1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Bismuth Subnitrate Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
         Wagholi - Pune - India  412 207
Telephone: +1-908-740-4000
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
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: ![Hazard Pictogram]
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:
P319 Get medical help 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;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</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>
</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 spills 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

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. Store in accordance with the particular national regulations.

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

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>TWA (Mist)</td>
<td>5 mg/m$^3$</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m$^3$</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m$^3$</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Total dust)</td>
<td>10 mg/m$^3$</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fumes)</td>
<td>5 mg/m$^3$</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Fumes)</td>
<td>10 mg/m$^3$</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m$^3$</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m$^3$</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>2 mg/m$^3$</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>
</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: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute oral toxicity</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subnitrate Formulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Petrolatum:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>OECD Test Guideline 401</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>OECD Test Guideline 402</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Zinc oxide:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>OECD Test Guideline 401</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5.7 mg/l</td>
<td>OECD Test Guideline 436</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>OECD Test Guideline 402</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 1,620 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 4.178 mg/l</td>
<td>OECD Test Guideline 403</td>
<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 6,000 mg/kg</td>
<td>OECD Test Guideline 401</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>OECD Test Guideline 402</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
<td></td>
</tr>
</tbody>
</table>
### 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
- **Method**: OECD Test Guideline 405
- **Result**: No eye irritation

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

**Zinc oxide:**
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

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

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

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
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
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Zinc oxide:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 476</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 473</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Petrolatum:

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

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

Zinc oxide:

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

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
</table>
Species: Rat  
Application Route: inhalation (dust/mist/fume)  
Method: OECD Test Guideline 474  
Result: negative  

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: inhalation (dust/mist/fume)  
Result: positive  

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Benzyl alcohol:  
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative  

2,6-Di-tert-butyl-p-cresol:  
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  

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

Test Type: Chromosome aberration test in vitro  
Result: negative  

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:

<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>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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
Remarks: Based on data from similar materials

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:

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:

Toxicity to fish:
LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

| Toxicity to algae/aquatic plants | NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials |

| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC: 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials |

**Zinc oxide:**

| Toxicity to fish | LC50: > 0.1 - 1 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials |

| Toxicity to algae/aquatic plants | ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l  
Exposure time: 72 h  
NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials |

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

| Toxicity to fish (Chronic toxicity) | NOEC: > 0.01 - 0.1 mg/l  
Exposure time: 14 Weeks  
Species: Jordanella floridae (flagfish)  
Remarks: Based on data from similar materials |

| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC: > 0.01 - 0.1 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)  
Remarks: Based on data from similar materials |

| M-Factor (Chronic aquatic toxicity) | 1 |

**Benzyl alcohol:**

| Toxicity to fish | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h |

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 230 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202 |
### 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

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**NOEC**: 51 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### 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 microorganisms**

**EC50**: > 10,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**

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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

**NOEC**: 0.316 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

**M-Factor (Chronic aquatic toxicity)**

1
Persistence and degradability

**Components:**

**Petrolatum:**

- **Biodegradability:** Result: Not readily biodegradable.  
  Biodegradation: 31 %  
  Exposure time: 28 d  
  Method: OECD Test Guideline 301F  
  Remarks: Based on data from similar materials

**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

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 16. OTHER INFORMATION

**Further information**

Sources of key data 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**

- **dd.mm.yyyy**

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **IN OEL**: India. Permissible levels of certain chemical substances in work environment.

**ACGIH / TWA**: 8-hour, time-weighted average

**ACGIH / STEL**: Short-term exposure limit

**IN OEL / TWA**: Time-Weighted Average Concentration (TWA) (8 hrs.)

**IN OEL / STEL**: Short-term exposure Limit STEL (15 min)

**Abbreviations**

- AIC - 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, Evalu-
SAFETY DATA SHEET

Bismuth Subnitrate Formulation

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

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