

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product Description: **Nevirapine**  
Cat No. : **461150000; 461150010; 461152500**  
CAS No **129618-40-2**  
Molecular Formula **C15 H14 N4 O**

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

Recommended Use Laboratory chemicals.  
Uses advised against No Information available

### 1.3. Details of the supplier of the safety data sheet

#### Company

**UK entity/business name**  
Fisher Scientific UK  
Bishop Meadow Road,  
Loughborough, Leicestershire LE11 5RG, United Kingdom

**EU entity/business name**  
Thermo Fisher Scientific  
Janssen Pharmaceuticaaan 3a, 2440 Geel, Belgium

E-mail address begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11  
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

##### Physical hazards

Based on available data, the classification criteria are not met

##### Health hazards

Acute oral toxicity

Category 4 (H302)

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## Environmental hazards

Chronic aquatic toxicity

Category 3 (H412)

Full text of Hazard Statements: see section 16

## 2.2. Label elements



Signal Word

Warning

## Hazard Statements

H302 - Harmful if swallowed

H412 - Harmful to aquatic life with long lasting effects

## Precautionary Statements

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

P312 - Call a POISON CENTER or doctor if you feel unwell

P264 - Wash face, hands and any exposed skin thoroughly after handling

P273 - Avoid release to the environment

P501 - Dispose of contents/ container to an approved waste disposal plant

## 2.3. Other hazards

No information available

This product does not contain any known or suspected endocrine disruptors

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

| Component  | CAS No      | EC No | Weight % | CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567 |
|------------|-------------|-------|----------|-----------------------------------------------------------------------------------------|
| Nevirapine | 129618-40-2 |       | <=100    | Acute Tox. 4 (H302)<br>Aquatic Chronic 3 (H412)                                         |

Full text of Hazard Statements: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

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|                                           |                                                                                                                                                  |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General Advice</b>                     | If symptoms persist, call a physician.                                                                                                           |
| <b>Eye Contact</b>                        | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.                                  |
| <b>Skin Contact</b>                       | Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.                                |
| <b>Ingestion</b>                          | Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.                                            |
| <b>Inhalation</b>                         | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.                                     |
| <b>Self-Protection of the First Aider</b> | Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. |

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

None reasonably foreseeable.

## **4.3. Indication of any immediate medical attention and special treatment needed**

**Notes to Physician** Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

### **5.1. Extinguishing media**

#### **Suitable Extinguishing Media**

Water spray, carbon dioxide (CO<sub>2</sub>), dry chemical, alcohol-resistant foam.

#### **Extinguishing media which must not be used for safety reasons**

No information available.

### **5.2. Special hazards arising from the substance or mixture**

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

#### **Hazardous Combustion Products**

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>), Carbon dioxide (CO<sub>2</sub>).

### **5.3. Advice 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**

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

### **6.2. Environmental precautions**

Should not be released into the environment. Do not flush into surface water or sanitary sewer system.

### **6.3. Methods and material for containment and cleaning up**

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Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

## 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

### 7.2. Conditions for safe storage, including any incompatibilities

To maintain product quality. Store in freezer. Keep container tightly closed in a dry and well-ventilated place.

**Technical Rules for Hazardous Substances (TRGS) 510**      Class 11  
**Storage Class (LGK) (Germany)**

### 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### **Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

#### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### **Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)**

No information available

#### **Predicted No Effect Concentration (PNEC)**

No information available.

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## 8.2. Exposure controls

### Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

### Personal protective equipment

**Eye Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

**Hand Protection** Protective gloves

| Glove material | Breakthrough time | Glove thickness | EU standard | Glove comments        |
|----------------|-------------------|-----------------|-------------|-----------------------|
| Nitrile rubber | See manufacturers | -               | EN 374      | (minimum requirement) |
| Neoprene       | recommendations   |                 |             |                       |
| Natural rubber |                   |                 |             |                       |
| PVC            |                   |                 |             |                       |

**Skin and body protection** Long sleeved clothing.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.  
To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

**Large scale/emergency use** Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced  
**Recommended Filter type:** Particulates filter conforming to EN 143

**Small scale/Laboratory use** Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.  
**Recommended half mask:-** Particle filtering: EN149:2001  
When RPE is used a face piece Fit Test should be conducted

**Environmental exposure controls** Prevent product from entering drains.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

|                          |                                 |
|--------------------------|---------------------------------|
| Physical State           | Solid                           |
| Appearance               | White to off-white              |
| Odor                     | No information available        |
| Odor Threshold           | No data available               |
| Melting Point/Range      | 247 - 249 °C / 476.6 - 480.2 °F |
| Softening Point          | No data available               |
| Boiling Point/Range      | No information available        |
| Flammability (liquid)    | Not applicable                  |
| Flammability (solid,gas) | No information available        |
| Explosion Limits         | No data available               |

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|                                         |                          |                                   |
|-----------------------------------------|--------------------------|-----------------------------------|
| Flash Point                             | No information available | Method - No information available |
| Autoignition Temperature                | No data available        |                                   |
| Decomposition Temperature               | No data available        |                                   |
| pH                                      | Not applicable           |                                   |
| Viscosity                               | Not applicable           | Solid                             |
| Water Solubility                        | No information available |                                   |
| Solubility in other solvents            | No information available |                                   |
| Partition Coefficient (n-octanol/water) |                          |                                   |
| Component                               | log Pow                  |                                   |
| Nevirapine                              | 3.89                     |                                   |
| Vapor Pressure                          | No data available        |                                   |
| Density / Specific Gravity              | No data available        |                                   |
| Bulk Density                            | No data available        |                                   |
| Vapor Density                           | Not applicable           | Solid                             |
| Particle characteristics                | No data available        |                                   |

## 9.2. Other information

|                   |                        |
|-------------------|------------------------|
| Molecular Formula | C15 H14 N4 O           |
| Molecular Weight  | 266.30                 |
| Evaporation Rate  | Not applicable - Solid |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

None known, based on information available

### 10.2. Chemical stability

No information available.

