

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

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

#### 1.1 Product identifier

Trade name : Sodium Selenite / Vitamin E Injection Formulation

Other means of identification : E-SE Injection (A000603)

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
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)

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.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)


# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version 6.2      Revision Date: 29.11.2023      SDS Number: 903941-00017      Date of last issue: 30.09.2023  
Date of first issue: 21.09.2016

- 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.  
H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
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

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

#### Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version 6.2      Revision Date: 29.11.2023      SDS Number: 903941-00017      Date of last issue: 30.09.2023  
Date of first issue: 21.09.2016

	Registration number		
(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		5,15
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319  Acute toxicity esti- mate  Acute oral toxicity: 1.620 mg/kg	2,19
Sodium selenite	10102-18-8 233-267-9 034-003-00-3	Acute Tox. 1; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH031  M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1  Acute toxicity esti- mate  Acute oral toxicity: 4,8 mg/kg	0,35 - 1,13

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).

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

- 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 (CO<sub>2</sub>)  
Dry chemical

- Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

- Hazardous combustion products : Carbon oxides

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	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 (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. 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
-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version 6.2      Revision Date: 29.11.2023      SDS Number: 903941-00017      Date of last issue: 30.09.2023  
Date of first issue: 21.09.2016

- 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 mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
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. Contaminated work clothing should not be allowed out of the workplace.  
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  
Self-reactive substances and mixtures  
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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
(dl)-a-Tocopheryl	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version 6.2      Revision Date: 29.11.2023      SDS Number: 903941-00017      Date of last issue: 30.09.2023  
Date of first issue: 21.09.2016

acetate				
Sodium selenite	10102-18-8	TWA	0,05 mg/m3 (selenium)	FOR-2011- 12-06-1358
	Further information: Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin			
		TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium selenite	Workers	Inhalation	Long-term systemic effects	0,11 mg/m3
	Workers	Skin contact	Long-term systemic effects	15,33 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,033 mg/m3
	Consumers	Skin contact	Long-term systemic effects	9,42 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,00942 mg/kg bw/day
	Polyethylene glycol castor oil	Workers	Inhalation	Long-term systemic effects
Workers		Skin contact	Long-term systemic effects	4,67 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	2,9 mg/m3
Consumers		Skin contact	Long-term systemic effects	1,67 mg/kg bw/day
Consumers		Ingestion	Long-term systemic effects	1,67 mg/kg bw/day
(dl)-a-Tocopheryl acetate		Workers	Inhalation	Long-term systemic effects
	Workers	Skin contact	Long-term systemic effects	416,6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	21,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	250 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12,5 mg/kg bw/day
	Benzyl alcohol	Workers	Inhalation	Long-term systemic effects
Workers		Inhalation	Acute systemic effects	110 mg/m3
Workers		Skin contact	Long-term systemic effects	8 mg/kg bw/day
Workers		Skin contact	Acute systemic effects	40 mg/kg bw/day

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version 6.2      Revision Date: 29.11.2023      SDS Number: 903941-00017      Date of last issue: 30.09.2023  
Date of first issue: 21.09.2016

	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute systemic effects	27 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Sodium selenite	Fresh water	0,00585 mg/l
	Marine water	0,00438 mg/l
	Freshwater - intermittent	0,012 mg/l
	Sewage treatment plant	3,285 mg/l
	Fresh water sediment	18 mg/kg dry weight (d.w.)
	Marine sediment	13,6 mg/kg dry weight (d.w.)
	Soil	0,22 mg/kg dry weight (d.w.)
Polyethylene glycol castor oil	Oral (Secondary Poisoning)	2,19 mg/kg food
	Fresh water	0,000 mg/l
	Freshwater - intermittent	0,0661 mg/l
	Marine water	0,000 mg/l
	Marine water - intermittent	0,00661 mg/l
	Fresh water sediment	0,0129 mg/kg dry weight (d.w.)
	Marine sediment	0,00129 mg/kg dry weight (d.w.)
(dl)-a-Tocopheryl acetate	Soil	0,00258 mg/kg dry weight (d.w.)
	Fresh water	0,27 mg/l
	Marine water	0,027 mg/l
	Intermittent use/release	0,27 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	212000 mg/kg
	Marine sediment	21200 mg/kg
Benzyl alcohol	Soil	74800 mg/kg
	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

### 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/face 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.  
Equipment should conform to NS 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 : Aqueous solution

Colour : amber

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper  
flammability limit : No data available

Lower explosion limit / Lower  
flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

### 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 : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed or if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 422,35 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 4,33 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

### **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): 4,8 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:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431

Species : reconstructed human epidermis (RhE)  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

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:**

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:**

Assessment : Probability or evidence of skin sensitisation in humans  
Remarks : Based on national or regional regulation.

### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

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

### **BenzyI 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: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

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

Species : Rat  
Application Route : Ingestion  
Exposure time : 104 weeks  
Result : negative

#### **BenzyI alcohol:**

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

### **Reproductive toxicity**

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

### 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 : 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 fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: 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  
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

### 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	:	0,88 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks

### 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 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.
------------	---	---

### Experience with human exposure

#### Components:

##### **Sodium selenite:**

Inhalation	:	Target Organs: Respiratory Tract Symptoms: Irritation, Oedema Target Organs: Cardio-vascular system Symptoms: Lowered blood pressure Target Organs: Digestive organs Symptoms: Nausea, Vomiting, Irritability
------------	---	--



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

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

### 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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100  
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 microorganisms : EC50 : > 927 mg/l  
Exposure time: 30 min  
Method: ISO 8192

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

##### **Benzyl alcohol:**

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

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

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 770  
plants : mg/l

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Sodium selenite:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1 - 10 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

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 (Chlamydomonas reinhardtii (green algae)): > 0,1 - 1 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

NOEC (Chlamydomonas reinhardtii (green algae)): > 0,1 - 1 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

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

Toxicity to fish (Chronic toxicity) : NOEC: 0,022 mg/l  
Exposure time: 258 d  
Species: Lepomis macrochirus (Bluegill sunfish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,096 mg/l  
Exposure time: 28 d

M-Factor (Chronic aquatic toxicity) : 1

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

### 12.2 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

### 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

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

---

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. Do not dispose of waste into sewer.
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

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

#### 14.2 UN proper shipping name

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

#### 14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

### 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, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

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 (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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

#### Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### The components of this product are reported in the following inventories:

AICS : not determined

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

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

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.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.  
EUH031 : Contact with acids liberates toxic gas.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
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  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.2	29.11.2023	903941-00017	Date of first issue: 21.09.2016

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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Acute Tox. 4	H302
Acute Tox. 4	H332
Skin Sens. 1	H317
STOT RE 2	H373
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

NO / EN