Application General

eBS Logo

Product Name:	Digestive Enymes Plus
Product Code:	Other products
Client Name:	SunaHealth Labs Pty Ltd
Sponsor Name:	SunaHealth Labs Pty Ltd
Is this Application in response to a Section 30:	No
Can this product be used as a code stock:	s47
This application is to:	create a new ARTG Entry
Submission Cost:	$983.00
Payment Exemption No:	
Application Status:	Completed
Application Type:	New (A new AUST L will be generated)
Validation Report:	9/07/2024 3:37:41 PM

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

Must be derived from Aspergillus oryzae or Aspergillus niger.

Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline.

Pass with conditions - Must be derived from Aspergillus oryzae and comply with the relevant USP monograph.

Must be derived from Trichoderma longibrachiatum only.

Permitted for use only when derived from Rhizopus oryzae. Lipase must comply with the relevant compositional guideline.

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Ingredient Restriction Rule - Permitted for use only in medicines containing 20,000 lipase units (equivalent to 20,000 BP units) or less of lipase activity per dosage unit (Ingredient(s) concerned: 'Lipase')

PRODUCT DETAILS

Dosage Form: Capsule, hard

Route of Administration: Oral

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

Ingredient: Perilla frutescens 75 mg

Plant Part: leaf

Plant Preparation: Extract dry concentrate

Ratio: (12:1)

Equivalent Preparation: Dry 900 mg

Preparation Steps:

Plant Preparation:

Plant Preparation Step:

s47

Solvents:

Solvents:

Ingredient: protease 80 Thousand HUT

Ingredient: Amylase 24 thousand DU

Ingredient: tilactase 1.5 thousand ALU

Ingredient: cellulase 1 thousand CU

Ingredient: lipase 2.5 thousand LipU

EXCIPIENT INGREDIENTS:

STANDARD

Ingredient: maltodextrin

Ingredient: microcrystalline cellulose

Ingredient: croscarmellose sodium

Ingredient: hypromellose

Ingredient: colloidal anhydrous silica

PROPRIETARY INGREDIENTS

Ingredient: s47 [redacted]

MANUFACTURER DETAILS

s47 [redacted]

Name:
Manufacturer ID:
Licence ID:
Location:
Manufacturing Steps:

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Location:

Manufacturing Steps:

Name:

Manufacturer ID:

Licence ID:

Location:

Manufacturing Steps:

Name:

Manufacturer ID:

Licence ID:

Location:

Manufacturing Steps:

INDICATIONS & WARNINGS

Warning:

(S) If symptoms persist consult your healthcare practitioner (or words to that effect).

(VITMIN) Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Subsection 26B(1) Notification:

s47

Application General

eBS Logo

Product Name:	Clinical Gut Relief
Product Code:	Other products
Client Name:	SunaHealth Labs Pty Ltd
Sponsor Name:	SunaHealth Labs Pty Ltd
Is this Application in response to a Section 30:	No
Can this product be used as a code stock:	s47 [redacted]
This application is to:	create a new ARTG Entry
Submission Cost:	$983.00
Payment Exemption No:	
Application Status:	Completed
Application Type:	New (A new AUST L will be generated)
Validation Report:	17/07/2024 12:03:56 PM

Information Messages

Restricted word found: Relief. Requirements in Part 2 - General requirements for the advertising of therapeutic goods of the Therapeutic Goods Advertising Code may apply to your medicine: if an advertisement contains a claim relating to a symptom of a disease, condition, ailment or defect, the advertisement must contain either or both of the following statements as appropriate to the duration or recurrence of the symptoms, prominently displayed or communicated: (a) If symptoms persist, talk to your health professional; or (b) if symptoms worsen or change unexpectedly, talk to your health professional. Refer to the legislation to check any conditions or exceptions. Note: This requirement has changed, existing medicines using this word may have been required to include the (S) or (GEN2) warning statement in the ARTG entry, if it is no longer required this can be removed as free change by the applicant in this application.

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47 [redacted]

[redacted]

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (Ingredient(s) concerned: 'Maltodextrin')

The preparation may only contain a recommended daily dose of 34 milligrams or less of zinc sourced from the ingredient 'Polaprezinc'. (Ingredient(s) concerned: 'polaprezinc')

PRODUCT DETAILS

Dosage Form:	Powder, oral
Route of Administration:	Oral
Maximum daily dose:	7 g
Minimum weight of divided dosage form (tablets, capsules, metered dose sprays etc.):	-

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

Ingredient: glutamine 714.29 mg/g

Ingredient: Pistacia lentiscus 78.57 mg/g

- **Plant Part:** gum oleoresin
- **Plant Preparation:** Powder

Ingredient: Matricaria chamomilla 7.14 mg/g

- **Plant Part:** flower
- **Plant Preparation:** Extract dry concentrate
- **Ratio:** (8:1)
- **Equivalent Preparation:** Dry 57.12 mg/g
- **Preparation Steps:**
  - **Plant Preparation:** s47 [redacted]
  - **Plant Preparation Step:**
    - **Solvents:**
    - **Solvents:**

Ingredient: polaprezinc 10.71 mg/g

- **Equivalents:** zinc 2.3 mg/g

Ingredient: Glycyrrhiza glabra 21.43 mg/g

Plant Part: root wood

Plant Preparation: Extract dry concentrate

Ratio: (13:1)

Equivalent Preparation: Dry 278.59 mg/g

Preparation Steps:

Plant Preparation: s47

Plant Preparation Step:

Solvents:

EXCIPIENT INGREDIENTS:

STANDARD

Ingredient: maltodextrin

Ingredient: glycine

Ingredient: colloidal anhydrous silica

Ingredient: Stevia rebaudiana 10 mg/g

Plant Part: leaf

Plant Preparation: Extract dry concentrate

Ratio: (10:1)

Equivalent Preparation: Dry 100 mg/g

Preparation Steps:

Plant Preparation: s47

Plant Preparation Step:

Solvents:

Ingredient: citric acid

PROPRIETARY INGREDIENTS

Ingredient: s47

MANUFACTURER DETAILS

Name: s47

Manufacturer ID:

Licence ID:

Location:

Manufacturing Steps:

s47

Name: [redacted]
Manufacturer ID: [redacted]
Licence ID: [redacted]
Location: [redacted]
Manufacturing Steps: [redacted]

Name: [redacted]
Manufacturer ID: [redacted]
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Licence ID:
Location:
Manufacturing Steps:

Name:
Manufacturer ID:
Licence ID:
Location:
Manufacturing Steps:

s47 [redacted]

INDICATIONS & WARNINGS

Warning:

(S) If symptoms persist consult your healthcare practitioner (or words to that effect).

(SULF) Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

Subsection 26B(1) Notification:

s47 [redacted]