SAFETY DATA SHEET

Recombinant Follicle Stimulating Hormone Formulation

Version 5.0  Revision Date: 2020/10/16  SDS Number: 26810-00017  Date of last issue: 2020/03/23
Date of first issue: 2014/10/31

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Recombinant Follicle Stimulating Hormone Formulation

Supplier's company name, address and phone number
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33rd floor
          Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
E-mail address: EHSSTEWARD@organon.com
Emergency telephone number: 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity: Category 1B

Specific target organ toxicity - repeated exposure
Category 1 (male reproductive organs, female reproductive organs)

GHS label elements
Hazard pictograms:

Signal word: Danger

Hazard statements:
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (male reproductive organs, female reproductive organs) through prolonged or repeated exposure.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
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.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>CAS-No.</td>
</tr>
<tr>
<td></td>
<td>Concentration (% w/w)</td>
</tr>
<tr>
<td></td>
<td>ENCS No.</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
</tr>
<tr>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
</tr>
<tr>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>3-1011</td>
</tr>
<tr>
<td>Recombinant Follicle Stimulating Hormone</td>
<td>146479-72-3</td>
</tr>
<tr>
<td></td>
<td>&gt;= 0.1 - &lt; 0.3</td>
</tr>
<tr>
<td></td>
<td>7-110, 8-55</td>
</tr>
<tr>
<td>Polyethylene glycol sorbitan monolaurate</td>
<td>9005-64-5</td>
</tr>
<tr>
<td></td>
<td>&lt; 0.1</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 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: May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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.

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: Exposure to combustion products may be a hazard to health.
- Hazardous combustion products: Carbon oxides, Metal 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.

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 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
7. HANDLING AND STORAGE

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.

Avoidance of contact:
- Oxidizing agents

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.

Storage

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>OEL-C</td>
<td>25 mg/m³</td>
<td>JP OEL JSOH</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>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Engineering measures: Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type
Hand protection: Combined particulates and organic vapour type

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.

Eye protection: Wear the following personal protective equipment: Safety glasses

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).

9. 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

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: No data available
Decomposition temperature: No data available
pH: No data available
Evaporation rate: No data available
Auto-ignition temperature: No data available
Viscosity
  Viscosity, dynamic: No data available
  Viscosity, kinematic: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Vapour pressure: No data available
Density and / or relative density
  Density: No data available
  Relative vapour density: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle characteristics
  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: Can react with strong oxidizing agents.
Conditions to avoid: None known.
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: > 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:**

**Sucrose:**

- Acute oral toxicity: LD50 (Rat): 29,700 mg/kg

**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

**Polyethylene glycol sorbitan monolaurate:**

- Acute inhalation toxicity: LC50 (Rat): > 5.1 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

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

**Components:**

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

Polyethylene glycol sorbitan monolaurate:
Species: Rabbit  Method: OECD Test Guideline 404  Result: No skin irritation

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

Components:

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

Polyethylene glycol sorbitan monolaurate:
Species: Rabbit  Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Benzy alcohol:
Test Type: Maximisation Test  Exposure routes: Skin contact  Species: Guinea pig  Method: OECD Test Guideline 406  Result: negative

Polyethylene glycol sorbitan monolaurate:
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:

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

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

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

Polyethylene glycol sorbitan monolaurate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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 resorptions, Reduced fertility
  Result: positive
  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.

Polyethylene glycol sorbitan monolaurate:
- Effects on foetal development: Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Ingestion
  Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (male reproductive organs, female reproductive organs) through prolonged or repeated exposure.
## Components:

### Recombinant Follicle Stimulating Hormone:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>male reproductive organs, female reproductive organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

#### Components:

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1.072 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

**Recombinant Follicle Stimulating Hormone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.17 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.86 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Number of exposures</td>
<td>daily</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Reproductive organs</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.14 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.14 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Endocrine system</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.14 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.14 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.028 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.28 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 year</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.028 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.28 mg/kg</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 year</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis</td>
</tr>
</tbody>
</table>
### Aspiration toxicity
Not classified based on available information.

### Experience with human exposure

**Components:**

**Recombinant Follicle Stimulating Hormone:**

**Inhalation**
- Symptoms: gynecomastia, Skin disorders, Headache, Nausea, Vomiting, Diarrhoea

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 230 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
</tr>
<tr>
<td>Method</td>
</tr>
</tbody>
</table>

**NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l**

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>NOEC (Daphnia magna (Water flea)): 51 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
</tr>
<tr>
<td>Method</td>
</tr>
</tbody>
</table>

**Polyethylene glycol sorbitan monolaurate:**

<table>
<thead>
<tr>
<th>LL50 (Danio rerio (zebra fish)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
</tr>
<tr>
<td>Method</td>
</tr>
</tbody>
</table>

**NOEC (Daphnia magna (Water flea)): 10 mg/l**

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>21 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

Persistence and degradability

Components:

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

Polyethylene glycol sorbitan monolaurate:
- Biodegradability: Result: Readily biodegradable. Biodegradation: > 60 %. Exposure time: 28 d

Bioaccumulative potential

Components:

Sucrose:
- Partition coefficient: n-octanol/water: Pow: < 1

Benzyl alcohol:
- Partition coefficient: n-octanol/water: log Pow: 1.05

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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

**National Regulations**
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

<table>
<thead>
<tr>
<th>Priority Assessment Chemical Substance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Number</td>
</tr>
<tr>
<td>Mono(or poly)ether of (mono ester of anhydro(or dianhydro)glucitol and dodecanoic acid) and alpha-hydro-omega-hydroxypoly(oxyethylene)</td>
<td>222</td>
</tr>
</tbody>
</table>

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable

**Substances Prevented From Impairment of Health**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**
Not applicable

**Substances Subject to be Notified Names**
Not applicable

**Substances Subject to be Indicated Names**
Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**
Not applicable

**Ordinance on Prevention of Lead Poisoning**
Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**
Not applicable
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Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
SAFETY DATA SHEET

Recombinant Follicle Stimulating Hormone Formulation

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

Full text of other abbreviations:

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.