

In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

## 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identit	fier			
Trade name Chemical descripti Chemical formula SMILES Product code	: C12H15N3O2S : O=C(OC)Nc2nc1ccc(SCCC)cc1n2 : M1002			
1.2. Relevant ident	ified uses of the substance or mixture and uses advised against			
Use	: Restricted use as an active ingredient in pharmaceutical industry.			
1.3. Details of the s	1.3. Details of the supplier of the safety data sheet			
Company identifica	tion : UNIÓN QUÍMICO FARMACÉUTICA Calle 37 este nº 126 Telf: 01 777 329 5000 Fax: 01 7777 329 5029 62587 Cuernavaca MEXICO David Torruella: dtorruella@uquifa.com			
1.4. Emergency telephone number				
Phone nr	: [ Office hours (monday to friday, 9 am- 17 pm GTM -6) ] Telf: 01 777 329 5000			
2. Hazards identifica	2. Hazards identification			
2.1. Classification	2.1. Classification of the substance or mixture			
Classification EC 6	Classification EC 67/548 or EC 1999/45			
Classification	: Xn; R22 N; R50			
Hazard Class and Category Code Regulation EC 1272/2008 (CLP)				
Health hazards	: Acute toxicity, Oral - Category 4 - Warning (CLP : Acute Tox. 4) H302 Reproductive toxicity - Category 1 - Danger (CLP : Repr. 1A) H360			
Environmental haz	ards       : Hazardous to the aquatic environment - Acute hazard - Category 1 - Warning (CLP         : Aquatic Acute 1) H400			
2.2. Label elements	<u>5</u>			

## Labelling EC 67/548 or EC 1999/45

In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE



# 2. Hazards identification (continued)

Symbol(s)	
Symbol(s)	: T : Toxic N : Dangerous for the environment
R Phrase(s)	: R22 : Harmful if swallowed. R50 : Very toxic to aquatic organisms. R61 : May cause harm to the unborn child.
S Phrase(s)	<ul> <li>S36/37 : Wear suitable protective clothing and gloves.</li> <li>S53 : Avoid exposure - obtain special instructions before use.</li> <li>S57 : Use appropriate container to avoid environmental contamination.</li> </ul>
Contains	: ALBENDAZOLE
Labelling Regulation EC 1272/200	<u>8 (CLP)</u>
Hazard pictograms	
Signal words	: Danger
Hazard statements	<ul> <li>H360 : May damage fertility or the unborn child.</li> <li>H302 : Harmful if swallowed.</li> <li>H400 : Very toxic to aquatic life.</li> </ul>
Precautionary statements &&	
• General	: P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood.
Prevention	<ul> <li>P264: Wash thoroughly after handling.</li> <li>P270: Do not eat, drink or smoke when using this product.</li> <li>P273: Avoid release to the environment.</li> <li>P281: Use personal protective equipment as required.</li> </ul>
• Response	<ul> <li>P301+P312+P330: IF SWALLOWED : Call a POISON CENTER or doctor if you feel unwell. Rinse mouth.</li> <li>P308+P313: If exposed or concerned : get medical advice.</li> <li>P391: Collect spillage.</li> </ul>
Storage	: P405: Store locked up.
<ul> <li>Disposal considerations</li> </ul>	: P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Contains	: ALBENDAZOLE
2.3. Other hazards	
None under normal conditions.	



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

Repr. 1 \_ H360 Acute Tox. 4 (oral) \_ H302 Aquatic Acute 1 \_ H400

## 3. Composition/information on ingredients

Substance / Preparati	on		) :054965-21-8 259-414-7 No :					
RTECS nr		: FD1100	000					
Contains no other com	ponents or imp	ourities which	will influence th	e classifica	ation of the p	product.		
Substance name		Contents	CAS No	EC No	Annex No	REACH Ref.	Classification	
ALBENDAZOLE	:	100	54965-21-8	259-414-7		&	T; R61 Xn; R22 N; R50	

#### 4. First aid measures

## 4.1. Description of first aid measures

Inhalation	: Assure fresh air breathing. If not breathing, give artificial respiration, preferably mouth to mouth. Allow the victim to rest.
Skin contact	: Wash skin with mild soap and water. Take a shower. Continue to rinse with clean water for 20-30 minutes.
Eye contact	<ul> <li>In case of eye contact, immediately rinse with clean water for 10-15 minutes.</li> <li>Obtain medical attention if pain, blinking or redness persist.</li> </ul>
Ingestion	<ul> <li>If swallowed, rinse mouth with water (only if the person is conscious).</li> <li>IF SWALLOWED : Rinse mouth. Immediately call a POISON CENTER or doctor.</li> <li>Specific treatment.</li> </ul>
4.2. Most important symptoms and e	effects, both acute and delayed
Symptoms relating to use	: Not expected to present a significant hazard under anticipated conditions of normal use.
4.3. Indication of any immediate med	dical attention and special treatment needed
General information	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label or SDS where possible).
. Fire-fighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Water spray. Foam. Dry powder. Carbon dioxide. Sand.
Unsuitable extinguishing media Surrounding fires	: Do not use a heavy water stream. : Use water spray or fog for cooling exposed containers.

