**Zinc oxide:**

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

**Acute inhalation toxicity**
- LC50 (Rat): > 5.7 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

**Acute dermal toxicity**
- LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

**Benzyl alcohol:**

**Acute oral toxicity**
- LD50 (Rat): 1,620 mg/kg
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

Version 7.0
Revision Date: 2020/10/10
SDS Number: 656842-00014
Date of last issue: 2020/03/23
Date of first issue: 2016/05/02

Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 403

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
 Method: OECD Test Guideline 401

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
 Method: OECD Test Guideline 402
 Assessment: The substance or mixture has no acute dermal toxicity

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

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Zinc oxide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

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

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

Benzyl alcohol:
- Species: Rabbit
- Result: Irritation to eyes, reversing within 21 days
- Method: OECD Test Guideline 405

2,6-Di-tert-butyl-p-cresol:
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
- Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Bismuth hydroxide nitrate oxide:
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative

Petrolatum:
- Test Type: Buehler Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

Remarks: Based on data from similar materials

Zinc oxide:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Benzyl alcohol:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

2,6-Di-tert-butyl-p-cresol:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Bismuth hydroxide nitrate oxide:
<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

Petrolatum:
<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Genotoxicity in vivo:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal injection</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 474</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
Zinc oxide:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 476</td>
<td></td>
</tr>
<tr>
<td>Result: equivocal</td>
<td></td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td></td>
</tr>
<tr>
<td>Result: equivocal</td>
<td></td>
</tr>
</tbody>
</table>

Genotoxicity in vivo:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: inhalation (dust/mist/fume)</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
<td></td>
</tr>
<tr>
<td>Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>positive</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: inhalation (dust/mist/fume)</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

Germ cell mutagenicity - Assessment:

- Weight of evidence does not support classification as a germ cell mutagen.

Benzyl alcohol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

2,6-Di-tert-butyl-p-cresol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>
Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Petrolatum:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Zinc oxide:
Species: Mouse
Application Route: Ingestion
Exposure time: 1 Year
Result: negative
Remarks: Based on data from similar materials

Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

2,6-Di-tert-butyl-p-cresol:
Species: Rat
Application Route: Ingestion
Exposure time: 22 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 foetal development: Test Type: Embryo-foetal development
### Bismuth Subnitrate Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>OECD Test Guideline 414</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Petrolatum:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reproduction/Developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Skin contact</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

**2,6-Di-tert-butyl-p-cresol:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Embryo-foetal development</td>
</tr>
</tbody>
</table>
### 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.

##### Zinc oxide:
- **Assessment**: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

##### 2,6-Di-tert-butyl-p-cresol:
- **Assessment**: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

#### Repeated dose toxicity

##### Components:

##### Petrolatum:
- **Species**: Rat
- **NOAEL**: 5,000 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 yr

##### Zinc oxide:
- **Species**: Rat, male
- **NOAEL**: 0.0015 mg/l
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 3 Months
- **Method**: OECD Test Guideline 413

##### Benzyl alcohol:
- **Species**: Rat
- **NOAEL**: 1.072 mg/l
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 28 Days
- **Method**: OECD Test Guideline 412

##### 2,6-Di-tert-butyl-p-cresol:
- **Species**: Rat
# SAFETY DATA SHEET

## Bismuth Subnitrate Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>2020/10/10</td>
<td>656842-00014</td>
<td>2020/03/23</td>
<td>2016/05/02</td>
</tr>
</tbody>
</table>

### NOAEL
- **Application Route**: Ingestion
- **Exposure time**: 22 Months

#### Aspiration toxicity
Not classified based on available information.

#### Experience with human exposure

**Product:**
- **Ingestion**: Symptoms: The absorption of this product into the body may lead to the formation of methaemoglobin that, in sufficient concentration, causes cyanosis., May cause, Neurological disorders, Blood disorders, blood effects, central nervous system effects, Methaemoglobinemia

**Components:**
- **Bismuth hydroxide nitrate oxide**:
  - **Ingestion**
    - **Target Organs**: Blood
    - **Symptoms**: Methaemoglobinemia
    - **Target Organs**: Central nervous system
    - **Symptoms**: Neurological disorders

# 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
### Petrolatum:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>eativity &amp; method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l&lt;br&gt;Exposure time: 96 h&lt;br&gt;Test substance: Water Accommodated Fraction&lt;br&gt;Method: OECD Test Guideline 203&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l&lt;br&gt;Exposure time: 48 h&lt;br&gt;Test substance: Water Accommodated Fraction&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l&lt;br&gt;Exposure time: 72 h&lt;br&gt;Test substance: Water Accommodated Fraction&lt;br&gt;Method: OECD Test Guideline 201&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l&lt;br&gt;Exposure time: 21 d&lt;br&gt;Test substance: Water Accommodated Fraction&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

### Zinc oxide:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>eativity &amp; method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50: &gt; 0.1 - 1 mg/l&lt;br&gt;Exposure time: 96 h&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l&lt;br&gt;Exposure time: 72 h&lt;br&gt;NOEC (Pseudokirchneriella subcapitata (green algae)): &gt; 0.01 - 0.1 mg/l&lt;br&gt;Exposure time: 72 h&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Jordanella floridiae (flagfish)): &gt; 0.01 - 0.1 mg/l&lt;br&gt;Exposure time: 14 Weeks&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Ceriodaphnia dubia (water flea)): &gt; 0.01 - 0.1 mg/l&lt;br&gt;Exposure time: 7 d&lt;br&gt;Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Aspect</th>
<th>eativity &amp; method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</td>
<td></td>
</tr>
</tbody>
</table>
Exposure time: 96 h

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Exposure time: 48 h Method: OECD Test Guideline 202</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Exposure time: 48 h Method: OECD Test Guideline 202

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211


Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 0.57 mg/l Exposure time: 96 h Method: OECD Test Guideline 202

Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to fish: NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210

Exposure time: 21 d Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity): 1

Toxicity to microorganisms: EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Persistence and degradability

Components:

Petrolatum:

Benzyl alcohol:
- Biodegradability: Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d

2,6-Di-tert-butyl-p-cresol:
- Biodegradability: Result: Not readily biodegradable. Biodegradation: 4.5 % Exposure time: 28 d Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Zinc oxide:
- Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout) Bioconcentration factor (BCF): 78 - 2,060

Benzyl alcohol:
- Partition coefficient: n-octanol/water: log Pow: 1.05

2,6-Di-tert-butyl-p-cresol:
- Bioaccumulation: Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 330 - 1,800
- Partition coefficient: n-octanol/water: log Pow: 5.1

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide, 2,6-Di-tert-butyl-p-cresol)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Zinc oxide, 2,6-Di-tert-butyl-p-cresol)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide, 2,6-Di-tert-butyl-p-cresol)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-4-methylphenol</td>
<td>64</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=20 - &lt;30</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>188</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-4-cresol</td>
<td>262</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>188</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

Version: 7.0 | Revision Date: 2020/10/10 | SDS Number: 656842-00014 | Date of last issue: 2020/03/23

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format:

Full text of other abbreviations

ACGIH / TWA: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / STEL: Short-term exposure limit
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

All IC - 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

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.

JP / EN