Corifollitropin Alfa Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Corifollitropin Alfa Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : 30 Hudson Street, 33nd floor
          Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Aqueous solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May damage fertility.

GHS Classification
Reproductive toxicity : Category 1B

GHS label elements

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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/
Corifollitropin Alfa Formulation

Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage fertility.

Environmental hazards
Not classified based on available information.

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>Mixture</td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Corifollitropin Alfa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Corifollitropin Alfa</td>
<td>195962-23-3</td>
<td>&gt;= 0.01 - &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.

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

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 vapours or spray mist.
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.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

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

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>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Corifollitropin Alfa</td>
<td>195962-23-3</td>
<td>TWA</td>
<td>8 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>80 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
Filter type: Particulates type
Eye/face protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection:

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution
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
Flammability (liquids): No data available
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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
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: Not applicable

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

Exposure routes
  Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.
Components:

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

Skin corrosion/irritation
Not classified based on available information.

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

Corifollitropin Alfa:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: human lymphoblastoid cells
Method: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Method: Mutagenicity (micronucleus test)
Result: negative

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

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage fertility.
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**Components:**

**Corifollitropin Alfa:**

**Effects on fertility**
- Species: Rat
- Application Route: Subcutaneous
- Duration of Single Treatment: 2 d
- Fertility: LOAEL: 2 µg/kg
- Result: Superovulation

**Effects on foetal development**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 0.8 µg/kg
- Result: Postimplantation loss.
- Remarks: The mechanism or mode of action is not relevant in humans.

- Test Type: Fertility/early embryonic development
- Species: Rabbit
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 0.9 µg/kg
- Result: Teratogenic potential, Postimplantation loss.
- Remarks: The mechanism or mode of action is not relevant in humans.

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

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

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

**Repeated dose toxicity**

**Components:**

**Corifollitropin Alfa:**

**Species**
- Rat

**LOAEL**
- 0.00164 mg/kg

**Application Route**
- Subcutaneous

**Exposure time**
- 13 Weeks

**Target Organs**
- Reproductive organs, Endocrine system

**Species**
- Dog

**LOAEL**
- 0.00041 mg/kg

**Application Route**
- Subcutaneous

**Exposure time**
- 39 Weeks

**Target Organs**
- Endocrine system, Reproductive organs

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

Components:

Corifollitropin Alfa:
Ingestion: Symptoms: Nausea, Headache, Fatigue, breast tenderness

12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
No data available

Bioaccumulative potential

Components:

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

Mobility in soil
No data available

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

GB 6944/12268
Not regulated as a dangerous good

**Special precautions for user**
Not applicable

### 15. REGULATORY INFORMATION

**National regulatory information**

**Law on the Prevention and Control of Occupational Diseases**

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**

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


**Date format**

 yyyy/mm/dd

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIIC</td>
<td>Australian Inventory of Industrial Chemicals</td>
</tr>
<tr>
<td>ANTT</td>
<td>National Agency for Transport by Land of Brazil</td>
</tr>
<tr>
<td>ASTM</td>
<td>American Society for the Testing of Materials</td>
</tr>
<tr>
<td>bw</td>
<td>Body weight</td>
</tr>
<tr>
<td>CMR</td>
<td>Carcinogen, Mutagen or Reproductive Toxicant</td>
</tr>
<tr>
<td>DIN</td>
<td>Standard of the German Institute for Standardisation</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List (Canada)</td>
</tr>
<tr>
<td>ECx</td>
<td>Concentration associated with x% response</td>
</tr>
<tr>
<td>ELx</td>
<td>Loading rate associated with x% response</td>
</tr>
<tr>
<td>EmS</td>
<td>Emergency Schedule</td>
</tr>
<tr>
<td>ENCS</td>
<td>Existing and New Chemical Substances (Japan)</td>
</tr>
<tr>
<td>ErCx</td>
<td>Concentration associated with x% growth rate response</td>
</tr>
<tr>
<td>ERG</td>
<td>Emergency Response Guide</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IBC</td>
<td>International Code for the Construction and Equipment</td>
</tr>
<tr>
<td>ICAO</td>
<td>International Civil Aviation Organization</td>
</tr>
<tr>
<td>IECSC</td>
<td>Inventory of Existing Chemical Substances in China</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods</td>
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<tr>
<td>IMO</td>
<td>International Maritime Organization</td>
</tr>
<tr>
<td>ISHL</td>
<td>Industrial Safety and Health Law (Japan)</td>
</tr>
<tr>
<td>KECI</td>
<td>Korea Existing Chemicals Inventory</td>
</tr>
<tr>
<td>LC50</td>
<td>Lethal Concentration to 50% of a test population</td>
</tr>
<tr>
<td>LD50</td>
<td>Lethal Dose to 50% of a test population (Median Lethal Dose)</td>
</tr>
<tr>
<td>MARPOL</td>
<td>International Convention for the Prevention of Pollution from Ships</td>
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<tr>
<td>n.o.s.</td>
<td>Not Otherwise Specified</td>
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<tr>
<td>Nch</td>
<td>Chilean Norm</td>
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<tr>
<td>NO(A)EC</td>
<td>No Observed (Adverse) Effect Concentration</td>
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<td>NO(A)EL</td>
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<tr>
<td>NOELR</td>
<td>No Observable Effect Loading Rate</td>
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<tr>
<td>NOM</td>
<td>Official Mexican Norm</td>
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<td>NTP</td>
<td>National Toxicology Program</td>
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<td>NZIoC</td>
<td>New Zealand Inventory of Chemicals</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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</table>
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Corifollitropin Alfa 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>
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<tbody>
<tr>
<td>3.10</td>
<td>2020/10/16</td>
<td>26200-00017</td>
<td>2020/03/23</td>
<td>2014/10/29</td>
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Disclaimer

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.

CN / EN