SAFETY DATA SHEET

Bismuth Subnitrate Formulation

Version 5.0  Revision Date: 2020/10/10  SDS Number: 656839-00014  Date of last issue: 2020/03/23  Date of first issue: 2016/05/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Bismuth Subnitrate Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Specific target organ toxicity - repeated exposure: Category 1 (Central nervous system)
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>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>1304-85-4</td>
<td>&gt;= 60 - &lt;= 100</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.025 - &lt; 0.25</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 prod- : Nitrogen oxides (NOx)
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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 dyeing or other appropriate containment to keep material from spreading. If dyed 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

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.

Conditions for safe storage:
- Keep in properly labelled containers.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>Petrolatum</td>
<td>8009-03-8</td>
<td>NAB (Mist)</td>
<td>5 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method that does not collect vapour.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD (Mist)</td>
<td>10 mg/m³</td>
<td>ID OEL</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>NAB (Fumes)</td>
<td>5 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NAB (Inhalable dust)</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Total inhalable particulates, containing no asbestos and with a crystalline silica content of &lt; 1%.</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>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>2 mg/m³</td>
<td>ACGIH</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: Combined particulates and organic vapour type

Hand protection: 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: Safety glasses
Skin and body protection: Skin should be washed after contact.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>paste</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>Petroleum</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</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

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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

### 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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Petrolatum:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

#### Zinc oxide:

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

#### Benzyl alcohol:

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

2,6-Di-tert-butyl-p-cresol:
- Test Type: Human repeat insult patch test (HRIPT)
- Exposure routes: Skin contact
- Species: Humans
- Result: negative

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

Petrolatum:
- Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
  Result: negative
  Remarks: Based on data from similar materials

- 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

Zinc oxide:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

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

  Test Type: Chromosome aberration test in vitro
  Result: equivocal

- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Inhalation (dust/mist/fume)
  Method: OECD Test Guideline 474
### Germ cell mutagenicity - Assessment

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

### Benzyl alcohol:

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

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

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

### Carcinogenicity

Not classified based on available information.

### Components:

**Petrolatum:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
</tbody>
</table>
Result: negative

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Years</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>

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 451</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 414
  - Result: negative

**Petrolatum:**

- **Effects on fertility**
  - Test Type: Reproduction/Developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

- **Effects on foetal development**
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative
### Zinc oxide:

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: inhalation (dust/mist/fume)
- Method: OECD Test Guideline 414
- Result: negative
- Remarks: Based on data from similar materials

### Benzyl alcohol:

**Effects on fertility**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

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

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: negative

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

### 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
- **NOAEL:** 25 mg/kg
- **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:

<table>
<thead>
<tr>
<th>Route of Exposure</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Blood</td>
<td>Methaemoglobinemia</td>
</tr>
<tr>
<td></td>
<td>Central nervous system</td>
<td>Neurological disorders</td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Bismuth hydroxide nitrate oxide:

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Test substance</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>Water Accommodated Fraction</td>
<td>LL50 (Danio rerio (zebra fish)): &gt; 137 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>Water Accommodated Fraction</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 137 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>Water Accommodated Fraction</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 137 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOELR (Pseudokirchneriella subcapitata (green algae)): &gt;= 137 mg/l Exposure time: 72 h</td>
</tr>
</tbody>
</table>

Petrolatum:

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Test substance</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>Water Accommodated Fraction</td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>Water Accommodated Fraction</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l Exposure time: 48 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>Water Accommodated Fraction</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zinc oxide:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish: LC50: &gt; 0.1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): &gt; 0.01 - 0.1 mg/l Exposure time: 72 h Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity): 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity): NOEC (Jordanella floridai (flagfish)): &gt; 0.01 - 0.1 mg/l Exposure time: 14 Weeks Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): &gt; 0.01 - 0.1 mg/l Exposure time: 7 d Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish: LC50 (Pimpephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2,6-Di-tert-butyl-p-cresol:

**Toxicity to fish**
- LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 0.48 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

**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

**M-Factor (Acute aquatic toxicity)**
- 1

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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 0.316 mg/l
- Exposure time: 21 d

**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:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>31 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 301F</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>92 - 96 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 d</td>
</tr>
</tbody>
</table>

### 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

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.
## Bismuth Subnitrate Formulation

<table>
<thead>
<tr>
<th>Class</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>956</td>
</tr>
<tr>
<td>Packing instruction (passenger aircraft)</td>
<td>956</td>
</tr>
<tr>
<td>Environmentally hazardous</td>
<td>yes</td>
</tr>
</tbody>
</table>

**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.

**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 Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

- **Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**
  - Hazardous substances that must be registered: Not applicable

- **Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**
  - Hazardous substances approved for use: Not applicable
  - Prohibited substances: Not applicable
  - Restricted substances: Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Report Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>Not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>Not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information

Additional information sources used to compile the Safety Data Sheet:

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

Date format: yyyy/mm/dd

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ID OEL</td>
<td>Indonesia. Occupational Exposure Limits</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>ID OEL / NAB</td>
<td>Long term exposure limit</td>
</tr>
<tr>
<td>ID OEL / PSD</td>
<td>Short term exposure limit</td>
</tr>
</tbody>
</table>

AIIC - 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 Standardisation; KECI - Korea Existing Chemicals Inventory; IC50 - 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;
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

Version 5.0
Revision Date: 2020/10/10
SDS Number: 656839-00014
Date of last issue: 2020/03/23
Date of first issue: 2016/05/02

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.

ID / EN