

## SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 15-May-2023

Revision Number 1

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Product Code(s)** CAT 1282  
**Product Name** Solifenacin Succinate impurity standard  
**Form** Not applicable  
**Pure substance/mixture** Mixture

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

**Recommended use** Laboratory use  
**Uses advised against** No information available

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

##### Supplier

British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom

Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk

For further information, please contact

**E-mail address** bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

**Emergency Telephone** +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

##### **Emergency Telephone - §45 - (EC)1272/2008**

|                 |                          |
|-----------------|--------------------------|
| <b>Europe</b>   | <b>112</b>               |
| <b>Austria</b>  | No information available |
| <b>Bulgaria</b> |                          |

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|                |  |
|----------------|--|
| Croatia        |  |
| Cyprus         |  |
| Czech Republic |  |
| Denmark        |  |
| France         |  |
| Hungary        |  |
| Ireland        |  |
| Italy          |  |
| Lithuania      |  |
| Luxembourg     |  |
| Netherlands    |  |
| Norway         |  |
| Portugal       |  |
| Romania        |  |
| Slovakia       |  |
| Slovenia       |  |
| Spain          |  |
| Sweden         |  |
| Switzerland    |  |

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

|                                   |                     |
|-----------------------------------|---------------------|
| Acute toxicity - Oral             | Category 4 - (H302) |
| Skin corrosion/irritation         | Category 2 - (H315) |
| Serious eye damage/eye irritation | Category 2 - (H319) |

### 2.2. Label elements

Contains Solifenacin Succinate, Solifenacin Related Compound 33



Signal word

Warning

### Hazard statements

H302 - Harmful if swallowed

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H315 - Causes skin irritation

H319 - Causes serious eye irritation

EUH208 - Contains (1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline May produce an allergic reaction.

### Precautionary Statements - EU (§28, 1272/2008)

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

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

P280 - Wear protective gloves and eye/face protection

P337 + P313 - If eye irritation persists: Get medical advice/attention

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

### 2.3. Other hazards

No information available.

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

| Chemical name                                | EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation | EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Solifenacin Succinate                        | -                                                                                                                   | -                                                                          |
| Solifenacin Related Compound 33              | -                                                                                                                   | -                                                                          |
| (1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline | -                                                                                                                   | -                                                                          |

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

**Chemical nature** Mixture of organic compounds.

| Chemical name                        | Weight-%  | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP]    | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--------------------------------------|-----------|---------------------------|---------------------|--------------------------------------------------------------------|------------------------------------|----------|----------------------|
| Solifenacin Succinate<br>242478-38-2 | 90 - 100% | -                         | 620-505-5           | Acute Tox. 4 (H302)<br>Skin Irrit. 2 (H315)<br>Eye Irrit. 2 (H319) |                                    |          |                      |
| Solifenacin Related                  | 0 - 10%   | -                         | -                   | Acute Tox. 4 (H302)                                                |                                    |          |                      |

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|                                                             |         |   |           |                                                                                               |  |  |  |
|-------------------------------------------------------------|---------|---|-----------|-----------------------------------------------------------------------------------------------|--|--|--|
| Compound 33<br>1956436-64-8                                 |         |   |           |                                                                                               |  |  |  |
| (1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline<br>118864-75-8 | 0 - 10% | - | 445-640-5 | Acute Tox. 4 (H302)<br>Eye Irrit. 2 (H319)<br>Skin Sens. 1 (H317)<br>Aquatic Chronic 2 (H411) |  |  |  |

Full text of H- and EUH-phrases: see section 16

### Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

|                                           |                                                                                                                                                                                                                                                                                     |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General advice</b>                     | Show this safety data sheet to the doctor in attendance.                                                                                                                                                                                                                            |
| <b>Inhalation</b>                         | Remove to fresh air. Get medical attention immediately if symptoms occur.                                                                                                                                                                                                           |
| <b>Eye contact</b>                        | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists. |
| <b>Skin contact</b>                       | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.                                                                                                                                              |
| <b>Ingestion</b>                          | Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.                                                                                                                                                                          |
| <b>Self-protection of the first aider</b> | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).                                                                                                                                                                                       |

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

|                 |                                                               |
|-----------------|---------------------------------------------------------------|
| <b>Symptoms</b> | May cause redness and tearing of the eyes. Burning sensation. |
|-----------------|---------------------------------------------------------------|

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

|                        |                        |
|------------------------|------------------------|
| <b>Note to doctors</b> | Treat symptomatically. |
|------------------------|------------------------|

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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

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

**Specific hazards arising from the chemical** No information available.

### 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## SECTION 6: Accidental release measures

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

**Personal precautions** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

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

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

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### 6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

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

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

### 7.3. Specific end use(s)

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## 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 occupational exposure limits

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)** No information available.

