## Technical Description

### Structural Formula

- **Appearance**: Off-white crystalline powder
- **Solubility**: Solute in methanol
- **Identification**: IR, UV
- **Assay**: Hydroxymatairesinol + allo-isomer-potassium acetate
  - NLT 90 %
- **Related substances**: Matairesinol NMT 7 %
- **Water content**: NMT 10 %
- **Heavy metals**: NMT 20 ppm
- **Microbiology**: Complies with EP
- **Storage**: Preserve in tight container, protected from light, heat and humidity

## Bibliographic References


Lignans are a group of phytonutrients widely distributed in the plant kingdom. Their importance in health maintenance has been underscored by an increasingly large body of scientific knowledge and epidemiological data, which have identified them in a wide variety of foods such as cereal grain products, seeds, beans, lentils, fruits, and vegetables [1].

Unlike our ancestors’ diet, today’s Western diet does not include much in terms of lignan-containing foods so the amount of the phytonutrient is quite limited. Researchers suggest that the decrease in intake of foods containing lignans may have a weak estrogen-like effect, mimicking the presence of estrogens. When estrogen levels are high, lignans occupy and block the estrogen receptors, thereby smoothing both peaks and valleys [3].

Common Applications

Lignin intake increases serum enterolactones, which correlates with a decrease in the risk of coronary heart disease and cardiovascular disease, which is correlated with a decrease in the risk of breast cancer [10]. Results of many clinical studies support the hypothesis that dietary lignans positively influence estrogen balance in postmenopausal women (average age 54, range 30-70 years) suffering at least 14 hot flushes per week. In a 2006 Swedish study, Hedelin et al. investigated the possibility of phytoestrogens protecting against prostate cancer and the relationships between lignan intake and serum phytoestrogen concentrations and prostate cancer and the relationships between elevated enterolactone levels and the risk of breast and prostate cancer [13,14].

Toxicity and Safety

As this is a novel lignin source, the researchers conducted extensive safety testing in accordance with the rules of pharmacological GMP (Good Clinical Practice). In a 13-week toxicity study high systemic exposure to HMRlignan™ was tested by dose-related increases in the total incorporated and unconjugated plasma concentration of 7-HMR and the metabolites enterodiol and enterolactone. Enterodiol was selected as the main metabolite. HMRlignan™ exposure did not significantly affect clinical or biochemical, neurobehavioral, or motor activity. The observed adverse effects of HMRlignan™ were seen at 0.25% in food, corresponding to 100 mg/kg body weight. In May 2004, New Dietary Ingredients (FDI) clearance from the FDA was obtained for the ingredient.