

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version
2.1

Revision Date:
02-10-2020

Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

SECTION 1. IDENTIFICATION

Product name : KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Product code : RO530-4020/F02

Common name(s), syno- : T-DM1 with excipients lyophilized
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

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

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

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.

KADCYLA(R) Lyophilized Powder in Vials (160 mg)
Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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.

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

- 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 (NO_x)
- 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.

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version 2.1 Revision Date: 02-10-2020 Date of last issue: 06-10-2017
 Date of first issue: 10-30-2015

- Environmental precautions : Ensure adequate ventilation.
 : 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 parame-	Basis
------------	---------	------------	-----------------	-------

KADCYLA(R) Lyophilized Powder in Vials (160 mg)
Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

		(Form of exposure)	ters / Permissible concentration	
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Trastuzumab emtansine	1018448-65-1	IOEL	0.0003 mg/m ³	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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version 2.1 Revision Date: 02-10-2020 Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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

SECTION 10. STABILITY AND REACTIVITY

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version 2.1 Revision Date: 02-10-2020 Date of last issue: 06-10-2017
 Date of first issue: 10-30-2015

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 Acute toxicity estimate (Mouse): 0.5 mg/kg
---------------------	---	---

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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.

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

Assessment : The substance or mixture is not classified as specific target

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

organ toxicant, single exposure.

Trastuzumab emtansine:

Assessment : May cause damage to organs.

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.

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

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

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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

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

KADCYLA(R) Lyophilized Powder in Vials (160 mg)Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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- : 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).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.

KADCYLA(R) Lyophilized Powder in Vials (160 mg)
Version
2.1Revision Date:
02-10-2020Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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.

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

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3249
 Proper shipping name : Medicine, solid, toxic, n.o.s.
 Class : 6.1
 Packing group : III
 Labels : Division 6.1 - Toxic substances
 ERG Code : 151
 Marine pollutant : no

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version
2.1

Revision Date:
02-10-2020

Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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)
------------	---------	---------------------

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Germ cell mutagenicity
Reproductive toxicity

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.

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.

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version
2.1

Revision Date:
02-10-2020

Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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

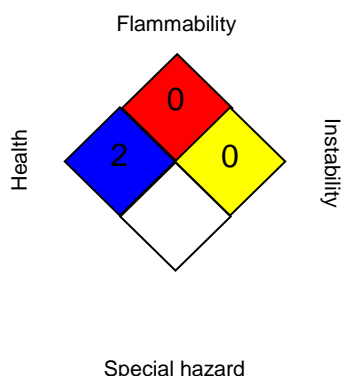
TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

NFPA:



HMIS® IV:

HEALTH	*	2
FLAMMABILITY	0	
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. 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

KADCYLA(R) Lyophilized Powder in Vials (160 mg)

Version 2.1 Revision Date: 02-10-2020 Date of last issue: 06-10-2017
Date of first issue: 10-30-2015

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 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

Revision Date : 02-10-2020

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