## 5.2. Special hazards arising from the substance or mixture

5.

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In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# **ALBENDAZOLE**

5.	Fire-fighting measures (continued)			
	Hazardous combustion products	: Under fire conditions, hazardous fumes will be present. Explosion may result if is dispersed and finds an ignition source.		
	5.3. Advice for fire-fighters			
	Protection against fire	: Do not enter fire area without proper protective equipment, including respiratory protection.		
	Special procedures	: Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.		
6.	Accidental release measures			
	6.1. Personal precautions, protective e	equipment and emergency procedures		
	For emergency responders	: Wear protective equipment specified in paragraph 8 of this Safety Data Sheet. Ventilate area.		
	6.2. Environmental precautions			
	Environmental precautions	: Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.		
	6.3. Methods and material for containment and cleaning up			
	Clean up methods	: Follow the instructions on handling and technical measures of paragraph 7. On land, sweep or shovel into suitable containers.		
	6.4. Reference to other sections			
7.	Handling and storage			
	7.1. Precautions for safe handling			
	Technical protective measures	<ul> <li>Provide adequate ventilation of the area to prevent the formation of explosive atmospheres.</li> <li>Proper grounding procedures to avoid static electricity should be followed. Use</li> </ul>		
	Handling	<ul> <li>only non-sparking tools.</li> <li>Wear protective equipment specified in paragraph 8 of this Safety Data Sheet.</li> <li>For even minor contact, immediately remove contaminated clothing. Wash skin thoroughly with mild soap and water. Wash clothing before re-using.</li> </ul>		
	7.2. Conditions for safe storage, including any incompatibilities			
	Storage	: Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.		
	Storage - away from	: Strong bases. Strong acids. Sources of ignition. Direct sunlight.		
	7.3. Specific end use(s)			



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

7. Handling and storage (continued)				
Specific end use(s)	: None.			
8. Exposure controls/personal protection				
8.1. Exposure controls				
Personal protection	: Avoid all unnecessary exposure.			
Respiratory protection	: Wear approved mask.			
<ul> <li>Hand protection</li> </ul>	: Wear gloves.			
Eye protection	: Chemical goggles or safety glasses.			
Others	: Wash hands and other exposed areas with soap and water before leaving work.			
Technical protective measures	: Should always be handled in a closed system. Both local exhaust and general room ventilation are usually required.			

## 8.2. Control parameters

No data available.

## 9. Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state at 20 °C	: Solid.
Colour	: Pale
Odour	: Odourless.
Odour threshold	: No data available.
pH value	: Not applicable.
Melting point [°C]	: 208 210
Critical temperature [°C]	: Not applicable.
Auto-ignition temperature [°C]	: No data available.
Flammability (solid, gas)	: Not flammable.
Flash point [°C]	: Not applicable.
Initial boiling point [°C]	: Not applicable.
Final boiling point [°C]	: Not applicable.
Evaporation rate	: Not applicable.
Acid/alkali reserve [g NaOH/100g]	: No data available.
Explosion limits - lower [%]	: No data available.
Vapour pressure [20°C]	: No data available.
Vapour density	: No data available.
Density [kg/m3]	: No data available.
Relative density, liquid (water=1)	: Not applicable.
Solubility in water	: Partially soluble.
Viscosity at 40°C [mm2/s]	: No data available.



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

## 9. Physical and chemical properties (continued)

	9.2. Other information	
	Explosive properties	: Class St2 Kst 234 bar m/s Maximum pressure 8,3 bar Resistivity 2.00 e11 ohm m (24% RH), 1.30 e13 ohm m (< 1%) Minimum Ignition Temperature (layer) no ignition untl 400°C Minimum Ignition Temperature (cloud) 490 °C Minimum ignition energy (cloud) < 18 - 20 mJ
	Oxidising properties	: No data available.
10.	Stability and reactivity	
	10.1. Reactivity	
	Reactivity	: Not established.
	10.2. Chemical stability	
	Chemical stability	: Stable under recommended storage conditions.
	10.3. Possibility of hazardous reaction	<u>ns</u>
	Hazardous reactions	: Not established.
	10.4. Conditions to avoid	
	Conditions to avoid	: Direct sunlight. Extremely high or low temperatures.
	10.5. Incompatible materials	
	Materials to avoid	: Strong acids. Strong bases.
	10.6. Hazardous decomposition produ	ucts
	Hazardous decomposition products	: Fumes.
11.	Toxicological information	
	11.1. Information on toxicological effe	ects
	Acute toxicity Rat oral LD50 [mg/kg] Corrosion Irritation	<ul> <li>Harmful if swallowed.</li> <li>2400</li> <li>No data available.</li> <li>No data available.</li> </ul>



