

Safety Data Sheet for Drug product



Date of issue: 29-SEP-2014

Replaces version of: 28-JUN-2012

FARYD HGC 10MG 06ACP 6PC.003 886011 (MARS)

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

Product name FARYD HGC 10MG 06ACP 6PC.003
Chemical Class Indole derivative
Generic Name (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate
Pharmacological Action Antitumour
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
(E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate	5 - 11 %	960055-56-5

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 carbon oxides, nitrogen oxides
Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

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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:

(E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide mono-DL-lactate

List type	µg/m ³	
	<0.1	/
Novartis Internal Exposure Limit (from OHB Value)	0.1	/

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Disposable fine dust protection mask (EN149); Double disposable gloves (EN374) Disposable dust-proof lab coat

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 (E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide mono-DL-lactate MNLD: 10 mg/kg Route: intravenous Species: rat, Sex: female
	Data of (E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide mono-DL-lactate MNLD: 50 mg/kg Route: intravenous Species: mouse, Sex: male
	Data of (E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide mono-DL-lactate MNLD: 75 mg/kg Route: intravenous Species: mouse, Sex: female
	Data of (E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide

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	mono-DL-lactate MNL D: 50 mg/kg Route: intravenous Species: rat, Sex: male
Irritation, Corrosion	Values of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate The substance has an irritating potential. Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Skin (Species: rabbit) non irritant Method: 92/69/EC (L383) B.4 * Acute toxicity (skin irritation) Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Skin (Species: mouse) irritant Method: Assessment of contact allergenic potential with the murine local lymph node assay (LLNA TIER II) Test result of the pure substance. Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Eyes irritant
Sensitisation	Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Skin (Species: mouse) sensitizing Method: 67/548/EEC Annex V, B.42
Mutagenicity	Values of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate The product showed positive results in in vitro mutagenicity studies. Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Positive (AMES-Test (reverse mutation assay)) Cell: Strains of salmonella typhimurium. Method: AMES test Value from another salt form Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate Positive (in vitro) Cell: Cultured peripheral human lymphocytes Method: OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test) Value from another salt form
Chronic Effects	Values of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate The substance has a cardiotoxic potential. The substance is known to be carcinogenic to animals. There is sufficient evidence to establish a causal association between human exposure to this substance and the development of cancer. Handling this substance, precautionary measures should be taken according to workplace health risk assessment. Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate (Repeated Dose Toxicity) NTEL: < 0.15 mg/kg/d Route: oral Species: rat Duration: 4 weeks Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate (Repeated Dose Toxicity) MTD: 12.9 mg/kg/d Route: oral Species: rat

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Duration: 4 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

MTD: 43 mg/kg/d

Route: oral

Species: rat

Duration: 13 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

MTD: 32 mg/kg/d

Route: oral

Species: rat

Duration: 26 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

MTD: 0.6 mg/kg/d

Route: oral

Species: dog

Duration: 4 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

NOAEL: 0.06 mg/kg/d

Route: oral

Species: monkey

Duration: 13 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

NOAEL: 0.06 mg/kg/d

Route: oral

Species: dog

Duration: 39 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

MTD: 0.43 mg/kg/d

Route: intravenous

Species: rat

Duration: 13 weeks

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
(Repeated Dose Toxicity)

LOAEL: 0.03 mg/kg/d

Route: intravenous

Species: dog

Duration: 13 weeks

Reproduction Toxicity

Values of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate

This substance has been shown to have unwanted effects on the reproductive system of both sexes. It is recommended that persons working with or around this substance are informed and their exposure evaluated according to local policies. Handling this substance, precautionary measures should be taken according to workplace health risk assessment. This substance may have unwanted effects on pregnancy and/or unborn/offspring.

Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide

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mono-DL-lactate
Reproductive effects at maternally toxic dose (Fertility and early Embryonic Development)
NOAEL: 4.3 mg/kg/d
Route: oral
Species: rat, Sex: female
Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
Effect on embryo-fetal development at maternally toxic doses; no teratogenicity. (Embryo-Fetal Development)
LOAEL: 30 mg/kg/d
Route: oral
Species: rat, Sex: female
Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
Paternal toxicity (Fertility and early Embryonic Development)
NOAEL: 1.4 mg/kg/d
Route: oral
Species: rat, Sex: male

12. Ecological information

Biological Elimination Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
Degradation: 0 % (aerobic: Temperature: 22.4 - 24 °C CO₂)
Not readily degradable
Initial conc.: 22.8 mg/l, Duration: 28 days
Method: 92/69/EC (L383) C.4-C * Carbon dioxide (CO₂) evolution

Fish acute toxicity Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
LC50: 3.7 mg/l
Species: zebra fish (danio rerio)
Exp. time: 96 hours
Method: 92/69/EEC (L383) C.1 * Acute toxicity for fish
Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
NOEC: < 6.3 mg/l
Species: zebra fish (danio rerio)
Exp. time: 96 hours
Method: 92/69/EEC (L383) C.1 * Acute toxicity for fish

Fish chronic toxicity Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
LOEC: 0.042 mg/l
NOEC: NOEC: 0.016 mg/l
Species: fathead minnow (pimephales promelas)
Exp. time: 31 days
Method: OECD 210 * 1992

Aquatic invertebrate acute toxicity Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
EC50: 5.3 mg/l
Species: daphnia magna (water flea)
Exp. time: 48 hours
Method: 92/69/EEC (L383) C.2 * Acute toxicity for daphnia
Data of (E)-N-Hydroxy-3-(4-{{2-(2-methyl-1H-indol-3-yl)ethylamino}methyl}phenyl)acrylamide mono-DL-lactate
NOEC: 1.3 mg/l
Species: daphnia magna (water flea)
Exp. time: 48 hours
Method: 92/69/EEC (L383) C.2 * Acute toxicity for daphnia

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Aquatic invertebrate chronic toxicity Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate
LOEC: 0.029 mg/l
NOEC: NOEC: 0.01 mg/l
Species: daphnia magna (water flea)
Exp. time: 21 days
Method: OECD 211 * 2008

Algae Toxicity Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate
ErC50: 0.028 mg/l
Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)
Exp. time: 72 hours
Method: 92/69/EC (L383) C.3

Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate
NOEC: 0.008 mg/l
Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)
Exp. time: 72 hours
Method: 92/69/EC (L383) C.3

Bacterial Respiration Inhibition Data of (E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate
EC50: 313 mg/l
Species: activated sludge
Method: OECD 209 * 1984

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
(E)-N-Hydroxy-3-(4-[[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl]phenyl)acrylamide mono-DL-lactate	5 - 11 %	960055-56-5		D	H315, H319, H317, H341, H350, H361d, H372, H400, H410

Remaining components are inert ingredients.

16. Other information

Abbreviations used

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H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H341: Suspected of causing genetic defects.

H350: May cause cancer.

H361d: Suspected of damaging the unborn child.

H372: Causes damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

Recipient

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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.