



COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

LIST OF REFERENCES FOR ASSESSMENT OF:

Menthae piperitae aetheroleum

Mentha x piperita L.

(peppermint oil)

The EMEA acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.

Abdullah D., Ping QN, Liu GJ.: Enhancing effect of essential oils on the penetration of 5-fluorouracil through rat skin. Yao Xue Bao 1996; 31(3): 214 - 21.

Adam B., Liebrechts T., Best J., Bechmann L., Lackner C., Neumann J., Koehler S., Holtmann G.: A combination of peppermint oil and caraway oil attenuates the post-inflammatory Visceral hyperalgesia in a rat model. Scand J Gastroenterol 2006; 41(2): 155 - 60.

Andersen PH, Jensen NJ: Mutagenic investigation of peppermint oil in the Salmonella/mammalian-microsome test. Mutation Research 1984; 138: 17 - 20.

Anon.: Die gastroösophageale Refluxkrankheit. Dtsch Apoth Ztg 1990; 130: 2684.

Asao T., Kuwano H., Ide M., Hirayama I., Nakamura JI, Fujita KI, Horiuti R.: Spasmolytic effect of peppermint oil in barium during double-contrast barium enema compared with Buscopan. Clin Radiol. 2003; 58, (4): 301 - 5.

Barnick CG, Cardozo L.: The treatment of abdominal distension and dyspepsia with enteric coated peppermint oil following routine gynaecological intraperitoneal surgery. Journal of Obstetrics and Gynaecology 1990; 10: 423 - 24.

Bell GD, Doran J.: Gall stone dissolution in man using an essential oil preparation, Br Med J 1979; 279: 24.

Blumenthal M., Busse WR., Göldberg A. et al. (eds): The Complete Commission E Monographs: Therapeutic Guide to Herbal Medicines. Boston, MA: Integrative Medicine Communications 1998; 180 - 2.

Boyd EM, Sheppard EP: A bronchomucotropic action in rabbits from inhaled menthol and thymol. Arch. Int. Pharmacodyn. 1969; 162, N°1.

Carling L., Svedberg LE, Hulten S.: Short term treatment of the irritable bowel syndrome: a placebo-controlled trial of Peppermint oil against hyoscyamine. Opuscula Med 1989; 34: 55 - 57.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51

E-mail: mail@emea.europa.eu <http://www.emea.europa.eu>

Das PK, Rathor, Sinha PS, Santal AK: Effect on ciliary movements of some agents which come in contact with the respiratory tract. College of Medical Sciences, Banaras Hindu Univ 1970.

Davies SJ, Harding LM, Baranowski AP: A novel treatment of postherpetic neuralgia using peppermint oil. *Clin. J. Pain.* 2002; 18(3): 200 - 2.

Debelmas AM, Rochat J.: Pharmacologic study of essential oils; antispasmodic activity of fifty samples. *Plant. Med. Phytother.* 1967; 1 (1): 23-27.

Dew MJ, Evans BK, Rhodes J.: Peppermint oil for the irritable bowel syndrome: a multicentre trial. *Br J Clin Pract* 1984; 38(11 - 12): 394 - 8.

Dost FH, Leiber B.: Menthol and menthol-containing remedies. International Symposium, Paris 1966.

Dresser G., Wacher V., Wong S., BA, Wong H., Bailey BS: Evaluation of peppermint oil and ascorbyl palmitate as inhibitors of cytochrome P4503A4 activity in vitro and in vivo. *Clin Pharmacol Ther* 2002; 72: 247 - 55.

Duthie HL: The effect of peppermint oil on colonic motility in man. *Br J Surg* 1981; 68: 820.

Eccles R., Griffiths H., Newton CG, Tolley NS: The effects of menthol isomers on nasal sensation of airflow. *Clin. Otolaryng.* 1988; 13: 25 - 29.

Ellis & Bell.: Treatment of biliary duct stones with a terpene preparation. *British Medical Journal* 1981; 282: 611.

Ernst E.: Adverse effects of herbal drugs in dermatology. *B. J. Derm.* 2000; 143: 923 - 9.

ESCOPE monographs, 2nd Edition, Thieme 2003.

Fachinfo Euminz (R) N.: Peppermint oil. Lichtwer Pharma, GmbH, Berlin 1997.

