

Safety Data Sheet for Drug product



Date of issue: 28-SEP-2015

Replaces version of: 26-AUG-2015

GILEN HGC 0.5MG DUP (2X14) AT 718946 (MARS)

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

Product name GILEN HGC 0.5MG DUP (2X14) AT
Chemical Class Myriocin analogue
Generic Name Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
Pharmacological Action immunosuppressant, Anti-inflammatory, Transplantation of organs, Autoimmune diseases
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

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
Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride	0.5 - 5 %	162359-56-0

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
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.

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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:

Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride

List type	$\mu\text{g}/\text{m}^3$	
Internal exposure limit	1.3	/ HHA Database

Personal protection for open handling

Health care personnel	 	Safety glasses (EN166) Lab coat Disposable gloves (EN374)
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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 Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride LD50: > 2000 mg/kg Route: oral Species: dog Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride LD50: 300 - 600 mg/kg Route: oral Species: rat, Sex: both sexes
Irritation, Corrosion	Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Skin (Species: rabbit) irritant Method: 92/69/EC (L383) B.4 * Acute toxicity (skin irritation)
Sensitisation	Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Skin (Species: guinea pig) not sensitizing Method: OECD 406 * 1981 * Skin sensitisation Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Skin (Species: mouse) not sensitizing Method: OECD Guideline 429 (Skin Sensitisation - LLNA)
Mutagenicity	Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride

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	<p>Negative (Micronucleus Test) in vivo, Species: mouse, Cell: Bone marrow Method: OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of Salmonella typhimurium and Escherichia coli. Method: OECD Guideline 471 (Bacterial Reverse Mutation Assay)</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Negative (Chromosome Aberration Study) in vitroCell: Chinese hamster ovary (CHO) cells Method: OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Negative (Micronucleus Test) in vivo, Species: rat, Cell: Bone marrow Method: OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)</p>
Chronic Effects	<p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride (Repeated Dose Toxicity) NOAEL: 0.01 mg/kg/d Route: oral Species: dog, Organ: Multiple organs Duration: 26 weeks Method: OECD Guideline 452 (Chronic Toxicity Studies)</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Pathological findings (Repeated Dose Toxicity) NOEL: 0.025 mg/kg/d Route: oral Species: mouse Duration: 104 weeks Method: OECD Guideline 451 (Carcinogenicity Studies)</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride No oncogenic potential relevant to man. (Repeated Dose Toxicity) NOAEL: 2.5 mg/kg/d Route: oral Species: rat Duration: 104 weeks Method: OECD Guideline 451 (Carcinogenicity Studies)</p>
Reproduction Toxicity	<p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Negative (Fertility and early Embryonic Development) NOAEL: 10 mg/kg/d Route: oral Species: rat, Sex: both sexes</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Teratogenicity was found (Embryo-Fetal Development) LOEL: 1 mg/kg/d Route: oral Species: rat</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Embryotoxicity (Embryo-Fetal Development) NOAEL: 0.5 mg/kg/d Route: oral Species: rabbit</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Teratogenicity was found (Embryo-Fetal Development) NOAEL: 0.03 mg/kg/d Route: oral Species: rat</p> <p>Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride Fertility effects (Embryo-Fetal Development)</p>

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NOAEL: 0.3 mg/kg/d
Route: oral
Species: rat
Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
Maternal toxicity (Embryo-Fetal Development)
NOAEL: 1.5 mg/kg/d
Route: oral
Species: rabbit
Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
(Fertility and early Embryonic Development)
NOAEL: 3 mg/kg/d
Route: oral
Species: rat, Sex: both sexes

12. Ecological information

Biological Elimination Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
(aerobic: Temperature: 21 - 23 °C CO₂)
Not readily degradable
Initial conc.: 18 mg/l, Duration: 28 days
Method: 92/69/EC (L383) C.4-C * Carbon dioxide (CO₂) evolution

Fish acute toxicity unknown

Fish chronic toxicity Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
NOEC: 0.09 mg/l
LOEC: 0.31 mg/l
Species: zebra fish (danio rerio)
Exp. time: 34 days
Method: OECD 210 * 1992

Aquatic invertebrate acute toxicity Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
EC50: 0.12 mg/l
Species: daphnia magna (water flea)
Exp. time: 48 hours
Method: OECD 202 * 2004

Aquatic invertebrate chronic toxicity Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
NOEC: 0.089 mg/l
LOEC: 0.38 mg/l
Species: daphnia magna (water flea)
Exp. time: 21 days
Method: OECD 211 * 2008

Algae Toxicity Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
ErC50: 0.041 mg/l
EbC50: 0.026 mg/l
Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)
Exp. time: 72 hours
Method: OECD 201 * 1984 * Growth inhibition

Bacterial Respiration Inhibition Data of Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride
EC50: 22 - 100 mg/l
Species: activated sludge
Exp. time: 3 hours
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

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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
Amino-2-(2-(4-octylphenyl)ethyl)propane-1,3-diol hydrochloride	0.5 - 5 %	162359-56-0		D	H302, H315, H360d, H372, H400, H410

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H302: Harmful if swallowed.

H315: Causes skin irritation.

H360d: May damage 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.

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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.