

NATURAL HEALTH PRODUCT

AHCC EXTRACT – Granule

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 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 on the label.
- For products in powder form, refer to the "AHCC EXTRACT – Powder" monograph.

Date

October 25, 2024

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

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
AHCC ¹	AHCC	<i>Lentinula edodes</i>	Cultured mycelium	Extract

References: Proper name: Spierings et al. 2007, Matsui et al. 2002; Common name: Spierings et al. 2007, Matsui et al. 2002; Source information: Fujii et al. 2011, Sumiyoshi et al. 2010.

¹AHCC is a specific standardized extract of cultured *Lentinula edodes* mycelia. See 'Specifications' section for identity testing.

Route of administration

Oral

Dosage form(s)

The acceptable dosage form is limited to capsules.

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



Use(s) or Purpose(s)

- Source of antioxidants/Provides antioxidants (Ye et al. 2004, 2003; Wang et al. 2001).
- 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 (Ye et al. 2004, 2003; Wang et al. 2001).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 6 grams of AHCC extract (granule), per day (Fujii et al. 2011; Cowawintaweewat et al. 2006; Uno et al. 2000).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if symptoms such as nausea and diarrhea occur (Sumiyoshi et al. 2010; Matsui et al 2002).

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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.
- AHCC® is a specific standardized extract of cultured *Lentinula edodes* mycelia, and as such, although it has in the past been referred to in the literature as ‘active hexose correlated compound’, AHCC is not a single compound but contains several constituents including the fraction called ‘active hexose correlated compound’. AHCC® should be identity-tested to confirm its authenticity.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each capsule AHCC (<i>Lentinula edodes</i> – cultured mycelium) XX mg
Uses <ul style="list-style-type: none"> • Source of antioxidants. • Source of antioxidants that help protect cell against free radicals.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Stop use if symptoms such as nausea and diarrhea occur.
Directions Adults 18 years and older: Take X capsule(s), X time(s) a day.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.



References cited

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