

# SAFETY DATA SHEET

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



## **Acetyl Methionine / L-Arginine hydrochloride / Hydroxocobalamin Acetate Formulation**

Version Revision Date: SDS Number: Date of last issue: 28.09.2024  
2.0 14.04.2025 5473284-00014 Date of first issue: 02.03.2020

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

## 1.1 Product identifier

Trade name : Acetyl Methionine / L-Arginine hydrochloride / Hydroxocobalamin Acetate Formulation

## 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)

Not a hazardous substance or mixture

## 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Labelling (REACH Regulation (EC) No 1272/2008):  
No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### 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.

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**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.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Acetatocobalamin	22465-48-1 245-019-7	STOT RE 2; H373 (Kidney, Liver)	< 0.1
Substances with a workplace exposure limit :			
N-Acetyl-DL-methionine	1115-47-5 214-224-3		>= 20 - < 30

For explanation of abbreviations see section 16.

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### 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

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Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
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 Nitrogen oxides (NOx) Sulphur oxides Chlorine compounds
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### 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.

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### 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 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 : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.

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.

### 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  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

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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
N-Acetyl-DL-methionine	1115-47-5	TWA	2000 µg/m3 (OEB 1)	Internal
Acetatocobalamin	22465-48-1	OELV - 8 hrs (TWA)	0.02 mg/m3 (Cobalt)	IE OEL
Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans, Repr 1B - Substances which are presumed human reproductive toxicants				
		TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
L-Arginine hydrochloride	Workers	Inhalation	Long-term systemic effects	668.2 mg/m3
	Workers	Skin contact	Long-term systemic effects	947.5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	164.8 mg/m3
	Consumers	Skin contact	Long-term systemic effects	473.8 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	47.8 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
L-Arginine hydrochloride	Fresh water	2.2 mg/l
	Marine water	0.22 mg/l
	Intermittent use/release	22 mg/l
	Sewage treatment plant	12000 mg/l
	Fresh water sediment	4.437 mg/kg
	Marine sediment	0.444 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).

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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

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. Equipment should conform to I.S. 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	:	liquid
Colour	:	pink
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

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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 : 5 - 7

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

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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Acute inhalation toxicity : LC50 (Rat): > 5.25 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Acetatocobalamin:

Remarks : No data available

##### N-Acetyl-DL-methionine:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Acetatocobalamin:

Remarks : No data available

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Acetatocobalamin:

Remarks : No data available

##### N-Acetyl-DL-methionine:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

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### Germ cell mutagenicity

||| Not classified based on available information.

### Components:

#### Acetatocobalamin:

Genotoxicity in vitro : Test Type: Mutagenicity (Escherichia coli - reverse mutation assay)  
Result: negative

Test Type: Ames test  
Test system: Salmonella typhimurium  
Result: negative

Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Result: negative

#### N-Acetyl-DL-methionine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative  
Remarks: Based on data from similar materials

### Carcinogenicity

||| Not classified based on available information.

### 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.

### Components:

#### Acetatocobalamin:

Target Organs : Kidney, Liver  
Assessment : May cause damage to organs through prolonged or repeated

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exposure.

### Repeated dose toxicity

#### Components:

##### **Acetatocobalamin:**

Species	:	Dog
LOAEL	:	300 mg/kg
Application Route	:	Oral
Number of exposures	:	3 days
Target Organs	:	Kidney, Liver
Symptoms	:	kidney effects, liver function change
Remarks	:	May cause damage to organs.

  

Species	:	Dog
LOAEL	:	75 mg/kg
Application Route	:	Intravenous
Number of exposures	:	4 weeks
Target Organs	:	Kidney, Liver
Remarks	:	May cause damage to organs.

##### **N-Acetyl-DL-methionine:**

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408
Remarks	:	Based on data from similar materials

### Aspiration toxicity

|| Not classified based on available information.

## 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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### Experience with human exposure

## Components:

**Acetatocobalamin:** General Information : Symptoms: asthenia, Dizziness, Headache, Nausea, sinusitis  
Remarks: The most common side effects are:

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## SECTION 12: Ecological information

## 12.1 Toxicity

## Components:-

### N-Acetyl-DL-methionine-

: LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

## 12.2 Persistence and degradability

## Components:

### N-Acetyl-DL-methionine:

: Result: Readily biodegradable.  
Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

## Components:

### N-Acetyl-DL-methionine:

Partition coefficient:  $n = 1.00$  log Pow: -0.313

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octanol/water Remarks: Calculation

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPyB assessment

### Product:

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## 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:

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## 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

## **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

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### 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
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
Regulation (EU) No 2024/590 on substances that de-	:	Not applicable

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plete the ozone layer  
Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable  
tants (recast)  
Regulation (EU) No 649/2012 of the European Parlia- : Not applicable  
ment and the Council concerning the export and import  
of dangerous chemicals  
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  
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

H373 : May cause damage to organs through prolonged or repeated exposure.

## Full text of other abbreviations

STOT RE : Specific target organ toxicity - repeated exposure  
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)

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boratory 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; 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/>

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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