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 :
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:
P201 Obtain special instructions before use.
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, bioaccumula-
tive and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</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>603-057-00-05</td>
<td></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</td>
<td>146479-72-3</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360FD STOT RE 1; H372 (male reproductive organs, female reproductive organs)</td>
<td>&gt;= 0,1 - &lt; 0,3</td>
</tr>
<tr>
<td>Hormone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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
Suitable extinguishing media
   : Water spray
   Alcohol-resistant foam
   Carbon dioxide (CO2)
   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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 Control 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>TWA OEL-RL</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>20 mg/m³</td>
<td>ZA 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>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</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>
</tbody>
</table>
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
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.
Safety Data Sheet

Recombinant Follicle Stimulating Hormone Formulation

Version 2.4  Revision Date: 09.04.2021  SDS Number: 26822-00017  Date of last issue: 16.10.2020
Date of first issue: 31.10.2014

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.

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

Appearance: liquid
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): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, dynamic: No data available
Viscosity, kinematic: No data available
Explosive properties: Not explosive

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Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information

- Flammability (liquids): No data available
- Molecular weight: No data available
- Particle size: 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 toxicological effects

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  
  - Test atmosphere: dust/mist  
  - Exposure time: 4 h  
  - 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.
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 cyogenetic 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

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.

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.
**SAFETY DATA SHEET**

**Recombinant Follicle Stimulating Hormone Formulation**

<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>

### 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
- **Remarks:** No significant adverse effects were reported

**Species:** Rat
- **LOAEL:** 0.14 mg/kg
- **Exposure time:** 13 Weeks
- **Target Organs:** Endocrine system
- **Remarks:** No significant adverse effects were reported

**Species:** Dog
- **LOAEL:** 0.14 mg/kg
- **Exposure time:** 13 Weeks
- **Target Organs:** Testis
- **Remarks:** No significant adverse effects were reported

**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.

### 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

**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

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

12.2 Persistence and degradability

**Components:**

**Benzyl alcohol:**

Biodegradability

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

12.3 Bioaccumulative potential

**Components:**

**Benzyl alcohol:**

Partition coefficient: n-octanol/water

- log Pow: 1,05

12.4 Mobility in soil

No data available
12.5 Results of PBT and vPvB assessment

**Product:**

**Assessment**

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.

12.6 Other adverse effects

**Product:**

**Endocrine disrupting potential**

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 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

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 Transport in bulk according to Annex II of Marpol and the IBC Code

**Remarks**

Not applicable for product as supplied.
SECTION 15: Regulatory information

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

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

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 exposure.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Eye Irrit.: Eye irritation
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure
- ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
- ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
- ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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
Further information

Classifications:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

ZA / EN