

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Multine B12 Selenised Formulation

Other means of identification : Multine B12 Selenised (A011766)

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                          |
|------------------------------------------------|----------------------------------------------------------|
| Long-term (chronic) aquatic hazard, Category 3 | H412: Harmful to aquatic life with long lasting effects. |
|------------------------------------------------|----------------------------------------------------------|

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name    | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                                                                                                                                                 | Concentration<br>(% w/w) |
|------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Antigen          | Not Assigned                                          |                                                                                                                                                                                                                                                                                                                | >= 20 - < 30             |
| Sodium selenate  | 13410-01-0<br>236-501-8<br>034-002-00-8               | Acute Tox. 2; H300<br>Acute Tox. 2; H330<br>Skin Irrit. 2; H315<br>STOT RE 1; H372<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity): 1<br>M-Factor (Chronic<br>aquatic toxicity): 1<br><br>Acute toxicity estimate<br><br>Acute oral toxicity:<br>5 mg/kg | >= 0,1 - < 0,25          |
| Acetatocobalamin | 22465-48-1<br>245-019-7                               | STOT RE 2; H373<br>(Kidney, Liver)                                                                                                                                                                                                                                                                             | >= 0,1 - < 1             |
| Thiomersal       | 54-64-8<br>200-210-4<br>080-004-00-7                  | Acute Tox. 2; H300<br>Acute Tox. 2; H330<br>Acute Tox. 1; H310<br>Repr. 1B; H360                                                                                                                                                                                                                               | >= 0,0025 - < 0,025      |

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Commission Regulation (EU) 2020/878



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|                |                              |                               |                                                                   |
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|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |
|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | <p>STOT RE 1; H372<br/>(Central nervous system, Cardio-vascular system, Gastrointestinal tract, Kidney)<br/>Aquatic Acute 1; H400<br/>Aquatic Chronic 1; H410</p> <hr/> <p>M-Factor (Acute aquatic toxicity): 10<br/>M-Factor (Chronic aquatic toxicity): 10</p> <hr/> <p>specific concentration limit<br/>STOT RE 2; H373<br/>≥ 0,1 %</p> <hr/> <p>Acute toxicity estimate</p> <hr/> <p>Acute oral toxicity: 10 mg/kg<br/>Acute inhalation toxicity (dust/mist): 0,1 mg/l<br/>Acute dermal toxicity: 10 mg/kg</p> |  |
|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.                      |
| 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). |
| If inhaled                 | : If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.                                                                                                |
| In case of skin contact    | : Wash with water and soap as a precaution.                                                                                                                                   |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
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| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

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.

### 4.2 Most important symptoms and effects, both acute and delayed

None known.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides  
Sulphur oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
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Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

|                         |   |                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 vapour or mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Take care to prevent spills, waste and minimize release to the environment. |
| 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.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment,        |

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according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

Version 3.0      Revision Date: 28.09.2024      SDS Number: 11274292-00004      Date of last issue: 06.04.2024  
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appropriate degowning and decontamination procedures,  
industrial hygiene monitoring, medical surveillance and the  
use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components                                | CAS-No.                                                                                                                                                                                                                      | Value type (Form of exposure) | Control parameters                | Basis               |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------|---------------------|
| Aluminium potassium sulfate dodecahydrate | 7784-24-9                                                                                                                                                                                                                    | TWA                           | 2 mg/m <sup>3</sup> (Aluminium)   | FOR-2011-12-06-1358 |
| Sodium selenate                           | 13410-01-0                                                                                                                                                                                                                   | TWA                           | 0,05 mg/m <sup>3</sup> (selenium) | FOR-2011-12-06-1358 |
|                                           | Further information: Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin                                                   |                               |                                   |                     |
|                                           |                                                                                                                                                                                                                              | TWA                           | 20 µg/m <sup>3</sup> (OEB 3)      | Internal            |
|                                           |                                                                                                                                                                                                                              | Wipe limit                    | 200 µg/100 cm <sup>2</sup>        | Internal            |
| Acetatocobalamin                          | 22465-48-1                                                                                                                                                                                                                   | TWA                           | 10 µg/m <sup>3</sup> (OEB 3)      | Internal            |
|                                           |                                                                                                                                                                                                                              | Wipe limit                    | 100 µg/100 cm <sup>2</sup>        | Internal            |
| Thiomersal                                | 54-64-8                                                                                                                                                                                                                      | TWA                           | 0,01 mg/m <sup>3</sup> (Mercury)  | FOR-2011-12-06-1358 |
|                                           | Further information: Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin, Chemicals that can be absorbed through the skin. |                               |                                   |                     |
|                                           |                                                                                                                                                                                                                              | STEL                          | 0,03 mg/m <sup>3</sup> (Mercury)  | FOR-2011-12-06-1358 |
|                                           | Further information: Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin, Chemicals that can be absorbed through the skin. |                               |                                   |                     |

