SAFETY DATA SHEET

Sodium Selenite / Vitamin E Injection Formulation


1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sodium Selenite / Vitamin E Injection Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Acute toxicity (Inhalation): Category 4
Skin sensitisation: Category 1
Specific target organ toxicity - repeated exposure: Category 2 (Kidney, Blood, Nervous system, Endocrine system, Skin)

GHS label elements
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 (Kidney, Blood, Nervous system, Endocrine system, Skin) through prolonged or repeated exposure.

Precautionary statements:
Prevention:
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
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.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>7695-91-2</td>
<td>5.15</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>2.19</td>
</tr>
<tr>
<td>Sodium selenite</td>
<td>10102-18-8</td>
<td>0.35 -1.13</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

Most important symptoms and effects, both acute and delayed: Harmful if swallowed or if inhaled. May cause an allergic skin reaction. May cause 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: 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 and personal protective equipment recommendations.

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.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate contain-
7. HANDLING AND STORAGE

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.

Conditions for safe storage : Keep in properly labelled containers.
                              Keep tightly closed.
                              Keep in a cool, well-ventilated place.
                              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>(dl)-a-Tocopheryl acetate</td>
<td>7695-91-2</td>
<td>TWA</td>
<td>5000 ug/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium selenite</td>
<td>10102-18-8</td>
<td>PEL (long term)</td>
<td>0.2 mg/m³ (selenium)</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.2 mg/m³ (selenium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures : Use appropriate engineering controls and manufacturing
technologies to control airborne concentrations (e.g., dripless 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 uncontrollable areas (e.g., open-face containment devices).
Minimize open handling.

### 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        | Material: Chemical-resistant gloves |
| Eye protection         | Remarks: Consider double gloving. |
|                        | 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.  |
| 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.  |
| 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.  |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance            | : viscous liquid |
| Colour                | : amber |
| Odour                 | : No data available |
| Odour Threshold       | : No data available |
**10. STABILITY AND REACTIVITY**

- **Reactivity:** Not classified as a reactivity hazard.
- **Chemical stability:** Stable under normal conditions.
- **Possibility of hazardous reac-** Can react with strong oxidizing agents.

**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.

**Particle size:** Not applicable
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: 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
Result : No eye irritation
Method : OECD Test Guideline 405

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

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

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
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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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Sodium selenite:
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tion

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

Effects on foetal development:  
Species: Rabbit  
Application Route: Ingestion  
Result: negative  

**Benzyl alcohol:**  
Effects on fertility:  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials  

**Sodium selenite:**  
Effects on 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 (Kidney, Blood, Nervous system, Endocrine system, Skin) 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  
NOAEL: 500 mg/kg  
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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

(dl)-α-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
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100
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Date of first issue: 21.09.2016

Plants

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

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l
Exposure time: 28 d

Toxicity to microorganisms : EC50: > 927 mg/l
Exposure time: 30 min
Method: ISO 8192

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

Sodium selenite:

Toxicity to fish : LC50: 7.2 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.2 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 10.0 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Lepomis macrochirus (Bluegill sunfish)): 0.022 mg/l
Exposure time: 258 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.22 mg/l
Exposure time: 24 d

Toxicity to microorganisms: EC50: 180 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

(dl)-a-Tocopheryl acetate:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 21.7 - 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

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

Bioaccumulative potential

Components:

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

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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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


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
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Sodium Selenite / Vitamin E Injection Formula-

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>SG OEL</td>
<td>Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>SG OEL / PEL (long term)</td>
<td>Permissible Exposure Level (PEL) Long Term</td>
</tr>
</tbody>
</table>

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.

SG / EN