

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	17.07.2024	28658	Date of first issue: 17.07.2024

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

### 1.1 Product identifier

#### ENHERTU

Details of the supplier of the  
safety data sheet

: ASTRAZENECA  
1 Francis Crick Avenue  
Cambridge Biomedical Campus  
Cambridge  
CB2 0AA  
UNITED KINGDOM  
+ 44 20 3749 5000  
SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone  
+44 (0) 1235 239 670

#### Alternative Names

Trastuzumab deruxtecan for injection 100mg

REACH No. :  
CAS No. : Not applicable  
EC No. : Not applicable

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

Use of the Sub-  
stance/Mixture : Antibody Drug Conjugate (ADC) Treatment of breast  
cancer, non-small cell lung cancer (NSCLC) or gastric or gas-  
troesophageal junction adenocarcinoma.

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)**

Not a hazardous substance or mixture.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI  
2019/720, and UK SI 2020/1567)**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) re-  
quired

#### Additional Labelling

EUH210 Safety data sheet available on request.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumula-  
tive and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or  
higher.

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May form explosible dust-air mixture if dispersed.  
See Section 11.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Trastuzumab deruxtecan	1826843-81-5 -		17.35
Substances with a workplace exposure limit :			
Sucrose	57-50-1 200-334-9 -		78.12

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- |                         |   |
|-------------------------|---|
| If inhaled              | : Remove patient from exposure, keep warm and at rest.<br>Obtain immediate medical attention.   |
| In case of skin contact | : Remove contaminated clothing.<br>Wash skin with water.<br>Obtain medical attention if ill effects occur.  |
| In case of eye contact  | : Irrigate with eyewash solution or clean water, holding the eye-lids apart, for at least 10 minutes.<br>Obtain medical attention if ill effects remain.  |
| If swallowed            | : Provided the patient is conscious, wash out mouth with water and give 200-300 ml of water to drink.<br>Do NOT induce vomiting as a First-Aid measure.<br>Obtain medical attention if ill effects occur. |

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

- |          |                              |
|----------|------------------------------|
| Symptoms | : Refer to sections 2 and 11 |
|----------|------------------------------|

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

- |           |   |
|-----------|---|
| Treatment | : Symptomatic treatment and supportive therapy as indicated.<br>Emergency medical treatment advice varies within different countries.<br>For further information consult the Local National Poisons Information Services. |
|-----------|---|

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.

Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

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

Specific hazards during fire-fighting : If involved in a fire, it may burn and emit noxious and toxic fumes.

### 5.3 Advice for firefighters

Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

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## SECTION 6: Accidental release measures

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

Personal precautions : Ensure suitable personal protection during removal of spillages.  
Avoid dispersal of dust in the air.

### 6.2 Environmental precautions

Environmental precautions : Prevent entry into drains, sewers or watercourses.

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

Methods for cleaning up : Clear up spillages.  
Transfer to a container for disposal.  
Wash the spillage area clean with water and detergent.

### 6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : Avoid contact with skin and eyes.  
Avoid breathing dust.  
Minimize dust generation and accumulation.  
The material may form explosible dust-air mixture if dispersed.  
Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.  
See Section 8.

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

Requirements for storage : Store in a tightly closed amber glass vial with protection from

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areas and containers light. Keep refrigerated. Do not freeze.

Recommended storage temperature : 2 - 8 °C

## 7.3 Specific end use(s)

Specific use(s) : Not applicable, refer to Section 1

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	GB EH40
		STEL	20 mg/m3	GB EH40
Trastuzumab deruxtecan	1826843-81-5	TWA	0.23 mg/m3	COM

### 8.2 Exposure controls

#### Engineering measures

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

#### Personal protective equipment

- Eye/face protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
- Skin and body protection : Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.
- Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.
- Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	lyophilised powder
Colour	:	white to yellowish-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

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## 9.2 Other information

Molecular weight : No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No known reactivity hazard under normal conditions.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : None known.

### 10.4 Conditions to avoid

Conditions to avoid : No conditions producing hazardous situations known.

### 10.5 Incompatible materials

Materials to avoid : None known.

