Version: 2.0

SAFETY DATA SHEET

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

1.1. Product identifier

Product name: Datopotamab Deruxtecan for Injection 100 mg

Product code: DS-1062a

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

Relevant identified uses: Medicinal products

Use for research and / or commercial

Uses advised against: No information

1.3. Details of the supplier of the safety data sheet

Name of manufacturer in Japan: DAIICHI SANKYO CO., LTD.

Department in Charge Technology Business Management Department

Address 1-12-1, Shinomiya, Hiratsuka, Kanagawa 254-0014, Japan

Telephone number +81-(0)463-31-6953 **Fax number** +81-(0)463-31-6950

e-mail address contact sds jp@daiichisankyo.com

1.4. Emergency telephone number +81-(0)3-6225-1111

(on business days 9:00 AM to 5:00 PM JST)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008:

Muta.2:H341 Repr.1B:H360

2.2. Label elements

Hazard pictograms







Datopotamab Deruxtecan for Injection 100 mg Date of issue: 7th November 2019 Date of revision: 2nd December 2024

Version: 2.0

Signal word Danger

Hazard Statements H341: Suspected of causing genetic defects. H360: May damage fertility or the unborn child.

Precautionary Statements

[Prevention] P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been

read and understood.

P280: Wear protective gloves/protective clothing/eye

protection/face protection/hearing protection.

[Emergency response] P308+P313: IF exposed or concerned: Get medical

advice/attention.

[Storage] P405: Store locked up.

[Disposal] P501: Dispose of contents/ container in accordance with

related laws and local/regional regulations.

Supplemental information Not applicable

2.3. Other hazards

The product does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances Not applicable

3.2. Mixtures

Product Name: Datopotamab Deruxtecan for Injection 100 mg

Information on ingredients:

Chemical name	CAS registry number	EC No.	Index No.	REACH Registrat ion No.*	Concentrat ion (wt %)	Classification**	Specific Concentration limits/ M-factor/ Acute Toxicity Estimate
Datopotamab Deruxtecan	2238831-6 0-0	-	-	-	100	Muta. 2:H341 (Deruxtecan as a component) Repr.1B:H360 (Deruxtecan as a component)	-
Sucrose	57-50-1	200-334-9	-	-	100	-	-
L-Histidine hydrochloride monohydrate	5934-29-2	611-821-4	-	-		-	-
L-Histidine	71-00-1	200-745-3	-	-]	-	-
Polysorbate 80	9005-65-6	500-019-9	-	-		-	-

^{*} Registration numbers of ingredients which shall be in compliance with Regulation (EC) No 1907/2006 will be filled in later.

^{**} Full texts of relevant hazard statements and risk phrases can be seen in SECTION 16 of this SDS.

Version: 2.0



SECTION 4: First aid measures

4.1. Description of first aid measures

GENERAL ADVICE If you feel unwell, call doctor/physician.

IF INHALED Remove the victim to fresh air. Seek medical advice.

IF ON SKIN Remove all contaminated clothing and wash the affected area

with soap and water for 15 minutes. Consult a doctor.

IF IN EYES Gently rinse the affected eyes with clean water for at least 15

minutes. Consult a doctor.

IF SWALLOWED Rinse mouth thoroughly with water. Get medical

advice/attention.

Self-Protection of the First Aider Wear appropriate eyes and skin protective equipment.

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

Suspected of causing genetic defects.

May damage fertility or the unborn child.

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

No information

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Use water spray, carbon dioxide, extinguishing powder, foam, inert gas.

Unsuitable extinguishing media

No information

5.2. Special hazards arising from the substance or mixture

When exposed to high temperatures may produce hazardous decomposition products such as carbon monoxide and dioxide, smoke, nitrogen oxides (NOx).

5.3. Advice for firefighters

Fire fighters should wear appropriate personal protective equipment (protective clothing, chemical safety goggles or rubber gloves).

Version: 2.0

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Keep non-essential and unprotected persons away from the area.

For emergency responders:

Wear proper protecting equipment to prevent contact with skin and inhalation of dust.

Ventilate area. Stop leak if safe to do so.

Keep away from open flame and source of ignition.

Prevent further leakage if safe to do so.

