

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078057734

N/A

## Gonadorelin Formulation

Version 5.2      Revision Date: 09/13/2019      SDS Number: 613544-00009      Date of last issue: 04/24/2019  
Date of first issue: 04/27/2016

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### SECTION 1. IDENTIFICATION

Product name : Gonadorelin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - U.S.A. 07033  
Telephone : 908-740-4000  
Telefax : 908-735-1496  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 1 (Endocrine system)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs (Endocrine system) through prolonged or repeated exposure if swallowed.

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 mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

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

#### Storage:

P405 Store locked up.

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### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 - < 5
Gonadorelin	34973-08-5	>= 0.001 - < 0.1

Actual concentration is withheld as a trade secret

## 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 : Flush eyes with water as a precaution.  
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. Suspected of damaging the unborn child.  
 Causes damage to organs through prolonged or repeated exposure if swallowed.
- 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.

## SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing : None known.

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media  
Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.  
Hazardous combustion products : Carbon 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 fire-fighters : 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 and personal protective equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Avoid inhalation of vapor or mist.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

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assessment  
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Gonadorelin	34973-08-5	TWA	0.2 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
 Minimize workplace exposure concentrations.

#### 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 : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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.

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Eye protection : Wear the following personal protective equipment:  
Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

Odor : No data available

Odor 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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

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

Density : No data available

Solubility(ies)  
Water solubility : No data available

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

Autoignition temperature : No data available

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Decomposition temperature : No data available

Viscosity  
  Viscosity, dynamic : No data available

  Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

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 : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

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

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l

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Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

**Gonadorelin:**

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg  
LD50 (Mouse): > 4,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Benzyl alcohol:**

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

**Gonadorelin:**

Remarks : No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

**Gonadorelin:**

Remarks : No data available

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Test Type : Maximization Test  
Routes of exposure : Skin contact



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Species : Guinea pig  
 Method : OECD Test Guideline 406  
 Result : negative

**Gonadorelin:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Intraperitoneal injection  
 Result: negative

**Gonadorelin:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
 Result: negative  
 Remarks: Based on data from similar materials

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Species : Mouse  
 Application Route : Ingestion  
 Exposure time : 103 weeks  
 Method : OECD Test Guideline 451  
 Result : negative

**Gonadorelin:**

Species : Mouse

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Exposure time : 2 Years  
 LOAEL : 2.4 mg/kg body weight  
 Result : positive  
 Remarks : Based on data from similar materials

Species : Rat  
 Exposure time : 1 Years  
 LOAEL : 0.05 mg/kg body weight  
 Result : negative  
 Remarks : Benign tumor(s)  
 The mechanism or mode of action may not be relevant in humans.  
 Based on data from similar materials

**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 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

Suspected of damaging fertility. Suspected of damaging the unborn child.

### Components:

#### **Benzyl alcohol:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

#### **Gonadorelin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat, female  
 Application Route: Subcutaneous  
 Fertility: LOAEL: 50 µg/kg  
 Result: Effects on fertility.  
 Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development  
 Species: Rat, male  
 Application Route: Subcutaneous  
 Fertility: LOAEL: 500 µg/kg  
 Result: Effects on fertility.  
 Remarks: Based on data from similar materials

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Test Type: Fertility/early embryonic development  
 Species: Rabbit  
 Application Route: Subcutaneous  
 Fertility: LOAEL: 1,000 µg/kg  
 Result: Effects on fertility.

Test Type: Fertility/early embryonic development  
 Species: Dog, male and female  
 Application Route: Subcutaneous  
 Fertility: LOAEL: 107 - 214 µg/kg  
 Result: Effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: >= 2 µg/kg  
 Result: Effects on fetal development.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: > 20 µg/kg  
 Result: Effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Endocrine system) through prolonged or repeated exposure if swallowed.

### Components:

#### Gonadorelin:

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

### Repeated dose toxicity

### Components:

#### Benzyl alcohol:

Species : Rat  
 NOAEL : 1.072 mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 412

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### Gonadorelin:

Species : Rat  
 NOAEL : 0.12 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 15 Days  
 Remarks : No significant adverse effects were reported

Species : Rat  
 NOAEL : 0.072 mg/kg  
 Application Route : Intravenous  
 Exposure time : 15 Days  
 Remarks : No significant adverse effects were reported

Species : Dog  
 NOAEL : 0.12 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 15 Days  
 Remarks : No significant adverse effects were reported

Species : Dog  
 NOAEL : 0.072 mg/kg  
 Application Route : Intravenous  
 Exposure time : 15 Days  
 Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

### Gonadorelin:

Ingestion : Symptoms: Nausea, Abdominal pain, Headache, Palpitation, acne, liver function change, bronchospasm, anaphylaxis

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

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NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Persistence and degradability****Components:****Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

**Bioaccumulative potential****Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

**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**

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.

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### 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 (lbs)	Calculated product RQ (lbs)
Acetic acid	64-19-7	5000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

#### 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** : Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Water 7732-18-5  
 Benzyl alcohol 100-51-6

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET



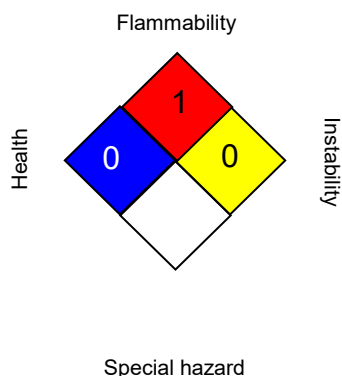
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	3
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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
US WEEL / TWA : 8-hr TWA

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 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

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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

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

Revision Date : 09/13/2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8