according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Daptomycin Injection Formulation - 2nd Generation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 690889-00022 Date of first issue: 19.05.2016

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

1.1 Product identifier

Trade name : Daptomycin Injection Formulation - 2nd Generation

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 : MSD

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Specific target organ toxicity - repeated exposure, Category 2

H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

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

Hazard pictograms

Signal word : Warning

Hazard statements : H373 May cause damage to organs through prolonged

or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Precautionary statements : Prevention:

P260 Do not breathe dust.

Response:

P314 Get medical advice/ attention if you feel unwell.

#### Hazardous components which must be listed on the label:

Daptomycin

#### 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.

Ecological information: 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.

Toxicological information: 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.

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**

## 3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		(/0 11/11/
	Registration number		
Daptomycin	103060-53-3	STOT RE 2; H373	>= 30 - < 50
		(muscle, Kidney,	
		Nervous system)	

For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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).

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

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, 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

Risks : 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.

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

## 5.2 Special hazards arising from the substance or mixture

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 prod: :

ucts

Carbon oxides

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 5.3 Advice for firefighters

Special protective equipment :

for firefighters

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

Use personal protective equipment.

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.

#### **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective 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. 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 : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine 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.

## **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 get on skin or clothing. Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

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

sessment

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

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 contami-

nated 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.

#### 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

7.3 Specific end use(s)

No data available Specific use(s)

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

## **Occupational Exposure Limits**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
		OELV - 15 min (STEL)	20 mg/m3	IE OEL
Daptomycin	103060-53- 3	TWA	800 μg/m3 (OEB 2)	Internal

#### 8.2 Exposure controls

#### **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection

Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

## **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state : lyophilised cake

Colour : light brown

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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range

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 6.5 - 7.3

(as aqueous solution)

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

#### **Acute toxicity**

Not classified based on available information.

## Skin corrosion/irritation

Not classified based on available information.

### **Components:**

## Daptomycin:

Species : Rabbit

Result : Mild skin irritation

# Serious eye damage/eye irritation

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### **Components:**

Daptomycin:

Species : Rabbit

Result : Mild eye irritation

## Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Daptomycin:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Hamster

Application Route: Intraperitoneal injection

Result: negative

#### Carcinogenicity

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### Reproductive toxicity

Not classified based on available information.

## **Components:**

## Daptomycin:

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

Species: Rat

Application Route: Intravenous injection Fertility: NOAEL: 150 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 75 mg/kg body weight Result: No significant adverse effects were reported

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 75 mg/kg body weight Result: No significant adverse effects were reported

#### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### **Components:**

## Daptomycin:

Target Organs : muscle, Kidney, Nervous system

Assessment : May cause damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### **Components:**

#### Daptomycin:

Species : Dog
NOAEL : 20 mg/kg
LOAEL : 40 mg/kg
Application Route : Intravenous
Exposure time : 3 Months
Target Organs : Skeletal muscle

Species : Monkey NOAEL : 10 mg/kg

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Application Route : Intravenous Exposure time : 1 Months

Remarks : No significant adverse effects were reported

Species : Dog

Application Route : Intravenous Exposure time : 28 Days

Target Organs : Skeletal muscle, Nervous system

Symptoms : muscle twitching

Species : Juvenile dog LOAEL : 50 mg/kg Application Route : Intravenous Exposure time : 28 Days

Target Organs : Skeletal muscle, Nervous system

### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

# **Endocrine disrupting properties**

## **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

#### **Experience with human exposure**

#### **Components:**

Daptomycin:

General Information : Symptoms: Rash, Diarrhoea, vaginitis

### **SECTION 12: Ecological information**

## 12.1 Toxicity

No data available

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

#### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

#### 12.7 Other adverse effects

No data available

#### **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## **SECTION 14: Transport information**

#### 14.1 UN number or ID 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
ADR : Not regulated as a dangerous good

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RID : Not regulated as a dangerous goodIMDG : Not regulated as a dangerous goodIATA : 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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

: Not applicable

Not applicable

Not applicable

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REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### 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.

#### **SECTION 16: Other information**

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** 

H373 : May cause damage to organs through prolonged or repeated

exposure in contact with skin.

Full text of other abbreviations

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference peri-

(STEL) oc

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 La-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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boratory 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; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to : compile the Safety Data

eChem Portal search results and European Chemicals Agen-Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

STOT RE 2 H373 Calculation method

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.

Internal technical data, data from raw material SDSs, OECD

IE / EN