

SAFETY DATA SHEET



Ivomec® F, Injectable solution (finished product)

Version 1.0 Revision Date: 10/05/2017 SDS Number: 000000049426 Date of last issue: -
Date of first issue: 10/05/2017

SECTION 1. IDENTIFICATION

Product name : Ivomec® F, Injectable solution (finished product)
Synonyms : with API: Ivermectin, Clorsulon
Ivomec® Plus, Ivomec® Super, Ivomec® C, Ivomec® D

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG
Address : Binger Str. 173
Ingelheim am Rhein 07 55216
Telephone : +498007790900
Prepared by : EHS-Services@Boehringer-Ingelheim.com
Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning
Hazard statements : H319 Causes serious eye irritation.
Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.

Response:

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

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to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : organic
Substance name : with API: Ivermectin, Clorsulon

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Propylenglycol	57-55-6	>= 50 - < 70
Glycerol Formal	5464-28-8	>= 30 - < 50
Clorsulon	60200-06-8	>= 10 - < 20
Ivermectin	70288-86-7	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.

If swallowed : Rinse mouth.
Drink plenty of water.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.

Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
Symptomatic treatment (decontamination, vital functions).

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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Product itself is non-combustible.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
The product is not flammable.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Conditions for safe storage : No special storage conditions required.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylenglycol	57-55-6	TWA	10 mg/m ³	US WEEL

Hazardous components without workplace control parameters

Components	CAS-No.
Glycerol Formal	5464-28-8
Clorsulon	60200-06-8
Ivermectin	70288-86-7

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : Use NIOSH approved respiratory protection.

Hand protection

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.43 mm
Directive : Protective gloves against chemicals and micro-organisms
Protective index : Class 6

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Colour : No data available
Odour : No data available

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Odour Threshold : No data available

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Bulk density : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : Not tested

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

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Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

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: 150 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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

Components:

Propylenglycol:

Acute oral toxicity : LD50 (Rat): = 19,400 - 36,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): = 20,800 mg/kg

Glycerol Formal:

Acute oral toxicity : LD50 Oral (Rat): 10,200 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Assessment: Toxic effects cannot be excluded

Clorsulon:

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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Assessment: Toxic effects cannot be excluded

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Ivermectin:

Acute oral toxicity : LD50 (Mouse): = 25 mg/kg
LD50 (Rat): = 50 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 (Rabbit, male and female): = 406 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Propylenglycol:

Species: Rabbit
Result: No skin irritation

Glycerol Formal:

Remarks: No data available

Clorsulon:

Remarks: No data available

Ivermectin:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Propylenglycol:

Species: Rabbit
Result: No eye irritation

Glycerol Formal:

Result: Eye irritation

Clorsulon:

Result: Eye irritation

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Ivermectin:

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.

Components:**Propylenglycol:**

Result: No alert for skin sensitization

Glycerol Formal:

Remarks: No data available

Clorsulon:

Remarks: No data available

Ivermectin:

Remarks: No data available

Germ cell mutagenicity

Not classified based on available information.

Components:**Propylenglycol:**

Genotoxicity in vitro : Test Type: Ames-test
Result: negative
Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Remarks: No mutagenic effects reported.

Glycerol Formal:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Clorsulon:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

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

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Dose: 2000
Result: positive

Test Type: Chromosome aberration test in vitro
Species: Mouse
Dose: 500
Result: positive

Ivermectin:

Genotoxicity in vitro

: Test Type: Ames-test
Test system: Salmonella typhimurium
Result: negative

Test Type: Mouse lymphoma assay
Result: negative

Test Type: Unscheduled DNA synthesis
Test system: fibroblast cell line
Result: negative

Genotoxicity in vivo

: Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:

Propylenglycol:

Remarks: Did not show carcinogenic effects in animal experiments.

Glycerol Formal:

Remarks: No data available

Clorsulon:

Remarks: No data available

Ivermectin:

Remarks: No data available

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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Reproductive toxicity

Not classified based on available information.

Components:

Glycerol Formal:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Clorsulon:

Effects on fertility : Test Type: reproductive and developmental toxicity study
Species: Rat
Application Route: Ingestion
Dose: 2,20,100 milligram per kilogram
Result: No effects on fertility and early embryonic development were detected.