Fernández F.: *Menta piperita* en el tratamiento de síndrome de colon irritable. *Investigacion medica internacional* 1990; 17: 42 - 6.

Final report on the Safety Assessment of *Mentha Piperita* (Peppermint) Oil, *Mentha Piperita* Leaf extract, *Mentha Piperita* Leaf, and *Mentha Piperita* Leaf Water. *International Journal of Toxicology* 2001; 20 (Suppl. 3): 61 - 73.

Food and Drug Research Labs., Inc. 1973.: Teratologic evaluation of FDA 71-57 (Menthol natural, Brazilian).

Franzios G., Mirotsoy M., Hatziapostolou E., Kral J., Scouras Z., and Mavragani-Tsipidou P.: Insecticidal and Genotoxic Activities of Mint Essential Oils. *J. Agric. Food Chem.* 1997; 45: 2690 - 4.

Futami T.: Actions of counterirritants on the muscle contractile mechanism and nervous system. *Folia Pharmacol. Japon.* 1984; 83: 207-218; English Summary.

Gaworsky G., Vollmut T., Dozier M., Heck J., Dunn L.: An immunotoxicity assessment of food flavoring ingredients. *Fd Chem. Toxic* 1994; 32 (5): 409 - 15.

Gelal A., Balkan D., Czeybek D., Kaplan Y., Gurier S., Guven H., Benowitz N.: Effect of menthol on the pharmacokinetics and pharmacodynamics of Felodipine in healthy subjects. *Eur J Clin Pharmacol* 2005; 60: 785–790.

Giacchetti D., Taddei E., Taddei I.: Pharmacological activity of essential oils on Oddi's sphincter. *Planta Medica* 1988; 54(5): 389-392.

Göbel H., Schmidt G., Soyka D.: Effect of peppermint and eucalyptus oil preparations on neurophysiological and experimental algesimetric headache parameters. *Cephalalgia* 1994; 14: 228 - 34.

Göbel H et al: *Cephalalgia* 1994; 14: 228-34; published with modifications in *Phytomedicine* 1995; 2: 93 - 102.

Göbel H.: Controlled randomized double blind, double dummy study: Efficacy and safety of external application of *Mentha pip. aetheroleum* versus ASS in Tension Headache, unpublished data.

Göbel H.: Effekte von Pfefferminz und Eucalyptusölpräparationen auf experimentelle Kopfschmerzmechanismen im Humanversuch. Abstract 5. Phytotherapiekongress Bonn Nov. 1993.

Göbel H et al.: Effectiveness of oleum menthae piperitae and paracetamol in therapy of headache of the tension type. *Nervenarzt* 1996; 67:672 - 81.

Göbel H. et al.: Essential plant oils and headache mechanisms. *Phytomedicine* 1995; 2(2): 93 - 102.

Göbel H.: Pfefferminzöl- Lösung bei Spannungskopfschmerz. *Nofall* 27, 2001, Nr. 1.

Göbel H. et al.: Effekt von Pfefferminz-und Eucalyptusölpräparationen in experimentellen Kopfschmerzmodellen. *Zeitschrift für Phytotherapie* 1995; 16: 23 - 33.

Goel N., Lao RP: Sleep changes vary by odor perception in young adults. *Biological Psychology* 2006; 71(3): 341 - 9.

Goerg KJ, Spilker TH: Effect of Peppermint oil and caraway oil on gastrointestinal motility in healthy volunteers: a pharmacodynamic study using simultaneous determination of gastric and gall-bladder emptying and orocecal transitime. *Aliment Pharmacol Ther* 2003; 17: 445 - 51

Gordonoff T. et al.: On the pharmacology of carminatives Hippocrates 1960; 31: 335 - 8.

Grigoleit HG, Grigoleit P.: Gastrointestinal clinical pharmacology of peppermint oil. *Phytomedicine* 2005; 12(8): 607-11

Grigoleit HG, Grigoleit P.: Peppermint oil in irritable bowel syndrome. *Phytomedicine* 2005; 12(8): 601 - 6.

Hadley SK, Gaarder SM: Treatment of irritable bowel syndrome. *American Family Physician* 2005 Dec. 15; 72 (12): 2501.

Harries N., James K., Pugh W.: Antifoaming and carminative actions of volatile oils. *J. Clin. Pharmacy* 1978; 2: 171 - 177.

