

# SAFETY DATA SHEET

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



## Fidaxomicin Formulation

Version 2.10      Revision Date: 30.09.2023      SDS Number: 1732338-00013      Date of last issue: 04.04.2023  
Date of first issue: 05.06.2017

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

#### 1.1 Product identifier

Trade name : Fidaxomicin Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Acute toxicity, Category 4      H302: Harmful if swallowed.

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.

### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Hazardous components which must be listed on the label:

Fidaxomicin

### 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)
Fidaxomicin	873857-62-6	Acute Tox. 4; H302	>= 40 - <= 60

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : 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.

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).

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- 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 unless directed to do so by medical personnel.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

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

- Risks : Harmful if swallowed.

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

- Treatment : Treat symptomatically and supportively.
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## 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 : 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.

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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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
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.

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### 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 : Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Do not eat, drink or smoke when using this product.  
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.

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### 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:  
Strong oxidizing agents

### 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 of exposure)	Control parameters	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m3 (OEB 2)	Internal

### 8.2 Exposure controls

#### Engineering measures

Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

#### Personal protective equipment

- Eye/face protection : Wear the following personal protective equipment:  
Safety glasses  
Equipment should conform to NS EN 166
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- Skin and body protection : Skin should be washed after contact.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to NS EN 143
- Filter type : Particulates type (P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	:	solid
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	175 - 185 °C Active ingredient
Initial boiling point and boiling range	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
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	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	Not applicable
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 4,4 Active ingredient
Vapour pressure	:	No data available
Density	:	No data available
Relative vapour density	:	No data available

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Particle characteristics  
Particle size : No data available

### 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 : 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 833,33 mg/kg  
Method: Calculation method

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### Components:

#### **Fidaxomicin:**

Acute oral toxicity : LD50 (Rat): > 1.000 mg/kg  
LD50 (Dog): > 120 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 200 mg/kg  
Application Route: Intravenous

#### **Skin corrosion/irritation**

Not classified based on available information.

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

Not classified based on available information.

#### **Respiratory or skin sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Fidaxomicin:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Rat  
Application Route: Intravenous  
Result: negative

Test Type: comet assay  
Species: Rat  
Result: negative

#### **Carcinogenicity**

Not classified based on available information.

#### **Reproductive toxicity**

Not classified based on available information.



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### Components:

#### **Fidaxomicin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: 6,3 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 12,6 mg/kg body weight  
Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 7 mg/kg body weight  
Remarks: No significant adverse effects were reported

#### **STOT - single exposure**

Not classified based on available information.

#### **STOT - repeated exposure**

Not classified based on available information.

#### **Repeated dose toxicity**

### Components:

#### **Fidaxomicin:**

Species : Rat  
NOAEL : 90 mg/kg  
Application Route : Oral  
Exposure time : 28 D  
Remarks : No significant adverse effects were reported

Species : Rat  
NOAEL : 62,5 mg/kg  
Application Route : Intravenous  
Exposure time : 14 D

Species : Dog  
NOAEL : 9.600 mg/kg  
Application Route : Oral  
Exposure time : 3 M  
Symptoms : Vomiting  
Remarks : No significant adverse effects were reported

Species : Monkey  
NOAEL : 90 mg/kg  
Application Route : Oral  
Exposure time : 28 D

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Remarks : No significant adverse effects were reported

Species : Juvenile rat  
NOAEL : 200 mg/kg  
Application Route : Oral  
Exposure time : 28 D  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### 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.

### Experience with human exposure

#### Components:

##### **Fidaxomicin:**

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, constipation

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **Fidaxomicin:**

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): > 18,4 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

NOEC (Anabaena flos-aquae (cyanobacterium)): 5,8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 50 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC : 5,9 mg/l

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Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 8,91 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 19,6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### **Fidaxomicin:**

Partition coefficient: n-octanol/water : log Pow: 4,4

### 12.4 Mobility in soil

#### Components:

##### **Fidaxomicin:**

Distribution among environmental compartments : log Koc: 0,80

### 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.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |
- 

### SECTION 14: Transport information

#### 14.1 UN number or ID 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 |
| 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 |

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**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 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) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## 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.

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### Full text of H-Statements

H302 : Harmful if swallowed.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

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/>

### Classification of the mixture:

Acute Tox. 4

H302

### Classification procedure:

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

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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.

NO / EN