

NUTROPIN Cartridges 20 mg/2ml
Version
1.0Revision Date:
06/15/2025Date of last issue: -
Date of first issue: 06/15/2025
SECTION 1. IDENTIFICATION

Product name : NUTROPIN Cartridges 20 mg/2ml

Product code : RO682-3852/F03-00

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

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

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Somatropin	12629-01-5	1
Sodium chloride (NaCl)	7647-14-5	0.88
Sodium citrate dihydrate	6132-04-3	0.27
Phenol	108-95-2	0.25
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	9005-65-6	0.19
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	0.02
Water	7732-18-5	97

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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 : Wash off with soap and water.
- 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 : None known.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing
- Notes to physician : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Carbon monoxide
Nitrogen oxides (NOx)
Sulfur oxides
- 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

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for fire-fighters

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.
- 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

- 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.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Materials to avoid : No materials to be especially mentioned.
- Storage temperature : Protect from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Autoinjector

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Somatropin	12629-01-5	IOEL	0.02 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Phenol	108-95-2	TWA	5 ppm 19 mg/m ³	ACGIH NIOSH REL

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		C	15.6 ppm 60 mg/m ³	NIOSH REL
		TWA	5 ppm 19 mg/m ³	OSHA Z-1
		TWA	5 ppm 19 mg/m ³	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Phenol	108-95-2	Phenol	Urine	End of shift (As soon as possible after exposure ceases)	250 mg/g creatinine	ACGIH BEI

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Nitrile rubber
 Break through time : > 30 min
 Glove thickness : > 0.11 mm

Material : butyl-rubber
 Break through time : > 480 min
 Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance : Aqueous solution, Clear liquid, sterile

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Self-ignition : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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Explosive properties : No data available

Oxidizing properties : No data available

Particle characteristics

Particle Size Distribution : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

Conditions to avoid : No data available

No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition products : No data available

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Somatropin:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Sodium chloride (NaCl):

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l
Test atmosphere: dust/mist

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Acute dermal toxicity : LD50 Dermal (Rabbit): > 10,000 mg/kg

Sodium citrate dihydrate:Acute oral toxicity : LD50 Oral (Mouse): 5,400 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materialsAcute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.
The value is given in analogy to the following substances:
citric acid**Phenol:**Acute oral toxicity : LD50 Oral (Rat): 317 mg/kg
LD50 Oral (Mouse): 270 mg/kgAcute inhalation toxicity : LC50 (Rat): 0.9 mg/l
Exposure time: 8 h
Test atmosphere: vapor

Acute dermal toxicity : LD50 Dermal (Rabbit): 630 mg/kg

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:Acute oral toxicity : LD50 (Rat, male): 11,700 mg/kg
Method: OECD Test Guideline 401Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402**Skin corrosion/irritation**

Not classified due to lack of data.

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Species : Rabbit
Assessment : No skin irritation
Result : negative
Remarks : Not classified

Sodium chloride (NaCl):

Species : Rabbit
Result : No skin irritation

Sodium citrate dihydrate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Test substance : anhydrous substance

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Species : Rabbit
Exposure time : 72 h
Method : Draize Test
Result : No skin irritation
GLP : No information available.
Test substance : anhydrous substance

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:**Sodium chloride (NaCl):**

Species : Rabbit
Result : No eye irritation

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Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Test substance : anhydrous substance

Phenol:

Result : Risk of serious damage to eyes.

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Species : Rabbit
Result : No eye irritation
Exposure time : 168 h
Method : Draize Test
GLP : No information available.
Test substance : anhydrous substance

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Species : Rabbit
Result : Irritating to eyes.
Method : OECD Test Guideline 405

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:**Sodium citrate dihydrate:**

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Test substance : anhydrous substance

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Species : Humans
Result : Not a skin sensitizer.
GLP : No information available.
Test substance : anhydrous substance

Germ cell mutagenicity

Not classified due to lack of data.

Components:**Somatropin:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: positive

Sodium chloride (NaCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (micronucleus test)
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat (female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 475
Result: positive

Sodium citrate dihydrate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: Micronucleus test
Test system: Human lymphocytes
Method: OECD Test Guideline 487
Result: positive

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Application Route: Oral
Method: Regulation (EC) No. 440/2008, Annex, B.22

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Result: negative

Test Type: Chromosome aberration test in vitro
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative

Phenol:

Genotoxicity in vitro : Remarks: In vitro tests showed mutagenic effects
Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: *Salmonella typhimurium*
Result: negative

Genotoxicity in vivo : Species: Rat (male)
Cell type: Bone marrow
Method: OECD Test Guideline 475
Result: negative

Carcinogenicity

Not classified due to lack of data.

