

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

#### 1.1. Product identifier

Product form : Mixtures  
Trade Name : Trastuzumab deruxtecan for Injection 100mg

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : For clinical and / or commercial

##### 1.2.2. Uses advised against

No information available.

#### 1.3. Details of the supplier of the safety data sheet

DAIICHI SANKYO CO., LTD. Process Technology Group, Supply Chain Technology & Procurement Department, Supply Chain Division  
3-5-1, Nihonbashi-honcho, Chuo-ku  
Tokyo 103-8426, Japan  
T +81-(0)3-3246-7039 - F +81-(0)3-3246-6919

#### 1.4. Emergency telephone number

Emergency number : +81-3-6225-1111 (on business days 8:45 AM to 5:30 PM JST)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification not possible

##### Adverse physicochemical, human health and environmental effects

No information available.

#### 2.2. Label elements

There is no labelling obligation for this product.

#### 2.3. Other hazards

Other hazards not contributing to the classification : No information available. A certain % of the mixture consists of ingredient of unknown acute toxicity.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Chemical name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Trastuzumab deruxtecan		17	Classification not possible	Classification not possible
Sucrose	(CAS number) 57-50-1 (EC-No.) 200-334-9		Classification not possible	Classification not possible
L-Histidine hydrochloride monohydrate	(CAS number) 5934-29-2 (EC-No.) 211-438-9		Classification not possible	Classification not possible
L-Histidine	(CAS number) 71-00-1 (EC-No.) 200-745-3		Classification not possible	Classification not possible
Polysorbate 80	(CAS number) 9005-65-6 (EC-No.) 500-019-9		Classification not possible	Classification not possible

Comments :

Full text of R- and H-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Inhalation : Remove the victim to fresh air. Seek medical advice.

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Skin contact	: Remove all contaminated clothing and wash the affected area with soap and water for 15 minutes. Consult a doctor.
Eye contact	: Gently rinse the affected eyes with clean water for at least 15 minutes. Consult a doctor.
Ingestion	: Rinse mouth thoroughly with water. Get medical advice/attention.

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

Symptoms/effects : No information available to date.

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

No information available to date.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing agents : Water spray. Carbon dioxide. Extinguishing powder. Foam. Inert gas.  
Prohibited extinguishing agents : No information available to date.

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

Specific hazard level under fire conditions : No information available.

### 5.3. Advice for firefighters

Protection during firefighting : Fire fighters should wear appropriate personal protective equipment (protective clothing, chemical safety goggles or rubber gloves).  
Other information : When exposed to high temperatures may produce hazardous decomposition products such as carbon monoxide and dioxide, smoke, nitrogen oxides (NOx).

## SECTION 6: Accidental release measures

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

General measures : Wear proper protecting equipment to prevent contact with skin and inhalation of dust. Keep non-essential and unprotected persons away from the area.

#### 6.1.1. For non-emergency personnel

Emergency procedures : Prevent further leakage if safe to do so.

#### 6.1.2. For emergency responders

Emergency procedures : Ventilate area. Stop leak if safe to do so. Keep away from open flame and source of ignition.

### 6.2. Environmental precautions

Ventilate the area after cleaning in completed. Do not allow material to be released to the environment without proper governmental permits.

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

Methods for cleaning up : Carefully sweep up and remove the contaminant. Do not wash away into sewer or waterways. Ventilate the area after the cleaning is complete.

### 6.4. Reference to other sections

For disposal see section 13. For exposure controls see section 8.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wear proper protective equipment to avoid contact with skin and eyes. Do not breathe dust.  
Handling temperature : Room temperature  
Appropriate hygiene measures : Practice good personal hygiene after handling this product, especially before eating, drinking, smoking or using the toilet.

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

Technical measures : Use in well-ventilated areas.  
Storage conditions : Store in a tightly closed amber glass vial with protection from light.  
Storage temperature : Refrigerated

### 7.3. Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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### 8.2. Exposure controls

#### Appropriate technical controls:

Refer to chapter 7. No further action is necessary.

