SECTION 1. IDENTIFICATION

Product name: Iron Dextran / Nicotinamide Formulation

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Additional Labeling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2,87 %

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Iron dextran</td>
<td>9004-66-4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Nicotinamide</td>
<td>98-92-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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:

- None known.

Protection of first-aiders:

- No special precautions are necessary for first aid responders.

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 firefighting:

- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:

- Metal oxides
- Carbon oxides
- Nitrogen oxides (NOx)
- Chlorine compounds

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:

- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

- 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: 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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: Combined particulates and organic vapor 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. 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: suspension
Color: dark brown
Odor: characteristic
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: -1,0 °C
Initial boiling point and boiling range: 98,5 °C
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
### SAFETY DATA SHEET

**Iron Dextran / Nicotinamide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>27.08.2021</td>
<td>4910474-00005</td>
<td>09.04.2021</td>
<td>20.09.2019</td>
</tr>
</tbody>
</table>

- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: 0.9950 - 1,1500
- **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**
Not classified based on available information.

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: > 5.000 mg/kg
Components:

**Aluminum hydroxide:**
- **Acute oral toxicity:** LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity
- **Acute inhalation toxicity:** LC50 (Rat): > 5,09 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials

**Iron dextran:**
- **Acute oral toxicity:** LD50 (Mouse): 1,000 mg/kg

**Nicotinamide:**
- **Acute oral toxicity:** LD50 (Rat): > 2,500 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity
- **Acute inhalation toxicity:** LC50 (Rat): > 3,8 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 436
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials
- **Acute dermal toxicity:** LD50 (Rabbit): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**
Not classified based on available information.

Components:

**Aluminum hydroxide:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

**Nicotinamide:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
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</tbody>
</table>

#### Serious eye damage/eye irritation
Not classified based on available information.

#### Components:

##### Aluminum hydroxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

##### Nicotinamide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 7 days</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

#### Respiratory or skin sensitization

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

#### Components:

##### Aluminum hydroxide:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
</tbody>
</table>

##### Nicotinamide:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Germ cell mutagenicity
Not classified based on available information.

#### Components:

##### Aluminum hydroxide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro Result: positive</th>
</tr>
</thead>
</table>
Remarks: Based on data from similar materials
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: equivocal
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Nicotinamide:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity
Not classified based on available information.

Components:
Aluminum hydroxide:
Species: Rat
Application Route: inhalation (dust/mist/fume)
Exposure time: 86 weeks
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:
Aluminum hydroxide:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
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Iron Dextran / Nicotinamide Formulation

Remarks: Based on data from similar materials

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Nicotinamide:
Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Aluminum hydroxide:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 364 Days
Method: OECD Test Guideline 426
Remarks: Based on data from similar materials

Species: Rat
NOAEL: > 0.2 mg/kg
Application Route: Inhalation (dust/mist/fume)
Exposure time: 12 Months
Remarks: Based on data from similar materials

Nicotinamide:
Species: Rat
NOAEL: 215 mg/kg
Application Route: Ingestion
Exposure time: 28 Days
Method: OECD Test Guideline 407

Aspiration toxicity
Not classified based on available information.
## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Aluminum hydroxide:**
- **Toxicity to fish**
  - LL50 (Salmo trutta (brown trout)): > 100 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**
  - EL50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
- **Toxicity to algae/aquatic plants**
  - EL50 (Selenastrum capricornutum (green algae)): > 100 mg/l
  - Exposure time: 96 h

**Iron dextran:**
- **Ecotoxicology Assessment**
  - **Acute aquatic toxicity**
    - Toxic effects cannot be excluded
  - **Chronic aquatic toxicity**
    - Toxic effects cannot be excluded

**Nicotinamide:**
- **Toxicity to fish**
  - LC50 (Poecilia reticulata (guppy)): > 1.000 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
  - Exposure time: 24 h
  - Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants**
  - EC50 (Desmodesmus subspicatus (green algae)): > 1.000 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- **Toxicity to microorganisms**
  - NOEC (Pseudomonas putida): 4.235 mg/l
  - Exposure time: 18 h
  - Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

**Nicotinamide:**
- **Biodegradability**
  - Result: Readily biodegradable.
  - Biodegradation: 95 %
  - Exposure time: 28 d
Method: OECD Test Guideline 301E

Bioaccumulative potential

Components:

Nicotinamide:
Partition coefficient: n-octanol/water: log Pow: -0.38
Mobility in soil
No data available
Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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:
SAFETY DATA SHEET

Iron Dextran / Nicotinamide Formulation

SECTION 16. OTHER INFORMATION

Further information
Sources of key data used to compile the Material Safety Data Sheet:

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 other abbreviations
ACGIH / TWA: USA. ACGIH Threshold Limit Values (TLV)

ACGIH - USA. ACGIH Threshold Limit Values (TLV)
AICIS - 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; SACD - 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.