Components:**Phenol:**

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

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

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

IARC No ingredient 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

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on OSHA's list of regulated carcinogens.

NTP No ingredient 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

Based on available data, the classification criteria are not met.

Product:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Components:**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Target Organs : Respiratory system
Assessment : May cause respiratory irritation.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Product:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Components:**Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Components:****1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

NOAEL : 4,000 mg/kg
Application Route : Oral
Exposure time : 10 days

Aspiration toxicity

Not classified due to lack of data.

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No data available

Further information**Product:**

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Sodium chloride (NaCl):**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 874 mg/l
Exposure time: 48 h
Test Type: static test

LC50 (Daphnia magna (Water flea)): 4,136 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50: 2,430 mg/l
Exposure time: 120 h
Test Type: static test
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d
Test Type: flow-through test
Method: OECD Test Guideline 210
GLP: no
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia): 314 mg/l
Exposure time: 21 d
Test Type: semi-static test
Method: OECD Test Guideline 211

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.

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Other organisms relevant to the environment : No data available

Sodium citrate dihydrate:

- Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 18,000 - 32,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 5,600 - 10,000 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 18,000 - 32,000 mg/l
Exposure time: 96 h
- Toxicity to microorganisms : EC50 (Bacteria): 1,800 - 3,200 mg/l
Exposure time: 8 h

Phenol:

- Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 1.75 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 370 mg/l
Exposure time: 96 h
- Toxicity to microorganisms : (Pseudomonas putida): 64 mg/l
Exposure time: 16 h

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 471 mg/l
Exposure time: 96 h
Test Type: static test
GLP: No information available.
- Toxicity to daphnia and other aquatic invertebrates : LC50 (Mysidopsis bahia (opossum shrimp)): 165 mg/l
Exposure time: 96 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
Remarks: Expert judgment
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Remarks: Expert judgment
- Toxicity Data on Soil : Not expected to adsorb on soil.

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Remarks: Expert judgment

Other organisms relevant to the environment : No data available
Remarks: Expert judgment

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 440 - 760 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 120 mg/l
Exposure time: 72 h

Toxicity to algae/aquatic plants : EC0 (Scenedesmus quadricauda (Green algae)): 640 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Somatropin:

Biodegradability : Result: Globular proteins are generally well biodegradable

Sodium chloride (NaCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Sodium citrate dihydrate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

Biodegradability : Result: Inherently biodegradable.
Biodegradation: 64 %
Exposure time: 29 d
Method: OECD Test Guideline 301B
GLP: yes

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

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Biodegradability : aerobic
Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential**Components:****Somatropin:**

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

Sodium chloride (NaCl):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Sodium citrate dihydrate:

Bioaccumulation : Bioconcentration factor (BCF): 3.2
Remarks: Based on data from similar materials

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

Phenol:

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

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.:

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

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.72 (68 °F / 20 °C)

Water:

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

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

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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 : No data available

Components:**Somatropin:**

Additional ecological information : Protein with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

Phenol:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

Domestic regulation**49 CFR**

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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SECTION 15. REGULATORY INFORMATION
CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
SARA 311/312 Hazards	:	No SARA Hazards

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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

Phenol	108-95-2	>= 0.1 - < 1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Phenol	108-95-2	>= 0.1 - < 1 %
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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

Phenol	108-95-2
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Pennsylvania Right To Know

Water	7732-18-5
Phenol	108-95-2

Maine Chemicals of High Concern
Vermont Chemicals of High Concern

Phenol	108-95-2
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Washington Chemicals of High Concern

Phenol	108-95-2
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The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

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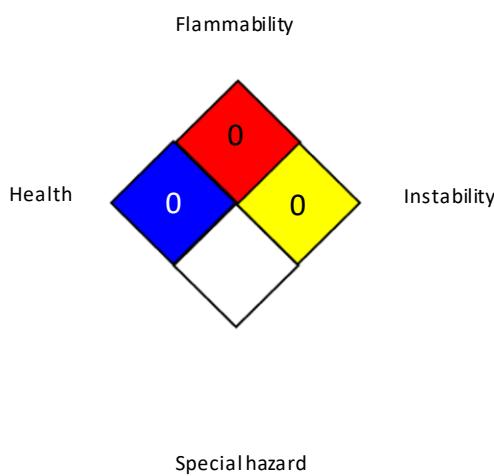
Somatropin

NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA 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.

SECTION 16. OTHER INFORMATION**Further information****NFPA 704:****HMIS® IV:**

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 "0" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
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
NIOSH REL / C	:	Ceiling value not be exceeded at any time.
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - 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; 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; TECI - 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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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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the

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specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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