SAFETY DATA SHEET

Iron Dextran / Nicotinamide Formulation

Version 2.0  Revision Date: 27.08.2021  SDS Number: 4910476-00005  Date of last issue: 09.04.2021  Date of first issue: 20.09.2019

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Iron Dextran / Nicotinamide Formulation

Manufacturer or supplier's details

Company: MSD
Address: Briahnager - Off Pune Nagar Road  Wagholi - Pune - India  412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Additional Labelling
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.

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>

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.

### 5. FIREFIGHTING 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 firefighters | Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.  

### 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 spills cannot be contained.  
| Methods and materials for | Soak up with inert absorbent material.  

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containment and cleaning up

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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 labelled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 (Aluminium)</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 expo-
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<thead>
<tr>
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<td>4910476-00005</td>
<td>09.04.2021</td>
</tr>
</tbody>
</table>

Filter type: Combined particulates and organic vapour type

**Hand protection**

Material: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Eye protection**

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

**Skin and body protection**

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures**

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: suspension
- **Colour**: dark brown
- **Odour**: characteristic
- **Odour 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
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour 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
Auto-ignition 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

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact
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Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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
Result: No skin irritation

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

Components:

Aluminum hydroxide:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation

nicotinamide:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 7 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Aluminum hydroxide:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

nicotinamide:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Aluminum hydroxide:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: positive
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:


nicotinamide:

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

nicotinamide:

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

Ecotoxicity

Components:

<table>
<thead>
<tr>
<th>Aluminum hydroxide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>LL50 (Salmo trutta (brown trout)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>EL50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>EL50 (Selenastrum capricornutum (green algae)): &gt; 100 mg/l</td>
</tr>
</tbody>
</table>

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

| Nicotinamide:                             |
| Toxicity to fish                          |
| Exposure time: 96 h                       |
| LC50 (Poecilia reticulata (guppy)): > 1,000 mg/l |
| Method: OECD Test Guideline 203            |
| Toxicity to daphnia and other aquatic invertebrates |
| Exposure time: 24 h                       |
| EC50 (Daphnia magna (Water flea)): > 1,000 mg/l |
| Method: OECD Test Guideline 202            |
| Toxicity to algae/aquatic plants          |
| Exposure time: 72 h                       |
| EC50 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l |
| Method: OECD Test Guideline 201            |
| NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l |
| Method: OECD Test Guideline 201            |
| Toxicity to microorganisms                 |
| Exposure time: 18 h                       |
| NOEC (Pseudomonas putida): 4,235 mg/l      |
| Method: OECD Test Guideline 209            |

Persistence and degradability

Components:

| Nicotinamide:                             |
| Biodegradation                            |
| 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

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.

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 IMO instruments
Not applicable for product as supplied.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
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IECSC: not determined

16. OTHER INFORMATION

Further information

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

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average

AICL - 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 Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only
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To the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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