



## NATURAL HEALTH PRODUCT

### MUSHROOMS

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

March 25, 2019

#### 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>Agaricus blazei</i>	Himematsutake	<i>Agaricus blazei</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Auricularia auricula-judae</i>	Jelly ear	<i>Auricularia auricula-judae</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Ganoderma applanatum</i>	Artist's conk	<i>Ganoderma applanatum</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Ganoderma lucidum</i>	<ul style="list-style-type: none"> <li>• Ganoderma</li> <li>• Ling zhi</li> <li>• Reishi</li> </ul>	<i>Ganoderma lucidum</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Grifola frondosa</i>	Maitake	<i>Grifola frondosa</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Hericium erinaceus</i>	Lion's Mane	<i>Hericium erinaceus</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Inonotus obliquus</i>	Chaga	<i>Inonotus obliquus</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried



Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Lentinula edodes</i>	Shiitake	<i>Lentinula edodes</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Ophiocordyceps sinensis</i>	<ul style="list-style-type: none"> <li>• Chinese caterpillar fungus</li> <li>• Cordyceps</li> <li>• Cordyceps sinensis</li> <li>• Dong chong xia cao</li> </ul>	<i>Ophiocordyceps sinensis</i>	Stroma	Dried
<i>Paecilomyces hepiali</i>	<ul style="list-style-type: none"> <li>• Cultured Chinese caterpillar fungus</li> <li>• Cordyceps</li> <li>• Fa jiao chong cao jun</li> </ul>	<i>Paecilomyces hepiali</i>	Cultured mycelium	Dried
<i>Schizophyllum commune</i>	Split Gill fungus	<i>Schizophyllum commune</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Trametes versicolor</i>	<ul style="list-style-type: none"> <li>• Kawaratake</li> <li>• Turkey Tail</li> <li>• Yunzhi</li> </ul>	<i>Trametes versicolor</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Tremella fuciformis</i>	<ul style="list-style-type: none"> <li>• Silver ear</li> <li>• White mushroom</li> </ul>	<i>Tremella fuciformis</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Fruiting body</li> <li>• Mycelium</li> </ul>	Dried
<i>Wolfiporia extensa</i>	<ul style="list-style-type: none"> <li>• Fu ling</li> <li>• Hoelen</li> <li>• Indian bread</li> <li>• Poria</li> <li>• Sclerotium of tuckahoe</li> </ul>	<i>Wolfiporia extensa</i>	<ul style="list-style-type: none"> <li>• Cultured mycelium</li> <li>• Sclerotium/mycelium</li> </ul>	Dried

References: CABI 2014; De Sà-Nakanishi et al. 2014; Zhao 2013; Dai et al. 2012; PPRC 2010; NLM 2009; Youn et al. 2009; Nakajima et al. 2007; USDA 2006; Bensky et al. 2004; Chang and Miles 2004; Hobbs 2003; Chu et al. 2002; Wasser 2002; Bisby et al. 2000; McGuffin et al. 2000; TGA 1999; Lonvah and Deosthale 1998; MHPRC 1998; Saar 1991; Ying 1987.



## 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 fungal polysaccharides with immunomodulating properties (Xu et al. 2014; Mizuno and Nishitani 2013; Dai et al. 2012; Jung et al. 2012; Won et al. 2011; Wang et al. 2009; Chang and Miles 2004; Bensky et al. 2004; Hobbs 2003; Li et al. 2002; Wasser 2002; MHPRC 1998; Bin and Yang 1991).

*Products containing Lentinula edodes fruiting body and/or (cultured) mycelium, a decocted fruiting body of Agaricus blazei, a decocted fruiting body of Hericium erinaceus, a decocted cultured mycelium of Paecilomyces hepiali and/or a decocted stroma of Ophiocordyceps sinensis*

- ▶ Source of/Provides antioxidants (De Sà-Nakanishi et al. 2014; Zheng et al. 2014; Han et al. 2013; Qi et al. 2013; Wang et al. 2011; Bisen et al. 2010; Xu et al. 2010).
- ▶ Source of/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effects of/the oxidative damage caused by/cell damage caused by) free radicals (De Sà-Nakanishi et al. 2014; Zheng et al. 2014; Han et al. 2013; Qi et al. 2013; Wang et al. 2011; Bisen et al. 2010; Xu et al. 2010).

