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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

LIST OF REFERENCES SUPPORTING THE ASSESSMENT REPORT ON:

**Menthae piperitae aetheroleum
Mentha x piperita L., aetheroleum
(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 - 221.

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 - 160.

Andersen PH, Jensen NJ: Mutagenic investigation of peppermint oil in the *Salmonella*/mammalian-microsome test. Mut. Res. 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 - 305.

Azpiroz F., Serra Jordi.: Treatment of excessive Intestinal Gas. Curr. Treatm. Options Gastroenterol. 2004, 7:299-305

Barnick CG, Cardozo L.: The treatment of abdominal distension and dyspepsia with enteric coated peppermint oil following routine gynaecological intraperitoneal surgery. J Obstet Gynaecol 1990; 10: 423 - 424.

Behrends M. et al.: Acute Lung Injury after Peppermint oil injection; Anesth Analg 2005; 101:1160-1162

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

Blumenthal M., Busse WR., Goldberg A. et al. (eds): The Complete Commission E Monographs: Therapeutic Guide to Herbal Medicines. Boston, MA: Integrative Med. Commun. 1998; 180 - 182.

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.

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 post-herpetic neuralgia using peppermint oil. Clin. J. Pain. 2002; 18(3): 200 - 202.

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

Defeudis F.V., Christen MO, State and use independent Ca²⁺ antagonists offer hope in control of GI disorders. Trends Pharmacol Sci. 1989 May; 10(5):170-172

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 - 398.

Dresser G., Wachter 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 - 255.

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.

Eccles R., Menthol: Effects on nasal sensation of airflow and the Drive to Breathe; Curr. Allergy Asthma Rep. 2003, 3:210-214

Eickolt T., Box R., Toxicities of peppermint and *Pycnanthemum albescens* oils, fam. *Labiatae*; J. Pharm. Scie., 1965 54 (7): 1071-1072

Ellis & Bell.: Treatment of biliary duct stones with a terpene preparation. Br. Med. J. 1981; 282: 611.

Ernst E.: Adverse effects of herbal drugs in dermatology. B. J. Derm. 2000; 143: 923 - 929.

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. Inv. Med. Internat. 1990; 17: 42 - 46.

Final report on the Safety Assessment of Mentha Piperita (Peppermint) Oil, Mentha Piperita Leaf extract, Mentha Piperita Leaf, and Mentha Piperita Leaf Water. Int. J. Toxicol. 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., Hatzia Apostolou E., Kral J., Scouras Z., and Mavragani-Tsipidou P.: Insecticidal and Genotoxic Activities of Mint Essential Oils. J. Agric. Food Chem. 1997; 45: 2690 - 2694.

Friedman G.: Nutritional Therapy of irritable Bowel Syndrome; Gastroenterology Clinics of North America, Vol. 18, No 3, September 1989.

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. Food Chem. Toxic 1994; 32 (5): 409 - 415.

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.

- Gilcherst BA Pruritus. Pathogenesis, therapy and significance in systemic disease states. Archives of Internal Medicine. 1982. Vol. 142/1 (101-105)
- Göbel H et al.: Effectiveness of oleum menthae piperitae and paracetamol in therapy of headache of the tension type. Nervenarzt 1996; 67: 672 - 681.
- Göbel H. et al.: Effekt von Pfefferminz-und Eukalyptusölpräparationen in experimentellen kopfschmerzmodellen. Zeitschr. Phytotherapie 1995; 16: 23 - 33.
- Göbel H. et al.: Essential plant oils and headache mechanisms. Phytomedicine 1995; 2(2): 93 - 102.
- Göbel H., Schmidt G., Soyka D.: Effect of peppermint and eucalyptus oil preparations on neurophysiological and experimental algometric headache parameters. Cephalalgia 1994; 14:228 - 234.
- 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 on Pfefferminz und Eukalyptusölpräparationen auf experimentelle kopfschmerzmechanismen im Humanversuch. Abstract 5. Phytotherapiekongress Bonn Nov. 1993.
- Göbel H.: Pfefferminzöl- Lösung bei Spannungskopfschmerz. Nofall 27, 2001, Nr. 1.
- Goel N., Lao RP: Sleep changes vary by odor perception in young adults. Biological Psychology 2006; 71(3): 341 - 349.
- 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 - 451
- Gordonoff T. et al.: On the pharmacology of carminatives Hippokrates 1960; 31: 335 - 338.
- Grigoleit HG, Grigoleit P.: Gastrointestinal clinical pharmacology of peppermint oil. Phytomedicine 2005; 12(8): 607-611
- Grigoleit HG, Grigoleit P.: Peppermint oil in irritable bowel syndrome. Phytomedicine 2005; 12(8): 601 - 606.
- 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 - 118.
- Herbmonograph, www.drugdigest.org; Revised in 2004
- Hiki N. et al.: Peppermint oil reduces gastric spasm during upper endoscopy: a randomized, double-blind, double-dummy controlled trial. Gastrointest. Endoscopy 2003; 57(4): 475 - 482
- Hills JM et al.: The mechanism of action of peppermint oil on gastrointestinal smooth muscle. Gastroenterology 1991; 101: 55 - 65.
- HMPC Public statement on the use of herbal medicinal products containing pulegone and menthofurane (EMA/HMPC/138386/2005)
- Ilmberger et al.: The influence of Essential Oils on Human Attention. I: Alertness. Chem. Senses 2001; 26: 239 - 245.
- 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 - 128.

