

**SAFETY DATA SHEET**

according to the OSHA Hazard Communication Standard

**GONAL-F 300 IU PEN (WITH SERUM)**

Version	Revision Date:	SDS Number:	Date of last issue: 04/11/2024
2.2	05/03/2024	90MDGM353376	Date of first issue: 08/10/2023

**SECTION 1. IDENTIFICATION**

Product name : GONAL-F 300 IU PEN (WITH SERUM)

**Manufacturer or supplier's details**

Company : EMD Serono, Inc.  
One Technology Place  
MA-02370 Rockland  
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroup.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)  
+1-703-527-3887 CHEMTREC (International)  
613-996-6666 CANUTEC (Canada)  
24 Hours/day; 7 Days/week

**Recommended use of the chemical and restrictions on use**


Recommended use : Pharmaceutical production

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin irritation : Category 2

Eye irritation : Category 2A

**GHS label elements**

Hazard pictograms : 

Signal word : Warning

Hazard statements : H315 Causes skin irritation.  
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ eye protection/ face protection.

**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 Take off contaminated clothing and wash before reuse.

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### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Saccharose	57-50-1	$\geq 5 - < 10$
m-cresol	108-39-4	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : Remove contaminated clothing.  
Rinse with water.  
If symptoms persist, call a physician.

In case of eye contact : Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : Fever  
Headache  
ovarian dysfunction  
Causes skin irritation.  
Causes serious eye irritation.

Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire-fighting : Not combustible.  
Ambient fire may liberate hazardous vapours.

Hazardous combustion products : No hazardous combustion products are known

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment : Wear self-contained breathing apparatus for firefighting if nec-

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for firefighters      essary.  
Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:  
Do not breathe vapours, aerosols.  
Evacuate the danger area, observe emergency procedures, consult an expert.  
Advice for emergency responders:  
Use personal protective equipment.  
Dispose of promptly.  
Inform the responsible authorities in case of gas leakage, or of entry into waterways, soil or drains.  
Indications about waste treatment see section 13.
- Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").
- Local/Total ventilation : Ensure adequate ventilation.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Observe label precautions.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.  
Keep container tightly closed in a dry and well-ventilated place.
- Materials to avoid : No materials to be especially mentioned.
- Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Saccharose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Res-	5 mg/m <sup>3</sup>	NIOSH REL

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		pirable)		
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
		TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
m-cresol	108-39-4	TWA	2.3 ppm 10 mg/m3	NIOSH REL

**Engineering measures** : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

### Personal protective equipment

Respiratory protection : required when vapours/aerosols are generated.

Filter type : filter ABEK

Hand protection

Material : Protective equipment only chosen according to specific regulatory requirements after a risk assessment.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures : General industrial hygiene practice.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless

Odour : not significant

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Odour Threshold	:	Not applicable
pH	:	6.7 - 7.3
Melting point/range	:	ca. 32 °F / 0 °C
Boiling point/boiling range	:	ca. 212 °F / 100 °C
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	ca. 1 g/cm <sup>3</sup> (68 °F / 20 °C)
Solubility(ies)	:	
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not classified as explosive.
Oxidizing properties	:	none

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No decomposition if stored and applied as directed.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	Violent reactions possible with: The generally known reaction partners of water.
Conditions to avoid	:	No data available
Incompatible materials	:	Not applicable
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.

#### Product:

Acute oral toxicity : Remarks: No data available  
Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available  
Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### Saccharose:

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

##### m-cresol:

Acute oral toxicity : LD50 (Rat, male): 242 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : Symptoms: mucosal irritations, Cough, Shortness of breath,  
Possible damages:, damage of respiratory tract

Remarks: Corrosive to respiratory system.

Acute dermal toxicity : Acute toxicity estimate: 300.1 mg/kg  
Method: Expert judgement  
Assessment: The component/mixture is toxic after single contact with skin.

Remarks: absorption

#### Skin corrosion/irritation

Causes skin irritation.

#### Product:

Remarks : No data available

#### Components:

##### m-cresol:

Species : Rabbit  
Result : Causes burns.

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GLP : no  
Remarks : (ECHA)  
Assessment : Causes burns.

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

#### **Product:**

Remarks : No data available

#### **Components:**

##### **m-cresol:**

Assessment : Risk of blindness!  
Remarks : Risk of serious damage to eyes.

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

#### **Product:**

Remarks : No data available

### **Germ cell mutagenicity**

Not classified due to lack of data.

#### **Product:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

#### **Components:**

##### **Saccharose:**

Genotoxicity in vitro : Test Type: Mutagenicity (mammal cell test):  
Result: negative  
Remarks: (National Toxicology Program)

##### **m-cresol:**

Genotoxicity in vitro : Test Type: Ames test  
Test system: Escherichia coli/Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test

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Test system: mouse lymphoma cells  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 476  
Result: negative  
GLP: yes

Genotoxicity in vivo : Test Type: Chromosome aberration test  
Species: Mouse (male and female)  
Cell type: Bone marrow  
Application Route: Oral  
Method: OECD Test Guideline 475  
Result: negative  
GLP: yes

### Carcinogenicity

Not classified due to lack of data.

**IARC** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Not classified due to lack of data.

#### STOT - single exposure

Not classified due to lack of data.

#### STOT - repeated exposure

Not classified due to lack of data.

### Repeated dose toxicity

#### Product:

Remarks : No data available

### Aspiration toxicity

Not classified due to lack of data.

### Further information

#### Product:

Remarks : Physiologically active substance.  
Therapeutically used substance.