### *Products containing Ganoderma lucidum*

#### Fruiting Body

- ▶ Used in Traditional Chinese Medicine (TCM) to dispel phlegm, stop cough and arrest wheezing (PPRC 2010; Bensky et al. 2004; Chen and Chen 2004).
- ▶ Used in Traditional Chinese Medicine (TCM) to nourish the Heart and strengthen qi and blood to treat Heart and Spleen deficiencies that manifest in insomnia, forgetfulness, fatigue, listlessness and poor appetite (PPRC 2010; Bensky et al. 2004; Chen and Chen 2004).
- ▶ Used in Traditional Chinese Medicine (TCM) to strengthen the body and tonify qi (PPRC 2010; Bensky et al. 2004; Chen and Chen 2004).



### Fruiting Body; Cultured Mycelium; Mycelium

- ▶ Source of/Provides antioxidants (Wachtel-Galor et al. 2011; Godfrey et al. 2010; Wicks et al. 2007).
- ▶ Used in Herbal Medicine as a liver tonic (Godfrey et al. 2010; Yarnell et al. 2003; Saunders 2000; Huang 1999; Peirce 1999; Belanger 1997; Hsu et al. 1986).
- ▶ Used in Herbal Medicine to support the immune system (Wachtel-Galor et al. 2011; Godfrey et al. 2010; Ko and Leung 2007; Lin 2005; Chen and Chen 2004; Wachtel-Galor et al. 2004; Hoffmann 2003; Yarnell et al. 2003; Wasser 2002; Peirce 1999; Belanger 1997; Hsu et al. 1986).
- ▶ 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) (Godfrey et al. 2010; Hobbs 2003; Hoffmann 2003; Leung and Foster 1996).

### *Products containing Grifola frondosa*

Used in Herbal Medicine to support the immune system (Godfrey et al. 2010; Hobbs 2003; Hoffmann 2003; derMarderosian and Beutler 2002).

### *Products containing Wolfiporia extensa*

- ▶ Used in Herbal Medicine to support the immune system (Rios 2011; Hobbs 2003; Hoffmann 2003).
- ▶ Used in Traditional Chinese Medicine (TCM) for small quantity of urination, dizziness and palpitation caused by phlegm-fluid retention, spleen deficiency, reduced food intake, sloppy stool, diarrhea, disquietude of heart spirit, and insomnia (PPRC 2010).
- ▶ Used in Traditional Chinese Medicine (TCM) to promote urination and leach out dampness (for urinary difficulty and cases of scanty urine due to damp-heat) (Bensky et al. 2004).
- ▶ Used in Traditional Chinese Medicine (TCM) to promote urination to drain dampness, fortify the spleen, and calm the heart (PPRC 2010).
- ▶ Used in Traditional Chinese Medicine (TCM) to strengthen the spleen and harmonize the middle burner: for spleen deficiency compounded by dampness with symptoms such as loss of appetite, diarrhea, and epigastric distention (Bensky et al. 2004).
- ▶ Used in Traditional Chinese Medicine (TCM) to strengthen the spleen and transform phlegm: for spleen deficiency with thin mucous in which phlegm moves upward with symptoms such as palpitations, headache, dizziness, and thick, greasy tongue coating (Bensky et al. 2004).

### *Products containing Ophiocordyceps sinensis stroma*

Used in Traditional Chinese Medicine (TCM) to help tonify and replenish the lungs and kidneys, and resolve phlegm (PPRC 2010; Liu et al. 2005; Bensky et al. 2004).

### *Products containing Paecilomyces hepiali cultured mycelium*

Used in Traditional Chinese Medicine (TCM) to help tonify and replenish the lungs and kidneys, tonify essence, and replenish qi (PPRC 2010).

*Products containing decocted fruiting body of *Trametes versicolor**

Used in Traditional Chinese Medicine (TCM) to fortify the spleen to drain dampness and clear toxic heat (PPRC 2010).

*Products containing decocted fruiting body of *Tremella fuciformis**

Used in Traditional Chinese Medicine (TCM) to nourish the stomach yin, moisten the lungs and generate fluids and for yin deficiency with ascendant yang (Bensky et al. 2004).

*Products containing fruiting body or (cultured) mycelium of *Lentinula edodes**

Used in Herbal Medicine to support the immune system (Hobbs 2003; Wasser 2002).

**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)**

Refer to Table 2 below.

