

## Human Chorionic Gonadotropin Formulation

Version 6.9      Revision Date: 25.09.2020      SDS Number: 22140-00015      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

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**Section 1: Identification**

Product name : Human Chorionic Gonadotropin 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

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**Section 2: Hazard identification****GHS Classification**

Reproductive toxicity : Category 1A

Specific target organ toxicity -  
repeated exposure : Category 1 (Ovary)

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H360Fd May damage fertility. Suspected of damaging the un-  
born child.  
H372 Causes damage to organs (Ovary) 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 dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P281 Use personal protective equipment as required.

**Response:**

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

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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**

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Gonadotropin, chorionic	9002-61-3	>= 60 -<= 100

**Section 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 : If in eyes, rinse well with water.  
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. Suspected of damaging the unborn child.  
Causes damage to organs through prolonged or repeated exposure.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- 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.

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**Section 5: Fire-fighting measures**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur 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.
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**Section 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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.
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**Section 7: Handling and storage**

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- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- 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 dust.  
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.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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.
- 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

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**Section 8: Exposure controls/personal protection**
**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Gonadotropin, chorionic	9002-61-3	TWA	OEB 4 (3 µg/m <sup>3</sup> )	Internal
		Wipe limit	25 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

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**Personal protective equipment**

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|--------------------------|---|---|
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  |
| Filter type              | : | Particulates type   |
| 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. |
| Eye protection           | : | Wear the following personal protective equipment:<br>Safety goggles   |
| Skin and body protection | : | Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.<br>Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).   |
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**Section 9: Physical and chemical properties**

- |  |   |   |
|--|---|---|
| Appearance                                       | : | powder  |
| Colour   | : | off-white   |
| Odour  | : | odourless   |
| 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                                      | : | Not applicable  |
| Evaporation rate                                 | : | No data available   |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available   |
| Upper explosion limit / Upper flammability limit | : | No data available   |
| Lower explosion limit / Lower                    | : | No data available   |

# SAFETY DATA SHEET



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flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)  
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

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.

Molecular weight : No data available

Particle size : No data available

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### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

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**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.

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

May damage fertility. Suspected of damaging the unborn child.

**Components:****Gonadotropin, chorionic:**

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Intravenous injection Fertility: LOAEL: 8.89 mg/kg body weight Result: Effects on fertility  Test Type: Fertility Application Route: Intraperitoneal injection Fertility: LOAEL: 0.883 mg/kg body weight Result: Effects on fertility  Test Type: Fertility Species: Monkey Fertility: LOAEL: 0.224 mg/kg body weight Result: Effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Hamster Application Route: Intraperitoneal injection Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight Result: Embryo-foetal toxicity
Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

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### **STOT - repeated exposure**

Causes damage to organs (Ovary) through prolonged or repeated exposure.

### **Components:**

#### **Gonadotropin, chorionic:**

Target Organs : Ovary  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

### **Components:**

#### **Gonadotropin, chorionic:**

Inhalation : Target Organs: ovaries  
Symptoms: effects on menstruation, gynecomastia, Head-ache, mental depression, Irritability, restlessness, Fatigue

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## **Section 12: Ecological information**

### **Ecotoxicity**

No data available

### **Persistence and degradability**

No data available

### **Bioaccumulative potential**

No data available

### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

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## **Section 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.

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## **Section 14: Transport information**

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**



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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

#### NZS 5433

Not regulated as a dangerous good

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## Section 15: Regulatory information

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

#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

#### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## Section 16: Other information

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

AllC - 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 Sys-

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tem; 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

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