

# SAFETY DATA SHEET

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



# **Nobilis EDS / Nobilis EDS + ND / Nobilis REO Inac Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2025  
4.4 29.09.2025 11310253-00008 Date of first issue: 12.12.2023

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

## 1.1 Product identifier

Trade name : Nobilis EDS / Nobilis EDS + ND / Nobilis REO Inac Formulation

Other means of identification : Nobilis REO inac (A009597)  
NOBILIS EDS INACTIVATED VACCINE FOR LAYING HENS  
(50008)  
NOBILIS EDS + ND COMBINED INACTIVATED VACCINE  
AGAINST EDS'76 AND NEWCASTLE DISEASE (58494)

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

## SECTION 2: Hazards identification

## 2.1 Classification of the substance or mixture

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

H304: May be fatal if swallowed and enters airways.

Long-term (chronic) aquatic hazard, Category 4 ways.  
H413: May cause long lasting harmful effects to aquatic life.

## 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word :

Danger

Hazard statements : H304 May be fatal if swallowed and enters airways.  
H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements : **Prevention:**

P273 Avoid release to the environment.

**Response:**

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P331 Do NOT induce vomiting.

**Storage:**

P405 Store locked up.

### Hazardous components which must be listed on the label:

Paraffin oil

### 2.3 Other hazards

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

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 30 - < 50
Antigen	Not Assigned		>= 10 - < 20

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For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice	<p>: ACCIDENTAL SELF-INJECTION: In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician. Show this document to the consulting physician. In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.</p>
Protection of first-aiders	<p>: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).</p>
If inhaled	<p>: If inhaled, remove to fresh air. Get medical attention if symptoms occur.</p>
In case of skin contact	<p>: Wash with water and soap as a precaution. Get medical attention if symptoms occur.</p>
In case of eye contact	<p>: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</p>
If swallowed	<p>: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.</p>

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

Risks : May be fatal if swallowed and enters airways.

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

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

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

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Dry chemical

Unsuitable extinguishing media : None known.

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

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

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

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

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items



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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin oil	8012-95-1	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m3	IE OEL

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m3
	Workers	Inhalation	Acute systemic effects	5 mg/m3
	Workers	Inhalation	Long-term local effects	5 mg/m3
	Workers	Inhalation	Acute local effects	5 mg/m3

#### 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.

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Respiratory protection	: Use appropriate degowning techniques to remove potentially contaminated clothing. If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to I.S. EN 14387
Filter type	: Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

## 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Form	:	Syringe, Emulsion
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available

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Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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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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## Reproductive toxicity

Not classified based on available information.

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Not classified based on available information.

## Repeated dose toxicity

## Components:

## Paraffin oil:

Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

## Aspiration toxicity

May be fatal if swallowed and enters airways.

## **Components:**

## Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

## 11.2 Information on other hazards

## Endocrine disrupting properties

Not classified based on available information.

**Product:**

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

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## SECTION 12: Ecological information

## 12.1 Toxicity

## Components:

**Paraffin oil:**  
Toxicity to fish : LL50 (*Scophthalmus maximus* (turbot)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

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Toxicity to daphnia and other aquatic invertebrates : EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### **Paraffin oil:**

Partition coefficient: n-octanol/water : log Pow: > 4  
Remarks: Calculation

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

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

### 12.6 Endocrine disrupting properties

#### Product:

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

### 12.7 Other adverse effects

No data available

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## **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 or ID number

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

## 14.2 UN proper shipping name

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

## 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good

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<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA (Cargo)</b>	:	Not regulated as a dangerous good
<b>IATA (Passenger)</b>	:	Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

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

: Conditions of restriction for the following entries should be considered:  
Number on list 3

Number on list 72: Formaldehyde

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Number on list 77: Formaldehyde

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

: Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

: Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

: Not applicable

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REACH - List of substances subject to authorisation : Not applicable  
(Annex XIV)  
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

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

AICS : not determined

CA, 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.

## Full text of H-Statements

H304 : May be fatal if swallowed and enters airways.  
H413 : May cause long lasting harmful effects to aquatic life.

## Full text of other abbreviations

Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Asp. Tox.	:	Aspiration hazard
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonised 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;

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IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; 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; 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 - Organisation 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Asp. Tox. 1	H304
Aquatic Chronic 4	H413

### Classification procedure:

Calculation method
Calculation method

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.

IE / EN