#### Personal protective equipment:

Gloves. Protective goggles. Dust mask.

#### Hands:

Wear rubber gloves or chemical resistant gloves.

#### Eyes:

Wear protective eyeglasses or chemical safety goggles.

#### Skin and body:

Wear chemical resistant gloves and suitable protective clothing.

#### Respiratory:

With correct and proper use, and under normal conditions, breathing protection is not required. Respiratory protection required in case of: aerosol or mist generation.



## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Description	: White to yellowish white cake-like masses.
Colour	: White to yellowish white.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Ignition point	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Vapour density	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosiveness	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

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### 10.2. Chemical stability

Stable under refrigerated condition and protection from light.

### 10.3. Possibility of hazardous reactions

No information available to date.

### 10.4. Conditions to avoid

Keep away from heat and direct sunlight.

### 10.5. Incompatible materials

No information available to date.

### 10.6. Hazardous decomposition products

No information available to date.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Classification not possible

#### L-Histidine hydrochloride monohydrate (5934-29-2)

Additional information	LD50 intraperitoneal mouse > 1677 mg/kg
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#### L-Histidine (71-00-1)

LD50 oral rat	≥ 15 g/kg
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#### Sucrose (57-50-1)

LD50 oral rat	29700 mg/kg (RTECS)
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#### Polysorbate 80 (9005-65-6)

LD50 oral rat	> 38000 mg/kg
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Skin corrosion/irritation : Classification not possible

Serious eye damage/irritation : Classification not possible

Respiratory or skin sensitisation : Classification not possible

Germ cell mutagenicity : Classification not possible

Carcinogenicity : Classification not possible

Reproductive toxicity : Classification not possible

STOT-single exposure : Classification not possible

STOT-repeated exposure : Classification not possible

Aspiration hazard : Classification not possible

Other information : IARC, NTP, and OSHA do not list this product or its ingredients as carcinogens.  
This product is Cytotoxic agent.

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Polysorbate 80 (9005-65-6)

LC50 fish 1	≈ 216 mg/l (rainbow trout)
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### 12.2. Persistence and degradability

#### Polysorbate 80 (9005-65-6)

Biodegradation	97.2 % 5days; 100% 19days (OECD static test method)
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### 12.3. Bioaccumulative potential

#### L-Histidine (71-00-1)

Log Pow	-3.32
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#### Sucrose (57-50-1)

Log Pow	-3.7 (experimental)
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### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

No information available.

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### 12.6. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.  
Residual waste : Dispose of waste in accordance with federal, state and local laws.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : Not applicable  
UN-No. (IMDG) : Not applicable  
UN-No. (IATA) : Not applicable  
UN-No. (ADN) : Not applicable  
UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable  
Proper Shipping Name (IMDG) : Not applicable  
Proper Shipping Name (IATA) : Not applicable  
Proper Shipping Name (ADN) : Not applicable  
Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) : Not applicable

#### IMDG

Transport hazard class(es) (IMDG) : Not applicable

#### IATA

Transport hazard class(es) (IATA) : Not applicable

#### ADN

Transport hazard class(es) (ADN) : Not applicable

#### RID

Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable  
Packing group (IMDG) : Not applicable  
Packing group (IATA) : Not applicable  
Packing group (ADN) : Not applicable  
Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No  
Marine pollutant : No  
Other information : No supplementary information available

### 14.6. Special precautions for user

#### - Overland transport

Not applicable

#### - Transport by sea

Not applicable

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### - Air transport

Not applicable

### - Inland waterway transport

Not applicable

### - Rail transport

Not applicable

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

##### Germany

AwSV Annex reference : Water hazard class (WGK) nwg, Non-hazardous to water (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

##### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Exemption clause : The information in this document is based on the present state of our knowledge and may be revised with new findings. Precautions in this document are only applicable to the product under normal use. For particular use, appropriate safety measures should be taken. This document only presents information and does not represent any guarantee.

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*