

NutropinAQ(R) NuSpin (5 mg/2 ml)

Version Revision Date: Date of last issue: 06-10-2017 1.3 Date of first issue: 12-03-2015

SECTION 1. IDENTIFICATION

Product name : NutropinAQ(R) NuSpin (5 mg/2 ml)

Product code : RO682-3852/F01

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : DNA Way 1

94080 South San Francisco

CA USA

Telephone : 001-(650) 225-1000 E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone num-

US Chemtrec phone (800)-424-9300

ber

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

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	0.25
Sodium chloride (NaCl)	7647-14-5	0.88
Sodium citrate	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



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7732-18-5 > 98.0 Water

SECTION 4. FIRST AID MEASURES

General advice Do not leave the victim unattended.

If inhaled Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact If on skin, rinse well with water.

In case of eye contact Immediately flush eye(s) with plenty of water.

> 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.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

The first aid procedure should be established in consultation Notes to physician

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod: :

ucts

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 :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

tive equipment and emer-

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



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gency procedures

Environmental precautions Local authorities should be advised if significant spillages

cannot be contained.

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.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Storage temperature Protected from heat and light

Further information on stor-

age 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
Phenol	108-95-2	TWA	5 ppm	ACGIH
		TWA	5 ppm 19 mg/m3	NIOSH REL
		С	15.6 ppm 60 mg/m3	NIOSH REL
		TWA	5 ppm 19 mg/m3	OSHA Z-1
		TWA	5 ppm 19 mg/m3	OSHA P0
Somatropin	12629-01-5	IOEL	0.02 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)



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Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling 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

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally

required.

Hand protection

Material : Protective gloves

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 : Handle in accordance with good industrial hygiene and safety

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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 : does not flash

Evaporation rate : No data available

Self-ignition : 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative 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

SECTION 10. STABILITY AND REACTIVITY

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

Chemical stability : Stable under normal conditions.

Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

Possibility of hazardous reac-

tions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.



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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 (NaCI):

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

LD50 Oral (Mouse): 4,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

Test atmosphere: dust/mist Method: Expert judgment

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

Sodium citrate:

Acute oral toxicity : LD50 Oral (Rat): > 8,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

Test atmosphere: dust/mist Method: Expert judgment

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

Method: Expert judgment

Phenol:

Acute oral toxicity : LD50 Oral (Rat): 317 mg/kg

LD50 Oral (Mouse): 270 mg/kg

Acute 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): 63,840 mg/kg

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

Acute oral toxicity : LD50 Oral (Rat): > 6,730 mg/kg

LD50 Oral (Rabbit): > 7,000 mg/kg

LD50 Oral (Mouse): 5,400 mg/kg



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Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium chloride (NaCl):

Remarks : This information is not available.

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

Remarks : May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium chloride (NaCl):

Remarks : This information is not available.

Sodium citrate:

Species : Rabbit

Remarks : slight irritation

Phenol:

Result : Risk of serious damage to eyes.

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

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Somatropin:

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

Result: positive

Phenol:

Genotoxicity in vitro : Remarks: In vitro tests showed mutagenic effects

Germ cell mutagenicity -

Assessment

: In vitro tests showed mutagenic effects



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Carcinogenicity

Not classified based on available information.

Components:

Sodium citrate:

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.

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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

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 based on available information.

STOT-single exposure

Not classified based on available information.

Product:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Components:

Sodium citrate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

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.

STOT-repeated exposure

Not classified based on available information.



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Product:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Components:

Sodium citrate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

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

Exposure time : 5d Number of exposures : 1

Aspiration toxicity

Not classified based on available information.

Components:

Sodium citrate:

No data available

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

No data available

SECTION 12. ECOLOGICAL INFORMATION

Components:

Sodium chloride (NaCI):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 48 h

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:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 18,000 - 32,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 5,600 - 10,000 mg/l

Exposure time: 48 h

EC50 (Ceriodaphnia dubia (water flea)): 735.4 mg/l

Exposure time: 48 h

Toxicity to algae : IC50 (Chlorella vulgaris (Fresh water algae)): > 18,000 -

32,000 mg/l

Exposure time: 96 h

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

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 : 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.:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

No data available

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

Toxicity to fish : LC0 (Carassius auratus (goldfish)): 625 mg/l



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aquatic invertebrates

Toxicity to daphnia and other : LC100 (Daphnia magna (Water flea)): 85 mg/l

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

Toxicity to microorganisms EC0 (Pseudomonas putida): > 10,000 mg/l

Exposure time: 16 h

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:

Biodegradability Biodegradation: 98 %

Exposure time: 3 d

Remarks: Expected to be biodegradable

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

Biodegradability Biodegradation: 98 %

Exposure time: 7 d

Method: OECD Test Guideline 302B

Bioaccumulative potential

Components:

Somatropin:

Partition coefficient: n-

octanol/water

Remarks: No data available

Sodium chloride (NaCl):

Partition coefficient: n-

octanol/water

: Remarks: No data available



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Sodium citrate:

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-:

Partition coefficient: n-

octanol/water

: log Pow: -1.72

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 Pro-

tection 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).

Components:

Somatropin:

Additional ecological infor-

mation

Protein with highly specific affinity to a certain antigen;

therefore, no appreciable ecotoxic potential is to be expected

Phenol:

Additional ecological infor-

mation

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

local regulations.



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Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal. Do not re-use empty containers.

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.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Phenol	108-95-2	1000	*

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Phenol	108-95-2	1000	*

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
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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).



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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 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table

117.3:

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

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Phenol 108-95-2

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

Washington Chemicals of High Concern

Phenol 108-95-2

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

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Somatropin

AICS : Not in compliance with the inventory

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 : Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.



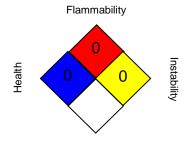
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No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA:



Special hazard

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 "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA PO : USA. OSHA - TABLE Z-1 Limits for Air Contaminants -

1910.1000

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its 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

AICS - Australian Inventory of Chemical Substances; 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 Pre-



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vention 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; 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

Revision Date : 02-13-2020

The information provided in this Material 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 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.

US / Z8 / 1810