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

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

Refer to "SECTION 8: Exposure controls/personal protection" and "SECTION 13: Disposal considerations" as appropriate.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

Install appropriate equipment and wear suitable protective apparatus described in "SECTION 8:

Exposure controls/ personal protection".

Wear proper protective equipment to avoid contact with skin and eyes. Do not breathe dust.

Handling temperature: Room temperature

Use in well-ventilated areas.

Avoid heat and direct sunlight.

Advice on general occupational hygiene:

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:

Install appropriate equipment and wear suitable protective apparatus described in "SECTION 8:

Exposure controls/ personal protection".

Use in well-ventilated areas.

Version: 2.0

Incompatible materials:

Oxidizing agents, reducing agents

Conditions for safe storage:

Store in a tight container with protection from light.

Avoid heat and direct sunlight.

Storage temperature: 5 °C (storage in a refrigerator)

Packing material:

Use a sealed container without damage or leakage.

7.3. Specific end use(s)

Medicinal products

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Acceptable concentration (exposure limit, biological exposure index)

EU BOEL Not listed

Long-term exposure limit values

(8 hours)

EU BOEL Not listed

Short-term exposure limit values

(15 minutes)

EU BLV Not listed
EU BGV Not listed
EU IOELV Not listed

Long-term exposure limit values

(8 hours)

EU IOELV Not listed

Short-term exposure limit values

(15 minutes)

ACGIH TLV-TWA (2024) Listed (Sucrose)

ACGIH TLV-STEL (2024) Not listed

8.2. Exposure controls

Appropriate engineering controls:

Refer to SECTION 7. No further action is necessary.

Personal protective equipment:

Respiratory protection With correct and proper use, and under normal conditions,



Datopotamab Deruxtecan for Injection 100 mg

Date of issue: 7th November 2019 Date of revision: 2nd December 2024

Version: 2.0

breathing protection is not required. Respiratory protection

required in case of: aerosol or mist generation.

Hand protection Wear rubber gloves or chemical resistant gloves.

Eye protection Wear protective eyeglasses or chemical safety goggles.
Skin and body protection Wear chemical resistant gloves and suitable protective

clothing.

Environmental exposure controls

Prevent product from entering drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid (cake-like masses)
Colour White to yellowish white

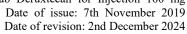
Odour No information
Melting point/freezing point No information
Boiling point or initial boiling point No information

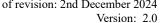
and boiling range

Flammability No information Lower and upper explosion limit Not applicable Flash point Not applicable Auto-ignition temperature Not applicable Decomposition temperature No information Not applicable pН Not applicable Kinematic viscosity Soluble in water Solubility Partition coefficient n-octanol/water No information

(log value)

Vapour pressure No information
Density and/or relative density No information
Relative vapour density Not applicable
Particle characteristics No information







9.2. Other information

9.2.1. Information with regard to physical hazard classes

No information **Explosives** Not applicable Flammable gases Not applicable Aerosols Not applicable Oxidising gases Not applicable Gases under pressure Not applicable Flammable liquids No information Flammable solids No information Self-reactive substances and mixtures Not applicable Pyrophoric liquids No information Pyrophoric solids No information Self-heating substances and mixtures No information Substances and mixtures, which emit flammable gases in contact with water

Not applicable Oxidizing liquids No information Oxidizing solids No information Organic peroxides No information Corrosive to metals No information Desensitised explosives

9.2.2 Other safety characteristics

No information Mechanical sensitivity No information Self-accelerating polymerisation

temperature

No information Formation of explosible dust/air

mixtures

No information Acid/alkaline reserve No information Evaporation rate No information Miscibility No information Conductivity No information Corrosiveness No information Gas group No information Redox potential No information Radical formation potential No information Photocatalytic properties

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

Version: 2.0



10.2. Chemical stability

Stable under refrigerated condition and protection from light.

10.3. Possibility of hazardous reactions

No information

10.4. Conditions to avoid

Avoid heat and direct sunlight.

