



European Medicines Agency

London, 12 November 2009
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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

PUBLIC STATEMENT ON *SALVIA OFFICINALIS* L., AETHEROLEUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2009 July 2009 September 2009 November 2009
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	12 November 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 May 2010
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; Public statement; traditional use; <i>Salvia officinalis</i> L.; Salviae officinalis aetheroleum; sage leaf essential oil
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PROBLEM STATEMENT

The HMPC has completed the Community herbal monograph for *Salvia officinalis* L., folium. The HMPC concurrently assessed the toxicological and safety aspects of sage essential oil and its conclusions can be found in the assessment report on *Salvia officinalis* L., folium. Sage essential oil is characterised by high levels of thujone. Consumption of the sage essential oil in single ingredient products involves a high risk of exceeding this maximum recommended daily intake of thujone. Thujone is toxic and may cause seizures at high doses as shown in animal studies and indicated from case reports. The presence of thujone in sage leaf preparations mentioned in the monograph is restricted to a daily intake of 5.0 mg/person for a maximum duration of 2 weeks.

CONCLUSIONS

Under the regulatory framework applicable to traditional herbal medicinal products laid down in Chapter 2a of Directive 2001/83/EC as amended and in particular Article 16a(1)(a) on their use in minor indications that do not require supervision of a medical practitioner, the findings from the assessment imply that the benefit-risk analysis of sage essential oil is negative. The extent and the quality of the available scientific data have not been sufficient to come to a positive benefit-risk assessment taken into account the expected benefit from the herbal medicinal products. As no data were retrieved for more serious conditions that could alter the benefit/risk assessment, the HMPC has therefore concluded that the benefits of sage essential oil do not outweigh its risks.

If information on clinical safety and efficacy of sage essential oil as a single ingredient is available, such documentation will be assessed by the HMPC. The available clinical and toxicological data on sage essential oil can not be considered adequate to fulfil the criteria required for developing a Community herbal monograph.

To read more about the toxicological aspects of sage essential oil, a link to the page where to access the assessment report on sage leaf (*Salvia officinalis* L., folium) is provided.

Link: http://www.ema.europa.eu/htms/human/hmpc/monograph/salviae_folium.htm