

Olmesartan / Hydrochlorothiazide Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 402469-00017 Date of last issue: 04.04.2023
Date of first issue: 07.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Olmesartan / Hydrochlorothiazide Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054

Telephone : +55 (19) 3758-2000

Emergency telephone : +55 (11) 3173-4931

E-mail address : EHSSTEWARD@organon.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**

Reproductive toxicity : Category 1A

Specific target organ toxicity - : Category 2 (Kidney, Parathyroid gland)
repeated exposure

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.
H373 May cause damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

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attention.

Storage:

P405 Store locked up.

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

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Olmesartan	144689-63-4	Acute toxicity (Oral), Category 4 Eye irritation, Category 2B Reproductive toxicity, Category 1A	≥ 5 - < 10
Cellulose	9004-34-6		≥ 5 - < 10
Hydrochlorothiazide	58-93-5	Acute toxicity (Oral), Category 5 Specific target organ toxicity - repeated exposure (Kidney, Parathyroid gland), Category 1	≥ 5 - < 10

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 : 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.
Rinse mouth thoroughly with water.

Most important symptoms : May damage the unborn child.

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and effects, both acute and delayed		May cause damage to organs through prolonged or repeated exposure. 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 (CO ₂) 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 Nitrogen oxides (NO _x) Chlorine compounds Sulfur 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.

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

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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 | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe dust.
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 assessment
Keep container tightly closed.
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.
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.
Wash contaminated clothing before re-use.
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. |
| Conditions for safe storage | : | Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Olmesartan	144689-63-4	TWA	30 µg/m ³ (OEB 3)	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Hydrochlorothiazide	58-93-5	TWA	100 µg/m ³ (OEB 2)	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. 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).
 Minimize open handling.

Personal protective equipment

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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

Appearance : powder

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

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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

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 : Not applicable

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

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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.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:**Olmesartan:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 2.000 mg/kg
LD50 (Dog): > 1.500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Hydrochlorothiazide:

Acute oral toxicity : LD50 (Rat): > 2.750 mg/kg
LD50 (Mouse): > 2.830 mg/kg

Acute toxicity (other routes of : LD50 (Rat): 990 mg/kg

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administration) Application Route: Intravenous

LD50 (Mouse): 590 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

Olmesartan:

Remarks : No data available

Hydrochlorothiazide:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Olmesartan:

Species : Rabbit
Result : Moderate eye irritation
Method : Draize Test

Hydrochlorothiazide:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Olmesartan:

Routes of exposure : Skin contact
Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Olmesartan:

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

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Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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

Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Hydrochlorothiazide:

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

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: positive

Test Type: in vitro test
Test system: mouse lymphoma cells
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Chinese hamster
Cell type: Bone marrow
Result: negative

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Test Type: in vivo assay
 Species: Mouse
 Cell type: Bone marrow
 Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:

Olmesartan:

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

Species : Mouse
 Application Route : Oral
 Exposure time : 6 Months
 Result : negative

Cellulose:

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

Hydrochlorothiazide:

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

Species : Mouse, male
 Application Route : Oral
 Exposure time : 2 Years
 Result : equivocal

Species : Rat, male and female
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

Olmesartan:

Effects on fertility : Test Type: Fertility

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Species: Rat
 Application Route: Oral
 Fertility: NOAEL: 1.000 mg/kg body weight
 Result: No effects on fertility.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Dose: 1000 milligram per kilogram
 Result: No teratogenic effects.

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Dose: 1 milligram per kilogram
 Result: No teratogenic effects.

Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: \geq 1,6 mg/kg body weight
 Symptoms: Malformations were observed., Reduced body weight
 Result: Effects on postnatal development.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

Hydrochlorothiazide:

Effects on fertility : Test Type: Fertility
 Species: Rat, male and female
 Application Route: oral (feed)
 Fertility: NOAEL: 4 mg/kg body weight
 Result: Effects on fertility.

Test Type: Fertility
 Species: Mouse, male and female
 Application Route: oral (feed)
 Fertility: NOAEL: 100 mg/kg body weight
 Result: Effects on fertility.

Effects on fetal development : Test Type: Development
 Species: Mouse

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Application Route: Oral
 Developmental Toxicity: NOAEL: 3.000 mg/kg body weight
 Result: No teratogenic effects.

Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
 Result: No teratogenic effects.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

Components:

Hydrochlorothiazide:

Target Organs : Kidney, Parathyroid gland
 Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Olmesartan:

Species : Rat
 NOAEL : 2.000 mg/kg
 Application Route : Oral
 Exposure time : 24 Months
 Remarks : No significant adverse effects were reported

Cellulose:

Species : Rat
 NOAEL : >= 9.000 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

Hydrochlorothiazide:

Species : Rat, male and female
 LOAEL : 10 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female
 NOAEL : 300 - 550 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Remarks : No significant adverse effects were reported

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Species : Dog
: 50 - 200 mg/kg
Application Route : Oral
Exposure time : 9 Months
Target Organs : Parathyroid gland

Aspiration toxicity

Not classified based on available information.

Components:**Hydrochlorothiazide:**

No aspiration toxicity classification

Experience with human exposure**Components:****Olmesartan:**

Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: hypotension
Remarks: May cause harm to the unborn child.
Based on Human Evidence

Hydrochlorothiazide:

Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Hydrochlorothiazide:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Persistence and degradability**Components:****Cellulose:**

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Biodegradability : Result: Readily biodegradable.

Hydrochlorothiazide:

Stability in water : Hydrolysis: 46,2 %(96 h)

Bioaccumulative potential

No data available

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

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)

Group 2B: Possibly carcinogenic to humans

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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

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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/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AllC - 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,

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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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