EXECUTIVE SUMMARY

Mineral Oil, USP or Food Grade – Oral Risk Assessment
(oil classification per the World Health Organization)

Mineral Oil Class	NOAEL mg/kg-day	Uncertainty Factor	Oral RfD, mg/kg-day	TAC[1,4] mg/L	SPAC[2,4] mg/L	STEL[3,4] mg/L
High viscosity, ≥ 11 centistokes	2,000	100	20	700	70	700
Medium and low viscosity, Class I 8.5-11 centistokes	2,000	100	20	700	70	700
Medium and low viscosity, Class II 7.0-8.5 centistokes	200	100	2	40	4	40
Medium and low viscosity, Class III 3.0-7.0 centistokes	20 20 20	100	0.2	1	0.1	2

[1]Group TAC [2]Group SPAC [3]Group STEL
[4] The solubility of a mineral oil in actual use as a direct or indirect drinking water additive should not be exceeded.

KEY STUDY and KEY REVIEWS	BIBRA Toxicology International. 1992a. A 90-day feeding study in the rat with six different white mineral oils [N15(H), N70(H), N70(A), P15(H), N10(A), and P100(H)], three different mineral waxes (a low melting point wax, a high melting point wax and a high sulphur wax) and coconut oil. Sponsored by CONCAWE, Brussels, Belgium. Project no. 3.1010. Report no. 1010/3/92. BIBRA Toxicology International. 1992b. Ninety-day feeding study in Fischer 344 rats of highly refined petroleum-derived food-grade white oils and waxes. Presented in part at The Toxicology Forum Special Meeting on Mineral Hydrocarbons, Green College, Oxford, United Kingdom, Sept. 21-23, 1992 and The Toxicology Forum 1993 Annual Winter Meeting, The Capital Hilton, Washington, D.C., February 15-17, 1993. WHO (World Health Organization). 1995a. Evaluation of certain food additives and contaminants. Technical Report Series No. 859. Forty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva. WHO (World Health Organization). 2002. Joint FAO/WHO Expert Committee on Food Additives. Fifty-ninth meeting. Geneva 4-13 June 2002. Summary and Conclusions (full report in preparation).
CRITICAL EFFECTS	The critical effects depended to some extent on the physical properties of the mineral oils tested. The two highest viscosity oils did not show any effects considered adverse at the highest dose tested. Other oils produced liver and/or spleen weight effects with liver granulomas or other liver pathology.
TOXICITY SUMMARY	The available toxicology information on USP and food grade mineral oils has been summarized by the World Health Organization at a number of meetings of the Joint FAO/WHO Expert Committee on Food Additives, and was not re-summarized in this document. The World Health Organization has taken the lead in the risk assessment of mineral oils, requesting or requiring additional studies as needed for clarification. It is clear from both human data and animal studies that mineral oil can accumulate to a small extent in organs and tissues. The liver is a target organ for the lower viscosity oils, based on liver weight effects, granulomas or micro-granulomas in the liver, and biochemical changes indicative of mild liver damage. Immune system effects of pigmented macrophages and lymph node histiocytosis have so far been observed in F-344 rats, but not in other rat strains or in Beagle dogs. Most genetic toxicity studies have shown that test results on mineral oils correlate directly with their polycyclic aromatic hydrocarbon content, suggesting the oil itself is not genotoxic. Oral exposure of humans to USP or food grade `mineral oil in food and pharmaceuticals over many decades has not produced any evidence of carcinogenicity. Several older long-term oral studies in laboratory animals have shown no evidence of carcinogenicity, although these studies were not conducted according to current regulatory guidelines. Since there are no human epidemiological studies and no adequate animal studies on mineral oil by the oral route, the "*data are inadequate for an assessment of human carcinogenic potential"*.
CONCLUSIONS	The drinking water action levels derived in this document are based on NOAEL values from well conducted subchronic studies of well characterized mineral oils. Based on these NOAEL values and appropriate uncertainty factors, the action levels are considered protective of the public health.