### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name</strong></td>
<td>Etonogestrel Formulation (Nexplanon)</td>
</tr>
<tr>
<td><strong>Product code</strong></td>
<td>NEXPLANON</td>
</tr>
<tr>
<td><strong>Manufacturer or supplier's details</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Company</strong></td>
<td>Organon &amp; Co.</td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td>30 Hudson Street, 33nd floor</td>
</tr>
<tr>
<td></td>
<td>Jersey City, New Jersey, U.S.A 07302</td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
<td>551-430-6000</td>
</tr>
<tr>
<td><strong>Emergency telephone number</strong></td>
<td>215-631-6999</td>
</tr>
<tr>
<td><strong>E-mail address</strong></td>
<td><a href="mailto:EHSSTEWARD@organon.com">EHSSTEWARD@organon.com</a></td>
</tr>
<tr>
<td><strong>Recommended use of the chemical and restrictions on use</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended use</strong></td>
<td>Pharmaceutical</td>
</tr>
</tbody>
</table>

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

- **Reproductive toxicity**: Category 1A

#### GHS label elements

- **Hazard pictograms**: ![Hazard Pictogram](image)
- **Signal word**: Danger
- **Hazard statements**: H360F May damage fertility.
- **Precautionary statements**: **Prevention**:  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P281 Use personal protective equipment as required.  
**Response**:  
P308 + P313 IF exposed or concerned: Get medical advice/attention.  
**Storage**:  
P405 Store locked up.  
**Disposal**:  
P501 Dispose of contents/ container to an approved waste
Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one</td>
<td>54048-10-1</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Barium sulfate</td>
<td>7727-43-7</td>
<td>&gt;= 10 - &lt; 30</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: 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: May damage fertility.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
Specific hazards during firefighting:
Hazardous combustion products:
- Exposure to combustion products may be a hazard to health.
- Metal oxides
- Sulphur oxides
- Carbon oxides

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.

Hazchem Code:
- 2Z

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.
- 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal 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.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 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:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not breathe vapours.
- 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
Keep container tightly closed.
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.

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.

Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
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

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>(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one</td>
<td>54048-10-1</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td>Barium sulfate</td>
<td>7727-43-7</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information:
This value is for inhalable dust containing no asbestos and < 1% crystalline silica

Engineering measures:
Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent 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
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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: Particulates type

Hand protection
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

Eye protection
- Wear safety glasses with side shields or 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
- Solid form

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
- No data available

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
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Etonogestrel Formulation (Nexplanon)

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

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

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one:

- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  - LD50 (Mouse): > 2,000 mg/kg

**Barium sulfate:**

- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one:

- Species: Mouse
  - Result: No skin irritation

- Species: Guinea pig
  - Result: No skin irritation

**Barium sulfate:**

- Species: reconstructed human epidermis (RhE)
  - Method: OECD Test Guideline 439
  - Remarks: Based on data from similar materials
  - Result: No skin irritation

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

**Components:**

**Barium sulfate:**

- Species: Rabbit
  - Result: No eye irritation
  - Method: OECD Test Guideline 405

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.
Components:

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Genotoxicity in vitro:
Test Type: reverse mutation assay
Test system: Salmonella typhimurium
Result: negative

Test Type: in vitro assay
Test system: Chinese hamster ovary cells
Result: negative

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

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

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

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.
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Etonogestrel Formulation (Nexplanon)

Version 4.16  Revision Date: 09.04.2021  SDS Number: 16609-00020  Date of last issue: 10.10.2020
Date of first issue: 29.09.2014

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Species: Rat
Application Route: Oral
Activity duration: 2 yr
Result: negative

Species: Rat
Application Route: Subcutaneous
Activity duration: 2 yr
Result: negative

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

Barium sulfate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
May damage fertility.

