SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formulation

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

1.1 Product identifier
Trade name : Sodium Selenite / Vitamin E Injection 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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
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)
Acute toxicity, Category 4 H302: Harmful if swallowed.
Acute toxicity, Category 4 H332: Harmful if inhaled.
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.

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

Signal word : Warning

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.
H317 May cause an allergic skin reaction.
H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:

**Prevention:**
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves.

**Response:**
- P314 Get medical advice/attention if you feel unwell.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:
- Benzyl alcohol
- Sodium selenite

2.3 **Other hazards**
None known.

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>7695-91-2 231-710-0</td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319</td>
<td>5.15</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6 202-859-9 603-057-00-5</td>
<td>Acute Tox. 2; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 STOT RE 1; H372 Aquatic Chronic 2; H411</td>
<td>2.19</td>
</tr>
<tr>
<td>Sodium selenite</td>
<td>10102-18-8 233-267-9 034-003-00-3</td>
<td>Acute Tox. 2; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 STOT RE 1; H372 Aquatic Chronic 2; H411</td>
<td>0.35 - 1.13</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.
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formula-
tion

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.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention if symptoms occur.

In case of skin contact:
In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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 unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks:
Harmful if swallowed or if inhaled.
May cause an allergic skin reaction.
May cause 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 fire-
Exposure to combustion products may be a hazard to health.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formula-
tion

Version 4.0 Revision Date: 09/13/2019 SDS Number: 903937-00007 Date of last issue: 24.04.2019
Date of first issue: 21.09.2016

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
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:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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. Keep tightly closed.
- Keep in a cool, well-ventilated place. 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

<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>(dL)-a-Tocopheryl</td>
<td>7695-91-2</td>
<td>TWA</td>
<td>5000 ug/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
**Sodium Selenite / Vitamin E Injection Formula-tion**

<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>Sodium selenite</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.11 mg/m³</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.04518 mg/m³</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.011141 mg/m³</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.012812 mg/kg bw/day</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.025625 mg/kg bw/day</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>73.5 mg/m³</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>416.6 mg/kg bw/day</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>21.7 mg/m³</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>250 mg/kg bw/day</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>12.5 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>5.4 mg/m³</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0  Revision Date: 09/13/2019  SDS Number: 903937-00007  Date of last issue: 24.04.2019

Date of first issue: 21.09.2016

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Inhalation</th>
<th>Acute systemic effects</th>
<th>27 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>20 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>Sodium selenite</td>
<td>Fresh water</td>
<td>0.00585 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.00438 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.012 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>3.285 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>18 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>13.6 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.22 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>2.19 mg/kg food</td>
</tr>
<tr>
<td>Polyethylene glycol castor oil</td>
<td>Fresh water</td>
<td>0.45 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.045 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.45 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0.28 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>976500003 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>976500003 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>468000000 mg/kg</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Fresh water</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.027 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>212000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>21200 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>74800 mg/kg</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.456 mg/kg</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**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
  - **Remarks**: Consider double gloving.

- **Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

- **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 (A-P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

- **Appearance**: Viscous liquid
- **Colour**: Amber
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
Sodium Selenite / Vitamin E Injection Formula-
tion

Version Revised Date: SDS Number: Date of last issue: Date of first issue:

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity
Viscosity, kinematic: No data available

Explosive properties: Not explosive

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

9.2 Other information
Flammability (liquids): No data available

Particle size: Not applicable

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 toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Harmful if swallowed or if inhaled.

Product:
Acute oral toxicity: Acute toxicity estimate: 614.32 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 4.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:
(dl)-a-Tocopheryl acetate:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rat): > 3,000 mg/kg
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

Sodium selenite:
Acute oral toxicity: LD50 (Rat): 7 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 0.052 - 0.51 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Skin corrosion/irritation
Not classified based on available information.

