

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

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Version: 00



ARIPIPAZOLUM

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

1.1 Product identifier

Product name: Aripiprazole
Aripiprazolum
Aripiprazol
Aripiprazole
Aripiprazol
N° CAS: 129722-12-9
N° EC: 603-355-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium
Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 3	H301
Acute Tox. 4	H302

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H302	Harmful if swallowed.

Precautionary statements:

P264	Wash hands and face thoroughly after handling.
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P270	Do not eat, drink or smoke when using this product.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P405	Store locked up.
P501	Dispose of contents/container in accordance with all local and national legislation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Aripiprazole
IUPAC name:	7-[4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy]-3,4-dihydroquinolin-2(1H)-one
Synonyms:	Abilify, Aripiprex
N° CAS:	129722-12-9
N° EC:	603-355-5
Molecular Formula:	C ₂₃ H ₂₇ Cl ₂ N ₃ O ₂
Content:	98.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove and wash/dispose of contaminated clothing promptly.
After inhalation:	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
After skin contact:	Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
After eye contact:	Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.
After ingestion:	If swallowed, wash out mouth with water provided person is conscious. Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Emits toxic fumes under fire conditions.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves.

For emergency responders

Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Turn leaking containers up to prevent further evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Sweep up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in a well-closed container. If the substance is sterile, store in a sterile, airtight, tamper-evident container.

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Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Required.

Skin protection: Industrial hygiene: Immediately change contaminated clothing. Wash hands and face after working with substance.

Hand protection: Required.

Respiratory protection: Required when dusts are generated.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white crystals or crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

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Relative density:	Not available.
Solubility:	Soluble in methylene chloride. Very slightly soluble in ethanol (96 %).
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 448.39

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: The Lethal Dose (LD₅₀) of Aripiprazole in rats is tabulated below:

Route	LD ₅₀
Oral (rat)	953 mg/kg
Oral (rat, female)	705 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

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Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Do not allow product to enter drinking water supplies, waste water or soil.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in accordance with all local and national legislation.

Packaging should be disposed of in accordance with all local and national legislation.

Handle contaminated containers as product.

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SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not regulated by USDOT as a hazardous material. Not regulated by IATA as a dangerous good.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.
R25 Toxic if swallowed.
R46 May cause heritable genetic damage.
R60 May impair fertility.
R61 May cause harm to the unborn child.
R36/38 Irritating to eyes and skin.

Safety phrases:

S1 Keep locked up
S20/21 When using do not eat, drink or smoke.
S46 If swallowed, seek medical advice immediately and show this container or label.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

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15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established 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, Authorization and Restriction of Chemicals (REACH), establishing the 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 Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be