



## NATURAL HEALTH PRODUCT

### HOLY BASIL – *OCIMUM TENUIFLORUM* – LEAF

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 ingredient.

#### 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

December 18, 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)	Preparation(s)
<i>Ocimum tenuiflorum</i>	<ul style="list-style-type: none"> <li>▶ Holy basil</li> <li>▶ Rama tulsi</li> <li>▶ Sacred basil</li> <li>▶ Tulsi</li> </ul>	<i>Ocimum tenuiflorum</i>	Leaf	Dried

References: Proper name: USDA 2018; McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, API 1999; Source material: API 1999, Agrawal et al. 1996.

#### 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)

- ▶ Traditionally used in Ayurveda (as an expectorant and/or demulcent) to help relieve cough (Kasa) and colds (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991).
- ▶ Traditionally used in Ayurveda (as an expectorant) to help relieve respiratory mucus buildup (catarrh) (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991).
- ▶ Traditionally used in Ayurveda as a cardi tonic (Hrdya) (Paranjpe 2005; Sudarshan 2005; Murthy 2004; Warriar 2003; Williamson 2002; Gogte 2000; API 1999).
- ▶ Traditionally used in Ayurveda to aid digestion (Dipani) and stimulate appetite (stomachic) (Paranjpe 2005; Murthy 2004; Warriar 2003; Kapoor 2001; Gogte 2000; API 1999; Khory 1999; Jain 1991).
- ▶ Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (in case of mental and physical fatigue related to stress) (McIntyre 2011; Winston and Maimes 2007; Hoffmann 2003; Williamson 2003).
- ▶ Source of/Provides antioxidants (Hakkim et al. 2007; Winston and Maimes 2007; Williamson 2003).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Ayurveda (as an expectorant and/or demulcent) to help relieve cough (Kasa) and colds and respiratory mucus buildup (catarrh) (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991).

### 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)

Methods of preparation: Dry, Powder, Non-Standardised Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

*Antioxidant*

Not to exceed 3 grams of dried leaf, per day (API 1999).



*Ayurveda; Adaptogen*

2 - 3 grams of dried leaf, per day (API 1999).

Methods of preparation: Non-Standardised Aqueous Extracts (Dry extract, Decoction, Infusion)

*Antioxidant*

Not to exceed 28 grams of dried leaf, per day (Williamson 2002; Kapoor 2001).

*Ayurveda*

7 - 28 grams of dried leaf, per day (Williamson 2002; Kapoor 2001).

*Adaptogen*

4.2 - 28 grams of dried leaf, per day (Winston and Maimes 2007; Williamson 2002; Kapoor 2001).

**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 breastfeeding, have a heart condition or diabetes (WHO 2002; Rai et al. 1997; Agrawal et al. 1996).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking any heart or blood pressure medication (Rai et al. 1997; Agrawal et al. 1996).

*Relief of cough/cold/respiratory mucus buildup; Digestive aid; Adaptogen*

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.



### **Contraindication(s)**

Do not use this product if you are pregnant (Prakash et al. 2005; Ahmed et al. 2002; WHO 2002; Wohlmuth 2002; Kapoor 2001).

### **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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