

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

36425-RUPATADINE TABLETS



Version: 5
Revision date: 17/10/2018

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: RUPATADINE TABLETS
Product Code: 36425
Chemical Name: 8-Chloro-6,11-dihydro-11-[1-[(5-methyl-3-pyridinyl)methyl]-4-piperidinylidene]-5H-benzo [5,6]cyclohepta[1,2-b]pyridine fumarate
CAS No: 182349-12-8
EC No: 642-920-0
Registration No: Exempt

1.2 Relevant identified uses of the substance and uses advised against.

PHARMACEUTICAL PRODUCT

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **URQUIMA S.A.**
Address: Arnau de Vilanova 22-42
City: 08105 Sant Fost de Campsentelles
Province: Barcelona (España)
Telephone: +34 93 570 54 50
Fax: +34 93 570 24 76
E-mail: msds@uriach.com

1.4 Emergency telephone number: +34 93 570 54 50 (Available 24 hours)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

EUH statements:
EUH210 Safety data sheet available on request.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Multi-constituent.

Chemical Name: 8-Chloro-6,11-dihydro-11-[1-[(5-methyl-3-pyridinyl)methyl]-4-piperidinylidene]-5H-benzo [5,6]cyclohepta[1,2-b]pyridine fumarate
CAS No: 182349-12-8
EC No: 642-920-0
Registration No: Exempt
[1] Substance with a Community workplace exposure limit (see section 8.1).

3.2 Mixtures.

Not Applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

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Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

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SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:
For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers.
In the application area, smoking, eating, and drinking must be prohibited.
Follow legislation on occupational health and safety.
Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

No special storage conditions in terms of maximum storage temperature need to be declared in the labelling since the product meets its corresponding stability specifications (as general storage measures, sources of heat, radiation, electricity and contact with food should be avoided).

Keep away from oxidising agents and from highly acidic or alkaline materials. "Store according to local legislation. Observe indications on the label. Store the containers in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Prevent the entry of non-authorized persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	PHARMACEUTICAL PRODUCT		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Protective gloves.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles with built-in frame.		
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against splashing liquid, dust, smoke, fog and vapour.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		



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CEN standards:	EN 340
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: N.A./N.A.
Colour: N.A./N.A.
Odour: N.A./N.A.
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: N.A./N.A.
Flash point: N.A./N.A.
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: 0,24 g/cm³
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: N.A./N.A.
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A.= Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Pour point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A.= Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

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10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;

Not conclusive data for classification.

Acute Toxicity Estimate (ATE):

Substances:

ATE (Oral) = 2.887 mg/kg

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

There is no information available on the biodegradability of the substances present.

12.2 Persistence and degradability.

There is no information available on the degradability of the substances present.

No information is available regarding the degradability. No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation.

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Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
8-Chloro-6,11-dihydro-11-[1-[(5-methyl-3-pyridinyl)methyl]-4-piperidinylidene]-5H-benzo [5,6]cyclohepta[1,2-b]pyridine fumarate N. CAS: 182349-12-8 EC No: 642-920-0	0,8	-	-	Very low

12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Transportation is not dangerous.

IMDG: Transportation is not dangerous.

ICAO/IATA: Transportation is not dangerous.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

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The product is not affected by Directive 2012/18/EU (SEVESO III).

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Classification codes:

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Sections changed compared with the previous version:

1,9,11,16

It is recommended that the product only be employed for the purposes advised.

Abbreviations and acronyms used:

BCF: Bioconcentration factor.

CEN: European Committee for Standardization.

EC50: Half maximal effective concentration.

PPE: Personal protection equipment.

LC50: Lethal concentration, 50%.

LD50: Lethal dose, 50%.

Log Pow: Logarithm of the partition octanol-water.

NOEC: No observed effect concentration.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.