

# SAFETY DATA SHEET



## Desloratadine Liquid Formulation



Version 4.0      Revision Date: 06.04.2024      SDS Number: 771479-00018      Date of last issue: 30.09.2023  
Date of first issue: 23.06.2016

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Desloratadine Liquid Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Desloratadine	100643-71-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411	$\geq 0,025 - < 0,1$

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

- Protection of first-aiders : No special precautions are necessary for first aid responders.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- 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 if symptoms occur.  
Rinse mouth thoroughly with water.

**4.2 Most important symptoms and effects, both acute and delayed**

None known.

**4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically and supportively.

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- 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

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for 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 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
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. Wash contaminated clothing before re-use.

**7.2 Conditions for safe storage, including any incompatibilities**

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

**7.3 Specific end use(s)**

- Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

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Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### Engineering measures

Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

#### Personal protective equipment

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

Hand protection

Remarks : Wash hands before breaks and at the end of workday.  
Skin and body protection : Skin should be washed after contact.  
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance : liquid  
Colour : clear  
Odour : sweet  
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  
Flash point : No data available  
  
Evaporation rate : No data available  
  
Flammability (solid, gas) : Not applicable  
  
Upper explosion limit / Upper flammability limit : No data available  
  
Lower explosion limit / Lower flammability limit : No data available

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Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

    Water solubility : soluble

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

    Auto-ignition temperature : No data available

    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.

### 9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Desloratadine:

Acute oral toxicity : LD50 (Rat): > 549 mg/kg  
LD50 (Mouse): 353 mg/kg  
LD50 (Monkey): > 250 mg/kg  
Symptoms: Vomiting  
Remarks: No mortality observed at this dose.

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Desloratadine:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Desloratadine:

Species : Rabbit  
Remarks : Severe eye irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Desloratadine:

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Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Result	: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Desloratadine:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
	Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Desloratadine:**

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Species	: Rat
Application Route	: Oral
LOAEL	: 10 mg/kg body weight
Result	: equivocal
Target Organs	: Liver
Remarks	: Based on data from similar materials The mechanism or mode of action may not be relevant in humans.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Desloratadine:**

Effects on fertility	: Test Type: Fertility Species: Rat, male Application Route: Oral Fertility: LOAEL: 12 mg/kg body weight
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		<p>Symptoms: Reduced fertility Result: positive Remarks: The mechanism or mode of action may not be relevant in humans.</p> <p>Test Type: Fertility Species: Rat, female Fertility: NOAEL: 3 mg/kg body weight Symptoms: No effects on fertility Result: negative</p>
Effects on foetal development	:	<p>Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 30 mg/kg body weight Result: No teratogenic effects</p> <p>Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 9 mg/kg body weight Symptoms: Preimplantation loss, Reduced body weight Result: Specific developmental abnormalities Remarks: The mechanism or mode of action may not be relevant in humans.</p> <p>Test Type: Two-generation study Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 18 mg/kg body weight Result: No adverse effects</p>
Reproductive toxicity - Assessment	:	<p>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.</p>

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Desloratadine:**

Species		: Rat
LOAEL		: 30 mg/kg
Application Route		: Oral
Exposure time		: 3 Months
Target Organs		: Kidney
Remarks		: Significant toxicity observed in testing The mechanism or mode of action may not be relevant in hu-

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|| Species : Monkey  
 || NOAEL : 6 mg/kg  
 || LOAEL : 12 mg/kg  
 || Application Route : Oral  
 || Exposure time : 3 Months  
 || Target Organs : Central nervous system  
 || Symptoms : Gastrointestinal disturbance

|| Species : Monkey  
 || NOAEL : 40 mg/kg  
 || Application Route : Oral  
 || Exposure time : 17 Months  
 || Remarks : No significant adverse effects were reported

|| Species : Monkey  
 || NOAEL : 6 mg/kg  
 || Application Route : Oral  
 || Exposure time : 3 Months  
 || Symptoms : Gastrointestinal disturbance, Fatigue

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Desloratadine:**

|| Inhalation : Remarks: May cause respiratory tract irritation.  
 || Eye contact : Symptoms: Eye irritation  
 || Ingestion : Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

**SECTION 12: Ecological information****12.1 Toxicity****Components:****Desloratadine:**

|| Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 9,2 mg/l  
 Exposure time: 96 h  
 Method: FDA 4.11

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,6 mg/l  
 Exposure time: 48 h  
 Method: FDA 4.08

|| Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 1,6 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

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		NOEC (Pseudokirchneriella subcapitata (green algae)): 0,36 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 (Natural microorganism): 53,7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC (Natural microorganism): 12 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,12 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,48 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

**12.2 Persistence and degradability****Components:****Desloratadine:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 67,4 % Exposure time: 28 d Method: OECD Test Guideline 314
		Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: FDA 3.11
Stability in water	:	Hydrolysis: < 10 % at 50 °C(5 d) Method: FDA 3.09

**12.3 Bioaccumulative potential****Components:****Desloratadine:**

Partition coefficient: n-octanol/water	:	log Pow: 1,24 Method: OECD Test Guideline 107
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**12.4 Mobility in soil****Components:****Desloratadine:**

Distribution among environmental compartments	:	log K <sub>oc</sub> : 3,00 Method: OECD Test Guideline 106
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**12.5 Results of PBT and vPvB assessment****Product:**

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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**12.6 Other adverse effects****Product:**

Endocrine disrupting potential	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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.

**SECTION 14: Transport information****14.1 UN number**

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

**14.2 UN proper shipping name**

ADN	:	Not regulated as a dangerous good
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**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

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

**AICS** : not determined  
**DSL** : not determined  
**IECSC** : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## SECTION 16: Other information

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

**Full text of H-Statements**

H302 : Harmful if swallowed.  
 H318 : Causes serious eye damage.  
 H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.  
 H411 : Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
 Aquatic Chronic : Long-term (chronic) aquatic hazard  
 Eye Dam. : Serious eye damage  
 Repr. : Reproductive toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

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

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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 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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