

**Safety Data Sheet**

# KADCYLA(R) Solution

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name	KADCYLA(R) Solution
Product code	CSE-3090
Synonyms	- T-DM1 (RO5304020) 2% aqueous solution with excipients

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use	- formulated pharmaceutical active substance (antineoplastic)
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### 1.3. Details of the supplier of the safety data sheet

Company information	Enquiries:	Local representation:
	Genentech, Inc.	
	1 DNA Way	
	South San Francisco	
	USA-CA 94080	
	United States of America	
	Phone 001-(650) 225-1000	
	E-Mail info.sds@roche.com	
	US Chemtrec phone:	
	(800)-424-9300	

### 1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300
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## SECTION 2: Hazards identification

### Classification of the substance or mixture / Label elements

#### GHS Classification

#### Health Hazards:

- 3.1 Acute toxicity (Category 4)
- H302 Harmful if swallowed.

Signalword: Warning

Label:



#### Precautionary statements:

- P312 Call a POISON CENTER or doctor/physician if you feel unwell.

### Other hazards

#### Note

- no further information available

## SECTION 3: Composition/information on ingredients

#### Characterization

antibody-drug conjugate consisting of the antibody trastuzumab (the active ingredient in Herceptin) linked to a cytotoxic agent that is a derivative of maytansine (DM1)

#### Ingredients

#### Concentration

#### GHS-Classification (pure ingredient)

ado-trastuzumab emtansine  
1018448-65-1

~ 2 %

- Combustible dust (No category), USH003
- Acute toxicity (Category 3), H311
- Acute toxicity (Category 2), H330
- Acute toxicity (Category 2), H300
- Skin corrosion/irritation (Category 2), H315
- Germ cell mutagenicity (Category 1B), H340
- Carcinogenicity (Category 2), H351
- Reproductive toxicity (Category 1B), H360FD
- Specific target organ toxicity - Single exposure (Category 2), H371

*For the full text of the H-phrases mentioned in this Section, see Section 16.*

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Eye contact

- rinse immediately with tap water for 10 minutes - open eyelids forcibly

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Skin contact                                - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation                                   - remove the casualty to fresh air and keep him/her calm  
- in the event of symptoms get medical treatment

### 4.2. Most important symptoms and effects, both acute and delayed

Note     - no information available

### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physician                        - treat symptomatically

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media           - adapt extinguishing media to surrounding fire conditions, water spray jet, dry powder, foam, carbon dioxide

Flash point (liquid)                       not applicable

### 5.2. Special hazards arising from the substance or mixture

Specific hazards                           - Does not present a fire hazard

### 5.3. Advice for firefighters

Protection of fire-fighters              - precipitate gases/vapours/mists with water spray

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions                    - avoid exposure

### 6.2. Environmental precautions

Environmental protection               - no special environmental precautions required

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up                - wash contaminated surfaces with sodium hydroxide solution, c(NaOH)=0.5 mol/l to 1 mol/l, and rinse with water

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Technical measures - avoid formation of aerosols

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below -20°C

Validity - 24 hours, 25 °C

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.0003 mg/m<sup>3</sup> \*1

### 8.2. Exposure controls

General protective and hygiene measures - instruction of employees recommended

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

\*1 referring to: ado-trastuzumab emtansine

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Color colorless

Form liquid

### 9.2. Other information

Note - no information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Note - no information available

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### 10.2. Chemical stability

Stability - do not dilute with glucose since there cause aggregation of the protein \*2

### 10.3. Possibility of hazardous reactions

Note - no information available

### 10.4. Conditions to avoid

Conditions to avoid - light  
- warming

### 10.5. Incompatible materials

Note - no information available

### 10.6. Hazardous decomposition products

Note - no information available

\*2 referring to: Herceptin Vials (2% Trastuzumab solution with excipients)

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity - HNSTD 30 mg/kg (i.v., cynomolgus monkey) \*1  
- HNSTD 20 mg/kg (i.v., rat) \*1  
- LD<sub>50</sub> 0 to 5 mg/kg (oral, mouse) \*3  
(OECD No. 423 (Acute Toxic Class Method))

Subacute toxicity - HNSTD 10 mg/kg/3w(i.v., cynomolgus monkey, 9 weeks) \*1

Sensitization - anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described \*4

Note - HNSTD = Highest Non-Severely Toxic Dose

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Potential Health Effects	<ul style="list-style-type: none"> <li>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</li> <li>- Target Organs: liver, Cardiovascular system, gastrointestinal system, Hematopoietic/blood system, Immune System, respiratory system</li> <li>- Acute Effects: May cause allergic reactions., Harmful if swallowed., May cause headache., May cause musculoskeletal effects., May cause general body weakness, fatigue and nausea.</li> <li>- Chronic Effects: May cause hepatic (liver) system effects., Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes)., May cause cardiovascular effects., Signs and symptoms may include increase or decrease in blood pressure, irregular heartbeat, chest pains and cardiac arrest., May cause blood system changes., May cause respiratory effects., Signs and symptoms may include difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest.</li> <li>- Carcinogenicity: not listed by NTP, IARC or OSHA</li> </ul>
Additional Health Information	<ul style="list-style-type: none"> <li>- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class.</li> </ul>
*1 referring to:	ado-trastuzumab emtansine
*3 referring to:	Ansamitocin P3
*4 referring to:	Trastuzumab

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none"> <li>- barely toxic for algae, growth inhibition possibly due to turbidity caused by test substance (Desmodesmus (=Scenedesmus) subspicatus) ErC<sub>50</sub> (72 h) &gt; 100 mg/l (nominal concentration) EyC<sub>50</sub> (72 h) ~ 100 mg/l (nominal concentration) (OECD No. 201) *1</li> <li>- barely toxic for planktonic crustaceans (Daphnia magna) EC<sub>50</sub> (48 h) &gt; 100 mg/l (nominal concentration) NOEC (48 h) 100 mg/l (nominal concentration) (OECD No. 202) *1</li> <li>- barely toxic for fish (guppy) LC<sub>50</sub> (96 h) &gt; 100 mg/l (nominal concentration) NOEC (96 h) &lt; 100 mg/l (nominal concentration) (OECD No. 203, semistatic) *1</li> <li>- barely inhibitory on aerobic bacterial respiration (activated sludge) concentration (14 d) 49.5 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1</li> </ul>
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### 12.2. Persistence and degradability

Ready biodegradability	<ul style="list-style-type: none"> <li>- readily biodegradable 84 %, 28 d (Manometric Respirometry Test, OECD No. 301 F) *1</li> </ul>
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### 12.3. Bioaccumulative potential

Note - no information available

### 12.4. Mobility in soil

Note - no information available

### 12.5. Results of PBT and vPvB assessment

Note - no information available

### 12.6. Other adverse effects

Note - no information available

\*1 referring to: ado-trastuzumab emtansine

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal  
- incinerate in qualified installation with flue gas scrubbing

## SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name  
non-regulated

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.  
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.  
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

Full text of H-Statements referred to under section 3

H300	Fatal if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H330	Fatal if inhaled.
H340	May cause genetic defects.
H351	Suspected of causing cancer.
H360FD	May damage fertility. May damage the unborn child.
H371	May cause damage to organs.
USH003	May form combustible dust concentrations in the air

Edition documentation - changes from previous version in sections 2, 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.