

SAFETY DATA SHEET



Suvorexant Formulation

Version
9.0

Revision Date:
28.09.2024

SDS Number:
21524-00025

Date of last issue: 26.09.2023
Date of first issue: 14.10.2014

SECTION 1. IDENTIFICATION

Product identifier : Suvorexant Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A
Parque Industrial Vice Presidente José Alencar Aparecida de
Goiás – GO, Brazil

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

Signal Word : None

Hazard Statements : H401 Toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**

P273 Avoid release to the environment.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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Chemical name	CAS-No.	Classification	Concentration (% w/w)
Suvorexant	1030377-33-3	STOT SE, 3 STOT RE, (Oral)(Central nervous system) , 2 Aquatic Acute, 1 Aquatic Chronic, 2	>= 5 -< 10
Magnesium stearate	557-04-0		>= 1 -< 5

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 if symptoms occur.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
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.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.

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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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust. 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 assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

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Hygiene measures	<p>environment.</p> <p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.</p>
Conditions for safe storage	<p>: Keep in properly labeled containers.</p> <p>Store in accordance with the particular national regulations.</p>
Materials to avoid	<p>: Do not store with the following product types:</p> <p>Strong oxidizing agents</p>

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Suvorexant	1030377-33-3	TWA	14 µg/m ³ (OEB 3)	Internal
		Wipe limit	140 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Engineering measures	<p>: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</p> <p>Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).</p> <p>Minimize open handling.</p>
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Personal protective equipment

Respiratory protection	<p>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</p>
Filter type	: Particulates type
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.

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Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: powder
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	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
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	: Not applicable
Relative vapor density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available

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Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:

Suvorexant:

Acute oral toxicity : LD50 (Rat): > 1.200 mg/kg
LD50 (Dog): > 1.125 mg/kg
LDLo (Mouse): 2.000 mg/kg

Magnesium stearate:

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Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**Suvorexant:**

Species	:	Rabbit
Result	:	No skin irritation

Magnesium stearate:

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Suvorexant:**

Species	:	Bovine cornea
Result	:	Mild eye irritation
Method	:	Bovine cornea (BCOP)

Magnesium stearate:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Suvorexant:**

Test Type	:	Local lymph node assay (LLNA)
Species	:	Mouse
Assessment	:	Does not cause skin sensitization.
Result	:	negative

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Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:**Suvorexant:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Alkaline elution assay Test system: rat hepatocytes Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
		Test Type: Micronucleus test Species: Rat Result: negative

Magnesium stearate:

Genotoxicity in vitro	:	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 Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

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Components:**Suvorexant:**

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	6 month(s)
Result	:	negative
Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:**Suvorexant:**

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male and female Application Route: Oral General Toxicity Parent: NOAEL: \geq 325 mg/kg body weight Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rabbit, female Application Route: Oral Developmental Toxicity: NOAEL: 150 mg/kg body weight Result: negative
	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 80 mg/kg body weight Result: negative

Magnesium stearate:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

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Not classified based on available information.

Components:**Suvorexant:**

Remarks	: Based on human experience.
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STOT-repeated exposure

Not classified based on available information.

Components:**Suvorexant:**

Routes of exposure	: Ingestion
Target Organs	: Central nervous system
Assessment	: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Suvorexant:**

Species	: Rat
NOAEL	: 325 mg/kg
LOAEL	: 1.200 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Blood, Pancreas

Species	: Dog
NOAEL	: 50 mg/kg
LOAEL	: 125 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Blood, Liver, Central nervous system

Species	: Rat
NOAEL	: 75 mg/kg
LOAEL	: 300 mg/kg
Application Route	: Oral
Exposure time	: 180 d
Target Organs	: Pancreas, Blood, Stomach

Species	: Dog
NOAEL	: 50 mg/kg
LOAEL	: 125 mg/kg
Application Route	: Oral
Exposure time	: 270 d
Target Organs	: Blood

Species	: Rat
NOAEL	: 40 mg/kg
LOAEL	: 80 mg/kg

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Application Route	:	Oral
Exposure time	:	18 Months
Target Organs	:	Eye, Central nervous system

Magnesium stearate:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Suvorexant:**

Ingestion	:	Symptoms: Drowsiness, Headache, abnormal dreams, Fatigue, Dizziness, dry mouth, Nausea, liver function change, upper respiratory tract infection, urinary tract infection, Cough, Diarrhea, Palpitation, tachycardia
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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Suvorexant:**

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Mysidopsis bahia (opossum shrimp)): 0,56 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 2,5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0,14 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,5 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

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Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability**Components:****Suvorexant:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 314

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Stability in water : Hydrolysis: < 10 %(5 d)
Method: OECD Test Guideline 111

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Suvorexant:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 358
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,04

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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

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ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024
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Further information

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/>

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 other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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 con-

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centration; 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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