SAFETY DATA SHEET
classified as per the OSHA Hazard Communication Standard

Iron Dextran / Nicotinamide Formulation

Version 2.4
Revision Date: 09/30/2023
SDS Number: 4910482-00009
Date of last issue: 04/04/2023
Date of first issue: 09/20/2019

SECTION 1. IDENTIFICATION

Product name: Iron Dextran / Nicotinamide Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Not a hazardous substance or mixture.

GHS label elements
No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components
<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>

Actual concentration is withheld as a trade secret

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: None known.
and effects, both acute and delayed
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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

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

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Metal oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
</tbody>
</table>

| 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 Gases

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., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any
hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

Eye protection

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

Skin and body protection

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

Hygiene measures

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension
Color: dark brown
Odor: characteristic
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: 30.2 °F / -1.0 °C
Initial boiling point and boiling range: 209.3 °F / 98.5 °C
Flash point: No data available
Evaporation rate: No data available
Iron Dextran / Nicotinamide Formulation

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
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
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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
Result: No eye irritation
Method: OECD Test Guideline 405

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

Respiratory or skin sensitization

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

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

**Components:**

**Aluminum hydroxide:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

**Nicotinamide:**
Test Type: Maximization Test
Routes of exposure: Skin contact
**Iron Dextran / Nicotinamide Formulation**

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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  

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

IARC
Group 2B: Possibly carcinogenic to humans
Iron dextran 9004-66-4

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
Reasonably anticipated to be a human carcinogen
Iron dextran 9004-66-4

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
Remarks: Based on data from similar materials

Effect 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
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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
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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.
- Do not dispose of waste into sewer.
- 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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Iron Dextran / Nicotinamide Formulation

Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water 7732-18-5
Aluminum hydroxide 21645-51-2
Iron dextran 9004-66-4
Phenol 108-95-2

California Prop. 65
WARNING: This product can expose you to chemicals including Iron dextran, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
Iron dextran 9004-66-4

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

AICS : not determined

DSL : not determined
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

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IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ 0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "***" represents a chronic hazard, while the "*" represents the absence of a chronic hazard.

Full text of other abbreviations

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

ACGIH - American Conference of Governmental Industrial Hygienists
AICL - Australian Inventory of Industrial Chemicals
ASTM - American Society for Testing and Materials
bw - Body weight
CMR - Carcinogen, Mutagen or Reproductive Toxicant
DIN - Standard of the German Institute for Standardisation
DOT - Department of Transportation
DSL - Domestic Substances List (Canada)
ECx - Concentration associated with x% response
EHS - Extremely Hazardous Substance
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
HMS - Hazardous Materials Identification System
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
IECS - Inventory of Existing Chemicals 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
MSHA - Mine Safety and Health Administration
NO(A)EC - No Observed (Adverse) Effect Concentration
NO(A)EL - No Observed (Adverse) Effect Level
NOELR - No Observable Effect Loading Rate
NTP - National Toxicology Program
NZIoC - New Zealand Inventory of
Iron Dextran / Nicotinamide Formulation

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


Revision Date: 09/30/2023

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.

US / Z8