

## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

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

#### 1.1 Product identifier

Trade name : Iron Dextran / Nicotinamide Formulation

#### 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  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

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)**

Not a hazardous substance or mixture.

#### 2.2 Label elements

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

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

**Additional Labelling**

EUH210 Safety data sheet available on request.

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

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

**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.

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Iron dextran	9004-66-4	Acute Tox. 4; H302	$\geq 1 - < 10$
nicotinamide	98-92-0 202-713-4	Eye Irrit. 2; H319	$\geq 1 - < 10$

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

Protection of first-aiders	: No special precautions are necessary for first aid responders.
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.

**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.

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

---

**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 : Metal oxides  
Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Chlorine compounds

**5.3 Advice for firefighters**

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. 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 : 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

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

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 | : | 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, 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:<br>Strong oxidizing agents<br>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	Control parameters	Basis
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## Iron Dextran / Nicotinamide Formulation

Version 5.0      Revision Date: 14.04.2025      SDS Number: 4910483-00012      Date of last issue: 28.09.2024  
 Date of first issue: 20.09.2019

		of exposure)		
Aluminum hydroxide	21645-51-2	OEL-RL (respirable dust fraction)	2 mg/m <sup>3</sup> (Aluminium)	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

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

Substance name	End Use	Exposure routes	Potential health effects	Value
L-Lysine hydrochloride	Workers	Inhalation	Long-term systemic effects	67,1 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	381 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	19,9 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	229 mg/kg bw/day
nicotinamide	Consumers	Ingestion	Long-term systemic effects	22,9 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	43,75 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	12,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	21,88 mg/m <sup>3</sup>
Choline chloride	Consumers	Skin contact	Long-term systemic effects	12,5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12,5 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	338,5 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	120 mg/kg bw/day
Aluminum hydroxide	Consumers	Inhalation	Long-term systemic effects	83,48 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	60 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12 mg/kg bw/day
	Workers	Inhalation	Long-term local effects	10,76 mg/m <sup>3</sup>
L-Glutamic acid, sodium salt, hydrate	Workers	Inhalation	Long-term local effects	10,76 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	4,74 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	10 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	179 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	107 mg/kg bw/day

## Iron Dextran / Nicotinamide Formulation

Version 5.0      Revision Date: 14.04.2025      SDS Number: 4910483-00012      Date of last issue: 28.09.2024  
Date of first issue: 20.09.2019

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

Substance name	Environmental Compartment	Value
L-Lysine hydrochloride	Sewage treatment plant	10 mg/l
nicotinamide	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	10 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,1085 mg/kg
	Marine sediment	0,1109 mg/kg
	Soil	0,33 mg/kg
Choline chloride	Fresh water	0,604 mg/l
	Marine water	0,0604 mg/l
	Intermittent use/release	5 mg/l
	Sewage treatment plant	112,9 mg/l
	Fresh water sediment	0,5 mg/kg
	Marine sediment	0,05 mg/kg
	Soil	0,09 mg/kg

**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.  
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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type (A-P)

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

**SECTION 9: Physical and chemical properties****9.1 Information on basic 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.

**9.2 Other information**

Molecular weight	: No data available
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**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

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Particle size : Not applicable

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**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.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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

**Components:****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

## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

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:****nicotinamide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****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:****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.

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

---

**Components:****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.

**Reproductive toxicity**

|| Not classified based on available information.

**Components:****nicotinamide:**

Effects on foetal development	: Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative
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**STOT - single exposure**

|| Not classified based on available information.

**STOT - repeated exposure**

|| Not classified based on available information.

**Repeated dose toxicity****Components:****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.

## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

**SECTION 12: Ecological information****12.1 Toxicity****Components:****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

**12.2 Persistence and degradability****Components:****nicotinamide:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301E
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**12.3 Bioaccumulative potential****Components:****nicotinamide:**

Partition coefficient: n-octanol/water	:	log Pow: -0,38
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## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

**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 Other adverse effects****Product:**

Endocrine disrupting potential : 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 13: Disposal considerations****13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
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****14.1 UN 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

## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

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

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 Transport in bulk according to Annex II of Marpol and the IBC Code**

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**

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.

**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.

## Iron Dextran / Nicotinamide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

**Full text of H-Statements**

H302 : Harmful if swallowed.  
H319 : Causes serious eye irritation.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
Eye Irrit. : Eye irritation  
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits  
ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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/>

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

**Iron Dextran / Nicotinamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	4910483-00012	Date of first issue: 20.09.2019

---

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.

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