

# SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.2  
Creation Date: July 15, 2019  
Revision Date: August 08, 2025

## SECTION 1: Identification

### 1.1 GHS Product identifier

Product name Valsartan Gene toxin Impurity 1

### 1.2 Other means of identification

Product number C4X-105750

Other names N-NITROSODIMETHYLAMINE; dimethyl-nitrosoamine; N-Methyl-N-nitrosomethanamine

### 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 3, Oral

Acute toxicity - Category 2, Inhalation

Carcinogenicity, Category 1B

Specific target organ toxicity – repeated exposure, Category 1

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)

H301 Toxic if swallowed

H330 Fatal if inhaled

H350 May cause cancer

H372 Causes 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.

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

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

P284 [In case of inadequate ventilation] wear respiratory protection.

P203 Obtain, read and follow all safety instructions before use.

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

P273 Avoid release to the environment.

|                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Response</b> | <p>P301+P316 IF SWALLOWED: Get emergency medical help immediately.</p> <p>P321 Specific treatment (see ... on this label).</p> <p>P330 Rinse mouth.</p> <p>P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P316 Get emergency medical help immediately.</p> <p>P320 Specific treatment is urgent (see ... on this label).</p> <p>P318 IF exposed or concerned, get medical advice.</p> <p>P319 Get medical help if you feel unwell.</p> <p>P391 Collect spillage.</p> |
| <b>Storage</b>  | <p>P405 Store locked up.</p> <p>P403+P233 Store in a well-ventilated place. Keep container tightly closed.</p>                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Disposal</b> | <p>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.</p>                                                                                                                                                                                                                                                                                                                  |

### 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 |
|---------------------------------|---------------------------|------------|-----------|---------------|
| Valsartan Gene toxin Impurity 1 | Dimethylnitrosoamine      | 62-75-9    | 200-549-8 | 100%          |

## 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 skin with plenty of water or shower.

#### Following eye contact

First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.

#### Following ingestion

Give a slurry of activated charcoal in water to drink. Refer for medical attention.

### 4.2 Most important symptoms/effects, acute and delayed

Exposure Routes: inhalation, skin absorption, ingestion, skin and/or eye contact Symptoms: nausea, vomiting, diarrhea, abdominal cramps; headache; fever; enlarged liver, jaundice; decreased liver, kidney, pulmonary function; [Potential occupational carcinogen] Target Organs: Liver, kidneys, lungs Cancer Site [in animals; lung, kidney, liver & nasal cavity tumors] (NIOSH, 2016)

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

Irrigate eyes with water. Wash contaminated areas of body with soap and water.

## SECTION 5: Fire-fighting measures

### 5.1 Suitable extinguishing media

Fire fighters should wear/ any self-contained breathing apparatus with a full facepiece and operated in a pressure demand or other positive pressure mode.

### 5.2 Specific hazards arising from the chemical

When heated to decomposition, it emits toxic fumes of nitrogen oxides. Avoid exposure to ultraviolet light. (EPA, 1998)

### 5.3 Special protective actions for fire-fighters

Use powder, carbon dioxide.

## SECTION 6: Accidental release measures

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

Evacuate danger area! Personal protection: chemical protection suit including self-contained breathing apparatus. Collect leaking and spilled liquid in sealable containers as far as possible. Absorb remaining liquid in sand or inert absorbent. Then store and dispose of according to local regulations.

### 6.2 Environmental precautions

Evacuate danger area! Personal protection: chemical protection suit including self-contained breathing apparatus. Collect leaking and spilled liquid in sealable containers as far as possible. Absorb remaining liquid in sand or inert absorbent. Then store and dispose of according to local regulations.

### 6.3 Methods and materials for containment and cleaning up

Spills of n-nitrosodiethylamine can be absorbed by celite or commercial spill absorbant. after absorbant containing major share of nitrosamine has been picked up (avoid dusts; do not sweep), surface should be thoroughly cleaned with strong detergent soln. if major spill occurs outside of ventilated area, room should be evacuated & cleanup operation should be carried out by persons equipped with self-contained respirators. those involved in this operation should wear rubber gloves, lab coats, & plastic aprons or equivalent protective apparel. n-nitrosodiethylamine, also applicable to other dialkyl nitrosamines

