

SAFETY DATA SHEETS

According to the UN GHS revision 10

Version: 1.1
Creation Date: July 15, 2024
Revision Date: January 28, 2025

SECTION 1: Identification

1.1 GHS Product identifier

Product name Dexmedetomidine Impurity 55

1.2 Other means of identification

Product number C4X-123055

Other names 3,4-XYLIDINE; aniline,3,4-dimethyl; 3,4-XYLIDINE (3,4-DIMETHYLANILINE)

1.3 Recommended use of the chemical and restrictions on use

Identified uses For laboratory and Industrial use only.

Uses advised against no data available

1.4 Supplier's details

Company CATO Research Chemicals Inc.

Address 3/F,Building B,No.179 BASIGO, Guangpu Rd East,Huangpu Dist,Guangzhou

Telephone +86-20-81960175

1.5 Emergency phone number

Emergency phone number +86-20-81960175

Service hours 'Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Category 4, Oral

Acute toxicity - Category 3, Dermal

Acute toxicity - Category 3, Inhalation

Specific target organ toxicity – repeated exposure, Category 2

Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 2

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Danger

Hazard statement(s)

H302 Harmful if swallowed

H311 Toxic in contact with skin

H331 Toxic if inhaled

H373 May cause damage to organs through prolonged or repeated exposure

H411 Toxic to aquatic life with long lasting effects

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

Response	P301+P317 IF SWALLOWED: Get medical help. P330 Rinse mouth. P302+P352 IF ON SKIN: Wash with plenty of water/... P316 Get emergency medical help immediately. P321 Specific treatment (see ... on this label). P361+P364 Take off immediately all contaminated clothing and wash it before reuse. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P319 Get medical help if you feel unwell. P391 Collect spillage.
Storage	P405 Store locked up. P403+P233 Store in a well-ventilated place. Keep container tightly closed.
Disposal	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Dexmedetomidine Impurity 55	3,4-xylydine	95-64-7	202-437-4	≈ 99%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Fresh air, rest. Refer for medical attention.

Following skin contact

Remove contaminated clothes. Rinse and then wash skin with water and soap. Refer for medical attention .

Following eye contact

Rinse with plenty of water for several minutes (remove contact lenses if easily possible).

Following ingestion

Rinse mouth. Refer for medical attention .

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound may include headaches, drowsiness, cyanosis, mental confusion, convulsions, anorexia, nervous system and blood effects, fatigue, loss of appetite, dizziness, and damage to the lungs, liver and kidneys.
ACUTE/CHRONIC HAZARDS: This compound may be absorbed through the skin and may cause irritation on contact. When heated to decomposition it emits toxic fumes. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

no data available

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Use water spray, dry chemical, foam, or co2. wear full protective clothing. xylydines

5.2 Specific hazards arising from the chemical

This chemical is combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Use water spray, carbon dioxide, foam, powder.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal protection: chemical protection suit and filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers.

6.2 Environmental precautions

Personal protection: chemical protection suit and filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers.

6.3 Methods and materials for containment and cleaning up

Environmental considerations - land spill: Dig a pit, pond, lagoon, holding area to contain liquid or solid material. /SRP: If time permits, pits, ponds, lagoons, soak holes, or holding areas should be sealed with an impermeable flexible membrane liner. / Dike surface flow using soil, sand bags, foamed polyurethane, or foamed concrete. Absorb bulk liquid with fly ash, cement powder, or commercial sorbents. Xylidines

SECTION 7: Handling and storage

7.1 Precautions for safe handling

NO open flames. Above 98°C use a closed system and ventilation. Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Separated from strong oxidants, acids, acid anhydrides, acid chlorides, hypochlorites, halogens and food and feedstuffs. Well closed. Provision to contain effluent from fire extinguishing. Store in an area without drain or sewer access.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

MAK: skin absorption (H); carcinogen category: 3A

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear safety spectacles or eye protection in combination with breathing protection.

Skin protection

Protective gloves. Protective clothing.

Respiratory protection

Use ventilation, local exhaust or breathing protection.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	Solid. Crystalline.
Colour	Brown coloured.
Odour	no data available
Melting point/freezing point	49.6 °C.
Boiling point or initial boiling point and boiling range	228 °C. Atm. press.:760 Torr. Remarks:Boiling Point : 228.0±0.0 °C.
Flammability	Combustible. Gives off irritating or toxic fumes (or gases) in a fire.
Lower and upper explosion limit/flammability limit	no data available
Flash point	98 °C.
Auto-ignition temperature	580 °C. Remarks:Pressure not known.
Decomposition temperature	no data available
pH	7. Remarks:Concentration : saturated solution.
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 66° F (NTP, 1992)
Partition coefficient n-octanol/water	log Pow = 1.8. Temperature:25 °C. Remarks:PH not known.
Vapour pressure	0.028 mm Hg. Temperature:25 °C.
Density and/or relative density	0.532 g/cm³. Temperature:25 °C.
Relative vapour density	(air = 1): 4.19
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Decomposes on burning. This produces toxic and corrosive fumes including nitrogen oxides. Reacts violently with strong oxidants. Reacts with hypochlorites. This produces explosive chloroamines. Reacts with acids, acid anhydrides, acid chlorides and halogens. Attacks plastic and rubber.

