

Efavirenz Liquid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 86828-00025 Date of first issue: 01.04.2015 6.0

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Efavirenz Liquid Formulation

Manufacturer or supplier's details

Company MSD

Address : Avenue Comendador Antônio Loureiro Ramos,

nº 1500 - Distrito Industrial

Montes Claros - MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

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

Reproductive toxicity : Category 1B

repeated exposure

Specific target organ toxicity - : Category 2 (Central nervous system, Skin)

Short-term (acute) aquatic

hazard

: Category 2

Long-term (chronic) aquatic

hazard

Category 2

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 (Central nervous system,

Skin) through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects.



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Precautionary Statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|----------------|-------------|--|-----------------------|
| Efavirenz | 154598-52-4 | Acute toxicity (Oral), Category 4 Eye irritation, Category 2B Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Central nervous system, Skin), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1 Category 1 Category 1 Category 1 Category 1 Category 1 | >= 2,5 -< 5 |
| Benzyl alcohol | 100-51-6 | Acute toxicity (Oral), Category 4 Acute toxicity (Inhala- tion), Category 4 Eye irritation, Category 2A | < 0,1 |

SECTION 4. FIRST AID MEASURES

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

advice immediately.



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When symptoms persist or in all cases of doubt seek medical

May cause damage to organs through prolonged or repeated

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. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

If swallowed

Get medical attention.

Rinse mouth thoroughly with water. May damage the unborn child.

Most important symptoms

and effects, both acute and

delayed exposure. 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 None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

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

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, protec- : tive equipment and emer-

gency 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.

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

oil barriers).



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Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 mist or vapors.

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.

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.

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 | Control parameters / Permissible | Basis |
|------------|-------------|------------------------|----------------------------------|----------|
| | | exposure) | concentration | |
| Efavirenz | 154598-52-4 | TWA | 100 μg/m³ | Internal |

Engineering measures : Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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. Combined particulates and organic vapor type

Filter type Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

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

breaks and at the end of workday.

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

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available



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Evaporation rate No data available

Flammability (solid, gas) Not applicable

No data available Flammability (liquids)

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure No data available

No data available Relative vapor density

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition 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.

No data available Molecular weight

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.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.



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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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:

Efavirenz:

Acute oral toxicity : LD50 (Rat, female): 419 mg/kg

LDLo (Rat, male): 1.000 mg/kg

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

Efavirenz:

Result : Mild skin irritation Remarks : slight irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Efavirenz:

Remarks : Moderate eye irritation



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Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Efavirenz:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitization.

Result : negative

Benzyl alcohol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Efavirenz:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral Result: negative

ŭ

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.



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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

Carcinogenicity

Not classified based on available information.

Components:

Efavirenz:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Target Organs : Lungs, Liver

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

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

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

Efavirenz:

Effects on fertility : Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 200 - 400 mg/kg body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 50 mg/kg body weight

Result: Embryo-fetal toxicity.



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Test Type: Embryo-fetal development

Species: Monkey Application Route: Oral

Developmental Toxicity: LOAEL: 60 mg/kg body weight

Symptoms: Malformations were observed.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 75 mg/kg body weight

Result: No embryotoxic effects.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.

Components:

Efavirenz:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Efavirenz:

Species : Rat
LOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Kidney

Species : Monkey LOAEL : 100 mg/kg



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Application Route : Oral Exposure time : 1 - 2 y

Target Organs : Central nervous system, Liver, Kidney, Thyroid, Adrenal gland

Species : Monkey
LOAEL : 90 mg/kg
Application Route : Oral
Exposure time : 1 Months

Target Organs : Central nervous system Symptoms : Lethargy, Weakness

Benzyl alcohol:

Species : Rat NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Efavirenz:

Ingestion : Target Organs: Skin

Symptoms: Rash

Target Organs: Central nervous system

Symptoms: Dizziness, insomnia

Target Organs: Heart

Symptoms: irregular heart beat

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Efavirenz:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,85 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,1 mg/l

Exposure time: 48 h Method: FDA 4.08

Toxicity to algae/aquatic

plants

NOEC (Selenastrum capricornutum (green algae)): 0,026 mg/l

Exposure time: 12 d Method: FDA 4.01

NOEC (Microcystis aeruginosa (blue-green algae)): 0,76 mg/l

Exposure time: 12 d



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Method: FDA 4.01

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0,066 mg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,16 mg/l Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1

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

ma/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:

Efavirenz:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 11 % Exposure time: 32 d Method: FDA 3.11

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 92 - 96 % Exposure time: 14 d



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Bioaccumulative potential

Components:

Efavirenz:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 454 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 5,4

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

Mobility in soil

Components:

Efavirenz:

Distribution among environmental compartments

log Koc: 3,36 Method: FDA 3.08

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

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Efavirenz)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Efavirenz)

Class : 9



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Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Efavirenz)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-/

EmS Code : F-A, S-F Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Efavirenz)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

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

Police

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

AICS : not determined

DSL : not determined



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IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024 Date format : dd.mm.yyyy

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 Agen-

cy, 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

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



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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.

BR / Z8