SAFETY DATA SHEET

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 13-Oct-2009 **Revision Date** 01-Feb-2017 **Revision Number** 14

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

1.1. Product identifier

Product Name	**ARIPIPRAZOLE**
Chemical Name	7-[4-[4-(2,3-dichlorophenyl)piperazin-1-yl]butoxy]-3,4-dihydro-1H-quinolin-2-one
Synonyms	Abilify ;Abilitat ;Aripiprazole; OPC 31 ; OPC-14597; ABILIFY; 7-[4-[4-(2,3-dichlorophenyl)piperazin-1-yl]butoxy]-3,4-dihydocarbostyl
Formula	$C_{23}H_{27}Cl_2N_3O_2$
CAS	129722-12-9
EINECS	No information available
Index No	No information available
Reach Registration Number	No information available

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

Identified Use	Active Pharmaceutical Ingredient
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier

Assia Chemical Industries Ltd. - Teva-Tech site
Neot-Hovav Eco-Industrial Park
P.O Box 2049, Emek Sara
Be'er Sheva 8412316 Israel
Tel: 972-8-6509555
Fax: 972-8-6509500

For further information, please contact

E-mail Address SDS.TevaIL@teva.co.il

1.4. Emergency Telephone Number

Emergency Telephone Number

United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008

Acute Tox. 4 H302
Carc. 2 H351
Repr. 2 H361fd
Lact. H362
STOT RE 1 H372
Aquatic Chronic 1 H410

2.2. Label Elements

Signal Word **Danger**

Hazard Statements

H302 - Harmful if swallowed
H351 - Suspected of causing cancer
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child
H362 - May cause harm to breast-fed children
H372 - Causes damage to organs through prolonged or repeated exposure
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust
P273 - Avoid release to the environment
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %
7-[4-[4-(2,3-dichlorophenyl)piperazin-1-yl]butoxy]-3,4-dihydro-1H-quinolin-2-one	-	Not available	129722-12-9	100

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.

Skin Contact Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

Inhalation Remove person to fresh air. If signs/symptoms continue, get medical attention.

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

Irritation No information available.

Corrosivity No information available.

Eyes May cause: blurred vision.

Skin No information available.

Inhalation May cause: cough, difficulty breathing.

Ingestion May cause: nausea, vomiting, constipation, salivation, difficulty swallowing.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO_2). Foam. Dry powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors. Avoid all unnecessary contact.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so. Report according to local regulations.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in a tightly closed container, protected from light and moisture. Keep in a dry place. Keep in properly labeled containers. Keep at 25°C. Excursion permitted up to 40°C.

7.3. Specific end use(s)

Exposure Scenario	No information available.
Other Guidelines	No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits Teva OEL (8hr-TWA): 10 µg/m³

Biological occupational exposure limits No information available.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures Appropriate Engineering Controls.

Personal protective equipment

Eye/face protection Use eye protection appropriate for the task.

Skin protection:

- Body protection: Use protective clothing appropriate for the task.
- Hand protection: Use appropriate protective gloves.

Respiratory Protection Use appropriate respiratory protection.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Color	Colorless
Physical State	crystalline powder
Odor	No information available
Odor Threshold	No information available
pH	No information available
Melting Point/Range	139 °C
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper	No information available
Lower	No information available
Vapor Pressure	No information available
Density	1.26 (at 20 deg C)
Vapor Density	No information available
Relative Density	No information available
Solubility	Slightly soluble in Methanol. Soluble in Acetone, Chloroform, Methylene chloride.
Water Solubility	Insoluble in water
Octanol/water Partition Coefficient (Log Kow)	4.5
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight 448.4

SECTION 10: Stability and reactivity

10.1. Reactivity
No information available.

10.2. Chemical Stability
Stable. Product darkens on exposure to light.

10.3. Possibility of hazardous reactions
Hazardous polymerization does not occur.

10.4. Conditions to avoid
Heat, Moisture, Direct light.

10.5. Incompatible materials.
Oxidizing substances.

10.6. Hazardous decomposition products
Toxic fumes of: Nitrogen oxides (NOx), carbon oxides, hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity	
LD50 Oral rat	705(female), 953(male) mg/kg
skin corrosion/irritation	No information available.
serious eye damage/irritation	No information available.
respiratory or skin sensitization	No information available.
germ cell mutagenicity	Some evidence of mutagenicity in non-clinical studies, classification not required.
carcinogenicity	Some evidence of carcinogenicity in animal studies.
reproductive toxicity	Some evidence of effects on fertility and teratogenicity in animal studies.
STOT - single exposure	No information available.
STOT - repeated exposures	Causes damage to organs through prolonged or repeated exposure.
aspiration hazard	No information available.

Other Information

Target Organ Effects	Central nervous system (CNS). Cardiovascular system. Endocrine System.
Musculoskeletal System	May cause: rigidity, uncontrolled muscle movements.
Central nervous system	May cause impaired coordination, May cause lightheadness, May cause: headache, dizziness, weakness, restlessness, tremor, anxiety, irritability, agitation, convulsions, confusion, sleepiness.
Cardiovascular system	May cause: cardiac arrhythmias, changes in blood pressure.
Body as a whole	May cause: fever, swelling, pain, weight gain, sweating.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity effects

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Microtox	Daphnia Magna (Water Flea)
7-[4-[4-(2,3-dichlorophenyl)piperazin-1-yl]butoxy]-3,4-dihydro-1H-quinolin-2-one	EC50 (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass and growth rate, 72 H): > 0.14 mg/l (highest mean concentration tested) NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass, 72 H): 0.026 mg/l NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae growth rate, 72H): 0.14 mg/l	LC50 (Oncorhynchus mykiss (rainbow trout), 96 H): > 0.12 mg/l (highest mean concentration tested) NOEC (Oncorhynchus mykiss (rainbow trout), 96 H): 0.047 mg/l		NOEC (Daphnia magna (Water flea), 48 H): 0.031 mg/l NOEC (Daphnia magna (Water flea)): 0.00261 mg/l (reproduction rate)

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

Half-Life Elimination in Human: 75h. Bioconcentration factor (BFC) 53.9-85.7.

12.4. Mobility in soil

Immobile in soil.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products Dispose of in accordance with local regulations.

Contaminated Packaging Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1.
UN-No 3077

14.2.
Proper Shipping Name Environmentally hazardous substances, solid, n.o.s. (Aripiprazole)

14.3. Transport hazard class(es)
ADR / RID / ADN (land transport) 9
IMDG (sea transport) 9
IATA / ICAO (air transport) 9

14.4.
Packing Group III

14.5. Environmental hazards
Marine Pollutant Yes

14.6. Special precautions for user
Emergency No. -
ADR/RID-Labels -

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Tecnical name -
Ship type -
Annex II -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

This safety data sheet complies with the requirements of: GHS

15.2. Chemical Safety Assessment
No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

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Training appropriate for workers is required to ensure protection of human health and environment.

Application/Drug Class	Antipsychotic.
SDS sections updated	Section 2

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
ECHA (European chemicals agency) databases
FDA (Food & Drug administration) database
EMA (European Medicines agency) documents
ChemAdvisor
Chemspider database

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Revision Note

Not applicable

Disclaimer

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End of Safety Data Sheet