Hawthorn M., Ferrante J., Luchowski E., Rutledge A., Wei XY., Triggle DJ.: The actions of peppermint oil and menthol on calcium channel dependent processes in intestinal, neuronal and cardiac preparations. *Aliment Pharmacol Ther.* 1988; 2(2): 101 - 18.

Hills JM et al.: The mechanism of action of peppermint oil on gastrointestinal smooth muscle. *Gastroenterology* 1991; 101: 55 - 65.

Hiki N. et al.: Peppermint oil reduces gastric spasm during upper endoscopy: a randomized, double-blind, double-dummy controlled trial. *Gastrointestinal endoscopy* 2003; 57(4): 475 - 82

Ilmberger et al.: The influence of Essential Oils on Human Attention. I: Alertness. *Chem. Senses* 2001; 26: 239 - 45.

Imaseki I, Katabake *Yakugaku Zasshi.*, 1962; 82: 1326-1328.

Jakab G., Green G.: The effect of the Vapors of a commonly used remedy for colds on pulmonary antibacterial defenses. *Chest* 1975; 68: 3.

Kline Robert et al.: Enteric coated, pH-dependent peppermint oil capsules for the treatment of irritable bowel syndrome in children. *J. Pediatr* 2001; 138: 126 - 8.

Kohlert, Rensen, März, Schindler, Graefe, Veit: Bioavailability and pharmacokinetics of natural volatile terpenes in animals and humans. *Planta Med* 2000; 66: 495 - 505.

Krag E.: Irritable bowel syndrome: current concept and future trends. *Scand J Gastroenterol* 1985; (Suppl. 109): 107 - 15.

Lawson MJ, Knight RE, Tran K., Walker G., Robers-Thomson I.: Failure of enteric-coated Peppermint oil in the irritable bowel syndrome: A randomized double-blind crossover study. *J Gastroent Hepatol* 1988; 3: 235 - 8.

Lazukta JR, Mierauskiene J., Slapsyte G., Dedonyte.: Genotoxicity of dill, peppermint and pine essential oils in human lymphocytes and *Drosophila melanogaster*. *Food and Chemical Toxicology* 2001; 39: 485 - 92.

Lech, Y. et al.: Behandling af colon irritabile med Pebermynteolie. En dobbeltblind undersogelse med placebo [Treatment of irritable bowel syndrome with peppermint oil. A double-blind study with a placebo]. *Ugeskr Laeger* 1988; 150(40): 2388 - 9.

Leicester RJ: Peppermint oil to reduce colonic spasm during endoscopy. *Lancet* 1982; II: 989.

Letters to the editor.: *The Lancet*, 1962; 222.

Liu, JH, Chen GH, Yeh HZ, Huang CK, Poon SK: Enteric-coated peppermint-oil capsules in the treatment of irritable bowel syndrome: a prospective, randomized trial. *J Gastroenterol* 1997; 32(6): 765 - 8.

Madsen C., Würtzen G., Carstensen J.: Short-term toxicity study in rats dosed with menthone; *Toxicology letters* 1986; 32: 147 - 152.

Martin et al.: Dermal absorption of camphor, menthol and methyl salicylate in humans. *J. Clin. Pharm.* 2004; 44: 1151 - 7.

Matthias B. et al.: Acute Lung Injury after Peppermint oil injection. *Anesth Analg* 2005; 101:1160-2

May B., Köhler S. & Schneider B.: Efficacy and tolerability of a fixed combination of peppermint oil and caraway oil in patients suffering from functional dyspepsia. *Aliment. Pharmacol. Ther.* 2000; 14: 1671 - 7

Nadkarni's KM: *Indian Materia Medica*, 3rd revised edition – 1976, reprinted 1999

Nash P., Gould SR, Bernardo DE: Peppermint oil does not relieve the pain of irritable bowel syndrome. *Br J Clin Pract* 1986; 40(7): 292 - 3

Natural Standard Research Collaboration Peppermint oil. Evidence based monograph 2005; Medlineplus

Pittler MH, Ernst E.: Peppermint oil for irritable bowel syndrome: A critical review and metaanalysis. *Am J Gastroenterol.* 1998; 93(7): 1131 - 5.

Plant OH et al.; *J Pharmakol. exptl. Ther* 1926; 27:149 -64.