Table 2. Uses or purposes and associated daily doses

Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
<i>Agaricus blazei</i>	Source of fungal polysaccharides	Decoction	Not to exceed 9 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 9 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
	Source of antioxidants	Decoction	Not to exceed 9 g of dried fruiting body per day
		Decoction standardized	Not to exceed 9 g of dried fruiting body per day and 40 % polysaccharides
<i>Auricularia auricula-judae</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 15 g of dried cultured mycelium/fruited body/mycelium per day
		Decoction standardized	Not to exceed 15 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
<i>Ganoderma applanatum</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruited body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 30 g of dried cultured mycelium/fruited body/mycelium per day
		Decoction standardized	Not to exceed 30 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
<i>Ganoderma lucidum</i>	Source of antioxidants/fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	Not to exceed 6 g of dried cultured mycelium/fruited body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	Not to exceed 6 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 15 g of dried cultured mycelium/fruited body/mycelium per day
		Decoction standardized	Not to exceed 15 g of dried cultured mycelium/fruited body/mycelium per day and 40 % polysaccharides
	Herbal Medicine Immune Support claim	Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 g of dried cultured mycelium/fruited body/mycelium per day



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day	
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides	
		Decoction	3-15 g of dried cultured mycelium/fruiting body/mycelium per day	
		Decoction standardized	3-15 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides	
	Other Herbal Medicine claims/TCM claims		Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 g of dried cultured mycelium/fruiting body/mycelium per day
			Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides
			Decoction	3-15 g of dried cultured mycelium/fruiting body/mycelium per day
			Decoction standardized	3-15 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides
	<i>Grifola frondosa</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Extract (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	Not to exceed 7 g of dried cultured mycelium/fruiting body/mycelium per day
			Standardized Extract (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	Not to exceed 7 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
		Herbal Medicine Immune Support claim	Dry, Powder, Non-Standardized Ethanolic Extract (Dry extract, Tincture, Fluid extract)	1.6-7 g of dried cultured mycelium/fruiting body/mycelium per day
Standardized Ethanolic Extract (Dry extract, Tincture, Fluid extract)			1.6-7 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides	



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
		Decoction	3-7 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	3-7 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides
<i>Hericium erinaceus</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 2.8 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 2.8 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 12 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 12 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
	Source of antioxidants	Decoction	Not to exceed 12 g of dried fruiting body per day
		Decoction standardized	Not to exceed 12 g of dried fruiting body per day and 40 % polysaccharides
<i>Inonotus obliquus</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid Extract, Decoction)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Extracts (Dry extract, Tincture, Fluid Extract, Decoction)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
<i>Lentinula edodes</i>	Source of antioxidants/fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 6 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 6 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides





Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
		Decoction	Not to exceed 16 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 16 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
	Herbal Medicine Immune Support claim	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.6-6 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.6-6 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides
		Decoction	6-16 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	6-16 g of dried cultured mycelium/fruiting body/mycelium per day and not to exceed 40 % polysaccharides
<i>Ophiocordyceps sinensis</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3 g of dried stroma per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3 g of dried stroma per day and 40 % polysaccharides
	Source of antioxidants/fungal polysaccharides	Decoction	Not to exceed 9 g of dried stroma per day
		Decoction standardized	Not to exceed 9 g of dried stroma per day and 40 % polysaccharides
	TCM claim	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.5-3 g of dried stroma per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.5-3 g of dried stroma per day and not to exceed 40 % polysaccharides
		Decoction	3-9 g of dried stroma per day



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
		Decoction standardized	3-9 g of dried stroma per day and not to exceed 40 % polysaccharides
<i>Paecilomyces hepiali</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3 g of dried cultured mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3 g of dried cultured mycelium per day and 40 % polysaccharides
	Source of antioxidants/fungal polysaccharides	Decoction	Not to exceed 9 g of dried cultured mycelium per day
		Decoction standardized	Not to exceed 9 g of dried cultured mycelium per day and 40 % polysaccharides
	TCM claim	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.5-3 g of dried cultured mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.5-3 g of dried cultured mycelium per day and not to exceed 40 % polysaccharides
		Decoction	3-9 g of dried cultured mycelium per day
		Decoction standardized	3-9 g of dried cultured mycelium per day and not to exceed 40 % polysaccharides
<i>Schizophyllum commune</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 16 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 16 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day
<i>Trametes versicolor</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 5 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 5 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 27 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 27 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
	TCM claim	Decoction	9-27 g of dried fruiting body per day
		Decoction standardized	9-27 g of dried fruiting body per day and not to exceed 40 % polysaccharides
<i>Tremella fuciformis</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
		Decoction	Not to exceed 9 g of dried cultured mycelium/fruiting body/mycelium per day
		Decoction standardized	Not to exceed 9 g of dried cultured mycelium/fruiting body/mycelium per day and 40 % polysaccharides
	TCM claim	Decoction	3-9 g of dried fruiting body per day
		Decoction standardized	3-9 g of dried fruiting body per day and not to exceed 40 % polysaccharides
<i>Wolfiporia extensa</i>	Source of fungal polysaccharides	Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/sclerotium/mycelium per day



