

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

Revision Date 19-Mar-2024 Revision Number 2.1

72622 72624 - Rosiglitazone

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number DX21134

Product Name Rosiglitazone

Synonym Avandia; BRL 49653;

5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione;

Pure substance/mixture Substance

Contains 5-{ [4-({ 2-[methyl(2-pyridinyl)amino]ethyl} oxy)phenyl]methyl} -1,3-thiazolidine-2,4-dione

Molecular weight 357.4

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

Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

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

Europe 112

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| Serious eye damage/eye irritation | Category 2 - (H319) |
|-----------------------------------|---------------------|
| Reproductive toxicity | Category 2 - (H361) |
| Acute aquatic toxicity | Category 1 - (H400) |
| Chronic aquatic toxicity | Category 1 - (H410) |

2.2. Label elements

Contains 5-{ [4-({ 2-[methyl(2-pyridinyl)amino]ethyl} oxy)phenyl]methyl} -1,3-thiazolidine-2,4-dione



Signal word Warning

Hazard statements

Hazard statements

H319 - Causes serious eye irritation

H361 - Suspected of damaging fertility or the unborn child

H410 - Very toxic to aquatic life with long lasting effects

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

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

Additional information

This product requires tactile warnings if supplied to the general public

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonym

| Chemical name | EC No. | CAS No. | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|---------------|--------|-------------|----------|---|---------------------------------|
| 5-{ [4-({ | - | 122320-73-4 | 100 | Repr. 2 (H361) | No data available |



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| 2-[methyl(2-pyridinyl)amino]ethyl) | Aquatic Acute 1 (H400) |
|------------------------------------|--------------------------|
| oxy)phenyl]methyl} | Aquatic Chronic 1 (H410) |
| -1,3-thiazolidine-2,4-dione | Eye Irrit. 2A (H319) |

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact 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.

Skin contact Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

Ingestion Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider 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

Symptoms Burning sensation.

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

Note to physicians Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

Unsuitable Extinguishing Media No information available.

5.2. Special hazards arising from the substance or mixture



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Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment 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. 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 See Section 12 for additional Ecological Information.

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 upTake up mechanically, placing in appropriate containers for disposal.

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

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 Remove contaminated clothing and shoes. 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.

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with

skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or

smoke when using this product.



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7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Store in accordance with information listed on the Product Information Sheet (PIS).

7.3. Specific end use(s)

Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material 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.

Derived No Effect Level (DNEL)No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with

skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or

smoke when using this product.

Environmental exposure controls No information available.



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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Solid Physical state **Appearance** Crystalline

No information available Color No data available. Odor **Odor threshold** No data available

Values Remarks • Method **Property**

рΗ No data available None known Melting point / freezing point No data available None known No data available Boiling point / boiling range None known No data available None known Flash point **Evaporation rate** No data available None known Flammability (solid, gas) Product is not flammable. None known Flammability Limit in Air None known

Upper flammability limit:

No data available Lower flammability limit: No data available No data available

None known Vapor pressure Vapor density No data available None known None known Relative density No data available No data available None known Water solubility Solubility(ies) DMF: 25 mg/mL; DMSO: 34 mg/mL; None known

DMSO: PBS (7.2 pH) (1:3): 0.5 mg/mL;

Ethanol: 1 mg/mL

Partition coefficient No data available None known No data available **Autoignition temperature** None known **Decomposition temperature** No data available None known No data available Kinematic viscosity None known No data available Dynamic viscosity None known

No information available **Explosive properties**

No information available **Oxidizing properties**

9.2. Other information

No information available Softening point

Molecular weight 357.4

Molecular formula C18H19N3O3S

VOC Content (%) No information available No information available **Liquid Density Bulk density** No information available

Section 10: STABILITY AND REACTIVITY



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10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage 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.

Hazardous polymerization Hazardous polymerization does not occur.

10.4. Conditions to avoid

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon dioxide (CO2). Carbon monoxide. Nitrogen oxides (NOx). Sulfur oxides.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

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. May cause irritation.

Prolonged contact may cause redness and irritation.



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Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes.

Numerical measures of toxicity

Acute toxicity

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

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

| Skin corrosion/irritation | May cause skin irritation. | | | | |
|-----------------------------------|---|--|--|--|--|
| Product Information | | | | | |
| | | | | | |
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Irritating to eyes. | | | | |
| Product Information | | | | | |
| | | | | | |
| Respiratory or skin sensitization | No information available. | | | | |
| Product Information | | | | | |
| | | | | | |
| Germ cell mutagenicity | No information available. | | | | |
| Product Information | | | | | |
| | | | | | |
| Carcinogenicity | No information available. | | | | |
| Product Information | | | | | |
| | | | | | |
| Reproductive toxicity | Classification based on data available for ingredients. | | | | |
| | | | | | |
| Product Information | | | | | |
| STOT - single exposure | No information available. | | | | |
| Product Information | | | | | |



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STOT - repeated exposure No information available.

Product Information

Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo information available.

12.6. Other adverse effects

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.

Contaminated packaging Do not reuse empty containers.

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Section 14: TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity

Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted

Quantity.

IMDG

14.1 UN Number UN3077

14.2 UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Rosiglitazone)

14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles

14.4 Packing Group

14.5 Marine pollutant Not applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

RID

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

<u>ADR</u>

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

<u>IATA</u>

14.1 UN Number UN3077

14.2 UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Rosiglitazone)

14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles

14.4 Packing Group

14.5 Environmental hazard Not applicable

14.6 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

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

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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)

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

| TSCA | Does not comply |
|---------------|-----------------|
| DSL/NDSL | Does not comply |
| EINECS/ELINCS | Does not comply |
| ENCS | Does not comply |
| IECSC | Does not comply |
| KECL | Does not comply |
| PICCS | Does not comply |
| AICS | Does not comply |

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 No information available



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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

H319 - Causes serious eye irritation

H361 - Suspected of damaging fertility or the unborn child

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

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

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. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.