SAFETY DATA SHEET

Multine B12 Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 19.09.2023
1.1	04.12.2023	11270903-00002	Date of first issue: 19.09.2023

SECTION 1. IDENTIFICATION

Product name : Multine B12 Selenised Formulation

Other means of identification : Multine B12 Selenised (A011766)

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 5

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Signal Word : Warning

Hazard Statements : H303 May be harmful if swallowed.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements :

Prevention:

P273 Avoid release to the environment.

Response:

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

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Antigen	Not Assigned	>= 20 -< 30
Aluminium potassium sulfate dodecahydrate	7784-24-9	>= 1 -< 5
Sodium selenate	13410-01-0	>= 0,1 -< 0,25
Acetatocobalamin	22465-48-1	>= 0,1 -< 1
Thiomersal	54-64-8	>= 0,0025 -< 0,025

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 if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

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 if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May be harmful 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
Carbon dioxide (CO2)
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
Metal oxides
Sulfur 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	:	Avoid inhalation of vapor or mist. 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 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
Aluminium potassium sulfate dodecahydrate	7784-24-9	CMP	2 mg/m³ (Aluminum)	AR OEL
Sodium selenate	13410-01-0	TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm²	Internal
		CMP	0,2 mg/m³ (selenium)	AR OEL
		TWA	0,2 mg/m³ (selenium)	ACGIH
Acetatocobalamin	22465-48-1	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm²	Internal
Thiomersal	54-64-8	CMP	0,01 mg/m³ (Mercury)	AR OEL
	Further information: Skin			
		CMP - CPT	0,03 mg/m³ (Mercury)	AR OEL
	Further information: Skin			
		TWA	0,01 mg/m³ (Mercury)	ACGIH
		STEL	0,03 mg/m³ (Mercury)	ACGIH

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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. 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

Appearance	:	Aqueous solution
Color	:	No data available
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.
Molecular weight	:	No data available
Particle size	:	Not applicable

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

May be harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 2.084 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l

Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Aluminium potassium sulfate dodecahydrate:

Acute oral toxicity : LD50 (Mouse): > 5.000 mg/kg
Remarks: Based on data from similar materials

Sodium selenate:

Acute oral toxicity : LD50 (Rat): > 5 - 50 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 0,052 - 0,51 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acetatocobalamin:

Acute oral toxicity : LD50 Oral (Mouse): > 5.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): > 2.000 mg/kg
Application Route: Intravenous

LDLo (Mouse): 1,4 mg/kg
Application Route: Intraperitoneal

LDLo (Mouse): 2,7 mg/kg
Application Route: Intravenous

Thiomersal:

Acute oral toxicity : LD50 (Rat): 75 mg/kg

Acute toxicity estimate: 10 mg/kg
Method: Expert judgment
Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Acute toxicity estimate: 0,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgment
Remarks: Based on national or regional regulation.

Acute dermal toxicity : Acute toxicity estimate: 10 mg/kg
Method: Expert judgment
Remarks: Based on national or regional regulation.

Skin corrosion/irritation

Not classified based on available information.

Components:

Aluminium potassium sulfate dodecahydrate:

Species	:	Mouse
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Sodium selenate:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431
Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 439
Result	:	Skin irritation

Acetatocobalamin:

Remarks	:	No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Aluminium potassium sulfate dodecahydrate:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

Sodium selenate:

Species	:	Bovine cornea
Method	:	OECD Test Guideline 437
Result	:	No eye irritation

Acetatocobalamin:

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:

Aluminium potassium sulfate dodecahydrate:

Test Type	:	Draize Test
Routes of exposure	:	Skin contact
Species	:	Rabbit

Result : negative
Remarks : Based on data from similar materials

Acetatocobalamin:
Remarks : No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Aluminium potassium sulfate dodecahydrate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Sodium selenate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Acetatocobalamin:
Genotoxicity in vitro : Test Type: Mutagenicity (Escherichia coli - reverse mutation assay)
Result: negative

Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative

Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative

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

Genotoxicity in vivo : Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Thiomersal:

Species	:	Rat
Exposure time	:	1 Years
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:

Aluminium potassium sulfate dodecahydrate:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OPPTS 870.3700 Result: negative Remarks: Based on data from similar materials

Sodium selenate:

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

Thiomersal:

Effects on fetal development	:	Species: Rat Application Route: Ingestion Result: positive Remarks: Based on data from similar materials
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on sexual function and fertility, and/or 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:

Sodium selenate:

Routes of exposure	:	Ingestion
Assessment	:	Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Acetatocobalamin:

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

Thiomersal:

Target Organs	:	Central nervous system, Cardio-vascular system, Gastrointestinal tract, Kidney
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Aluminium potassium sulfate dodecahydrate:

Species	:	Mouse
NOAEL	:	15.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	5 Weeks
Method	:	Directive 67/548/EEC, Annex V, B.33.

Sodium selenate:

Species	:	Rat
NOAEL	:	0,4 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks

Acetatocobalamin:

Species	:	Dog
LOAEL	:	300 mg/kg
Application Route	:	Oral
Number of exposures	:	3 days
Target Organs	:	Kidney, Liver
Symptoms	:	kidney effects, liver function change
Remarks	:	May cause damage to organs.

Species	:	Dog
LOAEL	:	75 mg/kg
Application Route	:	Intravenous
Number of exposures	:	4 weeks
Target Organs	:	Kidney, Liver

Remarks : May cause damage to organs.

Thiomersal:

Species : Rat
LOAEL : >= 0,5 mg/kg
Application Route : Ingestion
Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Acetatocobalamin:

General Information : Symptoms: asthenia, Dizziness, Headache, Nausea, sinusitis
Remarks: The most common side effects are:

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Aluminium potassium sulfate dodecahydrate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1.000 - < 10.000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Ecotoxicology Assessment

Chronic aquatic toxicity : No toxicity at the limit of solubility.

Sodium selenate:

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Chlamydomonas reinhardtii (green algae)): 245 µg/l
Exposure time: 96 h

NOEC (Chlamydomonas reinhardtii (green algae)): 197 µg/l
Exposure time: 96 h

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic tox- : NOEC (Lepomis macrochirus (Bluegill sunfish)): > 0,01 - 0,1

icity)		mg/l Exposure time: 258 d Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0,1 - 1 mg/l Exposure time: 28 d Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC10 (activated sludge): 590 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Thiomersal:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 0,01 - 0,1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0,01 - 0,1 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,01 - 0,1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia sp. (Water flea)): > 0,001 - 0,01 mg/l Exposure time: 21 d Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	10

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

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.

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.

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	:	04.12.2023
Date format	:	dd.mm.yyyy

Further information

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/

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)

AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AR OEL / CMP	:	TLV (Threshold Limit Value)
AR OEL / CMP - CPT	:	STEL (Short Term Limit Value)

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 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

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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