SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Recombinant Follicle Stimulating Hormone Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone: 551-430-6000
E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1B: H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: Danger

Signal word: Danger
Hazard statements:
H360FD: May damage fertility. May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.

Precautionary statements: Prevention:
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Recombinant Follicle Stimulating Hormone
Formulation

Version 2.5  Revision Date: 09.04.2021  SDS Number: 26806-00018  Date of last issue: 16.10.2020
Date of first issue: 31.10.2014

P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Recombinant Follicle Stimulating Hormone

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>603-057-00-5</td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Recombinant Follicle Stimulating Hormone</td>
<td>146479-72-3</td>
<td></td>
<td></td>
<td>Repr. 1B; H360FD STOT RE 1; H372 (male reproductive organs, female reproductive organs) specific concentration limit Repr. 1B; H360FD</td>
<td>&gt;= 0.1 - &lt; 0.3</td>
</tr>
</tbody>
</table>

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SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Dry chemical

Unsuitable extinguishing media: None known.

### 5.2 Special hazards arising from the substance or mixture

#### Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

#### Hazardous combustion products:
- Carbon oxides
- Metal oxides

### 5.3 Advice for firefighters

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

#### 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.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

**Personal precautions:**
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

**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.

#### 6.3 Methods and material for containment and cleaning up

**Methods for cleaning up:**
Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable 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 deter-
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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 mist or vapours. 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. Keep container tightly closed. Do not eat, drink or smoke when using this product. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

7.3 Specific end use(s)
Specific use(s): No data available
**SECTION 8: Exposure controls/personal protection**

### 8.1 Occupational parameters

#### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 15 min (STEL)</td>
<td>20 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Recombinant Follicle Stimulating Hormone</td>
<td>146479-72-3</td>
<td>TWA</td>
<td>5 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</td>
</tr>
</tbody>
</table>

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5.4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.456 mg/kg</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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8.2 Exposure controls

Engineering measures
Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Eye protection
Wear the following personal protective equipment:
Safety glasses
Equipment should conform to I.S. EN 166

Hand protection

Material
Chemical-resistant gloves

Remarks
Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.
Wash hands before breaks and at the end of workday.

Skin and body protection
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387

Filter type
Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state
liquid

Colour
No data available

Odour
No data available

Odour Threshold
No data available

Melting point/freezing point
No data available

Initial boiling point and boiling range
No data available

Flammability (solid, gas)
Not applicable

Flammability (liquids)
No data available

Upper explosion limit / Upper
No data available
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<thead>
<tr>
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</tr>
</thead>
</table>

- **flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **pH**: No data available
- **Viscosity**: No data available
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **Solubility(ies)**: No data available
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Vapour pressure**: No data available
- **Density**: No data available
- **Relative vapour density**: No data available
- **Particle characteristics**: No data available
- **Particle size**: No data available

### 9.2 Other information

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: No data available
- **Molecular weight**: No data available

---

**SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid: None known.

10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Benzyl 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

Recombinant Follicle Stimulating Hormone:

Acute toxicity (other routes of administration): LD50 (Rat): > 0.290 mg/kg
Application Route: Intravenous
LD50 (Monkey): > 0.290 mg/kg
Application Route: Intravenous
Skin corrosion/irritation
Not classified based on available information.

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

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

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

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
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
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Recombinant Follicle Stimulating Hormone:
Genotoxicity in vitro:
- Test Type: Ames test
  - Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  - Test system: mammalian cells
  - Result: negative
- Test Type: Chromosomal aberration
  - Test system: Human lymphocytes
  - Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  - Species: Mouse
  - Result: negative

Carcinogenicity:
Not classified based on available information.

Components:

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

Reproductive toxicity:
May damage fertility. May damage the unborn child.

