

SAFETY DATA SHEETS

This SDS packet was issued with item:

078074401

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078690897 078696673 078696681

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078917201 078917228 078917230

Safety Data Sheet



Sterile Water for Injection

NTI #: 18-808
Rev. Date: 26SEP18

-
- 1. Product and Company Identification:**
- Product Name:** Sterile Water for Injection
Company: Nova-Tech, Inc.
Address: 4705 Gold Core Road, Grand Island, NE 68801
Telephone: 308-381-8841
Fax: 308-381-6038
Recommended Use: Sterile Water for Injection is suitable for use as a diluent for the preparation of pharmaceutical solutions.
Restrictions on Use: Sterile Water for Injection is not suitable for intravascular injection without first having been made isotonic by addition of suitable solutes. Do not use the product if the seal has been broken or if the solution is not clear.
-
- 2. Hazards Identification:**
- Hazard Pictogram:** Not applicable according to 29CFR 1910.1200.
Signal Word: Not applicable according to 29CFR 1910.1200.
- Emergency Overview:** Health injuries are not known or expected under normal use.
Hazard Statements: Not applicable according to 29CFR 1910.1200.
Potential Health Effects
Routes of Exposure: None
Eyes: None
Skin: None
Inhalation: None
Ingestion: None
Potential environmental effects: Ecological injuries are not known or expected under normal use.
-
- 3. Composition / Information on Ingredients:**
- Water for Injection
-
- 4. First Aid Measures:**
- First Aid Procedures**
Eye Contact: None
Skin Contact: None
Inhalation: None
Ingestion: None
General Advice: If you feel unwell, seek medical advice (show label when possible).
-
- 5. Fire Fighting Measures:**
- Flammable Properties:** This product is not flammable. No unusual fire or explosion hazards noted.
Extinguishing Media: N/A
Protection of Firefighters
Specific Hazards Arising from the Chemical: N/A
Protective Equipment and Precautions for Firefighters: N/A
Specific Methods: N/A
-
- 6. Accidental Release Measures:**
- Personnel Precautions:** N/A
Environmental Precautions: N/A
Methods for containment: N/A
Methods for Cleaning Up: N/A
-
- 7. Handling and Storage:**
- Handling:** Handle in accordance with good industrial hygiene and safety practice.
Storage: Store in tightly closed containers in a dry cool place per label directions.

Safety Data Sheet



Sterile Water for Injection

NTI #: 18-808
Rev. Date: 26SEP18

8. Exposure Controls / Personal Protection:
Engineering Controls: Provide adequate ventilation
Personal Protective Equipment
Eye / Face Protection: None
Skin Protection: None
Respiratory Protection: Not required for normal use of this material.
General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties:
Appearance: Liquid
Physical State: Liquid
Form: Aqueous Solution
Color Light: Clear, Colorless
Odor: None
Boiling Point: 100°C
Flash Point: N/A
Flammability: Non-flammable
Vapor Pressure: N/A
Density: No Data Available
Solubility (Water): N/A
Viscosity: No Data Available
Vapor Density: N/A
Evaporation Rate: No Data Available
Melting Point: N/A
Freezing Point: No Data Available
Burning Index: No Data Available

10. Chemical Stability and Reactivity Information:
Chemical Stability: Material is stable under normal conditions.
Hazardous Decomposition Products: Not known.
Possibility of hazardous reactions: Not expected to occur.

11. Toxicological Information:
Toxicological Data
Product: Sterile Water for Injection
Sensitization: No Data Available
Chronic Effects: No Data Available
Carcinogenicity: No Data Available
Skin Corrosion / Irritation: No Data Available
Epidemiology: No Data Available
Mutagenicity: No Data Available
Neurological Effects: No Data Available
Reproductive Effects: No Data Available
Teratogenicity: No Data Available
Further Information: No Data Available

12. Ecological Information:
Ecotoxicological Data
Components: No Data Available
Test Results: No Data Available
Ecotoxicity: No Data Available
Environmental Effects: No Data Available
Persistence and Degradability: No Data Available

Safety Data Sheet



Sterile Water for Injection

NTI #: 18-808
Rev. Date: 26SEP18

13. Disposal Considerations: **Disposal Instructions:** According to Federal regulations (40CFR 261.4 (b) (4)), it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Disposal should be in accordance with all applicable regulations.

14. Transport Information: **DOT:** Not regulated as dangerous goods.

15. Regulatory Information: **US Federal Regulations:** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. All components are on the US EPA TSCA Inventory List.
CERCLA/SARA Hazardous Substances: Not applicable.
CERCLA (Superfund) Reportable Quantity: None.
Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard Categories Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No
Section 302 Extremely Hazardous Substance: No
Section 311 Hazardous Chemical: No

16. Other Information:
Prepared By: Nova-Tech, Inc. – Tel: 308-381-8841
Date: 26SEP18
Disclaimer:

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal, and release. It is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of SDS

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

SECTION 1. IDENTIFICATION

Product name : Sodium Selenite / Vitamin E Injection Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

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

GHS label elements

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled.
H317 May cause an allergic skin reaction.
H372 Causes damage to organs (Kidney, Blood, Nervous system, Endocrine system, Skin) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P260 Do not breathe mist or vapors.
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 must not be allowed out of the workplace.
P280 Wear protective gloves.

