



# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 20/03/2016

Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Aripiprazole
Chemical name	: 7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}-3,4-dihydroquinolin-2(1H)-one
CAS No.	: 129722-12-9
Product code	: AO
Formula	: C23H27N3O2Cl2
Product group	: Pharmaceutical product

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Main use category	: Industrial use, Professional use
Industrial/Professional use spec.	: Isolated intermediate
Function or use category	: Antipsychotic

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Hetero Labs Ltd  
7-2-A2, Hetero corporate,  
500082 Hyderabad - INDIA  
T 04023774009  
[www.heterodrugs.com](http://www.heterodrugs.com)

#### 1.4. Emergency telephone number

No additional information available

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40

Full text of R-phrases: see section 16.

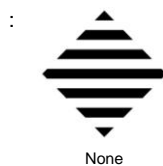
##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



None

CLP Signal word	: Warning
Hazard statements (CLP)	: H200 - Unstable explosives H332 - Harmful if inhaled H335 - May cause respiratory irritation
Precautionary statements (CLP)	: P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P235+P410 - Keep cool. Protect from sunlight P302+P350 - IF ON SKIN: Gently wash with plenty of soap and water P410 - Protect from sunlight
EUH phrases	: EUH210 - Safety data sheet available on request

#### 2.3. Other hazards

No additional information available

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name : Aripiprazole  
CAS No. : 129722-12-9  
EC no :  
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
7-(4-Bromobutoxy)-1,2,3,4-tetrahydroquinolin-2-one	(CAS No.) 129722-34-5		Not classified
Acetone	(CAS No.) 67-64-1 (EC no) 200-662-2 (EC index no) 606-001-00-8		F; R11 Xi; R36 R66 R67
Dimethyl sulfoxide	(CAS No.) 67-68-5		Not classified
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc.Cat.3; R40
Acetonitrile	(CAS No.) 75-05-8 (EC no) 200-835-2 (EC index no) 608-001-00-3		F; R11 Xn; R20/21/22 Xi; R36
7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}quinolin-2(1H)-one			Not classified
(4-(2,3-dichlorophenyl)-1-[4-(2-oxo-1,2,3,4-tetrahydroquinolin-7-yloxy)butyl]piperazin-1-oxide)			Not classified
1,1'-(Ethane-1,1-diyl)bis(2,3-dichloro-4-{4-[3,4-dihydroquinolin-2(1H)-one-7-yloxybutyl]piperazin-1-yl}benzene)			Not classified
Triethylamine	(CAS No.) 121-44-8 (EC no) 204-469-4 (EC index no) 612-004-00-5		F; R11 Xn; R20/21/22 C; R35
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5		F; R11
Hexanes	(CAS No.) 149845-06-7		Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
7-(4-Bromobutoxy)-1,2,3,4-tetrahydroquinolin-2-one	(CAS No.) 129722-34-5		Not classified
Acetone	(CAS No.) 67-64-1 (EC no) 200-662-2 (EC index no) 606-001-00-8		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Dimethyl sulfoxide	(CAS No.) 67-68-5		Not classified
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc. 2, H351
Acetonitrile	(CAS No.) 75-05-8 (EC no) 200-835-2 (EC index no) 608-001-00-3		Flam. Liq. 2, H225 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319
7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}quinolin-2(1H)-one			Not classified
(4-(2,3-dichlorophenyl)-1-[4-(2-oxo-1,2,3,4-tetrahydroquinolin-7-yloxy)butyl]piperazin-1-oxide)			Not classified
1,1'-(Ethane-1,1-diyl)bis(2,3-dichloro-4-{4-[3,4-dihydroquinolin-2(1H)-one-7-yloxybutyl]piperazin-1-yl}benzene)			
Triethylamine	(CAS No.) 121-44-8 (EC no) 204-469-4 (EC index no) 612-004-00-5		Flam. Liq. 2, H225 Skin Corr. 1A, H314 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5		Flam. Liq. 2, H225
Hexanes	(CAS No.) 149845-06-7		Not classified

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Full text of R-, H- and EUH-phrases: see section 16.

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: check the vital functions-Unconscious:maintain adequate airway and respiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
First-aid measures after inhalation	: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention . Remove the victim into fresh air-Respiratory problems:consult a doctor/medical service. Remove to fresh air and keep patient at rest. Seek medical attention immediately. Remove contaminated clothing. Flush area with large amount of water. USE SOAP. seek medical attention.
First-aid measures after skin contact	: Remove contaminated clothing. Flush area with large amount of water. USE SOAP. seek medical attention. Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention . Wash immediately with lots of water-Soap may be used-Do not apply(chemical)neutralizing agents-Take victim to a doctor if irritation persists.
First-aid measures after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Immediately flush eyes with running water for at least 15 minutes Seek medical attention. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmologist if irritation persists.
First-aid measures after ingestion	: If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Never give anything by mouth to an unconscious person.Wash out mouth with water.Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. Rinse mouth with water-Immediately after ingestion:give lots of water to drink.

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

No additional information available

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use carbon dioxide, dry chemical.

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

Fire hazard	: Flammable with air within explosion limits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level:ignition hazard.
Explosion hazard	: Not expected for the product, although the packaging is combustible.

### 5.3. Advice for firefighters

Precautionary measures fire : Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premises.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

### 6.3. Methods and material for containment and cleaning up

For containment	: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods for cleaning up	: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	: Wash clothing and equipment after handling.

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Gloves.

Handling temperature : 25 °C

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store the material at temperature 25±2°C.

Storage temperature : 25±2 °C

Storage area : Room.

Special rules on packaging : Material packed in double polythene bags inner transparent (purged with nitrogen), outer black, kept in HDPE drums.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

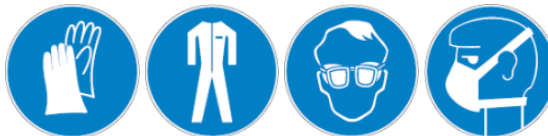
### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

Appropriate engineering controls : Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment : Gloves. Protective clothing. Protective goggles. Dust production: dust mask with filter type P2.



Materials for protective clothing : Chloroprene rubber nitrile rubber.

Hand protection : Gloves.

Eye protection : Protective goggles.

Skin and body protection : Protective clothing.

Respiratory protection : Gas mask with filter type A.

Other information : The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.

## SECTION 9: Physical and chemical properties

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

Physical state : Solid

Appearance : White to off-white crystalline powder.

Molecular mass : 448.39

Colour : off-white.

Odour : None.

Odour threshold : No data available

pH : No data available

Melting point : 139.0-139.5 °C

Solidification point : No data available

Boiling point : No data available

Flash point : No data available

Relative evaporation rate (butylacetate=1) : No data available

Flammability (solid, gas) : No data available

Explosive limits : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : No data available

Solubility : Freely soluble in dichloromethane, Sparingly soluble in toluene insoluble in methanol and water.

Log Pow : No data available

Log Kow : No data available

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable under defined conditions.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Insoluble in water.
Ecology - air	: Not dangerous for the ozone layer(1999/45/EC).

### 12.2. Persistence and degradability

Aripiprazole (129722-12-9)	
Persistence and degradability	% biodegradation.
Aripiprazole (129722-12-9)	
Persistence and degradability	% biodegradation.
Triethylamine (121-44-8)	
Persistence and degradability	% biodegradation.

### 12.3. Bioaccumulative potential

Aripiprazole (129722-12-9)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.
Aripiprazole (129722-12-9)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Triethylamine (121-44-8)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.

### 12.4. Mobility in soil

Aripiprazole (129722-12-9)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

Aripiprazole (129722-12-9)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

Triethylamine (121-44-8)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Other information : No other effects known.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.  
Ecology - waste materials : Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

## SECTION 14: Transport information

No dangerous good in sense of transport regulations.

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No Annex XVII restrictions  
Contains no REACH candidate substance

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

Full text of R-, H- and EUH-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Skin Corr. 1A	skin corrosion/irritation Category 1A
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled

# Aripiprazole

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H370	Causes damage to organs
R11	Highly flammable.
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R35	Causes severe burns.
R36	Irritating to eyes.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.
C	Corrosive
F	Highly flammable
T	Toxic
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*