

Olanzapine impurity A

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form	:	Substance
Substance name	:	Olanzapine impurity A
Chemical name	:	5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile
EC Index-No.	:	608-060-00-5
EC-No.	:	421-300-1
CAS-No.	:	138564-59-7
Product code	:	201601059

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

1.2.1. Relevant identified uses

Main use category	:	The product is intended for research, analysis and scientific education.
Use of the substance/mixture	:	For professional use only
Function or use category	:	Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use	:	Do not use : Ingestion, Inhalation, Dermal
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1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number	:	+33(0)390215608
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS09

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	:	P273 - Avoid release to the environment.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

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No labelling required

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile	CAS-No.: 138564-59-7 EC-No.: 421-300-1 EC Index-No.: 608-060-00-5	≤ 100	Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).
First-aid measures after eye contact : Rinse eyes with water as a precaution.

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 : Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

6.1.2. For emergency responders

No additional information available

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6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection:

Lab coat

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

No additional information available

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not available
Odour threshold	: Not available
Melting point	: 109 – 111 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 5,9 – 6,4
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 3,2 at 20°C
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

No additional information available

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10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile (138564-59-7)

LD50 dermal rabbit	> 2000 mg/kg
LC50 Inhalation - Rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified pH: 5,9 – 6,4
Serious eye damage/irritation	: Not classified pH: 5,9 – 6,4
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Presents no specific risk for the environment.
Hazardous to the aquatic environment, short-term : Very toxic to aquatic life.
(acute)
Hazardous to the aquatic environment, long-term : Very toxic to aquatic life with long lasting effects.
(chronic)

5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile (138564-59-7)

LC50 - Fish [1]	1,279 mg/l LC50-96 Hour - fish
EC50 - Crustacea [1]	0,319 mg/l EC50 - 48 Hour - Daphnia magna

12.2. Persistence and degradability

5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile (138564-59-7)

Biodegradation	0
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12.3. Bioaccumulative potential

5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile (138564-59-7)

Partition coefficient n-octanol/water (Log Pow)	3,2 at 20°C
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5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile (138564-59-7)

Bioaccumulative potential	Strong.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

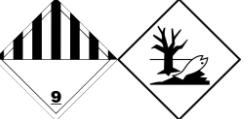
SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

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14.6. Special precautions for user

Overland transport

Classification code (ADR)	:	M7
Special provisions (ADR)	:	274, 335, 601, 375
Limited quantities (ADR)	:	5kg
Excepted quantities (ADR)	:	E1
Packing instructions (ADR)	:	P002, IBC08, LP02, R001
Special packing provisions (ADR)	:	PP12, B3
Mixed packing provisions (ADR)	:	MP10
Portable tank and bulk container instructions (ADR)	:	T1, BK1, BK2
Portable tank and bulk container special provisions (ADR)	:	TP33
Tank code (ADR)	:	SGAV, LGBV
Vehicle for tank carriage	:	AT
Transport category (ADR)	:	3
Special provisions for carriage - Packages (ADR)	:	V13
Special provisions for carriage - Bulk (ADR)	:	VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	:	CV13
Hazard identification number (Kemler No.)	:	90
Orange plates	:	
Tunnel restriction code (ADR)	:	E

Transport by sea

Special provisions (IMDG)	:	274, 335, 966, 967
Limited quantities (IMDG)	:	5 kg
Excepted quantities (IMDG)	:	E1
Packing instructions (IMDG)	:	P002, LP02
Special packing provisions (IMDG)	:	PP12
IBC packing instructions (IMDG)	:	IBC08
IBC special provisions (IMDG)	:	B3
Tank instructions (IMDG)	:	T1, BK1, BK2, BK3
Tank special provisions (IMDG)	:	TP33
EmS-No. (Fire)	:	F-A
EmS-No. (Spillage)	:	S-F
Stowage category (IMDG)	:	A
MFAG-No	:	171

Air transport

PCA Excepted quantities (IATA)	:	E1
PCA Limited quantities (IATA)	:	Y956
PCA limited quantity max net quantity (IATA)	:	30kgG
PCA packing instructions (IATA)	:	956
PCA max net quantity (IATA)	:	400kg
CAO packing instructions (IATA)	:	956
CAO max net quantity (IATA)	:	400kg
Special provisions (IATA)	:	A97, A158, A179, A197
ERG code (IATA)	:	9L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.