TURALIO
Safety Data Sheet
according to Regulation (EU) 2015/830
Date of issue: 26/Apr/2018 Revision date: 15/Oct/2022 : Version: 3.0

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

1.1. Product identifier

Product form : Mixtures
Trade Name : TURALIO
Product No. : PLX3397

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 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. 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 additional information available.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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]
Pexidartinib HCl	(CAS number) 1029044-16-3 (free base)	51.2	STOT RE 1, H372

This mixture contains no other components to be mentioned according to the criteria of section 3.2 of REACH Annex II

Full text of R- and H-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 : Rinse skin with water/shower. 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. Consult an ophtalmologist if irritation persists.
Ingestion : Rinse mouth thoroughly with water. Do not induce vomiting. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after ingestion : May be harmful if swallowed.

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

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents : Water spray. Carbon dioxide. Extinguishing powder. Foam. Inert gas.

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).

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.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate area.

6.1.2. For emergency responders

Emergency procedures : Stop leak if safe to do so. Recover as much product as possible. Keep recovered product for subsequent disposal.

6.2. Environmental precautions

Ventilate the area after cleaning in completed. Avoid raising the dust. 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 : 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 in well-ventilated areas.

Storage conditions : Store in a light-resistant tight container, protect from humidity.

Storage temperature : (at room temperature)

7.3. Specific end use(s)

No information available.

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	:	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	:	Wear an approved dust respirator.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Description	:	Capsule.
Colour	:	125 mg capsule: White opaque body and powder blue opaque cap with black print “DSC521” 200 mg capsule: White opaque body and dark green opaque cap with white print “T10”
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	:	Not applicable
Boiling point	:	Not applicable.
Flash point	:	No data available
Critical temperature	:	Not applicable.
Ignition point	:	Not applicable.
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
Log Pow	:	No data available
Log Kow	:	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.

10.2. Chemical stability

Stable at room temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

Keep away from heat, humidity and direct sunlight.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Classification not possible

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

Pexidartinib HCl (1029044-16-3 (free base))
Not mutagenic in a battery of studies, including Ames gene mutation, in vitro chromosomal aberration assay and micronucleus test

Carcinogenicity : Classification not possible

Reproductive toxicity : Classification not possible

Pexidartinib HCl (1029044-16-3 (free base))
NOAEL for teratogenicity in rats (10 mg/kg/day) and rabbits (20 mg/kg/day)

STOT-single exposure : Classification not possible

Pexidartinib HCl (1029044-16-3 (free base))
To date, no SAEs(Serious Adverse Effects) have been observed following administration of single 400 or 600 mg doses to healthy subjects. Overall, pexidartinib was well tolerated in these studies. All AEs were mild to moderate and resolved without intervention. Common drug related AEs included nausea, headache, dizziness, pruritis, and changes in bowel paterns

STOT-repeated exposure : Classification not possible

Pexidartinib HCl (1029044-16-3 (free base))
Category 1 NOAEL (oral, repeated dose studies) in the rat (4W – 26W; ≤ 0.5 mg/kg/day – 10 mg/kg/day, po) and dog (4W – 39W; ≥ 6 mg/kg/day, po). Pexidartinib caused hematological effects (anemia, decreased white blood cell counts, marrow hypocellularity and lymphoid depletion), increased liver enzymes, necrotizing inflammation of hepatocyte, exacerbated chronic progressive nephropathy, vascular inflamation and effects on the epidymides and testes of males and the ovary of females

Aspiration hazard : Classification not possible

SECTION 12: Ecological information

12.1. Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Pexidartinib HCl (1029044-16-3 (free base))	
Log Pow	3.35 (pexidartinib free base)

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 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.

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) : 3 - severe hazard to waters

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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