SAFETY DATA SHEET

Corifollitropin Alfa Formulation

Version: 3.4    Revision Date: 16.10.2020    SDS Number: 26208-00017    Date of last issue: 23.03.2020
Date of first issue: 29.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Corifollitropin Alfa Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
         Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements: H360F May damage fertility.
Precautionary statements
Prevention:
P203 Obtain, read and follow all safety instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P318 IF exposed or concerned, get medical advice.
Storage:
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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>Mixture</td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Corifollitropin Alfa</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.
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

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.

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

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 recommended guidelines, use respiratory protection.
  - Filter type
  - Hand protection
    - Material: Chemical-resistant gloves
    - Remarks: Consider double gloving.

Eye 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 facemask 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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

Information on likely routes of exposure : 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.

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

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

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

11. Repeated dose toxicity

   Components:

   Corifollitropin Alfa:
   Species: Rat
   LOAEL: 0.000164 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

12. Aspiration toxicity
    Not classified based on available information.

13. Experience with human exposure

   Components:

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

12. ECOLOGICAL INFORMATION

   14. Ecotoxicity
       No data available

   15. Persistence and degradability
       No data available

   16. Bioaccumulative potential

       Components:

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

   17. Mobility in soil
       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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for 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.

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