

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Creation Date 15-Feb-2018

Revision Date 12-Oct-2023

Revision Number 3

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

1.1. Product identifier

| Product Description: |
|----------------------|
| Cat No. : |
| Synonyms |
| Molecular Formula |

Metolazone BP2667-100 Zaroxolyn. C16H16CIN3O3S

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

Сс

| 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 Pharmaceuticalaan 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

Based on available data, the classification criteria are not met

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Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements

None required

2.3. Other hazards

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 |
|------------|------------|-------------------|----------|---|
| Metolazone | 17560-51-9 | EEC No. 241-539-3 | 100 | - |

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

| Eye Contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention. |
|------------------------------------|---|
| Skin Contact | Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur. |
| Ingestion | Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur. |
| Inhalation | Remove to fresh air. Get medical attention immediately if symptoms occur. |
| Self-Protection of the First Aider | No special precautions required. |
| 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

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, carbon dioxide (CO2), 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

None under normal use conditions.

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. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

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. Avoid contact with skin, eyes or 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.

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7.2. Conditions for safe storage, including any incompatibilities

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.

8.2. Exposure controls

Engineering Measures

None under normal use conditions.

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

Hand Protection Protective gloves

| Glove material Nitrile rubber Neoprene Natural rubber PVC | Breakthrough time See manufacturers recommendations | Glove thickness - | EU standard EN 374 | Glove comments (minimum requirement) |
|---|---|----------------------|-----------------------|---|
| Skin and body prote | ection Long sle | eved clothing. | | |

Skin and body protection siee

Inspect gloves before use.

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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 compatability, 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 | No protective equipment is needed under normal use conditions. |
|----------------------------|---|
| 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: Particle filter |
| Small scale/Laboratory use | Maintain adequate ventilation |

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| Physical State | Powder Solid | |
|--|--|-----------------------------------|
| Appearance Odor Odor Threshold Melting Point/Range Softening Point Boiling Point/Range Flammability (liquid) Flammability (solid,gas) Explosion Limits | White No information available No data available 248 - 250 °C / 478.4 - 482 °F No data available No information available No information available No data available No data available | Solid |
| Flash Point Autoignition Temperature Decomposition Temperature pH | Not applicable No data available No data available | Method - No information available |
| Viscosity Water Solubility Solubility in other solvents Partition Coefficient (n-octanol/wate Vapor Pressure Density / Specific Gravity | Not applicable Insoluble No information available er) No data available No data available | Solid |
| Bulk Density Vapor Density Particle characteristics | No data available Not applicable No data available | Solid |
| 9.2. Other information | | |
| Molecular Formula Molecular Weight Evaporation Rate | C16H16CIN3O3S 365.6433 Not applicable - Solid | |

SECTION 10: STABILITY AND REACTIVITY

| 10.1. Reactivity | None known, based on information available |
|---|--|
| 10.2. Chemical stability | Stable under normal conditions. |
| 10.3. Possibility of hazardous react | ions |
| Hazardous Polymerization Hazardous Reactions | No information available. None under normal processing. |
| 10.4. Conditions to avoid | Incompatible products. Excess heat. |
| 10.5. Incompatible materials | None known. |

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information

Metolazone

| (a) acute toxicity; | |
|---------------------|--|
| Oral | Based on available data, the classification criteria are not met |
| Dermal | No data available |
| Inhalation | No data available |

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|------------|---------------------|-------------|-----------------|
| Metolazone | LD50 > 5 g/kg (Rat) | - | - |
| | | | |

| (b) skin corrosion/irritation; | No data available |
|---|--|
| (c) serious eye damage/irritation; | No data available |
| (d) respiratory or skin sensitization; Respiratory Skin | No data available 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;

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No data available

Target OrgansNo information available.

(j) aspiration hazard; Not applicable Solid

Symptoms / effects,both acute and No information available. delayed

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

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

| 12.2. Persistence and degradability Persistence | Insoluble in water. | | |
|---|--|--|--|
| 12.3. Bioaccumulative potential | May have some potential to bioaccumulate | | |
| <u>12.4. Mobility in soil</u> | Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water solubility. | | |
| <u>12.5. Results of PBT and vPvB</u> assessment | No data available for assessment. | | |
| <u>12.6. Endocrine disrupting</u> properties Endocrine Disruptor Information | This product does not contain any known or suspected endocrine disruptors | | |
| <u>12.7. Other adverse effects</u> 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 | Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification. |
|--|---|
| Contaminated Packaging | Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use |

| | empty containers. |
|--------------------------------|--|
| European Waste Catalogue (EWC) | According to the European Waste Catalog, Waste Codes are not product specific, but application specific. |
| Other Information | Waste codes should be assigned by the user based on the application for which the product was used. |

SECTION 14: TRANSPORT INFORMATION

| IMDG/IMO | Not regulated |
|--|----------------------------------|
| <u>14.1. UN number</u> 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group | |
| ADR | Not regulated |
| <u>14.1. UN number</u> 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group | |
| ΙΑΤΑ | Not regulated |
| <u>14.1. UN number</u> 14.2. UN proper shipping name 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 |
|------------|------------|-----------|---------|--------------------------------|-------|------|------|-------|-------|
| Metolazone | 17560-51-9 | 241-539-3 | - | - | - | Х | - | - | - |
| | | | | | | | | | |
| Component | CAS No | TSCA | notific | ventory ation - Inactive | DSL | NDSL | AICS | NZIoC | PICCS |
| Metolazone | 17560-51-9 | - | | _ | X | - | - | - | - |

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Legend: X - Listed '-' - Not Listed

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

Not applicable

Authorisation/Restrictions according to EU REACH

Component CAS No REACH (1907/2006) -REACH (1907/2006) -**REACH Regulation (EC** Annex XIV - Substances Annex XVII - Restrictions 1907/2006) article 59 Subject to Authorization on Certain Dangerous **Candidate List of** Substances Substances of Very High Concern (SVHC) 17560-51-9 Metolazone --

Seveso III Directive (2012/18/EC)

| Component | CAS No | Seveso III Directive (2012/18/EC) - | Seveso III Directive (2012/18/EC) - |
|------------|------------|--|---|
| | | Qualifying Quantities for Major Accident | Qualifying Quantities for Safety Report |
| | | Notification | Requirements |
| Metolazone | 17560-51-9 | 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

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

WGK Classification

Water endangering class = 2 (self classification)

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

Legend

| CAS - Chemical Abstracts Service | TSCA - United States Toxic Substances Control Act Section 8(b) |
|--|---|
| | Inventory |
| EINECS/ELINCS - European Inventory of Existing Commercial Chemical | DSL/NDSL - Canadian Domestic Substances List/Non-Domestic |
| Substances/EU List of Notified Chemical Substances | Substances List |
| PICCS - Philippines Inventory of Chemicals and Chemical Substances | ENCS - Japanese Existing and New Chemical Substances |

| IECSC - Chinese Inventory of Existing Chemical Substances KECL - Korean Existing and Evaluated 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, | 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) RTECS |
| Training Advice | |

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

| Creation Date | 15-Feb-2018 |
|------------------|-----------------|
| Revision Date | 12-Oct-2023 |
| Revision Summary | Not applicable. |

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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