

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Nilvax Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/03/05
2.0	2024/09/28	11306344-00003	Date of first issue: 2023/12/04

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Nilvax Formulation

Other means of identification : Nilvax (A3832)

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : Aqueous solution

Colour : No data available

Odour : No data available

May be harmful if swallowed. Suspected of damaging the unborn child.

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.

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Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P312 Call a POISON CENTER/ doctor if you feel unwell.

Storage:
P405 Store locked up.

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

May be harmful if swallowed. Suspected of damaging the unborn child.

Environmental hazards

Not classified based on available information.

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	>= 1 -< 10
(S)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazoletriylium phosphate	32093-35-9	>= 3 -< 10

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.

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In case of eye contact	: Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
If swallowed	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: May be harmful if swallowed. 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.

5. FIREFIGHTING 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	: 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.

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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

Handling

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 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.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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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/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm ²	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

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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,

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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 - 4.4
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
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	:	

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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

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity	: Acute toxicity estimate: 4,173 mg/kg Method: Calculation method
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Components:

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

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.

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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 Species: Rat Application Route: Oral Result: No significant adverse effects were reported
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	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported
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Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity
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	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.
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STOT - single exposure

Not classified based on available information.

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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]thiazoletriylium phosphate:

Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l
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	Exposure time: 96 h
	Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 64 mg/l
	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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

IATA-DGR

UN/ID No.	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger)	: Not applicable

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ger aircraft)

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	:	This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.
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Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	:	Not listed
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Hazardous Chemicals for Priority Management under SAWS	:	Not listed
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Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals	:	Not listed
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Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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 : 2024/09/28

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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

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 Con-

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centration 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 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

Disclaimer

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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