Sodium Selenite / Vitamin E Injection Formula- tion

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

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 soap and 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.

P363 Wash contaminated clothing before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
(dl)-a-Tocopheryl acetate	7695-91-2	5.15
Benzyl alcohol	100-51-6	2.19
Sodium selenite	10102-18-8	0.35 - 1.13

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.
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.

Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
4.0	09/13/2019	895430-00007	Date of first issue: 09/21/2016

Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed or if inhaled. May cause an allergic skin reaction. Causes 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 (CO ₂) 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 fire-fighters	:	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 spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

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 vapors 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 labeled 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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m ³ (OEB 1)	Internal
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Sodium selenite	10102-18-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
		TWA	0.2 mg/m ³ (selenium)	OSHA Z-1
		TWA	0.2 mg/m ³ (selenium)	ACGIH
		TWA	0.2 mg/m ³ (selenium)	NIOSH REL

- Engineering measures : Use appropriate engineering controls and manufacturing

Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
4.0	09/13/2019	895430-00007	Date of first issue: 09/21/2016

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

- Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- 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.
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

SAFETY DATA SHEET



Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

Appearance	:	viscous liquid
Color	:	amber
Odor	:	No data available
Odor 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
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor 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
Autoignition 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

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

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.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 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

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

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 sensitization

Skin sensitization

May cause an allergic skin reaction.

Sodium Selenite / Vitamin E Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
4.0	09/13/2019	895430-00007	Date of first issue: 09/21/2016

Respiratory sensitization

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

Test Type	:	Draize Test
Routes of exposure	:	Skin contact
Species	:	Humans
Result	:	negative

Benzyl alcohol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Sodium selenite:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	positive

Assessment	:	Probability or evidence of skin sensitization 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
		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
-----------------------	---	--

Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
4.0	09/13/2019	895430-00007	Date of first issue: 09/21/2016

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 : 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

Sodium Selenite / Vitamin E Injection Formula- tion

Version 4.0	Revision Date: 09/13/2019	SDS Number: 895430-00007	Date of last issue: 04/24/2019 Date of first issue: 09/21/2016
----------------	------------------------------	-----------------------------	---

- IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
- NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Sodium selenite:

- Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Kidney, Blood, Nervous system, Endocrine system, Skin) through prolonged or repeated exposure.

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
 Date of first issue: 09/21/2016

Components:

Sodium selenite:

Routes of exposure : 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, Edema
 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

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
 Date of first issue: 09/21/2016

II

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
 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 : NOEC (Daphnia magna (Water flea)): 51 mg/l

Sodium Selenite / Vitamin E Injection Formula- tion

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

aquatic invertebrates (Chronic toxicity)	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

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

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****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.

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Sodium selenite)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : no
Remarks : THE ABOVE INFORMATION ONLY APPLIES TO PACKAGE SIZES WHERE THE HAZARDOUS SUBSTANCE MEETS THE REPORTABLE QUANTITY.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Sodium Selenite / Vitamin E Injection Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
 Date of first issue: 09/21/2016

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium selenite	10102-18-8		8849
Sodium selenite	10102-18-8	100	8849

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium selenite	10102-18-8	100	8849

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
Sodium selenite	10102-18-8	10000
Sodium selenite	10102-18-8	100*

*: Solid in the molten or powdered form (particles < 100 microns), in solution, or meeting the NFPA reactivity criteria

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
 Respiratory or skin sensitization
 Specific target organ toxicity (single or repeated exposure)

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Sodium selenite 10102-18-8 0.35 - 1.13 %

US State Regulations

Pennsylvania Right To Know

Water	7732-18-5
Polyethylene glycol sorbitan monooleate	9005-65-6
Polyethylene glycol castor oil	61791-12-6
(dl)-a-Tocopheryl acetate	7695-91-2
Benzyl alcohol	100-51-6
Sodium selenite	10102-18-8

California List of Hazardous Substances

Sodium selenite 10102-18-8

California Permissible Exposure Limits for Chemical Contaminants

Sodium selenite 10102-18-8

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

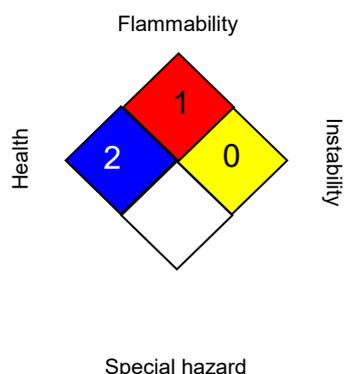
Sodium Selenite / Vitamin E Injection Formula- tion

Version 4.0 Revision Date: 09/13/2019 SDS Number: 895430-00007 Date of last issue: 04/24/2019
Date of first issue: 09/21/2016

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Pre-

Sodium Selenite / Vitamin E Injection Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
4.0	09/13/2019	895430-00007	Date of first issue: 09/21/2016

vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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

Revision Date : 09/13/2019

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 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.

US / Z8