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

Krag E.: Irritable bowel syndrome: current concept and future trends. *Scand. J. Gastroenterol.* 1985; (Suppl. 109): 107 - 115.

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 -238.

Lazukta JR, Mierauskiene J., Slapsyte G., Dedonyte.: Genotoxicity of dill, peppermint and pine essential oils in human lymphocytes and *Drosophila melanogaster*. *Food Chemical Toxicol.* 2001; 39: 485 - 492.

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 - 2389.

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

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

Liebregts A.B. et al, A combination of peppermint oil and caraway oil attenuates the post-inflammatory visceral hyperalgesia in a rat model. *Scand. J. Gastroenterol.* (Abstract), 2006 Feb;41(2):155-160.

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 - 768.

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

Martin et al.: Dermal absorption of camphor, menthol and methyl salicylate in humans. *J. Clin. Pharm.* 2004; 44: 1151 - 1157.

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 – 1677

MedlinePlus Medical Encyclopedia: Menthol overdose. www.nih.gov/medlineplus

Micklefield G., Jung O., Greving I., May B., Effects of Intraduodenal Application of Peppermint oil (WS® 1340) and Caraway Oil (WS® 1520) on Gastroduodenal Motility in healthy Volunteers, *Phytotherapy Research*, 17, 135-140 (2003).

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 - 293

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

Naumann H.N., Die Reaktion der Nasenschleimhaut auf verschiedene Medikamente, in *Menthol and Menthol-containing External Remedies*, Georg Thieme Verlag, 1967: 99-107.

Ostler H.B., The management of Ocular Herpesvirus Infections. *Survey Ophthalmology* Vol. 21, No2, September/October 1976.

Peppermint. Complete Peppermint information from Drugs.com. www.drugs.com. Accessed 16/10/2007

Pittler MH, Ernst E.: Peppermint oil for irritable bowel syndrome: A critical review and metaanalysis. *Am. J. Gastroenterol.* 1998; 93(7): 1131 - 1135.

Rajka Georg, Moderne Behandlung des atopischen Ekzems (neurodermitis diffusa); *Der Hautarzt* 28, 348-352 (1977).

Rees, WDW, Evans BK, Rhodes J.: Treating irritable bowel syndrome with peppermint oil. Br. Med. J. 1979, 2(6194): 835 - 836.

Reiter M., Brandt W.: Relaxant effects on tracheal and ileal smooth muscles of the guinea Pig. *Arzneim-Forsch/Drug Res* 1985; 35: 408 - 414

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 - 37.

Russin et al. Inhibition of rat mammary carcinogenesis by monoterpenoids. *Oxford J. Carcinogenesis* 1989; 10(11): 2161 - 2164.

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 - 58.

Schelz Z., Molnar J., Hohmann J.: Antimicrobial and antiplasmid activities of essential oils. *Fitoterapia*, 2006 Jun;77(4):279-285.

Schneider MME et al.: Efficacy of Colpermin in the treatment of patients with irritable bowel syndrome [abstract]. *Gastroenterol.* 1990; 98: A389.

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 - 510.

Shaw G. et al.: Stress management for irritable bowel syndrome: a controlled trial. *Digestion* 1991; 50: 36-42.

Siegers C., Guo Z., Pentz R.: Choleric properties of herbal drugs; *Progress Pharmacol. Clin. Pharmacol.* 1991; 8(4): 531-535

Sigmund DJ, McNally EF: The action of a carminative on the lower esophageal sphincter. *Gastroenterol.* 1969; 56: 13.

Somerville KW, Ellis WR, Whitten BH, Balfour TW and Bell GD: Stones in the common bile duct: experience with medical dissolution therapy, *Postgrad. Med. J.* 1985; (61): 313 - 316.

Sparks, MJ, O'Sullivan P., Herrington AA, Morcos SK: Does peppermint oil relieve spasm during barium enema? *Br. J. Radiol.* 1995; 68(812): 841 - 843.

Taddei I. et al.: Spasmolytic activity of peppermint, Sage and Rosemary essences and their major constituents. *Fitoterapia* 1988; 59(6): 463-468.

Tate S.: Peppermint oil: a treatment for postoperative nausea. *J. Adv. Nurs.* 1997; 26: 543 - 549.

Taylor BA et al.: Inhibitory effect of peppermint on gastrointestinal smooth muscle (Abstract). *Gut* 1983; 24: A992.

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. *Amer. J. Gastroenterol.* 1986; 81(2): 95 - 100.

Thompson WG: The irritable bowel. *Gut* 1984; 25: 305 - 332.

Trabace et al.: Choleric activity of some typical components of essential oils. *Planta Medica* 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.