

Dr Marion Balz  
William Wrigley Jr. Company  
*By Email*

17 October 2011

### **Supercritical Carbon Dioxide Extract of Magnolia Bark**

Dear Dr Balz,

I am writing to inform you of the outcome of your application made to the UK for the pre-market assessment of Magnolia Bark Extract in accordance with Articles 4 and 6 of the Novel Food Regulation (EC) Regulation 258/97.

1. In September 2009 an application was submitted by William Wrigley Jr. to the Food Standards Agency, the designated competent food assessment body in the UK, to place Magnolia Bark Extract on the EU market as a novel food ingredient.
2. On 19 July 2010 the Food Standards Agency issued its initial assessment report, having obtained advice from the Advisory Committee on Novel Foods and Processes (ACNFP), the independent Committee that advises the Agency on all novel food issues. This report concluded that Magnolia Bark Extract meets the criteria for acceptance as a novel food, as defined in Article 3(1) of the Regulation.
3. The Commission forwarded the initial assessment report to all member states on 27 July 2010. Within the 60 day period laid down in Article 6(4) of Regulation (EC) 258/97, no reasoned objections were presented by the Commission or the member states.

4. Certain points of clarification were requested by the German and French Authorities. These related to:
  - (a) Concerns about methyl eugenol levels in magnolia bark extract with a request to lower levels found in the novel ingredient
  - (b) Improvement in the method used to determine eudesmol
  - (c) Details on certification of laboratories
  - (d) Studies to assess safety and tolerance of magnolia bark extract in children and young people who are high level consumers of gums and mints
  - (e) A study on gene mutation in mammalian cells was requested
  - (f) Further reassurance to confirm the safety of the raw materials used to produce Magnolia Bark Extract
  
5. The Food Standards Agency has considered your responses which were submitted on 1 August 2011 and which we have forwarded to the French and German Authorities.
  - (a) You have indicated that the maximum limit for methyl eugenol will be reduced from 50 ppm to 10 ppm.
  - (b) You have provided a report from an accredited laboratory to show that the validated method used to determine eudesmol is accurate and reproducible down to a level of <0.10 mg/l and that this method can be used to monitor and minimise eudesmol levels.
  - (c) You have provided a certificate of accreditation for the laboratory that carried out the analyses for eudesmol.
  - (d) You have provided sufficient reassurance to justify the lack of safety and tolerance studies in children and young people.
  - (e) The ACNFP assessment did not raise any concerns relating to genotoxicity of Magnolia Bark Extract and no Member State

raised objections to the UK opinion. You have provided sufficient reassurance to justify that further data are not required.

(f) You have provided further reassurance about the manufacturing process and the quality assurance of the suppliers of magnolia bark extract in China.

6. Therefore, on the basis of the initial assessment report, it is established that Magnolia Bark Extract complies with the criteria laid down in Article 3(1) of Regulation 258/97 when placed on the market in accordance with the conclusions of the initial assessment report, namely:

I. Extract of Magnolia bark shall be obtained from the bark of *Magnolia officinalis* L and produced with supercritical carbon dioxide. Magnolia bark extract must comply with the specifications set out in the Annex to this letter.

II. Magnolia bark extract may be added to chewing gum and mint confectionery products at a maximum incorporation level of 0.2% for breath freshening purposes. Based on a 0.2% maximum incorporation level and a maximum gum/mint size of 1.5g each, each gum or mint serving will contain no more than 3 mg of magnolia bark extract.

7. William Wrigley Jr. Company may therefore place Magnolia Bark Extract on the EU market in accordance with the conditions in this letter. This letter will be published on the Food Standards Agency website and a copy will be forwarded to the Commission for transmission to all other Member States and general publication.

Yours sincerely,

Dr Manisha Upadhyay

Novel Foods Unit, Food Standards Agency

## Annex

Magnolia Bark extract produced by William Wrigley Jr Company will be obtained from the bark of the *Magnoliae officinalis* plant. The bark will be washed and oven dried to reduce moisture content before being crushed and extracted with supercritical carbon dioxide. The extract will be dissolved in medical-grade ethanol and re-crystallised to yield magnolia bark extract. Magnolia Bark Extract shall comply with the following specification:

Parameter	Specification
Appearance	Light Brownish Powder
Magnolol	92.5% min
Honokiol	0.5% min
Magnolol + Honokiol	94% min
Total Eudesmol	2% max
Moisture	0.5%
<b>Impurities</b>	
Arsenic (ppm)	0.5 max
Lead (ppm)	0.5 max
Total Heavy Metals (ppm)	10 max
Methyl Eugenol (ppm)	10 max
Turbocurarine (ppm)	2 max
Total Alkaloid (ppm)	100 max