

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nilvax Selenised Formulation

Version 1.1      Revision Date: 03/05/2024      SDS Number: 11306354-00002      Date of last issue: 12/04/2023  
Date of first issue: 12/04/2023

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### SECTION 1. IDENTIFICATION

Product name : Nilvax Selenised Formulation  
Other means of identification : Nilvax Selenised (A3977)

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
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  
Restrictions on use : Not applicable


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Blood, Testis)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapors.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

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### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Antigen	No data available	Not Assigned	4.3537
(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate	No data available	32093-35-9	4.26

## 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.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and 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.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.
- 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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



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Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

Carbon dioxide (CO<sub>2</sub>)  
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 : 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 (see section 7) and personal protective equipment recommendations (see section 8).

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.

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 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 : Use only with adequate ventilation.

Advice on safe handling : Do not breathe mist or vapors.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



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Version 1.1      Revision Date: 03/05/2024      SDS Number: 11306354-00002      Date of last issue: 12/04/2023  
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- Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
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
(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate	32093-35-9	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

- 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

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nilvax Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

Skin and body protection	:	Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	3.4 - 3.9
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

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according to the Hazardous Products Regulations



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Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

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.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

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### 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.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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## Nilvax Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Acute oral toxicity : LD50 (Rat): 180 mg/kg  
LD50 (Mouse): 223 mg/kg  
LD50 (Rabbit): 458 mg/kg  
LD50 (Rat): 180 mg/kg  
LD50 (Mouse): 223 mg/kg  
LD50 (Rabbit): 458 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

### **Skin corrosion/irritation**

Not classified based on available information.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Remarks : No data available

### **Serious eye damage/eye irritation**

Not classified based on available information.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Remarks : No data available

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Remarks : No data available

### **Germ cell mutagenicity**

Not classified based on available information.

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Version 1.1      Revision Date: 03/05/2024      SDS Number: 11306354-00002      Date of last issue: 12/04/2023  
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---

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 80 mg/kg body weight  
Remarks : No significant adverse effects were reported

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 40 mg/kg body weight  
Remarks : No significant adverse effects were reported

### **Reproductive toxicity**

Suspected of damaging the unborn child.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Result: No significant adverse effects were reported

Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: Fetotoxicity.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 40 mg/kg body weight



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nilvax Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

Result: Fetotoxicity.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletrilium phosphate:**

Target Organs : Blood, Testis  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletrilium phosphate:**

Species : Rat  
NOAEL : 2.5 mg/kg  
Application Route : Oral  
Exposure time : 18 Months  
Target Organs : Testis

Species : Dog  
LOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 18 Months  
Target Organs : Blood

Species : Dog  
LOAEL : 40 mg/kg  
Application Route : Oral  
Exposure time : 3 Months

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletrilium phosphate:**

Ingestion : Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension

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Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 64 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

#### **Persistence and degradability**

No data available

#### **Bioaccumulative potential**

No data available

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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### SECTION 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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### 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**

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nilvax Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

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### **TDG**

Not regulated as a dangerous good

### **Special precautions for user**

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

### **Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - 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; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



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Version	Revision Date:	SDS Number:	Date of last issue: 12/04/2023
1.1	03/05/2024	11306354-00002	Date of first issue: 12/04/2023

---

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 : 03/05/2024  
Date format : mm/dd/yyyy

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.

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