

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

1.1. Product identifier

Product form : Mixtures
 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 : Professional use
 Use of the substance/mixture : Use for reserch 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. 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

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

No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : No information available.

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		STOT RE 1, H372
Hydroxypropyl-β-cyclodextrin	(CAS number) 128446-35-5		Classification not possible
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) 51274-00-1 (EC-No.) 257-098-5		Classification not possible

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

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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.
- Skin contact : Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.
- Eye contact : 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 out 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), sulphur oxides (SOx), hydrogen chloride.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Stop leak if safe to do so. Avoid contact with skin and eyes.

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

6.2. Environmental precautions

Ensure waste is collected and contained. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Clean contaminated surfaces with an excess of water.

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. Do not subject to grinding, shock, friction.
- Handling temperature : Room temperature
- Appropriate hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a light-resistant tight container.
- Storage temperature : Stable at room temperature

7.3. Specific end use(s)

No information available.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No information available.

8.2. Exposure controls

- Appropriate technical controls : Refer to chapter 7. No further action is necessary.
Personal protective equipment : Gloves. Safety glasses. Protective goggles. Dust formation: dust mask.



- Hands : Protective gloves.
Eyes : Framed glasses.
Skin and body : Wear suitable protective clothing.
Respiratory : Wear appropriate mask.

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 : Not applicable
Freezing point : Not applicable
Boiling point : Not applicable
Flash point : No data available
Ignition point : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : No data available
Vapour pressure : Not applicable
Vapour pressure at 50 °C : Not applicable
Critical pressure : Not applicable
Vapour density : Not applicable
Relative density : Not applicable
Solubility : No data available
Log Pow : No data available
Log Kow : No data available
Viscosity, kinematic : Not applicable
Viscosity, dynamic : Not applicable
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.

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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

Hydroxypropyl- β -cyclodextrin (128446-35-5)	
LD50 oral rat	> 2243 mg/kg
LD50 dermal rat	> 2000 mg/kg

Microcrystalline Cellulose (9004-34-6)	
LD50 oral rat	> 5000 mg/kg (RTECS)
LD50 dermal rabbit	> 2000 mg/kg (RTECS)

Magnesium stearate (557-04-0)	
LD50 oral rat	> 2000 mg/kg

Triacetin (102-76-1)	
LD50 oral rat	3000 mg/kg (IUCLID)
LD50 dermal rabbit	> 5000 mg/kg (IUCLID)

Titanium dioxide (13463-67-7)	
LD50 oral rat	> 10000 mg/kg
LD50 dermal rabbit	> 10000 mg/kg

Yellow iron oxide (51274-00-1)	
LD50 oral rat	> 5000 mg/kg (Iron oxide hydrate)

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 - Description : Classification not possible

Reproductive toxicity : Classification not possible

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

Reproductive toxicity : Classification not possible

STOT-single exposure : Classification not possible

STOT-repeated exposure : Classification not possible

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)	
NOAEL (oral,rat,90 days)	4400 mg/kg bodyweight/day

Aspiration hazard : Classification not possible

SECTION 12: Ecological information

12.1. Toxicity

Hydroxypropyl- β -cyclodextrin (128446-35-5)	
LC50 Zebra fish (Danio rerio)	> 1131 mg/l
EC50 Daphnia magna	> 1084 mg/l
NOEC Carp (Cyprinus carpio) (28 d)	100 mg/l

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Hydroxypropyl-β-cyclodextrin (128446-35-5)	
NOEC Daphnia magna (21 d)	127 mg/l
Talc (14807-96-6)	
LC50 Zebra fish (Danio rerio)	> 100 mg/l (24h, (IUCLID))
Triacetin (102-76-1)	
EC50 Daphnia magna (Water flea)	380 mg/l
LC50 Leuciscus idus (Golden orfe)	170 mg/l (48h, (IUCLID))
Titanium dioxide (13463-67-7)	
LC50 other fish	> 1000 mg/l
EC50 Daphnia magna (Water flea)	> 1000 mg/l

12.2. Persistence and degradability

Quizartinib Dihydrochloride (1132827-21-4)	
Residual tendency / decomposability	No information available to date.
Hydroxypropyl-β-cyclodextrin (128446-35-5)	
Biodegradation	10 % 28d
Triacetin (102-76-1)	
Residual tendency / decomposability	Readily biodegradable.
Biodegradation	64 % 28 d

12.3. Bioaccumulative potential

Quizartinib Dihydrochloride (1132827-21-4)	
Log Pow	2.33
Biological accumulativity	No information available to date.
Hydroxypropyl-β-cyclodextrin (128446-35-5)	
Log Pow	< 0
Magnesium stearate (557-04-0)	
Log Pow	0.8
Triacetin (102-76-1)	
Log Pow	0.25

12.4. Mobility in soil

Quizartinib Dihydrochloride (1132827-21-4)	
Ecology - soil	No information available to date.

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 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

Not regulated for transport

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

- Other information : No supplementary information available.

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14.6. Special precautions for user

14.6.1. Overland transport

No information available.

14.6.2. Transport by sea

No information available.

14.6.3. Air transport

No information available.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 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

Water hazard class (WGK) : nwg - Non-hazardous to water

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 R-, H- and EUH-statements:

STOT RE 1	Specific target organ toxicity — Repeated exposure, Category 1
H372	Causes damage to organs through prolonged or repeated exposure.

0833 DS_SDS(EU)

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