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**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

#### Personal protective equipment

|                                        |                                                                                                                                                                                                                 |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye/face protection</b>             | If splashes are likely to occur, wear safety glasses with side-shields. Avoid contact with eyes. Wear safety glasses with side shields (or goggles).                                                            |
| <b>Hand protection</b>                 | Wear suitable gloves. Impervious gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves. |
| <b>Skin and body protection</b>        | Long sleeved clothing. Wear suitable protective clothing.                                                                                                                                                       |
| <b>Respiratory protection</b>          | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.                                        |
| <b>General hygiene considerations</b>  | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.                           |
| <b>Environmental exposure controls</b> | Do not allow into any sewer, on the ground or into any body of water.                                                                                                                                           |

## SECTION 9: Physical and chemical properties

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

|                        |                          |
|------------------------|--------------------------|
| <b>Physical state</b>  | Solid                    |
| <b>Appearance</b>      | Solid                    |
| <b>Colour</b>          | white                    |
| <b>Odour</b>           | Odourless.               |
| <b>Odour threshold</b> | No information available |

| <u>Property</u>                                | <u>Values</u>     | <u>Remarks • Method</u> |
|------------------------------------------------|-------------------|-------------------------|
| <b>Melting point / freezing point</b>          | No data available | None known              |
| <b>Initial boiling point and boiling range</b> | No data available | None known              |
| <b>Flammability</b>                            | No data available | None known              |
| <b>Flammability Limit in Air</b>               |                   | None known              |
| <b>Upper flammability or explosive limits</b>  | No data available |                         |
| <b>Lower flammability or explosive</b>         | No data available |                         |

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|                                 |                          |                          |
|---------------------------------|--------------------------|--------------------------|
| <b>limits</b>                   |                          |                          |
| Flash point                     | No data available        | None known               |
| Autoignition temperature        | No data available        | None known               |
| Decomposition temperature       |                          | None known               |
| pH                              | No data available        | None known               |
| pH (as aqueous solution)        | No data available        | No information available |
| Kinematic viscosity             | No data available        | None known               |
| Dynamic viscosity               | No data available        | None known               |
| Water solubility                | No data available        | None known               |
| Solubility(ies)                 | No data available        | None known               |
| Partition coefficient           | No data available        | None known               |
| Vapour pressure                 | No data available        | None known               |
| Relative density                | No data available        | None known               |
| Bulk density                    | No data available        |                          |
| Liquid Density                  | No data available        |                          |
| Relative vapour density         | No data available        | None known               |
| <b>Particle characteristics</b> |                          |                          |
| Particle Size                   | No information available |                          |
| Particle Size Distribution      | No information available |                          |

### 9.2. Other information

9.2.1. Information with regards to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

#### Explosion data

Sensitivity to mechanical impact None.  
Sensitivity to static discharge None.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

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### 10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

### 10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

## SECTION 11: Toxicological information

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

#### Information on likely routes of exposure

##### Product Information

|              |                                                                                                                                                                                                 |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inhalation   | Specific test data for the substance or mixture is not available.                                                                                                                               |
| Eye contact  | Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.                                   |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).                                                                                |
| Ingestion    | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components). |

#### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes.

#### Numerical measures of toxicity

No information available

#### Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 502.50 mg/kg

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### Delayed and immediate effects as well as chronic effects from short and long-term exposure

|                                          |                                                                                        |
|------------------------------------------|----------------------------------------------------------------------------------------|
| <b>Skin corrosion/irritation</b>         | Classification based on data available for ingredients. Causes skin irritation.        |
| <b>Serious eye damage/eye irritation</b> | Classification based on data available for ingredients. Causes serious eye irritation. |
| <b>Respiratory or skin sensitisation</b> | May cause sensitisation by skin contact.                                               |
| <b>Germ cell mutagenicity</b>            | No information available.                                                              |
| <b>Carcinogenicity</b>                   | No information available.                                                              |
| <b>Reproductive toxicity</b>             | No information available.                                                              |
| <b>STOT - single exposure</b>            | No information available.                                                              |
| <b>STOT - repeated exposure</b>          | No information available.                                                              |
| <b>Aspiration hazard</b>                 | No information available.                                                              |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

#### 11.2.2. Other information

**Other adverse effects** No information available.

## **SECTION 12: Ecological information**

### 12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

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**Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

| Chemical name                                | Algae/aquatic plants                                  | Fish                                  | Toxicity to microorganisms | Crustacea |
|----------------------------------------------|-------------------------------------------------------|---------------------------------------|----------------------------|-----------|
| (1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline | EC50: 5.5 mg/l (Pseudokirchneriella subcapitata, 72h) | LC50; 7.5 mg/l (Cyprinus carpio, 96h) | -                          | -         |

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

| Chemical name                                | Partition coefficient |
|----------------------------------------------|-----------------------|
| (1S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline | > 6.2                 |

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

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Contaminated packaging Do not reuse empty containers.