HMPC Public statement on the use of herbal medicinal products containing pulegone and menthofurane (EMEA/HMPC/138386/2005)

Rees, WDW, Evans BK, Rhodes J.: Treating irritable bowel syndrome with peppermint oil. *Br Med J* 1979, 2(6194): 835 - 6.

Reiter M., Brandt W.: Relaxant effects on tracheal and ileal smooth muscles of the guinea Pig. *Arzneim-Forsch/Drug Res* 1985; 35: 408 - 14

Reynolds JEF, editor. Peppermint oil. In: Martindale. *The Extra Pharmacopoeia*, 27th edition, London: Pharmaceutical Press 1977; 1024.

Reynolds JEF, editor. Peppermint oil. In: Martindale. *The Extra Pharmacopoeia* London: Pharmaceutical Press, 1993; 899.

Rogers SN et al, A form of stomatitis induced by excessive peppermint consumption. *Dent update.* 1995; 22(1): 36 - 7.

Russin et al. Inhibition of rat mammary carcinogenesis by monoterpenoids. *Oxford J.,Carcinogenesis* 1989; 10(11): 2161 - 4.

Sanaka Madhusudhan R., Ferguson D., Kyprianou A., Kale H., Mullen K., Amini S.: Does instillation of peppermint oil solution in the cecum facilitate terminal ileal intubation? A prospective, randomized, double-blind study. *Gastrointestinal endoscopy* 2004; 59(5): 265

Santos MA: Menthol induced Asthma: a case report; *J. Invest Allergol Clin Immunol* 2001; 11(1): 56 - 8.

Schelz Z., Molnar J., Hohmann J.: *Antimicrobial and antiplasmid activities of essential oils. Fitoterapia*, Elsevier 2006.

- Schneider MME et al.: Efficacy of Colpermin in the treatment of patients with irritable bowel syndrome [abstract]. *Gastroenterol.* 1990; 98: A389.
- Shaw G. et al.: Stress management for irritable bowel syndrome: a controlled trial. *Digestion* 1991; 50: 36-42.
- Schuhmacher A., Reichling J., Schnitzler P.: Virucidal effect of peppermint oil on the enveloped viruses herpes simplex virus type 1 and type 2 in vitro. *Phytomedicine* 2003; 10: 504 - 10.
- Siegers C., Guo Z., Pentz R.: Choleric properties of herbal drugs; *Progress in Pharmacology and clinical pharmacology* 1991; 8(4).
- Sigmund DJ, McNally EF: The action of a carminative on the lower esophageal sphincter. *Gastroent* 1969; 56: 13.
- Sparks, MJ, O'Sullivan P., Herrington AA, Morcos SK: Does peppermint oil relieve spasm during barium enema? *Br J Radiol* 1995; 68(812): 841 - 3.
- Somerville KW, Ellis WR, Whitten BH, Balfour TW and Bell GD: Stones in the common bile duct: experience with medical dissolution therapy, *Postgraduate Medical Journal* 1985; (61): 313 - 6.
- Taddei I. et al.: Spasmolytic activity of peppermint, Sage and Rosemary essences and their major constituents. *Fitoterapia* 1988; 59(6): 463-8.
- Taylor BA et al.: Inhibitory effect of peppermint on gastrointestinal smooth muscle (Abstract). *Gut* 1983; 24: A992.
- Tate S.: Peppermint oil: a treatment for postoperative nausea. *J. Advanced nursing* 1997; 26: 543 - 9.
- Teuscher E. et al.: Untersuchungen zum Wirkungsmechanismus ätherischer Öle. *Zt. Phytotherapie*, 1990; 11: 87 - 92.
- Thompson WG: A strategy for management of the irritable bowel. *The American Journal of Gastroenterology* 1986; 81(2): 95 - 100.
- Thompson WG: The irritable bowel. *Gut* 1984; 25: 305 - 32.
- Trabace et al.: Choleric activity of some typical components of essential oils. *Planta Med.* 1992; 58 (Suppl. 1).
- Wacher VJ et al.: Peppermint oil enhances cyclosporine oral bioavailability in rats: comparison with D-alpha-tocopheryl poly (ethylene glycol 1000) succinate (TPGS) and ketoconazole. *J. Pharm Sci.* 2002; 91(1): 77 - 90.
- WHO Geneve (2000). Evaluation of certain food additives. Fifty-first report of the Joint FAO/WHO Expert Committee on the Food Additives.
- WHO monographs on selected medicinal plants, volume 2, 2002.