PRUCALOPRIDE SUCCINATE 2mg TABLETS

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

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

1.1 Product Identifier

Product Name	PRUCALOPRIDE SUCCINATE 2mg TABLETS
	Mixture
	Contains PRUCALOPRIDE drug substance

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

Identified Use	Medicinal product
Uses advised against	Other uses different from identified.

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer	
Company Identification	Combino Pharm (Malta) Ltd.
Address of Manufacturer	60 Qasam Industriali Hal Far BBG3000, Hal Far, Birzebbugia Malta
E-mail	

1.4 Emergency telephone number

Emergency Phone No.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP) Not classified.

2.2 Label elements

According to Regulation (EC) No. 1272/2008 (CLP)

Product Name	PRUCALOPRIDE Tartrate 1 mg tablets
Hazard Pictogram(s)	Not classified.
Signal Word(s)	Not classified
Hazard Statement(s)	Not classified.
Precautionary Statement(s)	Not classified.

2.3 Other hazards This material contains an active pharmaceutical ingredient, PRUCALOPRIDE.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not aplicable.

3.2. Mixture

HAZARDOUS INGREDIENT(S)	CAS No.	EINECS No.	%(w/w)	Hazard Statement(s)	Hazard Pictogram(s)
PRUCALOPRIDE SUCCINATE	179474-85-2	680-639-5	*	H302	GHS07

*Proprietary data

The materials included in this section are those hazardous substances present in the composition.
The total composition and materials included in the mixture is confidential and proprietary information.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation Remove person to fresh air and keep comfortable for breathing.

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	If exposed or concerned: Get medical advice/attention. Call a poison center or a doctor if you feel unwell.
Skin Contact	Wash skin with plenty of water.
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE/doctor.
Ingestion	Do not give an unconscious person anything to drink. Rinse mouth. Call a poison center or a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

See section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media	Water spray. Dry powder. Foam.
Unsuitable extinguishing media	None identified.

5.2 Special hazards arising from the substance or mixture

May decompose in a fire, giving off toxic and irritant vapours.

5.3 Advice for firefighters

Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Dike fire control water for later disposal.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Minimize potential for exposure.
Do not attempt to take action without suitable protective equipment. For further information refer to section 8: “Exposure controls/personal protection”.

6.2 Environmental precautions

Avoid release to the environment.
Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

6.3 Methods and material for containment and cleaning up

Mechanically recover the product.
Notify authorities if product enters sewers or public waters.

6.4 Reference to other sections

See also sections 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Ensure good ventilation of the work station. Avoid dust formation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with skin, eyes, or clothing. Do not eat, drink, or smoke during use. Wash hands and potentially exposure skin immediately after handling the product. Wash contaminated clothes. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	Keep container tightly closed. Store in the original container to protect from moisture. Store at 20ºC to 25ºC; excursions permitted between 15ºC to 30ºC [see USP controlled room temperature].
Storage life	Stable under normal conditions.
Incompatible materials	None known.

7.3 Specific end use(s)

Medicinal product.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1. Internal Occupational Exposure Band:	OEB-3B (1-10 µg/m^3) [internal value] (prucalopride succinate)

8.2 Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation. A washing facility/water for eye and skin cleaning purposes should be present. Prioritize technical measures and work methods appropriate to the use of individual protection equipment.
8.2.2. Personal protection equipment	Adapt the most appropriate Personal Protection Equipment (PPE) according to the risk assessment carried out by the company in the workplace and in the working conditions. In those scenarios where the collective and general protections applied are not sufficient, PPE must be used in accordance with the indications of current regulations.

Eye Protection — Safety glasses in accordance with the EN 166 standard if potential for eye contact is identified.

Skin Protection — Recommended nitrile glove, 0.11mm, penetration time >480 minutes.
Recommended body protective clothing if there is a risk of exposure or contact.
Personal protective equipment for skin protection should meet current standards.

Respiratory protection — Use respiratory protective equipment according to the risk of exposure and the Occupational Exposure limits established.

Thermal hazards — None known.

8.2.3. Environmental Exposure Controls	Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Tablet.
Colour	Pink.
Odour	Odourless
Melting point/freezing point	Not known.
Boiling point or initial boiling point and boiling range	Not known.
Flammability	Not known.
Lower and upper explosion limit	Not known.
Flash Point	Not known.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
pH	Not known.
Kinematic Viscosity	Not known.
Solubility	Not known.
Partition coefficient n-octanol/water (log value)	Not known.
Vapour pressure	Not known.
Density and/or relative density	Not known.
Relative vapour density	Not known.
Particle characteristics	Not known.

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9.2 Other information

Not known.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None anticipated.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

Keep away from heat and direct sunlight. Avoid ignition sources.
Store in the original container to protect from moisture.

10.5 Incompatible materials

Keep away from oxidizers, strong acids and strong bases.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity - Ingestion	Harmful if swallowed. LD50 Oral (rat): > 640 mg/kg (data for prucalopride succinate drug substance)
Acute toxicity - Skin Contact	Not classified. No data available.
Acute toxicity - Inhalation	Not classified. No data available.
Skin corrosion/irritation	Not classified. No data available.
Serious eye damage/irritation	Not classified. No data available.
Skin sensitization data	Not classified. No data available.
Respiratory sensitization data	Not classified. No data available.
Germ cell mutagenicity	The weight of evidence from *in vitro* and *in vivo* assays showed no genotoxicity concern for prucalopride.
Carcinogenicity	There is no evidence that this product represents a carcinogenic risk under normal conditions of handling and use.
Reproductive toxicity	Not classified.
Lactation	Not classified.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Aspiration hazard	Not classified

11.2 Information on other hazards

Unknown.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not known.

12.2 Persistence and degradability

Not known.

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12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

Not known.

12.6 Endocrine disrupting properties

Not known.

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of contents in accordance with local, state or national legislation. Send to a licensed recycler, reclaimer or incinerator. Dispose of this material and its container to hazardous or special waste collection point. Dispose at suitable refuse site.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: TRANSPORT INFORMATION

This material is not regulated as dangerous for transport.

14.1 UN number or ID number

UN No.	Not regulated

14.2 UN proper shipping name

UN proper shipping name	Not regulated

14.3 Transport hazard class(es)

ADR/RID	
ADR/RID Class	Not regulated
IMDG	
IMDG Class	Not regulated
ICAO/IATA	
Labels	Not regulated

14.4 Packing group

Packing group	Not regulated

14.5 Environmental hazards

Environmental hazards	Not regulated

14.6 Special precautions for user

Special precautions for user	Not known.

14.7 Maritime transport in bulk according to IMO instruments

No information available

SECTION 15: REGULATORY INFORMATION

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

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
REACH: ANNEX XIV list of substances subject to authorisation	Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not listed
Community Rolling Action Plan (CoRAP)	Not listed
Regulation (EU) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed

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National regulations

Other	Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements:

None. New document (version 1.0).

LEGEND

Hazard Statement(s)	H302 – Harmful if swallowed.
Key literature references and sources for data used to compile the SDS	Regulation (EC) No. 1272/2008 (CLP) Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice. Safe Work Australia. Updated June 2023.
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