Safety Data Sheet for Drug product

Date of issue: 29-APR-2015
Replaces version of: 28-APR-2015
ZYKAD HGC 150MG ACP (4X10) DEH 730852 (MARS)

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

Product name	ZYKAD HGC 150MG ACP (4X10) DEH
Generic Name	Ceritinib
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) +1 813 248 0573

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
Ceritinib	0 - 40 %	1032900-25-6

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	sulfur oxides, nitrogen oxides, carbon oxides, hydrogen chloride
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.

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:
Ceritinib

List type	µg/m3	
Internal exposure limit	104	/ HHA Database

Personal protection for open handling

Health care personnel		Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation	Capsule
Flash Point	not available

10. Stability and reactivity

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

11. Toxicological information

Acute Toxicity	Data of Ceritinib LD0: 250 mg/kg Route: oral Species: cynomolgus monkey (Macaca fascicularis), Sex: male Method: Single Rising Dose Study
Irritation, Corrosion	Data of Ceritinib Skin (Species: rabbit) non irritant Method: OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Sensitisation	Data of Ceritinib Skin (Species: mouse) not sensitizing Method: OECD Guideline 429 (Skin Sensitisation - LLNA) EC 440/2008 B.42 (LLNA) EPA OPPTS 870.2600 (2003)
Mutagenicity	Data of Ceritinib 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) Data of Ceritinib Negative with and without metabolic activation (Micronucleus Test) in vitroCell: Cultured peripheral human lymphocytes

	Data of Ceritinib Weak positive without metabolic activation (Micronucleus Test) in vitroCell: TK6 cells
	Data of Ceritinib Polyploidy in the absence of chromosomal damage (Chromosome Aberration Study) in vitroCell: Cultured peripheral human lymphocytes
	Data of Ceritinib Negative (Micronucleus Test) in vivo, Species: rat, Cell: Bone marrow Method: OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)
Chronic Effects	Data of Ceritinib (Repeated Dose Toxicity) LOAEL: 3 mg/kg/d Route: oral Species: rat, Organ: Multiple organs Duration: 13 weeks
	Data of Ceritinib (Repeated Dose Toxicity) LOAEL: 3 mg/kg/d Route: oral Species: rat, Organ: Multiple organs Duration: 26 weeks
	Data of Ceritinib (Repeated Dose Toxicity) NOAEL: 10 mg/kg/d Route: oral Species: cynomolgus monkey (Macaca fascicularis), Organ: Multiple organs Duration: 13 weeks
Reproduction Toxicity	Data of Ceritinib No embryotoxicity at maternally toxic dose (Embryo-Fetal Development) NOAEL: 10 mg/kg/d Route: oral Species: rabbit Method: OECD 414 (Prenatal Developmental Toxicity Study)
	Data of Ceritinib No embryotoxicity at maternally toxic dose (Embryo-Fetal Development) NOAEL: 10 mg/kg/d Route: oral Species: rat Method: OECD 414 (Prenatal Developmental Toxicity Study)
	Data of Ceritinib Not teratogenic / not embryotoxic (Embryo-Fetal Development) NOAEL: 25 mg/kg/d Route: oral Species: rabbit Method: OECD 414 (Prenatal Developmental Toxicity Study)
	Data of Ceritinib Not teratogenic / not embryotoxic (Embryo-Fetal Development) NOAEL: 50 mg/kg/d Route: oral Species: rat Method: OECD 414 (Prenatal Developmental Toxicity Study)

12. Ecological information

Biological Elimination	Data of Ceritinib Not readily degradable Duration: 28 days

	Method: OECD 301B * 1992; EC No 440/2008 C.4-C * 2008; ISO 9439 * 1999
Fish acute toxicity	unknown
Fish chronic toxicity	Data of Ceritinib LC10: 0.069 mg/l LOEC: 0.164 mg/l NOEC: NOEC: 0.045 mg/l Species: zebra fish (danio rerio) Exp. time: 35 days Method: OECD Guidelines 210: Fish, Early-life Stage Toxicity Test
Aquatic invertebrate acute toxicity	unknown
Aquatic invertebrate chronic toxicity	Data of Ceritinib EC10: 0.42 mg/l LOEC: 0.92 mg/l NOEC: NOEC: 0.41 mg/l Species: daphnia magna (water flea) Exp. time: 21 days Method: OECD Guidelines 211: Daphnia magna Reproduction Test
Algae Toxicity	Data of Ceritinib ErC10: 0.12 mg/l ErC50: > 0.49 mg/l Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae) Exp. time: 72 hours Method: OECD 201 * 2006
Bacterial Respiration Inhibition	Data of Ceritinib EC10: > 100 mg/l EC20: > 100 mg/l EC50: > 100 mg/l Species: activated sludge Exp. time: 3 hours Method: OECD Guidelines 209 : Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation) Data of Ceritinib NOEC: >= 100 mg/l EC80: > 100 mg/l Species: activated sludge Exp. time: 3 hours Method: OECD Guidelines 209 : Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)
Ecotoxicity Summary	Data of Ceritinib 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			

ICAO/IATA-DGR: no dangerous good
Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Ceritinib	0 - 40 %	1032900-25-6		D	H372, H410, P

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H372: Causes damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.
P: Caution: Handle with care - product not fully tested!

Recipient

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Customer Interaction Center
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NJ

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.