

NATURAL HEALTH PRODUCT

ACTIVE HEXOSE CORRELATED COMPOUND Powder (AHCC-FD)

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.
- For products in granule form, refer to the "Active Hexose Correlated Compound Granule (AHCC-FG)" monograph.

Date

December 29, 2023

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

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

_		Source information		
Proper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)
Active hexose correlated compound	Active hexose correlated compoundAHCC	Lentinula edodes	Mycelium	Isolate

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

Route of administration

Oral

Dosage form(s)

The acceptable dosage form is limited to powder.

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 (an) antioxidant(s)/Provides (an) antioxidant(s) (Ye et al. 2004, 2003; Wang et al. 2001).
- Source of (an) antioxidant(s)/Provides (an) antioxidant(s) that help(s) 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).

Note: If AHCC is combined with other medicinal ingredients with antioxidant properties, there is an option to use the claims in plural. The singular should be used when the product only contains one chemical substance (e.g. AHCC) as the medicinal ingredient associated with the claim.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 3.6 grams of Active hexose correlated compound powder (AHCC-FD), per day (Fujii et al. 2011; Cowawintaweewat et al. 2006; Uno et al. 2000).

Direction(s) for use

Mix product well in at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous beverage) immediately before consumption.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

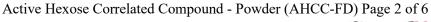
No statement required.

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, <u>Labelling of Natural Health Products</u> for more details.

Product Facts

Medicinal ingredient in each scoop

Active hexose correlated compound (*Lentinula edodes* – mycelium)

XX mg

Uses

- Source of an antioxidant/Provides an antioxidant
- Source of an antioxidant/Provides an antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals

Warnings

If applicable:

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 scoop(s), X times a day • Mix product well in at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous beverage) immediately before consumption.

Other information

(Add storage information)

Non-medicinal ingredients

List all NMIs

Questions? Call 1-XXX-XXX-XXXX





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