10.5. Incompatible materials

Oxidizing agents, reducing agents

10.6. Hazardous decomposition products

No information

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on product:

Classification not possible Acute toxicity:

No information

Classification not possible Skin corrosion/irritation:

No information

Classification not possible Serious eye damage/irritation:

No information

Classification not possible Respiratory sensitization:

No information

Classification not possible Skin sensitization:

No information

Category 2 Germ cell mutagenicity:

Deruxtecan as a component

The topoisomerase inhibitor component of the drug

(MAAA-1181a) was not mutagenic in an in vitro bacterial reverse mutation assay and clastogenic in both an in vitro Chinese hamster lung chromosome aberration assay and an in

vivo rat bone marrow micronucleus assay.

Classification not possible Carcinogenicity:

No information

Category 1B Reproductive toxicity:

Datopotamab as a component

No information

Deruxtecan as a component

Deruxtecan is toxic to rapidly dividing cells

(lymphatic/haematopoietic organs, intestine, or testes) and genotoxic, suggesting the potential for embryotoxicity and



Datopotamab Deruxtecan for Injection 100 mg

Date of issue: 7th November 2019 Date of revision: 2nd December 2024

Version: 2.0

teratogenicity.

STOT-single exposure: Classification not possible

No information

STOT-repeated exposure: Classification not possible

Supporting information:

Animal data:

Datopotamab Deruxtecan

NOAEL (monkey), intravenous: <10 mg/kg (3 months) Histopathological changes in the lung, gastrointestinal tract, kidney, liver, skin, cornea, thymus, and hip joint cartilage. These effects were observed following intravenous injection and therefore cannot be directly applied for the CLP

classification.

Deruxtecan as a component

NOAEL (monkey), intravenous: <1 mg/kg (4 weeks) Histopathological changes in heart, bone marrow, thymus, spleen, lymph nodes, Peyer's patches, liver, gastrointestinal

tract, and cornea.

These effects were observed following intravenous injection

and therefore cannot be directly applied for the CLP

classification.

Aspiration hazard: Classification not possible

No information

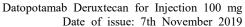
11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

11.2.2. Other information

No information





Date of revision: 2nd December 2019

Version: 2.0

SECTION 12: Ecological information

12.1. Toxicity:

Information on product:

Acute (short-term) toxicity: Classification not possible

No information

Chronic (long-term) toxicity: Classification not possible

No information

12.2. Persistence and degradability:

Information on product:

No information

12.3. Bioaccumulative potential:

Information on product:

No information

12.4. Mobility in soil:

Information on product:

No information

12.5. Results of PBT and vPvB assessment:

The product does not meet the PBT and vPvB criteria.

12.6. Endocrine disrupting properties:

This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

12.7. Other adverse effects:

No information

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste in accordance with federal, state and local laws.

When disposing, consult to a certificated waste trader or local offices if they deal with the waste.

Used container should be recycled after cleaning or dispose of in compliance with related laws and local regulations.

Contents should be removed completely when dispose of empty containers.

SECTION 14: Transport information

14.1. UN number or ID number	Not applicable
14.2. UN proper shipping name	Not applicable

O Daiichi-Sankyo

Date of issue: 7th November 2019 Date of revision: 2nd December 2024

Version: 2.0

14.3. Transport hazard class(es)Not applicable14.4. Packing groupNot applicable14.5. Environmental hazardsNot applicable

14.6. Special precautions for user

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU regulations:

The product and its ingredients are not regulated by specific provisions related to protection of human health or the environment at EU level, e.g. not considered as SVHCs or POPs.

National regulations:

Water hazard class 3 (AwSV, German Regulation) (Self-assessment): highly hazardous to water

15.2. Chemical safety assessment

Not conducted

SECTION 16: Other information

Key literature references and sources for data:

Information of DAIICHI SANKYO CO., LTD.

ACGIH, American Conference of Governmental Industrial Hygienists (2024) TLVs and BEIs.

Relevant hazard statements of which do not appear elsewhere in this SDS

Not applicable

Abbreviations

PBT: Persistent, Bioaccumulative and Toxic substance

POPs: Persistent Organic Pollutants STOT: Specific Target Organ Toxicity SVHC: Substances of Very High Concern

vPvB: Very Persistent and Very Bioaccumulative

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Muta.2	H341	On basis of test data
Repr.1B	H360	On basis of test data

[Disclaimer]

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It



Datopotamab Deruxtecan for Injection 100 mg

Date of issue: 7th November 2019 Date of revision: 2nd December 2024

Version: 2.0

is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations.