

# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 613526-00019 Date of first issue: 27.04.2016

**SECTION 1: IDENTIFICATION** 

Product name : Gonadorelin Formulation

Other means of identification : FERTAGYL SYNTHETIC GONADOTROPHIN RELEASING

**HORMONE (37210)** 

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street

Bendigo 3550, Victoria Austrailia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure (Oral)

Category 1 (Endocrine system)

**GHS** label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H361fd Suspected of damaging fertility. Suspected of damag-

ing the unborn child.

H372 Causes damage to organs (Endocrine system) through

prolonged or repeated exposure if swallowed.



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 61.3526-00019 Date of first issue: 27.04.2016

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 vapours. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

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

attention.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

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 -< 10
Gonadorelin	34973-08-5	>= 0.001 -< 1

#### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.



# **Gonadorelin Formulation**

Date of last issue: 06.04.2024 Version Revision Date: SDS Number: 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

> Thoroughly clean shoes before reuse. 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

In case of eye contact

May cause an allergic skin reaction.

Suspected of damaging fertility. Suspected of damaging the

unborn child.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **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 : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

Conditions for safe storage : Keep in properly labelled 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

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Components with workplace control parameters



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 613526-00019 Date of first issue: 27.04.2016

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Gonadorelin	34973-08-5	TWA	0.2 μg/m3 (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 : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Organic vapour type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Eye protection : Wear the following personal protective equipment:

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).

# **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available



# **Gonadorelin Formulation**

Version SDS Number: Date of last issue: 06.04.2024 **Revision Date:** 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

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

No data available Vapour pressure

Relative vapour density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

No data available Auto-ignition temperature

Decomposition temperature No data available

Viscosity

No data available Viscosity, dynamic

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 characteristics

Particle size No data available

### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 613526-00019 Date of first issue: 27.04.2016

Hazardous decomposition

products

: No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

### **Components:**

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

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



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 613526-00019 Date of first issue: 27.04.2016

#### 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 sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Gonadorelin:

Remarks : No data available

#### Chronic toxicity

#### 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 Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

П

#### 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 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 hu-

mans

Based on data from similar materials

### Reproductive toxicity

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



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

## **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 foetal develop-

ment

Test Type: Embryo-foetal 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

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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: >= 2 μg/kg Result: Effects on foetal development

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: > 20 µg/kg Result: Effects on foetal development



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

Reproductive toxicity - As-

sessment

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

ments.

#### 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

#### 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



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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



# **Gonadorelin Formulation**

Version SDS Number: Date of last issue: 06.04.2024 **Revision Date:** 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

П

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

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

International Regulations

**UNRTDG** 

**UN** number Not applicable Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels

Environmentally hazardous no

**IATA-DGR** 

UN/ID No. Not applicable Not applicable Proper shipping name Class Not applicable Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Class Not applicable



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 61.3526-00019 Date of first issue: 27.04.2016

Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

**ADG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

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

Therapeutic Goods (Poisons : Schedule 4

Standard) Instrument

Prohibition/Licensing Requirements : There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

**Further information** 

Revision Date : 28.09.2024

Sources of key data used to

compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 28.09.2024 613526-00019 Date of first issue: 27.04.2016

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

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