Medicinal Ingredients	Uses or purposes	Methods of Preparation	Doses (grams)/day	
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	Not to exceed 3.6 g of dried cultured mycelium/sclerotium/mycelium per day and 40 % polysaccharides	
		Decoction	Not to exceed 18 g of dried cultured mycelium/sclerotium/mycelium per day	
		Decoction standardized	Not to exceed 18 g of dried cultured mycelium/sclerotium/mycelium per day and 40 % polysaccharides	
	Herbal Medicine Immune Support claim		Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.6-3.6 g of dried cultured mycelium/sclerotium/mycelium per day
			Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid Extract)	1.6-3.6 g of dried cultured mycelium/sclerotium/mycelium per day and not to exceed 40 % polysaccharides
	Herbal Medicine Immune Support claim/TCM claims		Decoction	9-18 g of dried cultured mycelium/sclerotium/mycelium per day
			Decoction standardized	9-18 g of dried cultured mycelium/sclerotium/mycelium per day and not to exceed 40 % polysaccharides

References: Wachtel-Galor et al. 2011; Godfrey et al. 2010; PPRC 2010; Mori et al. 2009; Liu et al. 2008; Liu et al. 2005; Bensky et al. 2004; Chen and Chen 2004; Hobbs 2003; derMarderosian and Beutler 2002; Upton 2000; Huang 1999; Levy et al. 1998; MHPRC 1998; Ying 1987.

**Notes**

- ▶ For standardized extracts, as evidence mainly supports the quantity crude equivalent, both the quantity crude equivalent and the maximum concentration of the potency constituent must be met.
- ▶ *Ganoderma lucidum*: Non-extracted powder preparations are not acceptable to support the recommended use “Used in Herbal Medicine to support the immune system”.

**Direction(s) for use**

*Products containing Ganoderma lucidum*

Take with food/meal to avoid digestive upset (Flynn and Roest 1995).



## Duration(s) of use

### *Products containing Wolfiporia extensa*

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

## Risk information

- ▶ Consult Table 3 to determine the required risk statements for each medicinal ingredient.
- ▶ For products containing *Auricularia auricula-judae*, the caution and warning statement “Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding” will not be needed as it is covered by a contraindication for that subpopulation (statement #8).

## Caution(s) and warning(s)

1. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.
2. For claims related to reductions of symptoms: Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
3. Products providing 150 mg or more of dried *Grifola frondosa*, per day, prepared as dry, powder, dry ethanolic extract, tincture or fluid extract and/or 300 mg or more of dried *Grifola frondosa*, per day, prepared as decoction, and/or 300 mg or more of dried *Agaricus blazei* per day: Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Brinker 2010; Firenzuoli et al. 2008; Hsu et al. 2007; Konno 2003, 2001).
4. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (anti-coagulants) (Bisen et al. 2010; Wasser 2005).
5. Products making TCM claims based on *Ophiocordyceps sinensis* or *Paecilomyces hepiali*: Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have exterior pathogens/conditions (Bensky et al. 2004).
6. Products making TCM claims based on *Tremella fuciformis*: Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have cough from wind-cold (Bensky et al. 2004).
7. Products making TCM claims based on *Wolfiporia extensa*: Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a yin deficiency, sunken Spleen qi, or cold from deficiency with spermatorrhea (Bensky et al. 2004; Chen and Chen 2004).

## Contraindication(s)

8. Do not use this product if you are pregnant or breastfeeding.



**Known adverse reaction(s)**

9. Stop use if hypersensitivity/allergy occurs (derMarderosian and Beutler 2008; Bensky et al. 2004; Gao et al. 2003, 2002; Levy et al. 1998).
10. Diuretic effect may occur (PPRC 2010).

Table 3. Risk information

Medicinal Ingredients	Risk Information
<i>Agaricus blazei</i>	1, 3
<i>Auricularia auricula-judae</i>	8
<i>Ganoderma applanatum</i>	1
<i>Ganoderma lucidum</i>	2, 9
<i>Grifola frondosa</i>	3
<i>Hericium erinaceus</i>	1
<i>Inonotus obliquus</i>	1
<i>Lentinula edodes</i>	4, 9
<i>Ophiocordyceps sinensis</i>	1, 2, 5
<i>Paecilomyces hepiali</i>	1, 2, 5
<i>Schizophyllum commune</i>	1, 2
<i>Trametes versicolor</i>	1, 2
<i>Tremella fuciformis</i>	1, 2, 6
<i>Wolfiporia extensa</i>	7, 9, 10

**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.
- ▶ The product must not contain any traces of agaritine.

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