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

NO open flames. 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 and food and feedstuffs. Cool. Keep in the dark. Well closed. ALL BOTTLES OF N-NITROSODIETHYLAMINE SHOULD BE STORED & TRANSPORTED WITHIN UNBREAKABLE OUTER CONTAINER; STORAGE SHOULD BE IN VENTILATED STORAGE CABINET (OR IN HOOD). N-NITROSODIETHYLAMINE, ALSO APPLICABLE TO OTHER DIALKYL NITROSAMINES

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure limit values

TLV: (skin); A3 (confirmed animal carcinogen with unknown relevance to humans). MAK: skin absorption (H); carcinogen category: 2

#### 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 face shield or eye protection in combination with breathing protection.

#### Skin protection

Protective gloves.

#### 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                                           | N-nitrosodimethylamine is a yellow oily liquid with a faint characteristic odor. Boiling point 151-153°C. Can reasonably be expected to be a carcinogen. Used as an antioxidant, as an additive for lubricants and as a softener of copolymers. An intermediate in 1,1-dimethylhydrazine production. |
| Colour                                                   | Yellow, oily liquid                                                                                                                                                                                                                                                                                  |
| Odour                                                    | Faint, characteristic odor                                                                                                                                                                                                                                                                           |
| Melting point/freezing point                             | 16°C(lit.)                                                                                                                                                                                                                                                                                           |
| Boiling point or initial boiling point and boiling range | 208°C(lit.)                                                                                                                                                                                                                                                                                          |
| Flammability                                             | Combustible Liquid                                                                                                                                                                                                                                                                                   |
| Lower and upper explosion limit/flammability limit       | no data available                                                                                                                                                                                                                                                                                    |
| Flash point                                              | -8°C(lit.)                                                                                                                                                                                                                                                                                           |
| Auto-ignition temperature                                | no data available                                                                                                                                                                                                                                                                                    |
| Decomposition temperature                                | no data available                                                                                                                                                                                                                                                                                    |
| pH                                                       | no data available                                                                                                                                                                                                                                                                                    |
| Kinematic viscosity                                      | Low                                                                                                                                                                                                                                                                                                  |
| Solubility                                               | greater than or equal to 100 mg/mL at 66° F (NTP, 1992)                                                                                                                                                                                                                                              |
| Partition coefficient n-octanol/water                    | log Kow = -0.57                                                                                                                                                                                                                                                                                      |
| Vapour pressure                                          | 5 mm Hg ( 20 °C)                                                                                                                                                                                                                                                                                     |
| Density and/or relative density                          | 1.01 g/mL(lit.)                                                                                                                                                                                                                                                                                      |

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|                          |                                    |
|--------------------------|------------------------------------|
| Relative vapour density  | 2.56 (NTP, 1992) (Relative to Air) |
| Particle characteristics | no data available                  |

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

NIOSH considers N-nitrosodimethylamine to be a potential occupational carcinogen. Decomposes on heating. This produces nitrogen oxides. Reacts with strong oxidants and strong bases.

### 10.2 Chemical stability

Stable at room temperature for more than 14 days in neutral or alkaline solutions in the dark; slightly less stable in acidic solutions; sensitive to UV light.

### 10.3 Possibility of hazardous reactions

Combustible N-NITROSODIMETHYLAMINE is sensitive to exposure to light, especially ultraviolet light. Is stable at room temperature for more than 14 days in aqueous solution at neutral and alkaline pH in the absence of light. Slightly less stable at strongly acid pH at room temperature. Incompatible with strong oxidizing agents. Also incompatible with strong bases. Can be reduced by reducing agents. Incompatible with hydrogen bromide in acetic acid. Also photochemically reactive. (NTP, 1992)

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

Oxidants, especially peracids. Sensitive to UV light.

### 10.6 Hazardous decomposition products

When heated to decompose it emits toxic fumes of /oxides of nitrogen/.

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## SECTION 11: Toxicological information

#### Acute toxicity

- Oral: LD50 Rat oral 27-41 mg/kg
- Inhalation: LC50 Rat inhalation 78 ppm/4 hr
- 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

NTP: Reasonably anticipated to be a human carcinogen

#### Reproductive toxicity

No information is available on the reproductive or developmental effects of N-nitrosodimethylamine in humans. In a study of rats exposed to N-nitrosodimethylamine by injection, increased fetal mortality was observed but no birth defects were noted. N-Nitrosodimethylamine, when administered to pregnant rats, mice, and hamsters by several routes, has been shown to cause cancer in the offspring.