### SECTION 14: Transport information

#### IATA

|                                   |                |
|-----------------------------------|----------------|
| 14.1 UN number or ID number       | Not regulated  |
| 14.2 UN proper shipping name      | Not regulated  |
| 14.3 Transport hazard class(es)   | Not regulated  |
| 14.4 Packing group                | Not regulated  |
| 14.5 Environmental hazards        | Not applicable |
| 14.6 Special precautions for user |                |
| Special Provisions                | None           |

#### IMDG

|                                                              |                               |
|--------------------------------------------------------------|-------------------------------|
| 14.1 UN number or ID number                                  | Not regulated                 |
| 14.2 UN proper shipping name                                 | Not regulated                 |
| 14.3 Transport hazard class(es)                              | Not regulated                 |
| 14.4 Packing group                                           | Not regulated                 |
| 14.5 Marine pollutant                                        | Not applicable                |
| 14.6 Special precautions for user                            |                               |
| Special Provisions                                           | None No information available |
| 14.7 Maritime transport in bulk according to IMO instruments | No information available      |

#### RID

|                                   |                |
|-----------------------------------|----------------|
| 14.1 UN number or ID number       | Not regulated  |
| 14.2 UN proper shipping name      | Not regulated  |
| 14.3 Transport hazard class(es)   | Not regulated  |
| 14.4 Packing group                | Not regulated  |
| 14.5 Environmental hazards        | Not applicable |
| 14.6 Special precautions for user |                |
| Special Provisions                | None           |

#### ADR

|                                   |                |
|-----------------------------------|----------------|
| 14.1 UN number or ID number       | Not regulated  |
| 14.2 UN proper shipping name      | Not regulated  |
| 14.3 Transport hazard class(es)   | Not regulated  |
| 14.4 Packing group                | Not regulated  |
| 14.5 Environmental hazards        | Not applicable |
| 14.6 Special precautions for user |                |
| Special Provisions                | None           |

### SECTION 15: Regulatory information

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

**Water hazard class (WGK)** slightly hazardous to water (WGK 1)

#### Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

#### European Union

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.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

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#### Persistent Organic Pollutants

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### International Inventories

TSCA

Complies under research and development exemption or is regulated by a different government agency.

DSL/NDSL

Contact supplier for inventory compliance status

EINECS/ELINCS

Contact supplier for inventory compliance status

ENCS

Contact supplier for inventory compliance status

IECSC

Contact supplier for inventory compliance status

KECL

Contact supplier for inventory compliance status

PICCS

Contact supplier for inventory compliance status

AIIC

Contact supplier for inventory compliance status

#### Legend:

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

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

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

#### 15.2. Chemical safety assessment

##### Chemical Safety Report

A Chemical Safety Assessment has been carried out for this substance

### SECTION 16: Other information

#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

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H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H411 - Toxic to aquatic life with long lasting effects

### Legend

SVHC: Substances of Very High Concern for Authorisation:

### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)  
Ceiling Maximum limit value \* Skin designation

| Classification procedure                                        |                    |
|-----------------------------------------------------------------|--------------------|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used        |
| Acute oral toxicity                                             | Calculation method |
| Acute dermal toxicity                                           | Calculation method |
| Acute inhalation toxicity - gas                                 | Calculation method |
| Acute inhalation toxicity - Vapour                              | Calculation method |
| Acute inhalation toxicity - dust/mist                           | Calculation method |
| Skin corrosion/irritation                                       | Calculation method |
| Serious eye damage/eye irritation                               | Calculation method |
| Respiratory sensitisation                                       | Calculation method |
| Skin sensitisation                                              | Calculation method |
| Mutagenicity                                                    | Calculation method |
| Carcinogenicity                                                 | Calculation method |
| Reproductive toxicity                                           | Calculation method |
| STOT - single exposure                                          | Calculation method |
| STOT - repeated exposure                                        | Calculation method |
| Acute aquatic toxicity                                          | Calculation method |
| Chronic aquatic toxicity                                        | Calculation method |
| Aspiration hazard                                               | Calculation method |
| Ozone                                                           | Calculation method |

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AELG(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 15-May-2023

Revision Number 1

## CAT 1282 - Solifenacin Succinate impurity standard

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme  
Organisation for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

Revision date 15-May-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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**End of Safety Data Sheet**