

## Nilvax Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 04.12.2023  |
| 1.1     | 05.03.2024     | 11306359-00002 | Date of first issue: 04.12.2023 |

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Nilvax Selenised Formulation

Other means of identification : Nilvax Selenised (A3977)

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Acute toxicity (Oral) : Category 5

Reproductive toxicity : Category 2

##### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H303 May be harmful if swallowed.  
H361d Suspected of damaging the unborn child.

Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.

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P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P317 IF SWALLOWED: Get medical help.

P318 IF exposed or concerned, get medical advice.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name                                                           | CAS-No.      | Concentration (% w/w) |
|-------------------------------------------------------------------------|--------------|-----------------------|
| Antigen                                                                 | Not Assigned | $\geq 1 - < 5$        |
| (S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate | 32093-35-9   | $\geq 3 - < 5$        |

### 4. FIRST AID MEASURES

- |                                                             |                                                                                                                                                                                                                         |
|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                 |
| Most important symptoms and effects, both acute and delayed | : May be harmful if swallowed.<br>Suspected of damaging the unborn child.                                                                                                                                               |
| 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.                                                                                                                                                                               |

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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (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 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.

### 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

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Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
Advice on safe handling : Use only with adequate ventilation.  
Do not breathe mist or vapours.  
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 labelled 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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components                                                              | CAS-No.    | Value type<br>(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.

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|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Skin and body protection | : If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.<br>Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.                                                 |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Appearance                                       | : Aqueous solution  |
| Colour                                           | : No data available |
| Odour                                            | : No data available |
| Odour 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 |
| Vapour pressure                                  | : No data available |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Relative vapour 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                                           |
| Auto-ignition temperature              | : | No data available                                        |
| Decomposition temperature              | : | No data available                                        |
| Viscosity                              | : |                                                          |
| Viscosity, kinematic                   | : | No data available                                        |
| Explosive properties                   | : | Not explosive                                            |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | No data available                                        |
| Particle characteristics               | : |                                                          |
| Particle size                          | : | Not applicable                                           |

### 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. |

### 11. TOXICOLOGICAL INFORMATION

|                                          |   |                                                        |
|------------------------------------------|---|--------------------------------------------------------|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|------------------------------------------|---|--------------------------------------------------------|

#### Acute toxicity

May be harmful if swallowed.

#### Product:

|                     |   |                                                                    |
|---------------------|---|--------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: 4,226 mg/kg<br>Method: Calculation method |
|---------------------|---|--------------------------------------------------------------------|

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### 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 sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

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.

### Components:

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

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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]thiazoletrilium 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]thiazoletrilium phosphate:**

|                      |                                                                                                                                                              |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: Three-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>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 foetal development | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 20 mg/kg body weight<br>Result: Fetotoxicity |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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



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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**

Not classified based on available information.

### **Components:**

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

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

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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

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

Not applicable for product as supplied.

#### **Special precautions for user**

Not applicable

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### 15. REGULATORY INFORMATION

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

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

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

### 16. OTHER INFORMATION

Revision Date : 05.03.2024

**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/>

Date format : dd.mm.yyyy

**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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

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stances 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

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.

IN / EN