

**KADCYLA(R) Vials 100 mg**Version  
2.2Revision Date:  
05-11-2020Date of last issue: 02-10-2020  
Date of first issue: 10-30-2015**SECTION 1. IDENTIFICATION**

Product name : KADCYLA(R) Vials 100 mg  
Product code : RO530-4020/F03  
Common name(s),  
synonym(s) of the substance : T-DM1 with excipients lyophilized

**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.  
Address : DNA Way 1  
94080 South San Francisco  
CA  
USA  
Telephone : 001-(650) 225-1000  
E-mail address : info.sds@roche.com  
Emergency telephone  
Emergency telephone : US Chemtrec phone (800)-424-9300  
number

**Recommended use of the chemical and restrictions on use**

Recommended use : Formulated pharmaceutical active substance  
Restrictions on use : For professional users only.

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Acute toxicity (Oral) : Category 3  
Acute toxicity (Inhalation) : Category 4  
Germ cell mutagenicity : Category 1B  
Reproductive toxicity : Category 1B

**GHS label elements**

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H301 Toxic if swallowed.  
H332 Harmful if inhaled.  
H340 May cause genetic defects.  
H360FD May damage fertility. May damage the unborn child.

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## 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/ fume/ gas/ mist/ vapors/ spray.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P271 Use only outdoors or in a well-ventilated area.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.  
 P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture

:

Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Trastuzumab emtansine	1018448-65-1	24.4
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	73.4
Butanedioic acid, sodium salt (1:2)	150-90-3	2.0
Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	9005-64-5	0.2

**SECTION 4. FIRST AID MEASURES**

General advice

:

Move out of dangerous area.  
 Consult a physician.  
 Show this material safety data sheet to the doctor in attendance.  
 Symptoms of poisoning may appear several hours later.  
 Do not leave the victim unattended.

If inhaled

:

Move to fresh air.

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Consult a physician after significant exposure.  
If unconscious, place in recovery position and seek medical advice.

- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.  
Harmful if inhaled.  
May cause genetic defects.  
May damage fertility. May damage the unborn child.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NOx)
- 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 fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Prevent any exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.

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Ensure adequate ventilation.

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Wash contaminated surfaces with sodium hydroxide solution, c(NaOH)=0.5 mol/L to 1 mol/L, and rinse with water

Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Prevent unauthorized access.  
Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage temperature : 2 °C to 8 °C  
Do not freeze.  
Protect against light.

Further information on storage stability : Keep in a dry place.

Packaging material : Suitable material: Vials, glass

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

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type	Control	Basis
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		(Form of exposure)	parameters / Permissible concentration	
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Trastuzumab emtansine	1018448-65-1	IOEL	0.0003 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** : No data available

### Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

Hand protection

Material : Gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees mandatory

Hygiene measures : Avoid contact with skin, eyes and clothing.  
When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and immediately after handling the product.

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Appearance	:	powder, sterile, (lyophilized)
Color	:	off-white
Odor	:	Not applicable
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Self-ignition	:	No data available
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	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available

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Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions. Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed. Dust may form explosive mixture in air.
Conditions to avoid	:	Heat. Exposure to light. Exposure to moisture.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**Toxic if swallowed.  
Harmful if inhaled.**Product:**

Acute oral toxicity	:	Acute toxicity estimate: 113.81 mg/kg Method: Expert judgment
Acute inhalation toxicity	:	Acute toxicity estimate: 1.14 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Expert judgment

**Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Acute oral toxicity	:	LD50 Oral (Rat): 29,700 mg/kg  LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: > 30 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,001 mg/kg Method: Expert judgment

**Trastuzumab emtansine:**

Acute oral toxicity	:	Acute toxicity estimate (Mouse): 27.77 mg/kg Method: Expert judgment
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Acute toxicity estimate (Mouse): 0.5 mg/kg  
Method: OECD Test Guideline 423  
The value is given in analogy to the following substances:  
Ansamitosin P3

Acute inhalation toxicity : Acute toxicity estimate (Rat): 0.277 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgment

Acute toxicity estimate (Rat): 0.005 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
The value is given in analogy to the following substances:  
Ansamitosin P3

Acute toxicity (other routes of administration) : HNSTD (Highest Non-Severely Toxic Dose) (cynomolgus monkey): 30 mg/kg  
Application Route: i.v.

HNSTD (Highest Non-Severely Toxic Dose) (Rat): 20 mg/kg  
Application Route: i.v.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Trastuzumab emtansine:**

Result : Irritating to skin.  
Remarks : Expert judgment

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

May cause genetic defects.

**Product:**

Germ cell mutagenicity - Assessment : In vivo tests showed mutagenic effects

**Components:****Trastuzumab emtansine:**

Genotoxicity in vitro : Method: OECD Test Guideline 471



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Result: negative  
The value is given in analogy to the following substances:  
DM1

Genotoxicity in vivo : Method: Mutagenicity (micronucleus test)  
Result: positive  
The value is given in analogy to the following substances:  
DM1

Germ cell mutagenicity - Assessment : In vivo tests showed mutagenic effects

**Carcinogenicity**

Not classified based on available information.