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

3,4-XYLIDINE ignites on contact with fuming nitric acid (NTP, 1992). Neutralizes acids in exothermic reactions to form salts plus water. May be incompatible with isocyanates, halogenated organics, peroxides, phenols (acidic), epoxides, anhydrides, and acid halides. Flammable gaseous hydrogen may be generated in combination with strong reducing agents, such as hydrides.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizers, hypochlorite bleaches Xylidines

10.6 Hazardous decomposition products

When heated to decompose, xylidines emit highly toxic fumes. xylidines

SECTION 11: Toxicological information

Acute toxicity

- Oral: LD50 - rat - 812 mg/kg bw.
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

A3; Confirmed animal carcinogen with unknown relevance to humans. Xylidine (mixed isomers)

Reproductive toxicity

no data available

STOT-single exposure

Exposure at high levels could cause lowering of consciousness and formation of methaemoglobin. The effects may be delayed. Medical observation is indicated.

STOT-repeated exposure

The substance may have effects on the blood. This may result in anaemia.

Aspiration hazard

A harmful contamination of the air will be reached slowly on evaporation of this substance at 20°C; on spraying or dispersing, however, much faster.

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: LC50 - *Oryzias latipes* - 121 mg/L - 48 h.
- Toxicity to daphnia and other aquatic invertebrates: EC50 - *Daphnia magna* - 2.9 mg/L - 24 h.
- Toxicity to algae: EC50 - *Desmodesmus subspicatus* (previous name: *Scenedesmus subspicatus*) - 24 mg/L - 48 h.
- Toxicity to microorganisms: EC50 - *Tetrahymena pyriformis* - 234 mg/L - 48 h.

12.2 Persistence and degradability

3,4-Xylidine, present at 30 mg/l, reached 7.1% of the theoretical BOD in 4 weeks using an activated sludge inoculum(1). In the Japanese MITI test, 3,4-xylidine (present at 100 mg/l) was classified as slow to biodegrade indicating that only 0-29% of the theoretical BOD was reached in 2 weeks using an activated sludge inoculum(2). 3,4-Xylidine, present initially at 252 mg/L, was removed at a biodegradation rate of 30 mg COD/g-hr by an activated sludge inoculum(3). *E. coli* converted 3,4-xylidine to the corresponding (phenylazo)naphthol in the presence of nitrate with this reaction proceeding within 24 hours(4).

12.3 Bioaccumulative potential

BCF values of 1.9-3.3 and <10 were measured in carp for 3,4-xylydine at 1 and 0.1 mg/l, respectively, using a flow through system(1). According to a classification scheme(3), these BCF values suggest that bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

The Koc of 3,4-xylydine is estimated as approximately 240(SRC), using a measured log Kow of 1.84(1) and a regression-derived equation(2,SRC). According to a recommended classification scheme(3), this estimated Koc value suggests that 3,4-xylydine has moderate mobility in soil(SRC). However, anilines are expected to bind strongly to humus or soil organic matter in soils due to the high reactivity of the aromatic amino group(4,5). Low adsorption is observed at a neutral pH with pure clay minerals or soils for substituted anilines(5).

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN3452 (For reference only, please check.) IMDG: UN3452 (For reference only, please check.) IATA: UN3452 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: XYLIDINES, SOLID (For reference only, please check.) IMDG: XYLIDINES, SOLID (For reference only, please check.) IATA: XYLIDINES, SOLID (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.) IMDG: 6.1 (For reference only, please check.) IATA: 6.1 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: II (For reference only, please check.) IMDG: II (For reference only, please check.) IATA: II (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: Yes IMDG: Yes IATA: Yes

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
3,4-xylydine	3,4-xylydine	95-64-7	202-437-4
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.
Korea Existing Chemicals List (KECL)			Not Listed.

SECTION 16: Other information

Information on revision

Creation Date	July 15, 2024
Revision Date	January 28, 2025

Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Other Information

Depending on the degree of exposure, periodic medical examination is suggested. Specific treatment is necessary in case of poisoning with this substance; the appropriate means with instructions must be available. TLV only established for mixed isomers. See ICSCs 0451, 0600, 1519, 1686 and 1687.

Any questions regarding this SDS, Please send your inquiry to info@cato-chem.com

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.