

## KADCYLA(R) Solution

Version 1.3                      Revision Date: 02-10-2020                      Date of last issue: 04-17-2019  
Date of first issue: 06-01-2016

### SECTION 1. IDENTIFICATION

Product name                      : KADCYLA(R) Solution  
Product code                      : 00010141697  
Common name(s), syno-                      : KADCYLA aqueous solution  
nym(s) of the substance

#### 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                      : US Chemtrec phone                      (800)-424-9300  
Emergency telephone num-  
ber

#### 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 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.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Trastuzumab emtansine	1018448-65-1	2.0
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	6.0
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

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### 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 : Move to fresh air.  
 If unconscious, place in recovery position and seek medical advice.  
 If symptoms persist, call a physician.
- 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.  
 Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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### 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 (NOx)
- 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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal 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.
- 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.

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### 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.  
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 : Protected 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.

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

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

Storage temperature : to -20 °C  
Protected 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)

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.

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- Eye protection : Replace torn or punctured gloves promptly.  
: 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.

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### 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
- Boiling point/boiling range : No data available
- Flash point : does not flash
- Evaporation rate : No data available
- Flammability (solid, gas) : Does not sustain combustion.
- Flammability (liquids) : Does not sustain combustion.
- 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
- Solubility(ies)  
Water solubility : completely miscible

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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

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**SECTION 10. STABILITY AND REACTIVITY**

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

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No decomposition if stored and applied as directed.

Conditions to avoid : Exposure to light.  
Heat.

Incompatible materials : No data available

Hazardous decomposition products : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,389 mg/kg  
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

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- 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  
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**

Not classified based on available information.

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

- Genotoxicity in vitro : Method: OECD Test Guideline 471  
Result: negative  
The value is given in analogy to the following substances:

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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**

Not classified based on available information.

**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.

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

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

**Trastuzumab emtansine:**

Assessment : May cause damage to organs.



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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.

**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.

**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

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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 concentrationNOEC (Poecilia reticulata (guppy)): < 100 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: nominal concentrationToxicity 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 concentrationNOEC (Daphnia magna (Water flea)): 100 mg/l  
End point: Immobilization  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: nominal concentrationToxicity 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 concentrationEyC50 (Desmodesmus subspicatus (green algae)): ca. 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentrationToxicity to microorganisms : (activated sludge): 49.5 mg/l  
Exposure time: 14 d  
Test Type: Respiration inhibition

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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- : log Pow: -3.67  
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).

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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.  
Can be disposed as waste water, when in compliance with local regulations.

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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.

**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**

**49 CFR**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know**

**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 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.

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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

#### 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

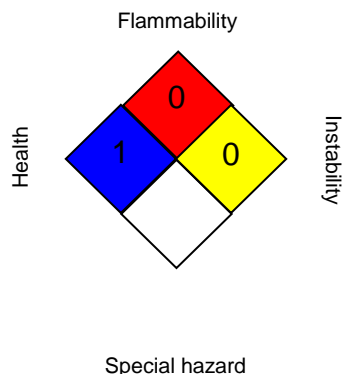
#### TSCA list

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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<b>HEALTH</b>	/	1
<b>FLAMMABILITY</b>		0
<b>PHYSICAL HAZARD</b>		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. 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; IECS - 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;

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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.

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