#### STOT-single exposure

The substance is irritating to the eyes, skin and respiratory tract. The substance may cause effects on the liver. This may result in jaundice. The effects may be delayed. See Notes. Medical observation is indicated.

#### STOT-repeated exposure

The substance may have effects on the liver. This may result in liver function impairment and cirrhosis. This substance is probably carcinogenic to humans.

#### Aspiration hazard

No indication can be given about the rate at which a harmful concentration of this substance in the air is reached on evaporation at 20°C.

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## SECTION 12: Ecological information

### 12.1 Toxicity

- Toxicity to fish: LD50; Species: *Oncorhynchus mykiss* (Rainbow trout) ip 1770 mg/kg for 10 days
- Toxicity to daphnia and other aquatic invertebrates: no data available

- Toxicity to algae: EC50; Species: *Anabaena flosaquae* (Blue-Green Algae) 10000 cells; Conditions: freshwater, static, 24 deg C; Concentration: 5100 ug/L for 96 hr; Effect: growth, general
- Toxicity to microorganisms: no data available

## 12.2 Persistence and degradability

No biodegradation of dimethylnitrosamine was observed in lake water samples during an observation period of 3.5 months, and a lag of nearly 30 days occurred before its slow disappearance from soil. The nitrosamine appeared to be degraded very slowly in sewage, but it was not affected by the anaerobic organisms /found in collected bog sediments/.

## 12.3 Bioaccumulative potential

An estimated BCF of 3 was calculated in fish for N-nitrosodimethylamine(SRC), using a log Kow of -0.57(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests that bioconcentration in aquatic organisms is low(SRC).

## 12.4 Mobility in soil

Kd (soil distribution coefficient) values of 0.45-0.64 L/kg were measured for N-nitrosodimethylamine in turfgrass, ground cover and bare surface soils that corresponded to Koc values 68-118(1). Similar results were observed in a study of subsurface soil samples including sand, sandy loam and loamy sand soils with Kd values ranging from 0.4-1.2 L/kg(2). According to a recommended classification scheme(3), the Koc values suggests that N-nitrosodimethylamine is expected to have high mobility in soil(SRC). N-Nitrosodimethylamine was found to leach through 4 different soils as readily as chloride ion(4). Another study also found that N-nitrosodimethylamine readily leached through soils(5). The leaching risk of N-nitrosodimethylamine in soils receiving reclaimed wastewater depend upon the hydraulic conductivity of the soil and irrigation intensity(6); proper irrigation volumes can reduce the leaching risk(6).

## 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: UN3382 (For reference only, please check.)      IMDG: UN3382 (For reference only, please check.)      IATA: UN3382 (For reference only, please check.)

## 14.2 UN Proper Shipping Name

|                                                                                                                                                                                                    |                                                                                                                                                                                                 |                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ADR/RID: TOXIC BY INHALATION LIQUID, N.O.S. with an LC50 lower than or equal to 1000 ml/m3 and saturated vapour concentration greater than or equal to 10 LC50 (For reference only, please check.) | IMDG: TOXIC BY INHALATION LIQUID, N.O.S. with an LC50 lower than or equal to 1000 ml/m3 and saturated vapour concentration greater than or equal to 10 LC50 (For reference only, please check.) | IATA: TOXIC BY INHALATION LIQUID, N.O.S. with an LC50 lower than or equal to 1000 ml/m3 and saturated vapour concentration greater than or equal to 10 LC50 (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: I (For reference only, please check.)      IMDG: I (For reference only, please check.)      IATA: I (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 |
|--------------------------------------------------------------------------|---------------------------|------------|-----------|
| Dimethylnitrosoamine                                                     | Dimethylnitrosoamine      | 62-75-9    | 200-549-8 |
| 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)                                     |                           |            | Listed.   |

## SECTION 16: Other information

### Information on revision

Creation Date July 15, 2019  
Revision Date August 08, 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](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

The symptoms of jaundice do not become manifest until some hours have passed. TLV Note: Exposure by all routes should be carefully controlled to levels as low as possible.

Any questions regarding this SDS, Please send your inquiry to [info@cato-chem.com](mailto: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.*