

# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

## **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Imipenem / Cilastatin Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

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** 

Serious eye damage/eye

irritation

Category 2A

Respiratory sensitization : Category 1

Reproductive toxicity : Category 2

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H361d Suspected of damaging the unborn child.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing dust.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.



# **Imipenem / Cilastatin Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

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

attention.

P337 + P313 If eye irritation persists: Get medical advice/ atten-

tion.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

#### Other hazards

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.	Concentration (% w/w)
Cilastatin	81129-83-1	>= 50 -< 70
Imipenem	74431-23-5	>= 30 -< 50

#### **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.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

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 : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms : Causes serious eye irritation.



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
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 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

and effects, both acute and

delayed

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Suspected of damaging the unborn child.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis,

reactive airways dysfunction syndrome).

Contact with dust can cause mechanical irritation or drying of

the skin.

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 prod-

ıcts

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. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.



# **Imipenem / Cilastatin Formulation**

Version Date of last issue: 26.09.2023 Revision Date: SDS Number: 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

Methods and materials for containment and cleaning up Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

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. 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 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 Advice on safe handling Use only with adequate ventilation.

Do not breathe dust. Do not swallow.

Do not get in eyes.

Avoid prolonged or repeated contact with skin.

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.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

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.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

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

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis	
		exposure)	concentration		
Cilastatin	81129-83-1	TWA	5 mg/m3 (OEB 1)	Internal	
Imipenem	74431-23-5	TWA	3000 ug/m3 (OEB	Internal	
			1)		
_	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	Internal	

**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

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

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.

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : white

Odor : sulfurous

Odor Threshold : No data available

pH : No data available



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

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) : Not applicable

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 : 1 g/cm<sup>3</sup>

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, dynamic : No data available

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**



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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 : No hazardous decomposition products are known.

products

### **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:**

### Cilastatin:

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg

LD50 (Mouse): 8,000 mg/kg

Imipenem:

Acute oral toxicity : LD50 (Mouse): 10,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): > 2,000 mg/kg Application Route: Intravenous

LD50 (Mouse): 1,500 mg/kg Application Route: Intravenous

### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

### Cilastatin:

Species : Rabbit

Result : No skin irritation

#### Serious eye damage/eye irritation

Causes serious eye irritation.



# **Imipenem / Cilastatin Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

**Components:** 

Cilastatin:

Species : Rabbit

Result : Moderate eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:** 

Cilastatin:

Routes of exposure : Skin contact Remarks : No data available

Routes of exposure : Inhalation

Remarks : No data available

Imipenem:

Remarks : May cause sensitization of susceptible persons by inhalation

of aerosol or dust.

Routes of exposure : Skin contact

Remarks : Not classified due to lack of data.

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Cilastatin:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Result: negative

Imipenem:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster lung cells

Result: negative

Test Type: reverse mutation assay

Result: negative

Test Type: unscheduled DNA synthesis assay

Result: negative

Test Type: Chromosomal aberration

Result: negative



# **Imipenem / Cilastatin Formulation**

Version Date of last issue: 26.09.2023 Revision Date: SDS Number: 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

Test Type: sister chromatid exchange assay

Result: negative

Test Type: In vivo micronucleus test Genotoxicity in vivo

Species: Mouse

Application Route: Intravenous

Result: negative

## Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

### Cilastatin:

Effects on fertility Test Type: Fertility/early embryonic development

Application Route: Intravenous

Fertility: LOAEL: 1,000

Symptoms: No adverse effects.

Result: No effects on fertility and early embryonic

development were detected.

### Imipenem:

Effects on fertility Test Type: Fertility/early embryonic development

> Species: Rat, male and female Application Route: Intravenous

Fertility: LOAEL: 80 mg/kg body weight

Symptoms: No adverse effects., Reduced fetal weight. Result: No effects on fertility and early embryonic

development were detected.

Test Type: Fertility/early embryonic development

Species: Rat, male and female Application Route: Subcutaneous Fertility: LOAEL: 320 mg/kg body weight

Symptoms: No adverse effects., Reduced fetal weight. Result: No effects on fertility and early embryonic

development were detected.

Effects on fetal development Test Type: Development

Species: Monkey

Application Route: Intravenous

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the

offspring were detected., No teratogenic effects.

Test Type: Development

Species: Rabbit

Application Route: Intravenous

Developmental Toxicity: NOAEL: 60 mg/kg body weight

Result: No teratogenic effects.



# **Imipenem / Cilastatin Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

Test Type: Development

Species: Rat

Application Route: Intravenous

Developmental Toxicity: NOAEL: 60 mg/kg body weight

Result: No teratogenic effects.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

### STOT-single exposure

Not classified based on available information.

#### **STOT-repeated exposure**

Not classified based on available information.

### Repeated dose toxicity

## **Components:**

#### Cilastatin:

Species : Rat

NOAEL : >= 500 mg/kg
Application Route : Intravenous
Exposure time : 90 Days

Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : >= 500 mg/kg
Application Route : Intravenous
Exposure time : 5 Weeks

Remarks : No significant adverse effects were reported

Imipenem:

Species : Monkey
NOAEL : 60 mg/kg
LOAEL : 150 mg/kg
Application Route : Intravenous
Exposure time : 6 Months
Target Organs : Kidney

Species : Monkey
NOAEL : 120 mg/kg
Application Route : Subcutaneous
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 180 mg/kg
Application Route : Intravenous
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Rabbit LOAEL : 150 mg/kg



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

Application Route : Intravenous Target Organs : Kidney

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Imipenem:

Inhalation : Symptoms: Nausea, Vomiting, Diarrhea, Fever, hypotension,

Dizziness, Drowsiness, Convulsions, pruritis, Rash

Remarks: May cause sensitization of susceptible persons by

inhalation of aerosol or dust.

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

Cilastatin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 99 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): > 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 99

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

EC10 (Pimephales promelas (fathead minnow)): > 9.9 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

EC10 (Daphnia magna (Water flea)): > 10 mg/l

aquatic invertebrates (Chron- Exposure time: 21 d



# **Imipenem / Cilastatin Formulation**

Version Date of last issue: 26.09.2023 Revision Date: SDS Number: 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

Method: OECD Test Guideline 211 ic toxicity)

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Imipenem:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 78 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0046 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.002 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 74

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 74

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 11 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

EC50: > 1,000 mg/lToxicity to microorganisms

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

**Components:** 

Cilastatin:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 27 % Exposure time: 28 d

Method: OECD Test Guideline 301B



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

Imipenem:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 29 % Exposure time: 28 d

Method: OECD Test Guideline 301B

**Bioaccumulative potential** 

**Components:** 

Cilastatin:

Partition coefficient: n-

octanol/water

log Pow: -3.53

Imipenem:

Partition coefficient: n-

octanol/water

log Pow: < -1

Mobility in soil

**Components:** 

Cilastatin:

Distribution among environ-

mental compartments

: log Koc: 2.3

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 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Imipenem)

Class : 9

Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3077

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



# **Imipenem / Cilastatin Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 7.3 28.09.2024 15836-00029 Date of first issue: 05.11.2014

(Imipenem)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo :

aircraft)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Imipenem)

Class : 9
Packing group : III
Labels : 9
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**

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Imipenem)

Class : 9
Packing group : III
Labels : 9

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined



# **Imipenem / Cilastatin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 7.3
 28.09.2024
 15836-00029
 Date of first issue: 05.11.2014

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

#### 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

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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8