

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

1.1. Product identifier

Product form : Mixture
Trade name : Quizartinib tablets
Product No. : AC220·2HCl

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

1.2.1. Relevant identified uses

Main use category : Pharmaceuticals
Use of the substance/mixture : Use for research 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. Technology Business Management Department
1-12-1, Shinomiya, Hiratsuka, Kanagawa 254-0014, Japan
T +81-(0)463-31-6953 - F +81-(0)463-31-6950
contact_sds_JP@daiichisankyo.com

1.4. Emergency telephone number

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

Specific target organ toxicity – Repeated exposure, Category 2 H373

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

Adverse physicochemical, human health and environmental effects

No information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

CLP Signal word : Warning
Contains : Quizartinib Dihydrochloride
Hazard statements (CLP) : H373 - May cause damage to organs (bone marrow, lymphoid system) through prolonged or repeated exposure.
Precautionary statements (CLP) : P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P314 - Get medical advice/attention if you feel unwell.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Quizartinib Dihydrochloride	CAS number: 1132827-21-4	8.1	STOT RE 1, H372
Hydroxypropyl- β -cyclodextrin	CAS number: 128446-35-5	-	Classification not possible

Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

Chemical name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Microcrystalline Cellulose	CAS number: 9004-34-6 EC-No.: 232-674-9	-	Classification not possible
Magnesium stearate	CAS number: 557-04-0 EC-No.: 209-150-3	-	Classification not possible
Hypromellose	CAS number: 9004-65-3	-	Classification not possible
Talc	CAS number: 14807-96-6 EC-No.: 238-877-9	-	Classification not possible
Triacetin	CAS number: 102-76-1 EC-No.: 203-051-9	-	Classification not possible
Titanium dioxide	CAS number: 13463-67-7 EC-No.: 236-675-5	-	Classification not possible
Yellow iron oxide	CAS number: 51724-00-1 EC-No.: 257-098-5	-	Classification not possible

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Evacuate danger area.
Inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
Skin contact	: Take off contaminated clothing. Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
Eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	: Rinse mouth. Get medical advice/attention.

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

Symptoms/effects	: No information available to date
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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. Foam. Inert gas. Extinguishing powder.
Prohibited extinguishing agents	: No information available to date

5.2. Special hazards arising from the substance or mixture

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), sulphur oxides (SOx), hydrogen chloride.

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 vapour. Keep non-essential and unprotected persons away from the area.
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6.1.1. For non-emergency personnel

Emergency procedures	: Prevent further leakage if safe to do so.
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6.1.2. For emergency responders

Emergency procedures	: Stop leak if safe to do so. Ventilate area.
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Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

6.2. Environmental precautions

Do not allow to enter drains or water courses. Ensure waste is collected and contained. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Sweep or shovel spills into appropriate container for disposal.
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	: Do not breathe the dust. Wear proper protective equipment to avoid contact with skin and eyes.
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 only in well-ventilated areas.
Storage conditions	: Store in a light-resistant tight container. Protect from moisture.
Storage temperature	: Room temperature

7.3. Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No information available

8.1.2. Recommended monitoring procedures

No information available

8.1.3. Air contaminants formed

No information available

8.1.4. DNEL and PNEC

No information available

8.1.5. Control banding

No information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate technical controls:

Refer to chapter 7.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Safety glasses. Protective goggles. Dust mask.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eyes:

Wear protective eyeglasses or chemical safety goggles.

8.2.2.2. Skin protection

Skin and body:

Wear chemical resistant gloves and suitable protective clothing.

Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

Hands:

Wear rubber gloves or chemical resistant gloves.

8.2.2.3. Respiratory protection

Respiratory:

Wear an approved dust respirator.

8.2.2.4. Thermal hazards

No information available

8.2.3. Environmental exposure controls

No information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Description	: Tablet
Colour	: White (20mg tablet) Yellow (30mg tablet)
Odour	: Odourless
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	: No data available
Partition coefficient n-octanol/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 information available to date

10.2. Chemical stability

Stable at room temperature for at least 48 months

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 (oral) : Classification not possible

Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

Acute toxicity (dermal) : Classification not possible
Acute toxicity (inhalation) : Classification not possible

Hydroxypropyl-β-cyclodextrin (128446-35-5)	
LD50 oral rat	> 2243 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)
LC50 Inhalation - Rat	> 2.95 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)

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

Quizartinib Dihydrochloride (1132827-21-4)	
Germ cell mutagenicity	Positive in Ames test, but negative in mammalian cell gene mutation test, in vitro chromosome aberration test, in vivo micronucleus test and transgenic rodent mutation test.

Carcinogenicity : Classification not possible
Reproductive toxicity : Classification not possible

Quizartinib Dihydrochloride (1132827-21-4)	
NOAEL (teratogenicity in rats)	2 mg/kg/day

STOT-single exposure : Classification not possible
STOT-repeated exposure : Category 2

Quizartinib Dihydrochloride (1132827-21-4)	
Category 1	NOAEL (oral, repeated dose studies) in the rat (4W –13W; < 5 mg/kg/day – 3 mg/kg/day), dog (4W – 13W; 10/5 mg/kg/day – 5 mg/kg/day) and monkey (4W –13W; 10 mg/kg/day – 3 mg/kg/day). The principal target organs affected by Quizartinib dihydrochloride were the bone marrow and lymphoid organs, and toxicological findings were observed in the kidney, liver, ovaries, vagina, and testes..

Hydroxypropyl-β-cyclodextrin (128446-35-5)	
LOAEL (inhalation, rat, dust/mist/fume)	0.1 mg/l air Animal: rat, Animal sex: male, Guideline: OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study)
NOAEL (oral, rat, 90 days)	≥ 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)

Aspiration hazard : Classification not possible

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Classification not possible
Hazardous to the aquatic environment, long-term (chronic) : Classification not possible

Hydroxypropyl-β-cyclodextrin (128446-35-5)	
LC50 - Fish [1]	> 1131 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 72h - Algae [1]	> 1182 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
EC50 96h - Algae [1]	> 1153 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
LOEC (chronic)	251 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	127 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	100 mg/l Test organisms (species): Cyprinus carpio Duration: '28 d'

Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Quizartinib Dihydrochloride (1132827-21-4)	
Partition coefficient n-octanol/water (Log Pow)	2.33

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: 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 / IMDG / IATA / ADN / RID

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
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IMDG

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

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

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

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

Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

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

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

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.

Full text of H- and EUH-statements:

H372	Causes damage to organs through prolonged or repeated exposure.
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Quizartinib tablets

Safety Data Sheet

according to Regulation (EC) No.878/2020

Full text of H- and EUH-statements:	
H373	May cause damage to organs through prolonged or repeated exposure.
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Safety Data Sheet (SDS), EU_DS

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.