according to the Globally Harmonized System



# **Levothyroxine Formulation**

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levothyroxine Formulation

Other means of identification : Leventa (A010426)

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Highly flammable liquids

## **GHS Classification**

Flammable liquids : Category 3

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 1 (Thyroid, Cardio-vascular system, Central nervous

system)

#### **GHS** label elements

Signal word

Hazard pictograms :



Danger

Hazard statements : H226 Flammable liquid and vapour.

H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeat-

according to the Globally Harmonized System



# **Levothyroxine Formulation**

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

ed exposure.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames

and other ignition sources. No smoking. P260 Do not breathe mist or vapours. P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water.

P318 IF exposed or concerned, get medical advice.

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

Vapours may form explosive mixture with air.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 10 - < 20
levothyroxine sodium	55-03-8	>= 0.1 - < 1

<sup>#:</sup> Voluntarily-disclosed substance

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

according to the Globally Harmonized System



# Levothyroxine Formulation

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

: Suspected of damaging fertility or the unborn child.

and effects, both acute and delayed

Causes damage to organs through prolonged or repeated

exposure.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread

fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Remove all sources of ignition.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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.

according to the Globally Harmonized System



# **Levothyroxine Formulation**

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

Methods and materials for containment and cleaning up

Non-sparking tools should be used. Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

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-

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Advice on safe handling : Do not breathe mist or vapours.

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 as-

sessment

Non-sparking tools should be used.

Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition.

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

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases Explosives

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m3	IN OEL
		STEL	1,000 ppm	ACGIH
levothyroxine sodium	55-03-8	TWA	0.1 μg/m3 (OEB 5)	Internal
		Wipe limit	1 μg/100 cm <sup>2</sup>	Internal

**Engineering measures** 

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to pre-

vent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems

are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the

workplace.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour type

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

Eye 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.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : colourless

Odour : slight

Odour Threshold : No data available

pH : 9.7 - 10.7

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 44 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.05 g/cm<sup>3</sup>

according to the Globally Harmonized System



# **Levothyroxine Formulation**

**Revision Date:** Date of last issue: 05.12.2023 Version SDS Number: 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

Solubility(ies)

Water solubility soluble

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature

No data available

Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

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

Particle characteristics

Particle size Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Flammable liquid and vapour.

Possibility of hazardous reac-

Vapours may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Incompatible materials Oxidizing agents

Acids

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

**Components:** 

**Ethanol:** 

Acute oral toxicity LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h

Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

levothyroxine sodium:

Acute oral toxicity : TDLo (Humans): 10 mg/kg

TDLo (Dog): 10 mg/kg

LD50 (Rat): > 1,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 50 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 20 mg/kg

Application Route: Intraperitoneal

LD50 (Rat): 50 mg/kg

Application Route: Subcutaneous

#### Skin corrosion/irritation

Not classified based on available information.

## **Components:**

#### Ethanol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

## **Components:**

## **Ethanol:**

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

# Respiratory sensitisation

Not classified based on available information.

# **Components:**

#### **Ethanol:**

Test Type : Mouse ear swelling test (MEST)

according to the Globally Harmonized System



# **Levothyroxine Formulation**

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

Exposure routes : Skin contact
Species : Mouse
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

#### **Ethanol:**

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion

Result: negative

## Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Suspected of damaging fertility or the unborn child.

#### Components:

#### **Ethanol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

**Application Route: Ingestion** 

Result: negative

### levothyroxine sodium:

Effects on foetal develop- : Test Type: Development

ment Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 0.25 mg/kg body weight

Test Type: Development

Species: Mouse Application Route: Oral

Developmental Toxicity: NOAEL: 3 mg/kg body weight

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

Test Type: Development

Species: Rabbit

Result: No teratogenic effects

Test Type: Development Species: Guinea pig

Result: No teratogenic effects

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

## STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeated exposure.

### **Components:**

# levothyroxine sodium:

Target Organs : Thyroid, Cardio-vascular system, Central nervous system
Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

# Ethanol:

Species : Rat

NOAEL : 1,730 mg/kg LOAEL : 3,200 mg/kg Application Route : Ingestion Exposure time : 90 Days

#### **Aspiration toxicity**

Not classified based on available information.

## **Experience with human exposure**

## **Components:**

### levothyroxine sodium:

Ingestion : Target Organs: Thyroid

Target Organs: Cardio-vascular system Target Organs: Central nervous system

Symptoms: Palpitation, hypotension, Tremors, Headache, increase in appetite, Sweating, Vomiting, Diarrhoea, Fever,

nervousness, weight loss

according to the Globally Harmonized System



# **Levothyroxine Formulation**

**Revision Date:** Date of last issue: 05.12.2023 Version SDS Number: 4.0 28.09.2024 1130732-00017 Date of first issue: 30.11.2016

#### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

### Components:

#### **Ethanol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 79 mg/lExposure time: 100 d

Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 9.6 mg/l Exposure time: 9 d

Species: Daphnia magna (Water flea)

### Persistence and degradability

### **Components:**

#### **Ethanol:**

Biodegradability Result: Readily biodegradable.

> Biodegradation: 84 % Exposure time: 20 d

## Bioaccumulative potential

#### **Components:**

#### **Ethanol:**

Partition coefficient: n-

octanol/water

: log Pow: -0.35

## Mobility in soil

No data available

#### Other adverse effects

No data available

according to the Globally Harmonized System



# **Levothyroxine Formulation**

**Revision Date:** Version SDS Number: Date of last issue: 05.12.2023 28.09.2024 1130732-00017 Date of first issue: 30.11.2016 4.0

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

#### International Regulations

#### **UNRTDG**

**UN** number UN 1170

Proper shipping name **ETHANOL SOLUTION** 

Class 3 Ш Packing group Labels 3 Environmentally hazardous no

**IATA-DGR** 

UN/ID No. UN 1170

Proper shipping name Ethanol solution

Class 3 Ш Packing group

Labels Flammable Liquids

Packing instruction (cargo 366

aircraft)

Packing instruction (passen: : 355

ger aircraft)

**IMDG-Code** 

UN number UN 1170

Proper shipping name **ETHANOL SOLUTION** 

Class 3 Packing group Ш Labels 3 EmS Code F-E, S-D Marine pollutant

## Transport in bulk according to IMO instruments

Not applicable for product as supplied.

# Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

#### 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

Revision Date : 28.09.2024

**Further information** 

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agen-

Internal technical data, data from raw material SDSs, OECD

Sheet cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

IN OEL : India. Permissible levels of certain chemical substances in

work environment.

ACGIH / STEL : Short-term exposure limit

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

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 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; 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

according to the Globally Harmonized System



# **Levothyroxine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.0
 28.09.2024
 1130732-00017
 Date of first issue: 30.11.2016

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; 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

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.

IN / EN