### 10.3. Possibility of hazardous reactions

|                          |                               |
|--------------------------|-------------------------------|
| Hazardous Polymerization | No information available.     |
| Hazardous Reactions      | None under normal processing. |

### 10.4. Conditions to avoid

Incompatible products.

### 10.5. Incompatible materials

Strong oxidizing agents.

### 10.6. Hazardous decomposition products

Carbon oxides. Nitrogen oxides (NOx). Carbon dioxide (CO<sub>2</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

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

#### Product Information

|                     |                   |
|---------------------|-------------------|
| (a) acute toxicity; |                   |
| Oral                | Category 4        |
| Dermal              | No data available |
| Inhalation          | No data available |

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|                                            |                                                           |
|--------------------------------------------|-----------------------------------------------------------|
| (b) skin corrosion/irritation;             | No data available                                         |
| (c) serious eye damage/irritation;         | No data available                                         |
| (d) respiratory or skin sensitization;     |                                                           |
| Respiratory                                | No data available                                         |
| Skin                                       | No data available                                         |
| (e) germ cell mutagenicity;                | No data available                                         |
| (f) carcinogenicity;                       | No data available                                         |
|                                            | There are no known carcinogenic chemicals in this product |
| (g) reproductive toxicity;                 | No data available                                         |
| (h) STOT-single exposure;                  | No data available                                         |
| (i) STOT-repeated exposure;                | No data available                                         |
| Target Organs                              | None known.                                               |
| (j) aspiration hazard;                     | Not applicable                                            |
|                                            | Solid                                                     |
| Symptoms / effects, both acute and delayed | No information available.                                 |

## 11.2. Information on other hazards

|                                 |                                                                                                                                     |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Endocrine Disrupting Properties | Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors. |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Ecotoxicity effects

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment.

### 12.2. Persistence and degradability

#### Persistence

#### Degradation in sewage treatment plant

No information available

Persistence is unlikely.

Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

### 12.3. Bioaccumulative potential

Bioaccumulation is unlikely

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| Component  | log Pow | Bioconcentration factor (BCF) |
|------------|---------|-------------------------------|
| Nevirapine | 3.89    | No data available             |

## 12.4. Mobility in soil

No information available

## 12.5. Results of PBT and vPvB assessment

No data available for assessment.

## 12.6. Endocrine disrupting properties

### Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

## 12.7. Other adverse effects

### Persistent Organic Pollutant Ozone Depletion Potential

This product does not contain any known or suspected substance  
This product does not contain any known or suspected substance

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from Residues/Unused Products

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

#### Contaminated Packaging

Dispose of this container to hazardous or special waste collection point.

#### European Waste Catalogue (EWC)

According to the European Waste Catalog, Waste Codes are not product specific, but application specific.

#### Other Information

Do not flush to sewer. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not let this chemical enter the environment.

## SECTION 14: TRANSPORT INFORMATION

### IMDG/IMO

Not regulated

#### 14.1. UN number

#### 14.2. UN proper shipping name

#### 14.3. Transport hazard class(es)

#### 14.4. Packing group

### ADR

Not regulated

#### 14.1. UN number

#### 14.2. UN proper shipping name

#### 14.3. Transport hazard class(es)

#### 14.4. Packing group

### IATA

Not regulated

#### 14.1. UN number

#### 14.2. UN proper shipping name



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## 14.3. Transport hazard class(es)

## 14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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

#### International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

| Component  | CAS No      | EINECS | ELINCS | NLP | IECSC | TCSI | KECL | ENCS | ISHL |
|------------|-------------|--------|--------|-----|-------|------|------|------|------|
| Nevirapine | 129618-40-2 | -      | -      | -   | -     | -    | -    | -    | -    |

| Component  | CAS No      | TSCA | TSCA Inventory notification - Active-Inactive | DSL | NDSL | AICS | NZIoC | PICCS |
|------------|-------------|------|-----------------------------------------------|-----|------|------|-------|-------|
| Nevirapine | 129618-40-2 | -    | -                                             | -   | -    | -    | -     | -     |

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

Authorisation/Restrictions according to EU REACH Not applicable

| Component  | CAS No      | REACH (1907/2006) - Annex XIV - Substances Subject to Authorization | REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances | REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC) |
|------------|-------------|---------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Nevirapine | 129618-40-2 | -                                                                   | -                                                                             | -                                                                                                     |

#### Seveso III Directive (2012/18/EC)

| Component  | CAS No      | Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification | Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements |
|------------|-------------|-------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Nevirapine | 129618-40-2 | Not applicable                                                                            | Not applicable                                                                           |

#### Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

#### Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

#### National Regulations

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UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification See table for values

| Component  | Germany - Water Classification (AwSV) | Germany - TA-Luft Class |
|------------|---------------------------------------|-------------------------|
| Nevirapine | WGK2                                  |                         |

## 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed

H412 - Harmful to aquatic life with long lasting effects

### Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

### Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date

08-Mar-2016

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|                  |                       |
|------------------|-----------------------|
| Revision Date    | 06-Oct-2023           |
| Revision Summary | SDS sections updated. |

**This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.**

## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**