

# **Enrofloxacin (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 28.09.2024 641484-00022 Date of first issue: 27.04.2016

#### **SECTION 1. IDENTIFICATION**

Product name : Enrofloxacin (10%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Acute toxicity (Oral) : Category 5

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 1 (cartilage, Testis)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.

H317 May cause an allergic skin reaction.



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H361f Suspected of damaging fertility.

H372 Causes damage to organs (cartilage, Testis) through

prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

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

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P312 Call a POISON CENTER/ doctor if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

P391 Collect spillage.

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.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Enrofloxacin	93106-60-6	>= 10 -< 20
Benzyl alcohol	100-51-6	>= 1 -< 5

#### **SECTION 4. 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.

If inhaled : If inhaled, remove to fresh air.



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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. Flush eyes with water as a precaution.

In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May be harmful if swallowed. May cause an allergic skin reaction. Suspected of damaging fertility.

Most important symptoms and effects, both acute and

delayed

Causes damage to organs through prolonged or repeated

exposure.

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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



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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 diking or other appropriate

containment to keep material from spreading. If diked 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.

#### **SECTION 7. HANDLING AND STORAGE**

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 get on skin or clothing.

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

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.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components CAS-No. Value type   Control parame-   Basis	Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration	
Enrofloxacin	93106-60-6	TWA	0.2 mg/m3 (OEB 2)	Internal

**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.

Laboratory operations do not require special containment.

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 Combined particulates and organic vapor type

Material Chemical-resistant gloves

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. 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.

Contaminated work clothing should not be allowed out of the

workplace.

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

liquid **Appearance** 

Color No data available

Odor No data available

Odor Threshold No data available

рΗ No data available

Melting point/freezing point No data available



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Initial boiling point and boiling

range

No data available

Flash point No data available

Evaporation rate No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure No data available

No data available Relative vapor density

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Not explosive Explosive properties

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

Particle characteristics

Particle size Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.



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products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Eye contact

**Acute toxicity** 

May be harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 4.725 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

**Components:** 

Enrofloxacin:

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg

LD50 (Rat): > 5.000 mg/kg

LD50 (Mouse): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Enrofloxacin:

Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation



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### Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

**Enrofloxacin:** 

Result : Mild eye irritation

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

### Respiratory sensitization

Not classified based on available information.

#### **Components:**

#### **Enrofloxacin:**

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization

rate in humans

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Enrofloxacin:**

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Mammalian bone marrow sister chromatid ex-

change

Species: Hamster



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Result: negative

Test Type: Chromosomal aberration

Species: Rat Result: negative

Benzyl alcohol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### **Enrofloxacin:**

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species: MouseApplication Route: OralExposure time: 2 YearsResult: negative

### Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

#### Reproductive toxicity

Suspected of damaging fertility.

### **Components:**

### **Enrofloxacin:**

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

Fertility: LOAEL: 15 mg/kg body weight

Result: Effects on fertility., alteration in sperm morphology

Effects on fetal development : Test Type: Development

Species: Rat



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Application Route: Oral

Developmental Toxicity: LOAEL: 210 mg/kg body weight Result: Reduced fetal weight., No teratogenic effects.

Remarks: Maternal toxicity observed.

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: No fetotoxicity., No teratogenic effects.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development

Species: Mouse

**Application Route: Ingestion** 

Result: negative

### STOT-single exposure

Not classified based on available information.

#### STOT-repeated exposure

Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.

#### **Components:**

#### **Enrofloxacin:**

Target Organs : cartilage, Testis

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### Components:

### **Enrofloxacin:**

Species : Rat

NOAEL : 36 mg/kg

LOAEL : 150 mg/kg

Application Route : Oral

Exposure time : 13 Weeks

Target Organs : Testis

 Species
 : Dog

 NOAEL
 : 3 mg/kg

 LOAEL
 : 9,6 mg/kg



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Application Route : Oral
Exposure time : 13 Weeks
Target Organs : cartilage

Species : Cat

NOAEL : 25 mg/kg

Application Route : Oral

Exposure time : 30 Days

Remarks : No significant adverse effects were reported

Benzyl alcohol:

Species : Rat NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

**Enrofloxacin:** 

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous sys-

tem effects, Sensitivity to light

#### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

### Components:

**Enrofloxacin:** 

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 79,5 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l

Exposure time: 96 h

LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Hyalella azteca (Amphipod)): > 206 mg/l

Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 79,9 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 3,1

mg/i

Exposure time: 72 h



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EC50 (Microcystis aeruginosa (blue-green algae)): 0,049 mg/l

Exposure time: 5 d

M-Factor (Acute aquatic tox- :

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

10

NOEC (Daphnia magna (Water flea)): 9,8 mg/l

Exposure time: 21 d

NOEC (Daphnia magna (Water flea)): 5 mg/l

Exposure time: 21 d

LOEC (Daphnia magna (Water flea)): 15 mg/l

Exposure time: 21 d

M-Factor (Chronic aquatic

toxicity)

10

Benzyl alcohol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Persistence and degradability

**Components:** 

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

Bioaccumulative potential

Components:

**Enrofloxacin:** 

Partition coefficient: n-

octanol/water

log Pow: 0,5



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Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

Mobility in soil

**Components:** 

**Enrofloxacin:** 

Distribution among environmental compartments

: Koc: 5.55

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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** 

International Regulations

**UNRTDG** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

()

9 Class Packing group Ш Labels 9 Environmentally hazardous yes

**IATA-DGR** 

UN/ID No. UN 3082

Environmentally hazardous substance, liquid, n.o.s. Proper shipping name

()

9 Class Ш Packing group

Labels Miscellaneous

Packing instruction (cargo 964

aircraft)

Packing instruction (passen-

ger aircraft)

964

Environmentally hazardous yes

**IMDG-Code** 

UN 3082 **UN** number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

()



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Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

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.

#### **SECTION 15. REGULATORY INFORMATION**

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

Argentina. Carcinogenic Substances and Agents

Registry.

: Not applicable

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

#### **Further information**

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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.

#### Full text of other abbreviations

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



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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 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.

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