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 foetal development:
- Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

Recombinant Follicle Stimulating Hormone:
Effects on fertility:
- Test Type: Fertility
  - Species: Rat
  - Application Route: Subcutaneous
  - Fertility: LOAEL: 0.11
  - Symptoms: Effect on estrous cycle, Increase of early resorp-
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<thead>
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</tr>
</thead>
</table>

- **Effects on fertility**
  - Test Type: Fertility
  - Species: Rabbit
  - Application Route: Subcutaneous
  - Fertility: LOAEL: 0.027
  - Symptoms: Reduced fertility, Reduced embryonic survival
  - Result: positive

- **Effects on foetal development**
  - Test Type: Development
  - Species: Rat
  - Application Route: Subcutaneous
  - Dose: 2.9 µg/kg
  - Result: positive, No teratogenic effects

- **Reproductive toxicity - Assessment**
  - Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
  - Clear evidence of adverse effects on development, based on animal experiments.

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

**STOT - repeated exposure**
Causes damage to organs through prolonged or repeated exposure.

**Components:**
Recombinant Follicle Stimulating Hormone:
- **Target Organs**: male reproductive organs, female reproductive organs
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**
Benzyl alcohol:
- **Species**: Rat
- **NOAEL**: 1.072 mg/l
- **Application Route**: inhalation (dust/mist/fume)
- **Exposure time**: 28 Days
- **Method**: OECD Test Guideline 412

Recombinant Follicle Stimulating Hormone:
- **Species**: Monkey
- **NOAEL**: 0.17 mg/kg
- **LOAEL**: 0.86 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 13 Weeks
- **Number of exposures**: daily
- **Target Organs**: Reproductive organs
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<thead>
<tr>
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</thead>
<tbody>
<tr>
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<td>26806-00018</td>
<td>16.10.2020</td>
</tr>
</tbody>
</table>

**Remarks:**

- No significant adverse effects were reported

**Species:** Rat

**LOAEL:** 0.14 mg/kg

**Exposure time:** 13 Weeks

**Target Organs:** Endocrine system

**Remarks:**

**Species:** Dog

**LOAEL:** 0.14 mg/kg

**Exposure time:** 13 Weeks

**Target Organs:** Testis

**Remarks:**

**Species:** Rat

**NOAEL:** 0.028 mg/kg

**LOAEL:** 0.28 mg/kg

**Application Route:** Subcutaneous

**Exposure time:** 1 year

**Target Organs:** Testis

**Species:** Monkey, male

**LOAEL:** 0.028 mg/kg

**Exposure time:** 1 year

**Target Organs:** Testis

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

**Product:**

**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Experience with human exposure

**Components:**

**Recombinant Follicle Stimulating Hormone:**

**Inhalation:** Symptoms: gynecomastia, Skin disorders, Headache, Nausea, Vomiting, Diarrhoea
## SECTION 12: Ecological information

### 12.1 Toxicity

<table>
<thead>
<tr>
<th>Components:</th>
<th>Benzyl alcohol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### 12.2 Persistence and degradability

<table>
<thead>
<tr>
<th>Components:</th>
<th>Benzyl alcohol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradability</td>
<td>Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d</td>
</tr>
</tbody>
</table>

### 12.3 Bioaccumulative potential

<table>
<thead>
<tr>
<th>Components:</th>
<th>Benzyl alcohol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>log Pow: 1.05</td>
</tr>
</tbody>
</table>

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**
Recombinant Follicle Stimulating Hormone Formulation

12.6 Endocrine disrupting properties

**Product:**

**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other 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 H-statements
H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H360FD : May damage fertility. May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

exposure.

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox.</td>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Eye Irrit.</td>
<td>Eye irritation</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>STOT RE</td>
<td>Specific target organ toxicity - repeated exposure</td>
</tr>
<tr>
<td>IE OEL</td>
<td>Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1</td>
</tr>
<tr>
<td>IE OEL / OELV - 8 hrs (TWA)</td>
<td>Occupational exposure limit value (8-hour reference period)</td>
</tr>
<tr>
<td>IE OEL / OELV - 15 min (STEL)</td>
<td>Occupational exposure limit value (15-minute reference period)</td>
</tr>
</tbody>
</table>

Further information

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

Classification of the mixture:
- Repr. 1B: H360FD

Classification procedure:
- Calculation method
Recombinant Follicle Stimulating Hormone Formulation

STOT RE 1  H372  Calculation method

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IE / EN