Remarks : Handle in accordance with good industrial hygiene and safety practice.



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### Components:

#### **Saccharose:**

- Remarks : Substances which occur in nature
- Remarks : Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.
- Remarks : Handle in accordance with good industrial hygiene and safety practice.

#### **m-cresol:**

- Remarks : After absorption:
- Remarks : Systemic effects:
- Remarks : Headache  
Nausea  
Vomiting  
Dizziness  
agitation, spasms  
respiratory arrest  
Unconsciousness  
cardiac arrest
- Remarks : Damage to:
- Remarks : Central nervous system  
Liver  
Kidney
- Remarks : This substance should be handled with particular care.
- 

## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Product:

- Toxicity to fish : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
- Toxicity to algae/aquatic plants : Remarks: No data available
- Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available
- Toxicity to microorganisms : Remarks: No data available

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### Components:

#### **m-cresol:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l  
Exposure time: 96 h  
Test Type: static test  
Remarks: (ECHA)
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex): > 99.5 mg/l  
Exposure time: 48 h  
Test Type: flow-through test  
Analytical monitoring: yes  
Method: US-EPA
- Toxicity to algae/aquatic plants : IC5 (Scenedesmus quadricauda (Green algae)): 15 mg/l  
Remarks: (Hommel)  
(maximum permissible toxic concentration)
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l  
Exposure time: 32 d  
Test Type: flow-through test  
Method: OECD Test Guideline 210  
Remarks: The value is given in analogy to the following substances:  
The value is given in analogy to the following substances: p-cresol
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1 mg/l  
Exposure time: 21 d  
Test Type: semi-static test  
Remarks: (ECHA)  
The value is given in analogy to the following substances:  
The value is given in analogy to the following substances: p-cresol
- Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 11.8 mg/l  
Exposure time: 30 min  
Remarks: (IUCLID)

### **Persistence and degradability**

#### Components:

#### **m-cresol:**

- Biodegradability : aerobic  
Result: Readily biodegradable.  
Biodegradation: 90 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D
- ThOD : 2,520 mg/g  
Remarks: (Lit.)

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BOD/ThOD : 68 %  
Remarks: (Lit.)

### Bioaccumulative potential

#### Components:

##### **Saccharose:**

Partition coefficient: n-octanol/water : log Pow: -3.277

##### **m-cresol:**

Bioaccumulation : Species: Leuciscus idus (Golden orfe)  
Bioconcentration factor (BCF): 17 - 20  
Exposure time: 3 d  
Concentration: 0.05 mg/l

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : Discharge into the environment must be avoided.

#### Components:

##### **m-cresol:**

Results of PBT and vPvB assessment : Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
The hazard and precautionary statements displayed on the label also apply to any residues left in the container.

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Packaging that is not properly emptied must be disposed of as the unused product.

### SECTION 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

#### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
m-cresol	108-39-4	100	100 (D024)

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Skin corrosion or irritation  
Serious eye damage or eye irritation

**SARA 313** : The following components are subject to reporting levels established by SARA Title III, Section 313:

m-cresol                      108-39-4                      >= 1 - < 5 %

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 112 (40 CFR 61):

m-cresol                      108-39-4                      >= 1 - < 5 %

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM Intermedi-ate or Final VOC's (40 CFR 60.489):

m-cresol	108-39-4	>= 1 - < 5 %
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### Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Ta-ble 116.4A:

m-cresol	108-39-4	>= 1 - < 5 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

disodium hydrogen or- thophosphate dihydrate	10028-24-7	>= 1 - < 5 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

### US State Regulations

#### Massachusetts Right To Know

m-cresol	108-39-4
disodium hydrogen orthophosphate dihydrate	10028-24-7

#### Pennsylvania Right To Know

water	7732-18-5
Saccharose	57-50-1
m-cresol	108-39-4
disodium hydrogen orthophosphate dihydrate	10028-24-7

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### California Permissible Exposure Limits for Chemical Contaminants

Saccharose	57-50-1
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#### The components of this product are reported in the following inventories:

TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
AIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Follitropin alpha
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory

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PICCS : Not in compliance with the inventory  
IECSC : Not in compliance with the inventory  
NZIoC : Not in compliance with the inventory  
TECI : Not in compliance with the inventory

### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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## SECTION 16. OTHER INFORMATION

### Company internal Occupational Exposure Limit (MOEL)

(146479-72-3)

: 0.07 µg/m<sup>3</sup>

Short Term Exposure (15 min) : 8  
Factor

Pregnancy risk groups : D

Either there are no data for an assessment of damage to the embryo, or foetus or the currently available data are not sufficient for classification in one of the other groups.

### Further information

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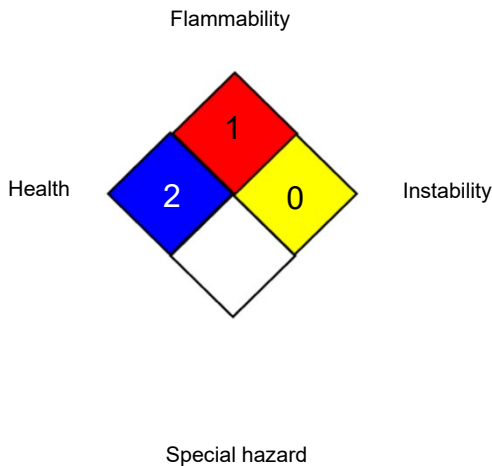
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### NFPA 704:



### HMIS® IV:

HEALTH	/	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level;

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## GONAL-F 300 IU PEN (WITH SERUM)

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NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; 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

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