according to the Hazardous Products Regulations



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SECTION 1. IDENTIFICATION

Product name : Multine B12 Selenised Formulation Other means of identification : Multine B12 Selenised (A011766)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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 availa- ble	Not Assigned	>= 10 - < 30 *
sulfate dodecahydrate	Sulfuric acid, aluminium po- tassium salt	7784-24-9	>= 1 - < 5 *
Sodium selenate	No data availa- ble	13410-01-0	>= 0.1 - < 1 *
Acetatocobalamin	No data availa- ble	22465-48-1	>= 0.1 - < 1 *

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

according to the Hazardous Products Regulations



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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. Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

: Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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

In case of skin contact

In case of eye contact

delayed

: None known.

Protection of first-aiders : F

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 prod: :

ucts

Carbon oxides Metal oxides

Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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.

according to the Hazardous Products Regulations



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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	TWA	2 mg/m³ (Aluminum)	CA AB OEL
-		TWAEV	5 mg/m ³	CA QC OEL

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		(respirable aerosol fraction)		
Sodium selenate	13410-01-0	TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm ²	Internal
		TWA	0.2 mg/m³ (selenium)	CA AB OEL
		TWAEV	0.2 mg/m ³ (selenium)	CA QC OEL
		TWA	0.1 mg/m³ (selenium)	CA BC OEL
		TWA	0.2 mg/m³ (selenium)	ACGIH
Acetatocobalamin	22465-48-1	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 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 Hand protection

Particulates type

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.

according to the Hazardous Products Regulations



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> 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

pН 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

No data available Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Autoignition temperature No data available

Not applicable

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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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

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

Acute inhalation toxicity : Acute toxicity estimate: > 5 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

according to the Hazardous Products Regulations



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П

Sodium selenate:

: LD50 (Rat): > 5 - 50 mg/kg Acute oral toxicity

Remarks: Based on data from similar materials

: LC50 (Rat): > 0.052 - 0.51 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acetatocobalamin:

: LD50 Oral (Mouse): > 5,000 mg/kg Acute oral toxicity

administration)

Acute toxicity (other routes of : 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

Skin corrosion/irritation

Not classified based on available information.

Components:

Aluminium potassium sulfate dodecahydrate:

Species

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.

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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

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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

Carcinogenicity

Not classified based on available information.

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

STOT-single exposure

Not classified based on available information.

according to the Hazardous Products Regulations



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STOT-repeated exposure

Not classified based on available information.

Components:

Sodium selenate:

Routes of exposure : Ingestion

: Shown to produce significant health effects in animals at con-Assessment

centrations of 10 mg/kg bw or less.

Acetatocobalamin:

Target Organs : Kidney, Liver

Assessment : May cause 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 : Rat : 0.4 mg/kg : Ingestion NOAEL Application Route Exposure time : 13 Weeks

Acetatocobalamin:

Species : Dog LOAEL : 300 mg/kg Application Route : Oral
Number of exposures : 3 days
Target Organs : Kidney : Kidney, Liver

: kidney effects, liver function change Symptoms : May cause damage to organs. Remarks

: Dog Species
LOAEL : /5 my/kg
Application Route : Intravenous
Number of exposures : 4 weeks
The Croans : Kidney, Liver
May cause da Species

Remarks May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

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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

aquatic invertebrates

Toxicity to daphnia and other : 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

Toxicity to fish (Chronic tox-

icity)

NOEC (Lepomis macrochirus (Bluegill sunfish)): > 0.01 - 0.1

mq/l

Exposure time: 258 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0.1 - 1 mg/lExposure time: 28 d

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (activated sludge): 590 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

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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.

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure 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

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 Agen-

cy, http://echa.europa.eu/

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

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