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

## 11. Toxicological information (continued)

Date : 17 / 12 / 2010	Revised edition no : 1 Page :
General	: Follow the instructions on handling and technical measures of paragraph 7. Avoid release to the environment. Can be burned in a chemical incinerator equipped with an afterburner and scrubber. Dispose in a safe manner in accordance with local/national regulations. This
13. Disposal considerations <u>13.1. Waste treatment methods</u>	
Environmental precautions	: Avoid release to the environment.
12.6. Other adverse effects	
Results of PBT and vPvB assessment	: Not applicable.
<b>12.5. Results of PBT and vPvB assess</b>	sment
	: Not established.
<u>12.4. Mobility in soil</u>	
Bioaccumulative potential	: Not established.
12.3. Bioaccumulative potential	
	: 3.14 #
	: Biodegradable.
12.2. Persistence - degradability	
	: [english only] Water:0.000024 g/l
48 Hour-EC50 - Daphnia magna [mg/l]	: 0.024 : 50 (Selenastrum Capricornutum)
Toxicity information	: Not established. Very toxic to aquatic life.
<u>12.1. Toxicity</u>	
12. Ecological information	
Aspiration hazard	: No data available.
	: No data available.
STOT-single exposure	: No data available.
Toxic for reproduction	: No data available. May damage fertility or the unborn child.
Carcinogenicity	: No data available.
Mutagenicity	: No data available.
Sensitization	: No data available.



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

## ALBENDAZOLE

## 13. Disposal considerations (continued)

material and its container must be disposed of as hazardous waste.

#### 14. Transport information

14.1. Land transport (ADR-RID)	
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ( ALBENDAZOLE)
UN N°	: 3077
H.I. nr	: 90
ADR - Class	: 9
Labelling - Transport	: 9
ADR - Classification code	: M7 M7
ADR - Group	: 111
ADR - Packing instructions	: P002 R001 LP002
ADR - Limited Quantity	: LQ 27
ADR - Tunnel code	: E : Passage forbidden through tunnels of category E.

#### 14.2. Sea transport (IMDG) [English only]

Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ( ALBENDAZOLE)		
UN N°	: 3077		
IMO-IMDG - Class or division	: 9		
IMO-IMDG - Packing group	: 111		
IMO- IMDG - Packing instructions	: P002 LP02		
IMO-IMDG - Limited quantities	: 5 kg		
IMO-IMDG - Marine pollution	: YES		
EMS-Nr	: F-A S-F		
14.3. Air transport (ICAO-IATA) [English only]			

# Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ( UN N° : 3077



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

# ALBENDAZOLE

## 14. Transport information (continued)

IATA - Class or division	: 9
IATA - Packing group	: 111
IATA - Passenger and Cargo Aircraft	: ALLOWED ALLOWED
- Passenger and Cargo - Packing instruction	: 911
- Passenger and Cargo - Maximum Quantity/Packing	: 400 kg
IATA - Cargo only	: ALLOWED
- Cargo only - Packing instruction	: 911
- Cargo only - Maximum Quantity/ Packing	: 400 kg
IATA - Limited Quantites	: 30 kg G
ERG-Nr	: 9L

## 15. Regulatory information

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

Safety, health and environmental regulations/legislation specific for the substance or mixture	: Ensure all national/local regulations are observed.
	: This product is not included in the lists of substances subject to diversion for illicit drug manufacture.
Chemical weapons [only English]	: This product is not included in the lists of the Chemical Weapons Convention.
15.2. Chemical Safety Assessment	
Chemical Safety Assessment	: Exempt under REACH for Active Ingredients and Synthesis' Intermediates.
16. Other information	
Revision	: Revision - See : *
Abbreviations and acronyms	<ul> <li>: &amp;&amp; Label only contains relevant P phrases.</li> <li># Estimated or calculated values.</li> <li>&amp; Exempt under REACH for Active Ingredients.</li> </ul>
Sources of key data used	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
List of relevant R phrases (heading 3)	<ul> <li>R22 : Harmful if swallowed.</li> <li>R50 : Very toxic to aquatic organisms.</li> <li>R61 : May cause harm to the unborn child.</li> </ul>
List of full text of H-statements in section 3	<ul> <li>: H400 : Very toxic to aquatic life.</li> <li>H302 : Harmful if swallowed.</li> <li>None.</li> <li>H360 : May damage fertility or the unborn child.</li> </ul>



In accordance with REACH Regulation (CE) Nº 1907/2006 and CLP Regulation (CE) Nº 1272/2008

## ALBENDAZOLE

## 16. Other information (continued)

Note

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