Test Type: reproductive and developmental toxicity study
Species: Rat
Application Route: Ingestion
Dose: 3,30,100 milligram per kilogram
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Mouse
Application Route: Ingestion
Dose: 2,10,50 milligram per kilogram
Remarks: Showed no teratogenic and / or embryotoxic effects in animal experiments.

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Dose: 2,10,50 milligram per kilogram
Remarks: Showed no teratogenic and / or embryotoxic effects in animal experiments.

Ivermectin:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : No toxicity to reproduction
Animal testing did not show any effects on foetal development.

STOT - single exposure

Not classified based on available information.

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Components:

Glycerol Formal:

Remarks: No data available

Clorsulon:

Remarks: No data available

Ivermectin:

Remarks: No data available

STOT - repeated exposure

Not classified based on available information.

Components:

Glycerol Formal:

Remarks: No data available

Clorsulon:

Remarks: No data available

Ivermectin:

Remarks: No data available

Aspiration toxicity

Not classified based on available information.

Components:

Glycerol Formal:

No data available

Clorsulon:

No data available

Ivermectin:

No data available

Further information

Components:

Ivermectin:

Remarks: No data available

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylenglycol:

- Toxicity to fish : LC50 (Onchorhynchus mykiss): = 40,613 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > > 100 mg/l
Exposure time: 48 h
- LC50 (Daphnia magna (Water flea)): = 43,500 mg/l
Exposure time: 48 h
- Toxicity to algae : EC50 (Selenastrum capricornutum): = 24,200 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50 (Pseudomonas putida): > > 20,000 mg/l
Exposure time: 18 h

Glycerol Formal:

- Toxicity to fish : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
- Toxicity to algae : Remarks: No data available
- Toxicity to fish (Chronic toxicity) : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available
- Toxicity to microorganisms : Remarks: No data available

Ecotoxicology Assessment

- Acute aquatic toxicity : Toxic effects cannot be excluded
- Chronic aquatic toxicity : Toxic effects cannot be excluded

Clorsulon:

- Toxicity to fish : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
- Toxicity to algae : Remarks: No data available

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Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l
Exposure time: 96 h
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0053 mg/l
Exposure time: 96 h

Toxicity to algae : Remarks: No data available

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (Hyallolella azteca (Amphipod)): 0.0017 mg/l
Exposure time: 10 d

NOEC (Hyallolella azteca (Amphipod)): 0.00021 mg/l
Exposure time: 10 d

M-Factor (Chronic aquatic toxicity) : 100

Toxicity to microorganisms : Remarks: No data available

Persistence and degradability

Components:

Glycerol Formal:

Biodegradability : Result: No data available

Clorsulon:

Biodegradability : Result: No data available

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Ivermectin:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Propylenglycol:

Partition coefficient: n-octanol/water : log Pow: -0.92

Glycerol Formal:

Bioaccumulation : Remarks: No data available

Clorsulon:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Ivermectin:

Bioaccumulation : Remarks: No data available

Mobility in soil

Components:

Glycerol Formal:

Distribution among environmental compartments : Remarks: No data available

Clorsulon:

Distribution among environmental compartments : Remarks: No data available

Ivermectin:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S.

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Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

Glycerol Formal:

Additional ecological information : No data available

Clorsulon:

Additional ecological information : No data available

Ivermectin:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Ivermectin)
Class : 9
Packing group : III
Labels : Miscellaneous Dangerous Goods
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.
(Ivermectin)
Class : 9
Packing group : III

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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.

National Regulations

49 CFR

UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : no

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

Act

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Propylenglycol	57-55-6	50 %
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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

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Clorsulon	60200-06-8
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Pennsylvania Right To Know

Propylenglycol	57-55-6
Glycerol Formal	5464-28-8
Clorsulon	60200-06-8

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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

REACH	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Glycerol Formal Clorsulon
AICS	: Not in compliance with the inventory
NZIoC	: Not in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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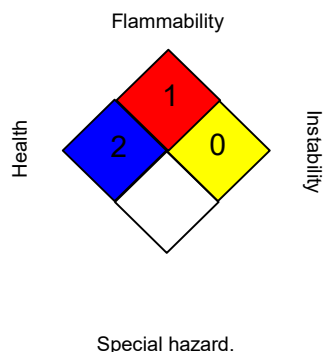
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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	/	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA
AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund

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Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

Vertical lines in the left hand margin indicate an amendment from the previous version.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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