**Components:**

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

**Trastuzumab emtansine:**

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

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

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Product:**

Reproductive toxicity - Assessment : Presumed human reproductive toxicant, May damage fertility. May damage the unborn child.

**Components:**

**Trastuzumab emtansine:**

Reproductive toxicity - Assessment : Presumed human reproductive toxicant, May damage fertility. May damage the unborn child.

**STOT-single exposure**

Not classified based on available information.

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Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Trastuzumab emtansine:**Target Organs : Nervous system, Reproductive organs, Bone marrow  
Assessment : May cause damage to organs.  
Remarks : i.v.**STOT-repeated exposure**

Not classified based on available information.

**Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Trastuzumab emtansine:**Target Organs : Nervous system, Reproductive organs, Bone marrow  
Assessment : May cause damage to organs through prolonged or repeated exposure.  
Remarks : i.v.**Repeated dose toxicity****Components:****Trastuzumab emtansine:**Species : cynomolgus monkey  
: 10 mg/kg  
Application Route : i.v.  
Exposure time : 9 Weeks  
Number of exposures : 3  
Remarks : Subacute toxicity**Aspiration toxicity**

Not classified based on available information.

**Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

No data available

**Further information****Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Remarks : Health injuries are not known or expected under normal use.

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**Trastuzumab emtansine:**

 Remarks : Globular proteins are generally well biodegradable  
 The value is given in analogy to the following substances: Trastuzumab

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**SECTION 12. ECOLOGICAL INFORMATION**
**Ecotoxicity**
**Components:**
**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

 Toxicity to fish : LC50: > 100 mg/l  
 Exposure time: 96 h

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Trastuzumab emtansine:**

 Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l  
 Exposure time: 96 h  
 Test Type: semi-static test  
 Method: OECD Test Guideline 203  
 GLP: yes  
 Remarks: nominal concentration

 NOEC (Poecilia reticulata (guppy)): < 100 mg/l  
 Exposure time: 96 h  
 Test Type: semi-static test  
 Method: OECD Test Guideline 203  
 GLP: yes  
 Remarks: nominal concentration

 Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
 End point: Immobilization  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202  
 GLP: yes  
 Remarks: nominal concentration

 NOEC (Daphnia magna (Water flea)): 100 mg/l  
 End point: Immobilization  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202  
 GLP: yes  
 Remarks: nominal concentration

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- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- EyC50 (Desmodesmus subspicatus (green algae)): ca. 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- Toxicity to microorganisms : (activated sludge): 49.5 mg/l  
Exposure time: 14 d  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 301F  
GLP: yes  
Remarks: Barely inhibitory on aerobic bacterial reproduction (activated sludge)  
nominal concentration

**Persistence and degradability****Components:****Trastuzumab emtansine:**

- Biodegradability : Concentration: 1,000 mg/l  
Theoretical oxygen demand  
Result: Not readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yes

**Bioaccumulative potential****Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

- Partition coefficient: n-octanol/water : log Pow: -3.67

**Trastuzumab emtansine:**

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

**Mobility in soil**

No data available

**Other adverse effects****Product:**

- Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

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

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### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.
- Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

- UN number : UN 3249  
Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S.  
Class : 6.1  
Packing group : III  
Labels : 6.1

##### IATA-DGR

- UN/ID No. : UN 3249  
Proper shipping name : Medicine, solid, toxic, n.o.s.  
Class : 6.1  
Packing group : III  
Labels :  
Packing instruction (cargo aircraft) : 677  
Packing instruction (passenger aircraft) : 670

##### IMDG-Code

- UN number : UN 3249  
Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S.  
Class : 6.1  
Packing group : III  
Labels : 6.1  
EmS Code : F-A, S-A  
Marine pollutant : no

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

Not applicable



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### US State Regulations

#### Massachusetts Right To Know

#### Maine Chemicals of High Concern

#### Vermont Chemicals of High Concern

#### Washington Chemicals of High Concern

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Trastuzumab emtansine

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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## SECTION 16. OTHER INFORMATION

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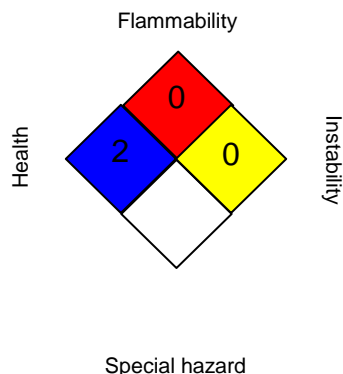
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### NFPA:



### HMIS® IV:

<b>HEALTH</b>	*	<b>2</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

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



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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 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

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1810