

KADCYLA 2% aqueous solutionVersion
1.0Revision Date:
06/19/2025Date of last issue: -
Date of first issue: 06/19/2025**SECTION 1. IDENTIFICATION**

Product name : KADCYLA 2% aqueous solution

Product code : RO530-4020Z99

Common name(s),
synonym(s) of the substance : KADCYLA aqueous solution**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on useRecommended use : Laboratory chemicals
Refer to product literature for further details.
Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.

Precautionary Statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.**Response:**P301 + P312 + P330 IF SWALLOWED: Call a POISON
CENTER/ doctor if you feel unwell. Rinse mouth.**Disposal:**

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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	2
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	6
Butanedioic acid, sodium salt (1:2)	150-90-3	0.14
Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	9005-64-5	0.02
Water	7732-18-5	91.84

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Wash off with soap and water.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Induce vomiting immediately and call a physician.
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.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

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Notes to physician : Treat symptomatically.

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 : No information available.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURESPersonal precautions, protective equipment and emergency procedures : Avoid exposure
Refer to protective measures listed in sections 7 and 8.Environmental precautions : 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

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : Do not breathe vapors/dust.

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For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Protect from heat and light

Keep container tightly closed in a dry and well-ventilated place.
 Electrical installations / working materials must comply with the technological safety standards.

Recommended storage temperature : < -4 °F / < -20 °C

 Storage temperature : to -20 °C
 Protect from heat and light

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
.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)

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are

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unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

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 : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees recommended

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Sterile liquid

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/ range : No data available

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Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	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	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
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	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

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

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Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	Exposure to light. Heat. No data available
Incompatible materials	:	No data available Not applicable
Hazardous decomposition products	:	No data available No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,389 mg/kg Method: Expert judgment
Acute inhalation toxicity	:	Acute toxicity estimate: 13.85 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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

Acute oral toxicity	:	LD50 Oral (Rat): 29,700 mg/kg
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Trastuzumab emtansine:

Acute oral toxicity	:	Acute toxicity estimate (Mouse): 27.77 mg/kg Method: Expert judgment 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

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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

Based on available data, the classification criteria are not met.

Product:

Assessment : No skin irritation
Remarks : Expert judgment

Components:**Trastuzumab emtansine:**

Result : Irritating to skin.
Remarks : Expert judgment

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Product:

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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

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

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 - : In vivo tests showed mutagenic effects
 Assessment

Carcinogenicity

Based on available data, the classification criteria are not met.

Product:

Carcinogenicity - : Weight of evidence does not support classification as a
 Assessment carcinogen

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 - : Limited evidence of a carcinogenic effect.
 Assessment

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

Not classified due to lack of data.

Product:

Reproductive toxicity - : Weight of evidence does not support classification for
 Assessment reproductive toxicity

Components:
Trastuzumab emtansine:

Reproductive toxicity - : Presumed human reproductive toxicant, May damage fertility.

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Assessment May damage the unborn child.

STOT-single exposure

Based on available data, the classification criteria are not met.

Product:

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

Remarks : Expert judgment

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

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

Based on available data, the classification criteria are not met.

Product:

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

Remarks : Expert judgment

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.

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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 due to lack of data.

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

No data available

Further information**Product:**

Remarks : No data available

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

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

Trastuzumab emtansine:Remarks : after parenteral application, rare cases of hypersensitivity,
including anaphylactic shock, can occur

The value is given in analogy to the following substances: Trastuzumab

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

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- 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
- 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

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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- : log Pow: -3.7 (68 °F / 20 °C)
octanol/water

Trastuzumab emtansine:

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

Mobility in soil

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

Additional ecological : No data available
information

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
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.
Do not re-use empty containers.

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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**49 CFR**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : Acute toxicity (any route of exposure)**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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

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.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know

Water 7732-18-5

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

Maine Chemicals of High Concern**Vermont Chemicals of High Concern****Washington Chemicals of High Concern****California Permissible Exposure Limits for Chemical Contaminants**

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

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

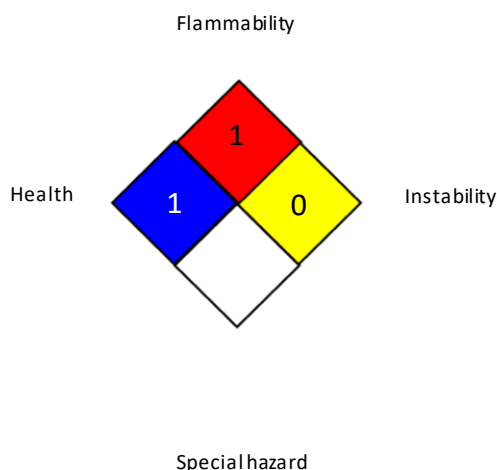
AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Trastuzumab emtansine
NZIoC	: Not in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: 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	: Product contains substance(s) not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION**Further information**

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HEALTH	/	1
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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
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

AIIC - Australian Inventory of Industrial Chemicals; 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

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

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The information provided in this 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.

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