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Sodium Selenite / Vitamin E Injection Formulation

Section 1: Identification

Product name: Sodium Selenite / Vitamin E Injection Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification

Acute toxicity (Oral): Acute Tox.4
Acute toxicity (Inhalation): Acute Tox.4
Skin sensitisation: Skin Sens.1
Specific target organ toxicity - repeated exposure: STOT RE2 (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.
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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 or doctor/physician if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician 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.
P363 Wash contaminated clothing before reuse.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

Section 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>(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>

Section 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.
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.
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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.

Section 5: Fire-fighting measures

Suitable extinguishing media:

Water spray

Alcohol-resistant foam

Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing media:

None known.

Specific hazards during fire-fighting:

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.

Section 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 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.

Section 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.

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.

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

Section 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>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Sodium selenite</th>
<th>10102-18-8</th>
<th>WES-TWA</th>
<th>0.1 mg/m³ (selenium)</th>
<th>NZ OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>0.2 mg/m³ (selenium)</td>
<td>ACGIH</td>
<td></td>
<td></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 uncontrolled 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

Remarks: Consider double gloving.

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.

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.

Section 9: Physical and chemical properties

Appearance: Viscous liquid
Colour: Amber
Odour: No data available
Odour Threshold: No data available
Section 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.

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.

Section 11: Toxicological information

Exposure routes:
- 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.
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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
Species: Humans
Result: negative
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**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

---

**Chronic toxicity**

**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
  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:**
- **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
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
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### Effects on foetal development

- **Species**: Rabbit
- **Application Route**: Ingestion
- **Result**: negative

### Benzyl alcohol:

- **Application Route**: Ingestion
- **Result**: negative

### Sodium selenite:

- **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**

#### (dl)-a-Tocopheryl acetate:

- **Species**: Rat
- **NOAEL**: 500 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
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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

Ecotoxicity

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
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
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**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:**  
**ErC50 (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

Section 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.

Section 14: Transport information

International Regulations
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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.

National Regulations

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 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

Full text of other abbreviations
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ACGIH
NZ OEL
ACGIH / TWA
NZ OEL / WES-TWA

USA, ACGIH Threshold Limit Values (TLV)
New Zealand, Workplace Exposure Standards for Atmospheric Contaminants
8-hour, time-weighted average
Workplace Exposure Standard - Time Weighted average

ACGIH: USA National Institute for Occupational Safety and Health.
NZ OEL: New Zealand, Ministry of Health.

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.

NZ / EN