

# SAFETY DATA SHEET



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

Version  
3.3

Revision Date:  
2025/09/29

SDS Number:  
11310231-00008

Date of last issue: 2025/09/26  
Date of first issue: 2023/12/12

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product 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)

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Aspiration hazard : Category 1

Long-term (chronic) aquatic hazard : Category 4

#### GHS label elements

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.

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### Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
P331 Do NOT induce vomiting.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Paraffin oil	8012-95-1	>= 40 - < 50	-
Antigen	Not Assigned	>= 10 - < 20	-
Formaldehyde	50-00-0	>= 0.0002 - < 0.0025	2-482

## 4. FIRST AID MEASURES

General advice

: 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.

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.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

: May be fatal if swallowed and enters airways.

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delayed  
Protection of first-aiders : 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).

Notes to physician : Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

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

Hazardous combustion products : Carbon oxides

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

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
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 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 absor-

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bent.

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

### Handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Avoid inhalation of vapour or mist.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

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.

### Storage

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

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

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type	Control param-	Basis
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		(Form of exposure)	ters / Concentration standard / Permissible concentration	
Paraffin oil	8012-95-1	OEL-M (Mist)	3 mg/m3	JP OEL JSOH
	Further information: Group 1: carcinogenic to humans			
Formaldehyde	50-00-0	ACL	0.1 ppm	JP OEL ISHL
		OEL-M	0.1 ppm 0.12 mg/m3	JP OEL JSOH
	Further information: Airway sensitizing agent; Group 2 substances which probably induce allergic reactions in humans., Skin sensitizing agent; Group 1 substances which induce allergic reactions in humans, Group 2A: probably carcinogenic to humans			
		OEL-C	0.2 ppm 0.24 mg/m3	JP OEL JSOH
	Further information: Airway sensitizing agent; Group 2 substances which probably induce allergic reactions in humans., Skin sensitizing agent; Group 1 substances which induce allergic reactions in humans, Group 2A: probably carcinogenic to humans			
		TWA	0.1 ppm	ACGIH
		STEL	0.3 ppm	ACGIH

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

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type

Hand protection

Material

Remarks

Eye protection

: Combined particulates and organic vapour type

: Chemical-resistant gloves

: Consider double gloving.

: 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

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**Skin and body protection** : potential for direct contact to the face with dusts, mists, or aerosols.  
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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : Syringe, Emulsion  
Colour : No data available  
Odour : No data available  
Odour Threshold : No data available  
Melting point/freezing point : No data available  
Boiling point, initial boiling point and boiling range : No data available  
Flammability (solid, gas) : Not applicable  
Flammability (liquids) : No data available  
Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Up- : No data available  
per flammability limit  
Lower explosion limit / : No data available  
Lower flammability limit  
Flash point : No data available  
Decomposition temperature : No data available  
pH : No data available  
Evaporation rate : No data available  
Auto-ignition temperature : No data available  
Viscosity  
Viscosity, kinematic : No data available  
Solubility(ies)  
Water solubility : No data available  
Partition coefficient: n-octanol/water : Not applicable

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Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

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## 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.

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## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### Paraffin oil:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

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### **Formaldehyde:**

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Acute toxicity estimate (Rat): 100 ppm  
Exposure time: 4 h  
Test atmosphere: gas  
Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): 270 mg/kg

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Paraffin oil:**

Species : Rabbit  
Result : No skin irritation

### **Formaldehyde:**

Result : Corrosive after 3 minutes to 1 hour of exposure  
Remarks : Based on national or regional regulation.

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Paraffin oil:**

Species : Rabbit  
Result : No eye irritation

### **Formaldehyde:**

Result : Irreversible effects on the eye  
Remarks : Based on skin corrosivity.

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### **Formaldehyde:**

Test Type : Human repeat insult patch test (HRIPT)  
Exposure routes : Skin contact

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Species	:	Humans
Result	:	positive
Assessment	:	Probability or evidence of high skin sensitisation rate in humans

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **Formaldehyde:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: positive
		Test Type: In vitro mammalian cell gene mutation test Result: positive
		Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	:	Test Type: In vivo mammalian alkaline comet assay Species: Mouse Application Route: Inhalation Result: positive
Germ cell mutagenicity - Assessment	:	Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### Carcinogenicity

Not classified based on available information.

#### Components:

##### **Formaldehyde:**

Species	:	Rat
Application Route	:	inhalation (gas)
Exposure time	:	28 Months
Result	:	positive
Carcinogenicity - Assessment	:	Sufficient evidence of carcinogenicity in animal experiments

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **Formaldehyde:**

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: inhalation (gas) Result: negative
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### STOT - single exposure

Not classified based on available information.

#### Components:

##### **Formaldehyde:**

Assessment : May cause respiratory irritation.

### 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.

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## 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### 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

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

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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

### **Formaldehyde:**

Toxicity to fish : LC50 (Morone saxatilis (striped bass)): 6.7 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 5.8 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.04 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (activated sludge): 19 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

### **Persistence and degradability**

#### **Components:**

### **Formaldehyde:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 99 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301A

### **Bioaccumulative potential**

#### **Components:**

### **Paraffin oil:**

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

### **Formaldehyde:**

Partition coefficient: n-octanol/water : log Pow: 0.35  
Remarks: Calculation

### **Mobility in soil**

No data available

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### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : 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.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

Not regulated as a dangerous good

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

Not regulated as a dangerous good

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

Refer to section 15 for specific national regulation.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Formaldehyde	25

#### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Mineral oil	>=40 - <50	-

#### Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Mineral oil	-

#### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

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### **Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

### **Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

### **Ordinance on Prevention of Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

### **Vessel Safety Law**

Not regulated as a dangerous good

### **Aviation Law**

Not regulated as a dangerous good

### **Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### **Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

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CA. DSL : not determined

IECSC : not determined

### 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

#### 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/>

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL ISHL : Japan. Administrative Control Levels

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

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

ACGIH / STEL : Short-term exposure limit

JP OEL ISHL / ACL : Administrative Control level

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

AIIC - 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 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; 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 - 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

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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

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