SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Atropine Sulfate Formulation

Manufacturer or supplier's details
Company: MSD
Address: Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>Acute toxicity (Oral), Category 4, Acute toxicity (Inhalation), Category 4, Eye irritation, Category 2A</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Acute toxicity (Oral), Category 5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>Acute toxicity (Oral), Category 4, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated</td>
<td>&gt;= 0,1 - &lt; 1</td>
</tr>
</tbody>
</table>
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. 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.

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: None known.

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.

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 products: Carbon oxides
Metal oxides
Chlorine compounds

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: In the event of fire, wear self-contained breathing apparatus.
for fire-fighters
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures**
  - Use personal protective equipment.
  - Follow safe handling advice (see section 7) and personal protective 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.

- **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**
  - Avoid inhalation of vapor or mist.
  - Do not swallow.
  - Avoid contact with eyes.
  - Avoid prolonged or repeated contact with skin.
  - 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.
SAFETY DATA SHEET

Atropine Sulfate Formulation

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>TWA</td>
<td>2 µg/m³ (OEB 4)</td>
<td></td>
</tr>
</tbody>
</table>

Further information:
Eye
Wipe limit 20 µg/100 cm²

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. Essentially no open handling permitted.
Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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 : Combined particulates and organic vapor type

Hand protection : 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. 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : Translucent-colorless to pale yellow
**SAFETY DATA SHEET**

**Atropine Sulfate Formulation**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>3.0 - 6.5</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>0.900 - 1.100 g/cm³</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 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
- Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:

Benzy1 alcohol:
- Acute oral toxicity: LD50 (Rat): 1.620 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 4,178 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403

Sodium chloride:
- Acute oral toxicity: LD50 (Rat): 3.550 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 42 mg/l
  Exposure time: 1 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg

Atropine Sulfate:
- Acute oral toxicity: LD50 (Rat): 500 mg/kg
  LD50 (Mouse): 75 mg/kg
LD50 (Rabbit): 600 mg/kg
LD50 (Guinea pig): 1.100 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Benzyl alcohol:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

Sodium chloride:
- Species: Rabbit
- Result: No skin irritation

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

Components:

Benzyl alcohol:
- Species: Rabbit
- Result: Irritation to eyes, reversing within 21 days
- Method: OECD Test Guideline 405

Sodium chloride:
- Species: Rabbit
- Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Benzyl alcohol:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Sodium chloride:
- Test Type: Local lymph node assay (LLNA)
SAFETY DATA SHEET

Atropine Sulfate Formulation

Routes of exposure: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Sodium chloride:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: positive

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

Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive

Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.
Atropine Sulfate Formulation

**Components:**

### Benzyl alcohol:
- **Species**: Mouse
- **Application Route**: Ingestion
- **Exposure time**: 103 weeks
- **Method**: OECD Test Guideline 451
- **Result**: negative

### Sodium chloride:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 2 Years
- **Result**: negative

### Atropine Sulfate:
- **Species**: Rat
- **Application Route**: Intraperitoneal injection
- **Exposure time**: 28 month(s)
- **NOAEL**: 2.5 mg/kg bw/day
- **Result**: negative

**Carcinogenicity - Assessment**: Weight of evidence does not support classification as a carcinogen

**Reproductive toxicity**
Not classified based on available information.

**Components:**

### 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
### Atropine Sulfate:

#### Effects on fertility
: Test Type: Fertility/early embryonic development  
  Species: Rat, male  
  Application Route: Ingestion  
  General Toxicity Parent: LOAEL: 62.5 mg/kg body weight  
  Result: Reduced fertility

Test Type: Fertility/early embryonic development  
Species: Rat, female  
Application Route: Intraperitoneal injection  
General Toxicity Parent: LOAEL: 1 mg/kg body weight  
Result: Effect on estrous cycle

#### Effects on fetal development
: Test Type: Fertility/early embryonic development  
  Species: Rat  
  Application Route: Intravenous injection  
  Developmental Toxicity: LOAEL: 50 mg/kg body weight  
  Result: Abnormalities of the musculoskeletal system.

#### Reproductive toxicity - Assessment
: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

### STOT-single exposure
Not classified based on available information.

### Components:

#### Atropine Sulfate:
: The substance or mixture is not classified as specific target organ toxicant, single exposure.

### STOT-repeated exposure
Not classified based on available information.

### Components:

#### Atropine Sulfate:
: Inhalation  
  Target Organs: Eye, Central nervous system  
  Assessment: Shown to produce significant health effects in animals at concentrations of 50 ppmV/6h/d or less.

### Repeated dose toxicity

### Components:

#### Benzyl alcohol:
: Rat  
  NOAEL: 1,072 mg/l  
  Application Route: inhalation (dust/mist/fume)  
  Exposure time: 28 Days  
  Method: OECD Test Guideline 412
Sodium chloride:
- **Species**: Rat
- **LOAEL**: 2.533 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 y

Atropine Sulfate:
- **Species**: Rabbit
- **LOAEL**: 59 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 100 d
- **Target Organs**: Central nervous system
- **Symptoms**: Convulsions, respiratory depression

- **Species**: Rat
- **LOAEL**: 0.5 mg/kg
- **Application Route**: Inhalation
- **Exposure time**: 21 d
- **Target Organs**: Eye
- **Symptoms**: Dilatation of the pupil

- **Species**: Dog
- **LOAEL**: 0.5 mg/kg
- **Application Route**: Inhalation
- **Exposure time**: 21 d
- **Target Organs**: Eye
- **Symptoms**: Dilatation of the pupil

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Atropine Sulfate:**
- **General Information**: Target Organs: Central nervous system
  Symptoms: dry mouth, Blurred vision, tachycardia, constipation, central nervous system effects, restlessness, Fatigue, delirium, mental depression

**Ecotoxicity**

**Components:**

**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
SAFETY DATA SHEET

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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 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Sodium chloride:

Toxicity to fish

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4.136 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants

EC50: > 2.000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity)

NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms

EC10: > 1.000 mg/l

Atropine Sulfate:

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 356 mg/l
Exposure time: 48 h

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability

Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water

log Pow: 1.05
Atropine Sulfate Formulation

Atropine Sulfate:
Partition coefficient: n-octanol/water: log Pow: 1.83

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

International Regulations

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

DSL: not determined
SAFETY DATA SHEET
Atropine Sulfate Formulation

SECTION 16. OTHER INFORMATION

Further 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 other abbreviations

AICS - 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; ICS0 - 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; 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.

BR / Z8