#### Biological occupational exposure limits

| Substance name | CAS-No. | Control parameters                       | Sampling time | Basis  |
|----------------|---------|------------------------------------------|---------------|--------|
| Thiomersal     | 54-64-8 | Mercury (Mercury):<br>30 µg/g creatinine |               | AN 361 |

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Commission Regulation (EU) 2020/878



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|    |  |         |  |
|----|--|---------|--|
| II |  | (Urine) |  |
|----|--|---------|--|

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name                            | End Use   | Exposure routes | Potential health effects   | Value                   |
|-------------------------------------------|-----------|-----------------|----------------------------|-------------------------|
| Aluminium potassium sulfate dodecahydrate | Workers   | Inhalation      | Long-term systemic effects | 13,05 mg/m <sup>3</sup> |
|                                           | Consumers | Ingestion       | Long-term systemic effects | 15,54 mg/kg bw/day      |
| Sodium selenate                           | Workers   | Inhalation      | Long-term systemic effects | 0,12 mg/m <sup>3</sup>  |
|                                           | Workers   | Skin contact    | Long-term systemic effects | 16,73 mg/kg bw/day      |
|                                           | Consumers | Inhalation      | Long-term systemic effects | 0,036 mg/m <sup>3</sup> |
|                                           | Consumers | Skin contact    | Long-term systemic effects | 10,28 mg/kg bw/day      |
|                                           | Consumers | Ingestion       | Long-term systemic effects | 0,01028 mg/kg bw/day    |

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name                            | Environmental Compartment  | Value                        |
|-------------------------------------------|----------------------------|------------------------------|
| Aluminium potassium sulfate dodecahydrate | Fresh water                | 0,112 mg/l                   |
|                                           | Freshwater - intermittent  | 1,1 mg/l                     |
|                                           | Marine water               | 0,011 mg/l                   |
|                                           | Sewage treatment plant     | 63 mg/l                      |
| Sodium selenate                           | Fresh water                | 6,38 µg/l                    |
|                                           | Freshwater - intermittent  | 6,38 µg/l                    |
|                                           | Marine water               | 4,09 µg/l                    |
|                                           | Sewage treatment plant     | 10 mg/l                      |
|                                           | Fresh water sediment       | 19,7 mg/kg dry weight (d.w.) |
|                                           | Marine sediment            | 12,6 mg/kg dry weight (d.w.) |
|                                           | Soil                       | 0,47 mg/kg dry weight (d.w.) |
|                                           | Oral (Secondary Poisoning) | 2,39 mg/kg food              |

## 8.2 Exposure controls

### 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

Eye/face protection : Wear safety glasses with side shields or goggles.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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|                |                              |                               |                                                                   |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|
| Version<br>3.0 | Revision Date:<br>28.09.2024 | SDS Number:<br>11274292-00004 | Date of last issue: 06.04.2024<br>Date of first issue: 19.09.2023 |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|

|                          |   |                                                                                                                                                                                                                                                                                             |
|--------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          |   | 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.                                   |
| Hand protection          |   |                                                                                                                                                                                                                                                                                             |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                   |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                    |
| Skin and body protection | : | 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. |
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Equipment should conform to NS EN 143                                                                               |
| Filter type              | : | Particulates type (P)                                                                                                                                                                                                                                                                       |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                                                  |   |                   |
|--------------------------------------------------|---|-------------------|
| Physical state                                   | : | Aqueous solution  |
| Colour                                           | : | No data available |
| Odour                                            | : | No data available |
| Odour Threshold                                  | : | No data available |
| Melting point/freezing point                     | : | No data available |
| Initial boiling point and boiling range          | : | 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 |
| Flash point                                      | : | No data available |



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|                |                              |                               |                                                                   |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|
| Version<br>3.0 | Revision Date:<br>28.09.2024 | SDS Number:<br>11274292-00004 | Date of last issue: 06.04.2024<br>Date of first issue: 19.09.2023 |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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:

##### **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:**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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|         |                |                |                                 |
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|                           |                                                                                                                                                                           |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : LD50 (Rat): 75 mg/kg<br>Acute toxicity estimate: 10 mg/kg<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation.                             |
| Acute inhalation toxicity | : Acute toxicity estimate: 0,1 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation. |
| Acute dermal toxicity     | : Acute toxicity estimate: 10 mg/kg<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation.                                                     |

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### 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:

#### Sodium selenate:

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

#### Acetatocobalamin:

|         |                     |
|---------|---------------------|
| Remarks | : No data available |
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# SAFETY DATA SHEET

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Acetatocobalamin:

Remarks : No data available

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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### Components:

#### Thiomersal:

|               |            |
|---------------|------------|
| Species       | : Rat      |
| Exposure time | : 1 Years  |
| Result        | : negative |

#### Reproductive toxicity

Not classified based on available information.

