

Safety Data Sheet for Drug product



Date of issue: 12-SEP-2016

Replaces version of: 01-SEP-2016

KISQA FCT 200MG 860591 (MARS)

1. Identification of the substance/preparation and of the company

Product name KISQA FCT 200MG
Generic Name LEE011-BBA
Pharmacological Action Antineoplastic
Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name Novartis Pharma AG
4002 Basel
Switzerland
Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
LEE011-BBA	60 %	1374639-75-4

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

Eye Contact Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation Remove the victim from danger zone, avoid further exposure.
Ingestion If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media No restrictions
Dangerous Combustion Products nitrogen oxides, carbon oxides
Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions Avoid contact with skin, eyes and clothing.
Environmental precautions Must not be released into sewers, drains or wells.

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Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

LEE011-BBA

List type	Value	Unit
Internal exposure limit	8	$\mu\text{g}/\text{m}^3$ HHA Database

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation

Tablet

Flash Point

not applicable

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity

Data of LEE011-BBA

MTD: 100 mg/kg

Route: oral

Species: dog

Irritation, Corrosion

Data of LEE011-BBA

Skin (Species: rabbit) non irritant

Method: OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Sensitisation

Data of LEE011-BBA

Skin (Species: mouse) not sensitizing

Method: OECD Guideline 429 (Skin Sensitisation - LLNA)

Value from salt form

Mutagenicity

Data of LEE011-BBA

Negative with and without metabolic activation (Micronucleus Test)

in vitroCell: TK6 cells

Method: OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test)

Data of LEE011-BBA

Negative with and without metabolic activation (Chromosome Aberration Study)

in vitroCell: Cultured peripheral human lymphocytes

Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)

Data of LEE011-BBA

Negative (Micronucleus Test)

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	in vivo, Species: rat, Cell: Bone marrow Method: OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) Data of LEE011-BBA Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of salmonella typhimurium. Method: OECD Guideline 471 (Bacterial Reverse Mutation Assay)
Chronic Effects	Data of LEE011-BBA (Repeated Dose Toxicity) NOAEL: 25 mg/kg/d Route: oral Species: rat, Organ: Multiple organs Dosage: <= 150 mg/kg/d, Duration: 15 weeks male Data of LEE011-BBA (Repeated Dose Toxicity) NOAEL: 300 mg/kg/d Route: oral Species: rat, Organ: Multiple organs Dosage: <= 300 mg/kg/d, Duration: 15 weeks female Data of LEE011-BBA (Repeated Dose Toxicity) LOAEL: 1 mg/kg/d Route: oral Species: dog, Organ: Multiple organs Dosage: <= 10 mg/kg/d, Duration: 15 weeks male Data of LEE011-BBA (Repeated Dose Toxicity) NOAEL: 10 mg/kg/d Route: oral Species: dog, Organ: Multiple organs Dosage: <= 10 mg/kg/d, Duration: 15 weeks female
Reproduction Toxicity	Data of LEE011-BBA Effect on embryo-fetal development (Embryo-Fetal Development) NOEL: 50 mg/kg/d Route: oral Species: rat Data of LEE011-BBA Maternal toxicity (Embryo-Fetal Development) NOAEL: 300 mg/kg/d Route: oral Species: rat Data of LEE011-BBA Effect on embryo-fetal development (Embryo-Fetal Development) NOEL: 10 mg/kg/d Route: oral Species: rabbit Data of LEE011-BBA Maternal toxicity (Embryo-Fetal Development) NOEL: 30 mg/kg/d Route: oral Species: rabbit

12. Ecological information

Biological Elimination Data of LEE011-BBA

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Degradation: 5 - 14 % (Temperature: 21.7 - 22.3 °C)
Not readily degradable
Initial conc.: 12 mg/l, Duration: 28 days
Method: OECD 301B * 1992; EC No 440/2008 C.4-C * 2008; ISO 9439 * 1999
ISO 10634

Fish acute toxicity Data of LEE011-BBA
LC50: 38 mg/l
Species: common carp (cyprinus carpio)
Exp. time: 96 hours
Method: OECD 203 * 1992 * acute toxicity
EC 440/2008 C.1
ISO 7346-1&2, 1996

Fish chronic toxicity Data of LEE011-BBA
LOEC: 2.2 mg/l
NOEC: NOEC: 1 mg/l
Species: fathead minnow (pimephales promelas)
Exp. time: 33 days
Method: OECD Guidelines 210: Fish, Early-life Stage Toxicity Test

Aquatic invertebrate acute toxicity Data of LEE011-BBA
EC50: > 33 mg/l
Species: daphnia magna (water flea)
Exp. time: 48 hours
Method: OECD 202 * 2004; EC 440/2008, Part C.2 * 2008; ISO 6341 * 1996

Aquatic invertebrate chronic toxicity Data of LEE011-BBA
NOEC: NOEC: 1.4 mg/l
Species: daphnia magna (water flea)
Exp. time: 21 days
Method: OECD Guidelines 211: Daphnia magna Reproduction Test

Algae Toxicity Data of LEE011-BBA
EC10: 0.71 mg/l
EC20: 1.21 mg/l
EC50: 3.38 mg/l
NOEC: 0.76 mg/l
Species: Green algae - fresh water (Pseudokirchneriella subcapitata)
Exp. time: 72 hours
Method: OECD 201 * 2006 * Growth inhibition; ISO 8692 * 2004
EC 440/2008 C.3
Value from another salt form

Bacterial Respiration Inhibition Data of LEE011-BBA
EC50: > 1000 mg/l
Species: activated sludge
Exp. time: 3 hours
Method: OECD 209 * 2010; EC 440/2008, L142 C11 * 1988; ISO 8192 (2007)

Ecotoxicity Summary Data of LEE011-BBA
Avoid release into soil, rivers or drains.

13. Disposal considerations

Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

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ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
LEE011-BBA	60 %	1374639-75 -4		W	H361, H373, H401, H411

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H361: Suspected of damaging fertility or the unborn child.

H373: May cause damage to organs through prolonged or repeated exposure.

H401: Toxic to aquatic life.(in EU not leading to classification as hazardous)

H411: Toxic to aquatic life with long lasting effects.

Recipient Henry Delima
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USA

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.