

NATURAL HEALTH PRODUCT

KELP PRODUCTS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date September 25, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
<i>Ascophyllum nodosum</i>	<ul style="list-style-type: none"> ▶ Knuppetang ▶ Norwegian kelp 	<i>Ascophyllum nodosum</i>	<ul style="list-style-type: none"> ▶ Thallus ▶ Whole
<i>Fucus vesiculosus</i>	<ul style="list-style-type: none"> ▶ Black tang ▶ Bladder fucus ▶ Kelpware ▶ Seawrack 	<i>Fucus vesiculosus</i>	<ul style="list-style-type: none"> ▶ Thallus ▶ Whole
<i>Laminaria digitata</i>	<ul style="list-style-type: none"> ▶ Horsetail kelp ▶ Kelp ▶ Silketare 	<i>Laminaria digitata</i>	<ul style="list-style-type: none"> ▶ Thallus ▶ Whole
<i>Laminaria japonica</i>	<ul style="list-style-type: none"> ▶ Hai dai ▶ Japanese kelp ▶ Makombu ▶ Sea tangle 	<i>Laminaria japonica</i>	<ul style="list-style-type: none"> ▶ Thallus ▶ Whole

References: Proper name: Guiry and Guiry 2018a,b; Common names: TGA 2016, The Biodiversity Committee of Chinese Academy of Science 2013; Source materials: Guiry and Guiry 2018a,b.

Route of administration

Oral



Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

All products

- ▶ Source of/Provides antioxidants (Murphy et al. 2013; CNF 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).
- ▶ Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Murphy et al. 2013; CNF 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).

Products providing 0.8 g or more of Fucus vesiculosus per day

- ▶ Traditionally used in Herbal Medicine as an alterative for the glandular system (Hoffman 2003; Duke 2002; Grieve 1931a,b; Felton and Lloyd 1898).
- ▶ Used in Herbal Medicine to support normal thyroid function (Bradley 1992; Grieve 1931a,b; Ellingwood 1919).

Products standardised to iodine

As per the Natural and Non-prescription Health Products Directorate (NNHPD) Multi-vitamin/mineral Supplements monograph.

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older



Quantity(ies)

Antioxidants

Methods of preparation: Dry, Powder, Non-standardised ethanolic extracts (fluid extract, tincture)

Not to exceed 1 gram of kelp per day (Barnes et al 2007; Mills and Bone 2005; Kolb et al 2004; Duke 2002; BHP 1996; Bradley 1992).

Fucus vesiculosus: alterative, support normal thyroid function

0.8 - 1 gram of *Fucus vesiculosus* per day (Mills and Bone 2005; Bradley 1992).

Iodine claims (Multi-vitamin/mineral Supplements monograph)

Methods of preparation: Standardized preparations

Medicinal ingredient(s) must provide the minimum amount of iodine outlined on the NNHPD Multi-vitamin/mineral Supplements monograph. Iodine should be indicated on the Product License Application form as a potency constituent.

Note

The total amount of iodine provided by the product must not exceed 800 microgram iodine per day (IOM 2006).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

- ▶ Consult a health care practitioner/health care provider/ health care professional/doctor/ physician prior to use if you are taking blood thinners (Gardner and McGuffin 2013; Ren et al 2013; Zhao et al 2012; Brinker 2010; Gruenwald et al 2007; Duke 2002).

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Brinker 2010; Barnes 2002).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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