

Safety Data Sheet for Drug product



Date of issue: 03-OCT-2016

Replaces version of: 21-MAR-2016

FARYDAK 20 MG ACP 6 CAP-AT 886011 (MARS)

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

Product name FARYDAK 20 MG ACP 6 CAP-AT
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) +1 813 676 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
(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	Value	Unit	
Internal exposure limit	0.4	µg/m ³	HHA Database

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 applicable

10. Stability and reactivity

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

11. Toxicological information

Acute Toxicity	no data available
Irritation, Corrosion	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)
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	Data of (E)-N-Hydroxy-3-(4-{[2-(2-methyl-1H-indol-3-yl)ethylamino]methyl}phenyl)acrylamide mono-DL-lactate Positive with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of salmonella typhimurium.

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Chronic Effects

Method: OECD Guideline 471 (Bacterial Reverse Mutation Assay)

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

Positive with and without metabolic activation (Comet assay)

in vitroCell: Lymphoma cells L5178Y of the mouse

Method: 93/21/EEC, OECD 476 * L5178Y +/- Mouse Lymphoma Assay

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

Positive with and without metabolic activation (Chromosome Aberration Study)

in vitroCell: Cultured peripheral human lymphocytes

Method: OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)

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

Haematological toxicity (Repeated Dose Toxicity)

Route: oral

Species: rat, Organ: Multiple organs

Dosage: <= 100 mg/kg, Duration: 13 weeks

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

Haematological toxicity (Repeated Dose Toxicity)

MTD: 75 mg/kg

Route: oral

Species: rat, Organ: Multiple organs

Dosage: <= 75 mg/kg, Duration: 26 weeks

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

Haematological toxicity (Repeated Dose Toxicity)

NOAEL: 0.15 mg/kg

Route: oral

Species: dog, Organ: Multiple organs

Dosage: <= 1 mg/kg, Duration: 13 weeks

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

Haematological toxicity (Repeated Dose Toxicity)

NOAEL: 0.15 mg/kg

MTD: 1 mg/kg

Route: oral

Species: dog, Organ: Multiple organs

Dosage: <= 1 mg/kg, Duration: 39 weeks

Reproduction Toxicity

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 (Embryo-Fetal Development)

NOAEL: 10 mg/kg/d

Route: oral

Species: rabbit

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 (Embryo-Fetal Development)

LOAEL: 30 mg/kg/d

Route: oral

Species: rat

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

Fertility effects (Fertility and early Embryonic Development)

Route: oral

Sex: male

12. Ecological information

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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 CO ₂) Not readily degradable Initial conc.: 22.8 mg/l, Duration: 28 days Method: 92/69/EC (L383) C.4-C * Carbon dioxide (CO ₂) 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
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

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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-met hyl-1H-indol-3-yl)ethylamino]meth yl)phenyl)acrylamide mono- DL-lactate	5 - 11 %	960055-56-5		D	H317, H341, H350, H361d, H372, H400, H410

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H317: May cause an allergic skin reaction.

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.