### Components:

#### Sodium selenate:

|                      |                                                                                                                                                                              |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                               |                                                                                                                                                               |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Thiomersal:

|                               |                                                                                                                     |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Effects on foetal development | : Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>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:

|                 |                                                                                                    |
|-----------------|----------------------------------------------------------------------------------------------------|
| Exposure routes | : 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. |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

### 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:

##### 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             | : $\geq 0,5$ mg/kg                     |
| Application Route | : Ingestion                            |
| Remarks           | : Based on data from similar materials |

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

|            |                                                                                                                                                                            |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|                |                              |                               |                                                                   |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|
| Version<br>3.0 | Revision Date:<br>28.09.2024 | SDS Number:<br>11274292-00004 | Date of last issue: 06.04.2024<br>Date of first issue: 19.09.2023 |
|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at  
levels of 0.1% or higher.

### Experience with human exposure

#### Components:

##### **Acetatocobalamin:**

|                     |                                                                                                            |
|---------------------|------------------------------------------------------------------------------------------------------------|
| General Information | : Symptoms: asthenia, Dizziness, Headache, Nausea, sinusitis<br>Remarks: The most common side effects are: |
|---------------------|------------------------------------------------------------------------------------------------------------|

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **Sodium selenate:**

|                                                                        |                                                                                                                                                                           |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Pimephales promelas (fathead minnow)): > 1 - 10 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials                                      |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials                                                |
| Toxicity to algae/aquatic plants                                       | : ErC50 (Chlamydomonas reinhardtii (green algae)): 245 µg/l<br>Exposure time: 96 h<br><br>NOEC (Chlamydomonas reinhardtii (green algae)): 197 µg/l<br>Exposure time: 96 h |
| M-Factor (Acute aquatic toxicity)                                      | : 1                                                                                                                                                                       |
| Toxicity to microorganisms                                             | : EC10 (activated sludge): 590 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209                                                                              |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: > 0,01 - 0,1 mg/l<br>Exposure time: 258 d<br>Species: Lepomis macrochirus (Bluegill sunfish)<br>Remarks: Based on data from similar materials                     |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: > 0,1 - 1 mg/l<br>Exposure time: 28 d<br>Remarks: Based on data from similar materials                                                                            |
| M-Factor (Chronic aquatic toxicity)                                    | : 1                                                                                                                                                                       |

##### **Thiomersal:**

|                  |                                                         |
|------------------|---------------------------------------------------------|
| Toxicity to fish | : LC50 (Poecilia reticulata (guppy)): > 0,01 - 0,1 mg/l |
|------------------|---------------------------------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue:             |
| 3.0     | 28.09.2024     | 11274292-00004 | 06.04.2024                      |
|         |                |                | Date of first issue: 19.09.2023 |

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

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

|                        |   |                                                                                                                                                                                                                                                                                                                    |
|------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

### SECTION 14: Transport information

#### 14.1 UN number or ID number

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.2 UN proper shipping name

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.3 Transport hazard class(es)

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.4 Packing group

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Number on list 18: Thiomersal

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

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### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## SECTION 16: Other information

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

### Full text of H-Statements

|      |   |                                                                    |
|------|---|--------------------------------------------------------------------|
| H300 | : | Fatal if swallowed.                                                |
| H310 | : | Fatal in contact with skin.                                        |
| H315 | : | Causes skin irritation.                                            |
| H330 | : | Fatal if inhaled.                                                  |
| H360 | : | May damage fertility or the unborn child.                          |
| H372 | : | Causes damage to organs through prolonged or repeated exposure.    |
| H373 | : | May cause damage to organs through prolonged or repeated exposure. |
| H400 | : | Very toxic to aquatic life.                                        |
| H410 | : | Very toxic to aquatic life with long lasting effects.              |

### Full text of other abbreviations

|                            |   |                                                                                                                                     |
|----------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------|
| Acute Tox.                 | : | Acute toxicity                                                                                                                      |
| Aquatic Acute              | : | Short-term (acute) aquatic hazard                                                                                                   |
| Aquatic Chronic            | : | Long-term (chronic) aquatic hazard                                                                                                  |
| Repr.                      | : | Reproductive toxicity                                                                                                               |
| Skin Irrit.                | : | Skin irritation                                                                                                                     |
| STOT RE                    | : | Specific target organ toxicity - repeated exposure                                                                                  |
| AN 361                     | : | Norway. Directive on measures and limit values for physical and chemical factors in the work environment (biological limit values). |
| FOR-2011-12-06-1358        | : | Norway. Occupational Exposure limits                                                                                                |
| FOR-2011-12-06-1358 / TWA  | : | Long term exposure limit                                                                                                            |
| FOR-2011-12-06-1358 / STEL | : | Short term exposure limit                                                                                                           |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### 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/>

### Classification of the mixture:

Aquatic Chronic 3 H412

### Classification procedure:

Calculation method

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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Multine B12 Selenised Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 06.04.2024  |
| 3.0     | 28.09.2024     | 11274292-00004 | Date of first issue: 19.09.2023 |

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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.

NO / EN