Bismuth Subnitrate (with Mineral Oil) Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Bismuth Subnitrate (with Mineral Oil) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Kilshelran
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 1
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :

   Signal word : Danger
   Hazard statements : H372 Causes damage to organs through prolonged or repeated exposure.
   Precautionary statements : Prevention:
   P264 Wash skin thoroughly after handling.
   P270 Do not eat, drink or smoke when using this product.
   Response:
P314  Get medical advice/ attention if you feel unwell.

**Hazardous components which must be listed on the label:**
Bismuth hydroxide nitrate oxide

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification (Central nervous system)</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>1304-85-4</td>
<td>215-136-8</td>
<td>STOT RE 1 ; H372</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).

**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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products: Nitrogen oxides (NOx)
Metal oxides
Carbon oxides

5.3 Advice for firefighters

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

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.
**SAFETY DATA SHEET**

**Bismuth Subnitrate (with Mineral Oil) Formulation**

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</tr>
</tbody>
</table>

### SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures**

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

**6.2 Environmental precautions**

**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.

**6.3 Methods and material for containment and cleaning up**

**Methods for 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.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

**7.1 Precautions for safe 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.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2.7 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.67 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth hydroxide nitrate oxide</td>
<td>Freshwater - intermittent</td>
<td>1.37 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater</td>
<td>0.137 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.014 mg/l</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures
Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment
Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387
Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : paste
Colour : White to light yellow
Odour : No data available
Odour Threshold : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flammability (solid, gas) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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tion

Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
    Viscosity, kinematic : Not applicable
Solubility(ies)
    Water solubility : No data available
Partition coefficient: n-octanol/water
    Vapour pressure : Not applicable
Relative density : No data available
Density : No data available
Relative vapour density : Not applicable
Particle characteristics
    Particle size : No data available

9.2 Other information
   Explosives : Not explosive
   Oxidizing properties : The substance or mixture is not classified as oxidizing.
   Evaporation rate : Not applicable
   Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

10.3 Possibility of hazardous reactions
   Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
   Conditions to avoid : None known.
10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure:
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:
Bismuth hydroxide nitrate oxide:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 5.07 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
Remarks: Based on data from similar materials

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

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
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

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

Carcinogenicity
Not classified based on available information.

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 develop-
Bismuth Subnitrate (with Mineral Oil) Formula-
tion

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs 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.

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components consid-
ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

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

SECTION 12: Ecological information

12.1 Toxicity

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
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## 12.2 Persistence and degradability

No data available

## 12.3 Bioaccumulative potential

No data available

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

### Product:

#### Assessment:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Endocrine disrupting properties

### Product:

#### Assessment:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods
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Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number
   Not regulated as a dangerous good

14.2 UN proper shipping name
   Not regulated as a dangerous good

14.3 Transport hazard class(es)
   Not regulated as a dangerous good

14.4 Packing group
   Not regulated as a dangerous good

14.5 Environmental hazards
   Not regulated as a dangerous good

14.6 Special precautions for user
   Not applicable

14.7 Maritime transport in bulk according to IMO instruments
   Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
   REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
   REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
   Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
   Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
   Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
   REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-statements
H372 : Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; ICAR - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of
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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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**


**Classification of the mixture:**

<table>
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<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT RE 1</td>
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<td>H372</td>
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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.

IE / EN