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### 11.1.1 Acute toxicity

Not classified due to lack of data.

#### Product:

Acute oral toxicity : Remarks: No information available.

Acute inhalation toxicity : Remarks: No information available.

Acute dermal toxicity : Remarks: No information available.

#### Components:

#### **Trastuzumab deruxtecan:**

Acute oral toxicity : Remarks: No information available.

Acute inhalation toxicity : Remarks: No information available.

Acute dermal toxicity : Remarks: No information available.

#### 11.1.2 Skin corrosion/irritation

Not classified due to lack of data.

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## **Product:**

Remarks : Signs of local (injection site) effects were reported from studies on animals receiving single and repeated i.v. injections.

## **Components:**

### **Trastuzumab deruxtecan:**

Remarks : No information available.

### **11.1.3 Serious eye damage/eye irritation**

Not classified due to lack of data.

## **Product:**

Remarks : No information available.

## **Components:**

### **Trastuzumab deruxtecan:**

Remarks : No information available.

### **11.1.4 Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

## **Product:**

Remarks : No information available.

## **Components:**

### **Trastuzumab deruxtecan:**

Remarks : No information available.

### **11.1.5 Germ cell mutagenicity**

Not classified due to lack of data.

## **Product:**

Germ cell mutagenicity- Assessment : Not expected to be genotoxic.

## **Components:**

### **Trastuzumab deruxtecan:**

Germ cell mutagenicity- Assessment : Evidence of clastogenicity based on in vitro and in vivo tests on the topoisomerase inhibitor.

### **11.1.6 Carcinogenicity**

Not classified due to lack of data.

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## **Product:**

Carcinogenicity - Assessment : No information available.

## **Components:**

### **Trastuzumab deruxtecan:**

Carcinogenicity - Assessment : No information available.

### **11.1.7 Reproductive toxicity**

Not classified due to lack of data.

## **Product:**

Reproductive toxicity - Assessment : Not expected to be toxic to reproduction.

## **Components:**

### **Trastuzumab deruxtecan:**

Reproductive toxicity - Assessment : General toxicity studies on animals on the topoisomerase inhibitor suggest the potential for teratogenicity and embryotoxicity.

### **11.1.8 STOT - single exposure**

Not classified due to lack of data.

## **Product:**

Remarks : No information available.

## **Components:**

### **Trastuzumab deruxtecan:**

Remarks : No information available.

### **11.1.9 STOT - repeated exposure**

Not classified due to lack of data.

## **Components:**

### **Trastuzumab deruxtecan:**

Remarks : Intravenous studies on animals have shown adverse effects in the intestine, bone marrow, skin, testes, teeth and kidneys.

### **11.1.10 Aspiration toxicity**

Not classified due to lack of data.

## **Product:**

No information available.

## **Components:**

### **Trastuzumab deruxtecan:**

No information available.



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## Further information

### Product:

Remarks : This health hazard assessment is based on a consideration of the composition of this product.

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Product:

Toxicity to fish : Remarks: No information available.

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : No data available  
Remarks: No environmental data is available for the product or trastuzumab deruxtecan. The toxic payload may have some aquatic toxicity, but it would be only 0.4% of the product.

### 12.2 Persistence and degradability

#### Product:

Biodegradability : Remarks: Expected to be biodegradable

### 12.3 Bioaccumulative potential

#### Product:

Bioaccumulation : Remarks: Unlikely to be bioaccumulative.

### 12.4 Mobility in soil

#### Product:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product	:	Disposal should be in accordance with local, state or national legislation.
Contaminated packaging	:	Empty container will retain residue. Observe all hazard precautions.

## SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable

#### Other regulations:

In order to comply with legal duties it is necessary to consult local and national legislation.

#### The components of this product are reported in the following inventories:

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not

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on the Canadian DSL nor NDSL.

Trastuzumab deruxtecan  
L-Histidine hydrochloride monohydrate

ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

## 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture.

## SECTION 16: Other information

### Full text of other abbreviations

GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CHINV - China Inventory; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold

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Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TWA – Long-term exposure limit 8h time-weighted average; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative.

## Further information

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.

GB / EN