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Effects on fertility: Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 0.012 mg/kg body weight
Result: Effects on fertility

Species: Rabbit, female
Application Route: Oral
Dose: 0.05 milligram per kilogram
Result: Effects on fertility

Effects on foetal development: Species: Rat, female
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOAEL: 1.8 mg/kg body weight
Result: No teratogenic effects

Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

Barium sulfate:
Effects on fertility: Test Type: Fertility/early embryonic development
SAFETY DATA SHEET

Etonogestrel Formulation (Nexplanon)

Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Rat
Application Route: Ingestion
Test Type: Embryo-foetal development
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Barium sulfate:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Species: Rat
LOAEL: 0.5 mg/kg
Application Route: Oral
Exposure time: 1 yr
Target Organs: Reproductive organs, Endocrine system

Species: Dog
LOAEL: 0.625 mg/kg
Application Route: Oral
Exposure time: 26 Weeks
Target Organs: Reproductive organs, Endocrine system

Barium sulfate:
Species: Rat
NOAEL: 61.1 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.
Experience with human exposure

**Components:**

**(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

**Inhalation:** Symptoms: Headache, Dizziness, Abdominal pain, Nausea, Skin disorders, effects on menstruation, vaginitis, breast tenderness, mood swings, male reproductive effects, Sweating

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

**Toxicity to fish:** LC50 ([Oncorhynchus mykiss (rainbow trout)]): 4.0 mg/l
Exposure time: 96 h
Method: FDA 4.11

LC50 ([Lepomis macrochirus (Bluegill sunfish)]): > 1.3 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

**Toxicity to daphnia and other aquatic invertebrates:** EC50 ([Daphnia magna (Water flea])]: > 3.9 mg/l
Exposure time: 48 h
Method: FDA 4.08
Remarks: No toxicity at the limit of solubility

**Toxicity to fish (Chronic toxicity):** NOEC ([Pimephales promelas (fathead minnow)]): 0.059 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

NOEC ([Oryzias latipes (Japanese medaka))]: 0.0000027 mg/l
Exposure time: 183 d
Method: OECD Test Guideline 229

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC ([Daphnia magna (Water flea])]: 1.2 mg/l
Exposure time: 21 d

**Toxicity to microorganisms:** NOEC: 70.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Barium sulfate:**

**Toxicity to fish:** LC50 ([Danio rerio (zebra fish))]: > 100 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity):
- NOEC (Danio rerio (zebra fish)): > 1 mg/l
  Exposure time: 33 d
  Method: OECD Test Guideline 210
  Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 21 d
  Remarks: Based on data from similar materials

Toxicity to microorganisms:
- EC50: > 600 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209
  Remarks: Based on data from similar materials
- NOEC: > 600 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209
  Remarks: Based on data from similar materials

Persistence and degradability

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Stability in water: Hydrolysis: < 10 % (5 d)
Method: FDA 3.09

Bioaccumulative potential

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Bioaccumulation:
- Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 128
Method: OECD Test Guideline 305
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Partition coefficient: n-octanol/water  log Pow: 3.5

**Barium sulfate:**
Bioaccumulation  Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Partition coefficient: n-octanol/water  log Pow: -1.03
Remarks: Calculation

**Mobility in soil**

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Distribution among environmental compartments  log Koc: 2.84
Method: FDA 3.08

**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**
UN number  : UN 3077
Proper shipping name  : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class  : 9
Packing group  : III
Labels  : 9

**IATA-DGR**
UN/ID No.  : UN 3077
Proper shipping name  : Environmentally hazardous substance, solid, n.o.s.
((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class  : 9
Packing group  : III
Labels  : Miscellaneous
Packing instruction (cargo aircraft)  : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(()(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

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.

National Regulations

ADG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(()(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 09.04.2021
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

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
SAFETY DATA SHEET

Etonogestrel Formulation (Nexplanon)

Version 4.16  Revision Date: 09.04.2021  SDS Number: 16609-00020  Date of last issue: 10.10.2020

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.

AU / EN