

## Metamizol Injection Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 12.07.2023  
3.1                30.09.2023                10558922-00011            Date of first issue: 14.01.2022

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name                                : Metamizol Injection 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                          : Veterinary product  
Restrictions on use                         : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity                      : Category 2  
  
Specific target organ toxicity             : Category 1 (Blood)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms                         :



Signal Word                                 : Danger  
  
Hazard Statements                         : H361 Suspected of damaging fertility or the unborn child.  
    : H372 Causes damage to organs (Blood) through prolonged or  
    : repeated exposure if swallowed.

Precautionary Statements                : **Prevention:**  
    : P201 Obtain special instructions before use.  
    : P202 Do not handle until all safety precautions have been read  
    : and understood.  
    : P260 Do not breathe mist or vapors.  
    : P264 Wash skin thoroughly after handling.  
    : P270 Do not eat, drink or smoke when using this product.  
    : P280 Wear protective gloves/ protective clothing/ eye protection/  
    : face protection.

#### Response:

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

#### Storage:

P405 Store locked up.

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**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

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.	Concentration (% w/w)
Metamizol	68-89-3	>= 30 -< 50
Benzyl alcohol	100-51-6	>= 1 -< 5

**SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.

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 and effects, both acute and delayed : Suspected of damaging fertility or the unborn child.  
 Causes damage to organs through prolonged or repeated exposure if swallowed.  
 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

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		Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon 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.

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### 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. Prevent spreading over a wide area (e.g., by containment or oil barriers). 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. 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. 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.

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### SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust
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- causing an explosion.  
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.  
 Advice on safe handling : Do not breathe mist or vapors.  
 Do not swallow.  
 Avoid contact with 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  
 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.  
 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

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Metamizol	68-89-3	TWA	3 mg/m <sup>3</sup> (OEB 1)	Internal

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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Laboratory operations do not require special containment.

**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	:	Combined particulates and organic vapor type
Hand protection	:	
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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	liquid
Color	:	colorless
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
Evaporation rate	:	No data available
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	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available

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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 : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**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

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Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

### Components:

#### **Metamizol:**

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg  
Target Organs: Central nervous system

LD50 Oral (Rabbit): 2,150 mg/kg  
Target Organs: Central nervous system

LD50 Oral (Guinea pig): 1,000 mg/kg  
Target Organs: Central nervous system

#### **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:

#### **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:

#### **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.

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### Components:

#### **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:

#### **Metamizol:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative  
  
Test Type: Mutagenicity (in vitro mammalian cytogenetic test)  
Test system: Chinese hamster lung cells  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

#### **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:

#### **Metamizol:**

Species : Mouse, male  
Application Route : oral (feed)  
Exposure time : 2 Years  
: 375 mg/kg bw/day  
Result : negative

Species : Mouse, female  
Application Route : oral (feed)  
Exposure time : 2 Years  
: 442 mg/kg bw/day  
Result : negative



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Species : Rat, male  
 Application Route : oral (drinking water)  
 Exposure time : 2 Years  
 : 150 mg/kg bw/day  
 Result : negative

Species : Rat, female  
 Application Route : oral (drinking water)  
 Exposure time : 2 Years  
 : 193 mg/kg bw/day  
 Result : negative

### **Benzyl alcohol:**

Species : Mouse  
 Application Route : Ingestion  
 Exposure time : 103 weeks  
 Method : OECD Test Guideline 451  
 Result : negative

### **Reproductive toxicity**

Suspected of damaging fertility or the unborn child.

### **Components:**

#### **Metamizol:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Oral  
 Early Embryonic Development: NOAEL: 100 mg/kg body weight  
 Result: Fetotoxicity., Maternal toxicity observed., May cause adverse reproductive effects.

Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Oral  
 Early Embryonic Development: NOAEL: 400 mg/kg body weight  
 Result: Fetotoxicity., Increased resorptions.

Test Type: Fertility/early embryonic development  
 Species: Rabbit  
 Application Route: Oral  
 Early Embryonic Development: NOAEL: 25 mg/kg body weight  
 Result: Fetotoxicity., Increased resorptions.

Effects on fetal development : Test Type: Two-generation study  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 250 mg/kg body weight  
 Result: Maternal toxicity observed., Reduced maternal body weight gain., Reduced maternal food consumption., Reduced

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number of viable fetuses.

Reproductive toxicity - Assessment : Suspected of damaging fertility. Suspected of damaging the unborn child.

**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**

Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.

**Components:****Metamizol:**

Routes of exposure : Oral  
Target Organs : Blood  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Metamizol:**

Species : Rat  
NOAEL : 50 mg/kg  
Application Route : Subcutaneous  
Exposure time : 28 d  
Target Organs : Blood  
Symptoms : blood effects

Species : Rat  
NOAEL : 150 mg/kg  
Application Route : Intravenous  
Exposure time : 28 d  
Target Organs : Blood  
Symptoms : blood effects

Species : Rat  
NOAEL : 300 mg/kg  
Application Route : Oral  
Exposure time : 26 Weeks

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Target Organs : Blood  
Symptoms : blood effects

Species : Dog  
NOAEL : 150 mg/kg  
Application Route : Subcutaneous  
Exposure time : 28 d  
Target Organs : Blood  
Symptoms : blood effects

Species : Dog  
NOAEL : 50 mg/kg  
Application Route : Intravenous  
Exposure time : 28 d  
Target Organs : Blood, Gastrointestinal tract  
Symptoms : blood effects, Salivation, Vomiting

Species : Dog  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 26 Weeks  
Target Organs : Blood, Liver, Kidney, spleen  
Symptoms : blood effects

**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:****Metamizol:**

Ingestion : Target Organs: Blood  
Symptoms: blood effects, Bloody urine, Diarrhea, Nausea,  
Rash, hypotension

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

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 47 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 50.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.725 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**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 mg/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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Persistence and degradability****Components:****Metamizol:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 18 - 23 %

**Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

**Bioaccumulative potential****Components:****Benzyl alcohol:**

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Partition coefficient: n-octanol/water : log Pow: 1.05

### Mobility in soil

No data available

### Other adverse effects

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)

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. (Metamizol)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

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### 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 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Metamizol)
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.

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## 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

## SECTION 16. OTHER INFORMATION

Revision Date	:	30.09.2023
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 Chemi-

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cal 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 Agency, <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