

Coopers Bovilis MH Single Shot RTU / MH + IBR Formulation

Version 2.5 Revision Date: 08.12.2023 SDS Number: 10876247-00008 Date of last issue: 27.11.2023
Date of first issue: 24.10.2022

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Coopers Bovilis MH Single Shot RTU / MH + IBR Formulation
Other means of identification : Coopers Bovilis MH Single-Shot Ready-to-Use MH Vaccine for Cattle (92022)
Coopers Bovilis MH+IBR Bovine Respiratory Disease (BRD) Vaccine (64608)
Bovilis MH+IBR (A011518)

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitization : Category 1
Carcinogenicity : Category 1B

GHS label elements

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H350 May cause cancer.

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 mist or vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/
attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P362 + P364 Take off contaminated clothing and wash it before
reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Antigen	Not Assigned	>= 50 -< 70
White mineral oil (petroleum)	8042-47-5	>= 5 -< 10
Glycerine	56-81-5	>= 1 -< 5
Formaldehyde	50-00-0	>= 0.2 -< 1

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 : Flush eyes with water as a precaution.
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 : May cause an allergic skin reaction.
May cause cancer.

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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).

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 : 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.

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.
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 : 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.
Avoid breathing mist or vapors.
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 assessment
Keep container tightly closed.
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.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	VLE-PPT (Mist)	5 mg/m ³	NOM-010-STPS-2014
		TWA (Inhalable particulate)	5 mg/m ³	ACGIH

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		matter)		
Glycerine	56-81-5	VLE-PPT (Mist)	10 mg/m ³	NOM-010- STPS-2014
Formaldehyde	50-00-0	VLE-P	0.3 ppm	NOM-010- STPS-2014
		TWA	0.1 ppm	ACGIH
		STEL	0.3 ppm	ACGIH

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.
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, inorganic gas/vapor 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : 6.0 - 8.0

Melting point/freezing point : 0 °C

Initial boiling point and boiling range : 100 °C
(1000 hPa)

Flash point : No data available

Evaporation rate : No data available

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Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	2.37 kPa (20 °C)
Relative vapor density	:	No data available
Relative density	:	1
Density	:	No data available
Solubility(ies) Water solubility	:	soluble
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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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 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

Acute inhalation toxicity : Acute toxicity estimate: > 30000 ppm
Exposure time: 4 h
Test atmosphere: gas
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**White mineral oil (petroleum):**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Formaldehyde:

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg
Method: Expert judgment

Acute inhalation toxicity : Acute toxicity estimate: 100 ppm
Exposure time: 4 h
Test atmosphere: gas
Method: Expert judgment

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Acute dermal toxicity : LD50 (Rabbit): 270 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rabbit
Result : No skin irritation

Glycerine:

Species : Rabbit
Result : No skin irritation

Formaldehyde:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rabbit
Result : No eye irritation

Glycerine:

Species : Rabbit
Result : No eye irritation

Formaldehyde:

Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

White mineral oil (petroleum):

Test Type : Buehler Test

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Routes of exposure : Skin contact
 Species : Guinea pig
 Result : negative

Formaldehyde:

Test Type : Local lymph node assay (LLNA)
 Routes of exposure : Skin contact
 Species : Mouse
 Method : OECD Test Guideline 429
 Result : positive

Assessment : Probability or evidence of high skin sensitization rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
 Species: Mouse
 Application Route: Intraperitoneal injection
 Method: OECD Test Guideline 474
 Result: negative
 Remarks: Based on data from similar materials

Glycerine:

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

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

Test Type: Chromosome aberration test in vitro
 Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
 Result: negative

Formaldehyde:

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

Test Type: Chromosome aberration test in vitro
 Result: positive

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Inhalation
Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

May cause cancer.

Components:

White mineral oil (petroleum):

Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

Glycerine:

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

Formaldehyde:

Species : Rat
Application Route : inhalation (gas)
Exposure time : 28 Months
Result : positive

Carcinogenicity - Assessment : Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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Glycerine:

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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Formaldehyde:

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (gas)
Result: negative

STOT-single exposure

Not classified based on available information.

Components:**Formaldehyde:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Components:**Formaldehyde:**

Routes of exposure : inhalation (gas)
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Components:****White mineral oil (petroleum):**

Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : ≥ 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

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Glycerine:

Species	:	Rat
NOAEL	:	0.167 mg/l
LOAEL	:	0.622 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	13 Weeks

Species	:	Rat
NOAEL	:	8,000 - 10,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 y

Species	:	Rabbit
NOAEL	:	5,040 mg/kg
Application Route	:	Skin contact
Exposure time	:	45 Weeks

Formaldehyde:

Species	:	Rat
NOAEL	:	6 ppm
LOAEL	:	10 ppm
Application Route	:	inhalation (gas)
Exposure time	:	28 Days

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chronic)	:	NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d

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Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,955 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

Formaldehyde:

Toxicity to fish : LC50 : 6.7 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): 5.8 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l
plants Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox- : NOEC (Oryzias latipes (Orange-red killifish)): >= 48 mg/l
icity) Exposure time: 28 d

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): >= 6.4 mg/l
aquatic invertebrates (Chron- Exposure time: 21 d
ic toxicity) Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 34.1 mg/l
Exposure time: 120 h

Persistence and degradability

Components:

White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Glycerine:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

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Formaldehyde:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 14 d
Method: OECD Test Guideline 301C
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Glycerine:

Partition coefficient: n-
octanol/water : log Pow: -1.75

Formaldehyde:

Partition coefficient: n-
octanol/water : log Pow: 0.35
Remarks: Calculation

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste
handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

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Special precautions for user

Not applicable

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

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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT
NOM-010-STPS-2014 / VLE- : Ceiling value
P

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median

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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