### MATERIAL SAFETY DATA SHEETS

# N-NITROSO-DABIGATRAN IMPURITY 8

### 1.IDENTIFICATION

#### 1.1 GHS PRODUCT IDENTIFIER

Product Name N-Nitroso-Dabigatran impurity 8

### 1.2 OTHER MEANS OF IDENTIFICATION

Product Name N-Nitroso-Dabigatran impurity 8

Other names N-(4-cyanophenyl)-2-((4-cyanophenyl)(nitroso)amino)acetamide

### 1.3 RECOMMENDED USE OF THE CHEMICAL AND RESTRICTIONS ON USE

**Identified uses** Industrial and scientific research uses

**Uses advised against** No data available

### 1.4 SUPPLIER'S DETAILS

**Company** Cleanchem Laboratories LLP

Address Plot No.R-80, 2nd Floor, Prama Instruments, TTC Industrial area, Rabale, Navi

Mumbai, Maharashtra-400 701

**Telephone** 022-27601987

### 2. HAZARD IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

NO DATA AVAILABLE

### 2.2 GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Pictogram(s)No data availableSignal wordNo data availableHazard statement(s)No data available

Precautionary statement(s)

PreventionNo data availableResponseNo data availableStorageNo data availableDisposalNo data available

**Hazard(s) not otherwise** None known

**classified (HNOC)** Pharmaceutical related compound of unknown potency.

Supplemental information

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 SUBSTANCES

NO DATA AVAILABLE

MOLECULAR FORMULA: C16H11N5O2 MOLECULAR WEIGHT: 305.3

Chemical name	Common names and synonyms	CAS number
N-(4-cyanophenyl)-2-((4- cyanophenyl)(nitroso)ami no)acetamide	NA	NA

### 4. FIRST-AID MEASURES

### 4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES

#### General advice

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance

#### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

# Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

# Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

# **Following ingestion**

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

# 4.2 MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED

may cause physiological effects

# 4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED, IF NECESSARY

Treat symptomatically

#### 5. FIRE-FIGHTING MEASURES

#### 5.1 EXTINGUISHING MEDIA

### Suitable extinguishing media

Water, use dry chemical, carbon dioxide or alcohol-resistant foam.

### 5.2 SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Carbon oxides, Nitrogen oxides, Hydrogen fluoride, Sulphur oxides

#### 5.3 SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS

Wear self-contained breathing apparatus for fire fighting if necessary.

#### 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid Inhalation of dust from the spilled material. Do not touch damaged containers or spilled material Unless wearing appropriate protective clothing. Ensure adequate ventilation.

### 6.2 ENVIRONMENTAL PRECAUTIONS

Avoid discharge into drains, water courses or onto the ground.

# 6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in Suitable container for disposal. Clean surface thoroughly to remove residual contamination. For Waste disposal

# 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry and well-ventilated place

Keep in a dry place.

Storage conditions: Refrigernator

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# 8.1 Control parametersg

# Occupational Exposure limit values

No exposure limits noted for ingredient

# 8.2 Appropriate engineering controls

A laboratory fume hood or other appropriate form of local exhaust ventilations

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

# Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

### Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

# **Respiratory protection**

Recommended respirators are NIOSH-approved N100 or CEN-approved FFP3 particulate respirators. These are to be only used as

a backup to local exhaust ventilation or other engineering controls. If the respirator is the only means of protection, a full-face

supplied air respirator must be used

### Thermal hazards

Wear appropriate thermal protective clothing, when necessary

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state NA Colour NA

Odour	NA
Melting point/ freezing point	NA
Boiling point or initial boiling point and boiling range	NA
Flammability	NA
Lower and upper explosion limit / flammability limit	NA
Flash point	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
pH	NA
Kinematic viscosity	NA
Solubility	NA
Partition coefficient n- octanol/water	NA
Vapour pressure	NA
Density and/or relative density	NA
Relative vapour density	NA
Particle characteristics	NA

# 10. STABILITY AND REACTIVITY

# **10.1 Reactivity**

The product is stable and non-reactive under normal conditions of use, storage and transport

# 10.2 Chemical stability

Material is stable under normal conditions

# 10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use

# 10.4 Conditions to avoid

Contact with incompatible materials

# 10.5 Incompatible materials

Strong oxidizing agents

# 10.6 Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

### 11. TOXICOLOGICAL INFORMATION

# **Acute toxicity**

ORAL LD50: NO DATA AVAILABLE
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

No data available

# Reproductive toxicity

No data available

# **STOT-single exposure**

No data available

# STOT-repeated exposure

No data available

# **Aspiration hazard**

Based on available data, the classification criteria are not met

#### 12. FCOLOGICAL INFORMATION

# 12.1 Ecotoxicity

There are no data on the ecotoxicity of this product.

# 12.2 Persistence and degradability

No data available

# 12.3 Bioaccumulative potential

No data available

# 12.4 Mobility in soil

No data available

#### 12.5 Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

# 13.1 Disposal methods

### **Product**

Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Contaminated packaging Dispose of as above.

#### 14. TRANSPORT INFORMATION

14.1 DOT: Not regulated as dangerous goods

IATA: Not regulated as dangerous goods

# 14.2 UN Proper Shipping Name

ADR/RID: No data available IMDG: No data available IATA: No data available

# 14.2 UN Proper Shipping Name

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# 14.3 Transport hazard class(es)

ADR/RID: No data available IMDG: No data available IATA: No data available

# 14.4 Packing group, if applicable

ADR/RID: No data available IMDG: No data available IATA: No data available

14.5 Environmental hazards

ADR/RID: No IMDG: No IATA: No

# 14.6 Special precautions for user

No data available

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

It is the shipper's responsibility to determine the correct transport classification at the time of shipment

# 15. Regulatory information

This product is not known to be a "Hazardous Chemical" as defined by the

**US federal regulations** OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

## TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### **European Union**

Not regulated.

# OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

### 16. OTHER INFORMATION

### Abbreviations and acronyms

- CAS: CHEMICAL ABSTRACTS SERVICE
- IATA: INTERNATIONAL AIR TRANSPORTATION ASSOCIATION
- LD50: LETHAL DOSE 50%

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