1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Rizatriptan Orally Disintegrating Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin corrosion/irritation: Category 3
Skin sensitisation: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Cardio-vascular system)

GHS label elements
Hazard pictograms
Signal word: Warning
Hazard statements: H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H373 May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.
Precautionary statements: Prevention:
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P260 Do not breathe dust.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P314 Get medical advice/attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td>8006-90-4</td>
<td>&gt;= 2.5 - &lt; 5</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Rizatriptan</td>
<td>145202-66-0</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

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.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with 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 : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Causes mild skin irritation.
May cause an allergic skin reaction.
May cause damage to organs through prolonged or repeated
### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Protection of first-aiders</th>
<th>Notes to physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust contact with the eyes can lead to mechanical irritation.</td>
<td>Treat symptomatically and supportively.</td>
</tr>
</tbody>
</table>

#### Suitable extinguishing media
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

#### Unsuitable extinguishing media
- None known.

#### Specific hazards during firefighting
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Exposure to combustion products may be a hazard to health.

#### Hazardous combustion products
- Carbon oxides
- Nitrogen oxides (NOx)

#### Specific extinguishing methods
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

#### Special protective equipment for firefighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Environmental precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use personal protective equipment. FOLLOW SAFE HANDLING ADVICE AND PERSONAL PROTECTIVE EQUIPMENT RECOMMENDATIONS.</td>
<td>Discharge into the environment must be avoided. 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods and materials for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWEEP UP OR VACUUM UP SPILLAGE AND COLLECT IN SUITABLE CONTAINER FOR DISPOSAL. AVOID DISPERAL OF DUST IN THE AIR (I.E., CLEARING DUST SURFACES WITH COMPRESSED AIR). DUST DEPOSITS SHOULD NOT BE ALLOWED TO ACCUMULATE ON SURFACES, AS THESE MAY FORM AN EXPLOSIVE MIXTURE IF THEY ARE RELEASED INTO THE ATMOSPHERE IN SUFFICIENT CONCENTRATION. 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.</td>
</tr>
</tbody>
</table>
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Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Rizatriptan</td>
<td>145202-66-0</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Personal protective equipment

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

Appearance : powder
Colour : No data available
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper : No data available
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<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
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<th>Date of first issue:</th>
</tr>
</thead>
</table>

flammability limit

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 : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

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.

Molecular weight : No data available

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

Incompatible materials : Oxidizing agents

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:
Cellulose:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Peppermint oil:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

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

Rizatriptan:
Acute oral toxicity : LD50 (Rat): 2,227 mg/kg
LD50 (Mouse): 700 - 1,631 mg/kg

Skin corrosion/irritation
Causes mild skin irritation.

Components:
Peppermint oil:
Species : Rabbit
Result : Skin irritation
Remarks : Based on data from similar materials

Rizatriptan:
Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Peppermint oil:
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Species : Rabbit
Result : Eye irritation
Remarks : Based on data from similar materials

Rizatriptan:
Species : Bovine cornea
Remarks : Moderate eye irritation

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Peppermint oil:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitisation in humans

Rizatriptan:
Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Rizatriptan:  
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: Alkaline elution assay  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
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: Mouse  
Application Route: Oral  
Result: negative  

Carcinogenicity  
Not classified based on available information.  

Components:  
Cellulose:  
Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative  

Rizatriptan:  
Species : Mouse  
Application Route : Oral  
Exposure time : 100 weeks  
NOAEL : 125 mg/kg body weight  
Result : negative  

Species : Rat  
Application Route : Oral  
Exposure time : 106 weeks  
NOAEL : 106 mg/kg body weight  
Result : negative  

Reproductive toxicity  
Not classified based on available information.  

Components:  
Cellulose:  
Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative
Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Rizatriptan:
Effects on fertility:
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 100 mg/kg body weight
Symptoms: altered estrus cycles
Result: No effects on fertility and early embryonic development were detected.

Species: Rat, male
Application Route: Oral
Fertility: NOAEL: 250 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development:
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: No teratogenic effects, Embryo-foetal toxicity

Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: No teratogenic effects, Embryo-foetal toxicity
Remarks: The effects were seen only at maternally toxic doses.

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

Components:

Rizatriptan:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.
Components:

Rizatriptan:
Target Organs: Cardio-vascular system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: &ge; 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Rizatriptan:
Species: Rat
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Symptoms: Dilatation of the pupil, Increased pulse rate, Redness

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Intravenous
Exposure time: 2 Weeks
Symptoms: Dilatation of the pupil, Increased pulse rate, Redness

Species: Dog
LOAEL: 0.2 mg/kg
Application Route: Oral
Exposure time: 1 yr
Symptoms: Dilatation of the pupil

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Rizatriptan:
Ingestion: Target Organs: Cardio-vascular system
Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness, Drowsiness
12.  ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**

Toxicity to fish:  
\[ \text{LC50 (Oryzias latipes (Japanese medaka)): } > 100 \text{ mg/l} \]
Exposure time: 48 h
Remarks: Based on data from similar materials

**Peppermint oil:**

Toxicity to fish:  
\[ \text{LL50 (Danio rerio (zebra fish)): } > 10 - 100 \text{ mg/l} \]
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:  
\[ \text{EL50 (Daphnia magna (Water flea)): } > 10 - 100 \text{ mg/l} \]
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:  
\[ \text{EL50 (Desmodesmus subspicatus (green algae)): } > 10 - 100 \text{ mg/l} \]
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to microorganisms:  
\[ \text{EC10: 51 mg/l} \]
Exposure time: 3 h
Remarks: Based on data from similar materials

**Rizatriptan:**

Toxicity to fish:  
\[ \text{LC50 (Pimephales promelas (fathead minnow)): } > 1,000 \text{ mg/l} \]
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:  
\[ \text{EC50 (Daphnia magna (Water flea)): 1,000 mg/l} \]
Exposure time: 48 h

Toxicity to algae/aquatic plants:  
\[ \text{EC50 (Pseudokirchneriella subcapitata (green algae)): } > 100 \text{ mg/l} \]
Exposure time: 72 h
Method: OECD Test Guideline 201

\[ \text{NOEC (Pseudokirchneriella subcapitata (green algae)): 48 mg/l} \]
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms:  
\[ \text{EC50: } > 1,000 \text{ mg/l} \]
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

\[ \text{NOEC: 1,000 mg/l} \]
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):
- NOEC: 9.6 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 110 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

Persistence and degradability

Components:

Cellulose:
- Biodegradability: Result: Readily biodegradable.

Peppermint oil:
- Biodegradability: Result: Readily biodegradable.
  - Remarks: Based on data from similar materials

Rizatriptan:
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 50 %
  - Exposure time: 13 d
  - Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Peppermint oil:
- Partition coefficient: n-octanol/water: log Pow: > 4
  - Remarks: Based on data from similar materials

Rizatriptan:
- Partition coefficient: n-octanol/water: log Pow: -0.649

Mobility in soil

Components:

Rizatriptan:
- Distribution among environmental compartments: log Koc: 3.83
  - Method: OECD Test Guideline 106
13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

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

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
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Revised Date: 09/13/2019  SDS Number: 818379-00008  Date of last issue: 24.04.2019

Date of first issue: 22.07.2016

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

AICS - Australian Inventory of Chemical Substances; 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 Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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; 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