Components:
(dl)-a-Tocopheryl acetate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Sodium selenite:
Method: OECD Test Guideline 439
Result: Skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
(dl)-a-Tocopheryl acetate:
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

Sodium selenite:
Method: OECD Test Guideline 437
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:
(dl)-a-Tocopheryl acetate:
Test Type: Draize Test
Exposure routes: Skin contact
Species: Humans
Result: negative

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

Sodium selenite:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: positive

Assessment: Probability or evidence of skin sensitisation in humans

Components:

(dl)-a-Tocopheryl acetate:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

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
Sodium Selenite / Vitamin E Injection Formula-
tion


Sodium selenite:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: positive

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cyogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

Carcinogenicity:
Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:
Species: Rat
Application Route: Ingestion
Exposure time: 104 weeks
Result: negative

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

Sodium selenite:
Species: Rat
Application Route: Ingestion
Exposure time: 1 Years

Reproductive toxicity:
Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0  Revision Date: 09/13/2019  SDS Number: 903937-00007  Date of last issue: 24.04.2019
Date of first issue: 21.09.2016

Effects on fertility
Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

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

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

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Sodium selenite:
Exposure routes: Ingestion
Target Organs: Kidney, Blood, Nervous system, Endocrine system, Skin
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Repeated dose toxicity

Components:

(dl)-a-Tocopheryl acetate:
Species: Rat
SAFETY DATA SHEET
gominated to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formulation


NOAEL
Application Route: Ingestion
Exposure time: 90 Days

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

Sodium selenite:
Species: Rat
NOAEL: 0.4 mg/kg
LOAEL: 0.8 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Sodium selenite:
Inhalation:
Target Organs: Respiratory system
Symptoms: bronchospasm, bronchitis, Oedema
Target Organs: Cardio-vascular system
Symptoms: tachycardia, Lowered blood pressure
Target Organs: Digestive organs
Symptoms: Nausea, Vomiting, stomach discomfort

Ingestion:
Target Organs: Nervous system
Symptoms: Neurological disorders
Target Organs: Endocrine system
Target Organs: Skin
Symptoms: hair loss, Skin disorders

SECTION 12: Ecological information

12.1 Toxicity

Components:

(dl)-a-Tocopheryl acetate:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Sodium Selenite / Vitamin E Injection Formulation

| Method                        | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
|-------------------------------|---------------------------------------------------------------------
| Exposure time                 | 72 h                                                                 |

Method: OECD Test Guideline 201

| NOEC (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l |
| Exposure time                 | 72 h                                                                 |

Method: OECD Test Guideline 201

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 927 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>30 min</td>
</tr>
</tbody>
</table>

Method: ISO 8192

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC: 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
</tbody>
</table>

Species: Oncorhynchus mykiss (rainbow trout)

Benzyl alcohol:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 201

| NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l |
| Exposure time                     | 72 h                                                              |

Method: OECD Test Guideline 201

Sodium selenite:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50: 7.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae)): 96.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 201

<table>
<thead>
<tr>
<th>Species: Daphnia magna (Water flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 51 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 211

16 / 21
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0  Revision Date: 09/13/2019  SDS Number: 903937-00007  Date of last issue: 24.04.2019
Date of first issue: 21.09.2016

12.2 Persistence and degradability

Components:

(dl)-a-Tocopheryl acetate:

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

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods

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
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 Transport in bulk according to Annex II of Marpol and the IBC Code
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 - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : 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 - Restrictions on the manufacture, placing on : Conditions of restriction for the fol-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formula-
tion

Version 4.0  Revision Date: 09/13/2019  SDS Number: 903937-00007  Date of last issue: 24.04.2019
Date of first issue: 21.09.2016

the market and use of certain dangerous substances, preparations and articles (Annex XVII)

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
IESCC : 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
H300 : Fatal if swallowed.
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H332 : Harmful if inhaled.
H372 : Causes damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
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)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sodium Selenite / Vitamin E Injection Formula-

Version 4.0    Revision Date: 09/13/2019     SDS Number: 903937-00007     Date of last issue: 24.04.2019
Date of first issue: 21.09.2016

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; AICS - Australian Inventory of Chemical Substances; 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; 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; 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 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>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
</tr>
<tr>
<td>H302</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
</tr>
<tr>
<td>H332</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
</tr>
<tr>
<td>H317</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
</tr>
<tr>
<td>H373</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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

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 mate-
Sodium Selenite / Vitamin E Injection Formulation

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