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Abstract

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Final safety assessment of Coal Tar as used in cosmetics.

Cosmetic Ingredient Review Expert Panel¹.

Author information

Abstract

Coal Tar is a semisolid by-product obtained in the destructive distillation of bituminous coal, which functions in cosmetic products as a cosmetic biocide and denaturant--antidandruff agent is also listed as a function, but this is considered an over-the-counter (OTC) drug use. Coal Tar is a nearly black, viscous liquid, heavier than water, with a naphthalene-like odor and a sharp burning taste, produced in cooking ovens as a by-product in the manufacture of coke. Crude Coal Tar is composed of 48% hydrocarbons, 42% carbon, and 10% water. In 2002, Coal Tar was reported to the Food and Drug Administration (FDA) to be used in four formulations, all of which appear to be OTC drug products. Coal Tar is monographed by the FDA as Category I (safe and effective) OTC drug ingredient for use in the treatment of dandruff, seborrhoea, and psoriasis. Coal Tar is absorbed through the skin of animals and humans and is systemically distributed. In short-term studies, mice fed a diet containing Coal Tar found it unpalatable, but no adverse effects were reported other than weight loss; rats injected with Coal Tar experienced malaise in one study and decreased water intake and increased liver weights in another; rabbits injected with Coal Tar residue experienced eating avoidance, respiratory difficulty, sneezing, and weight loss. In a subchronic neurotoxicity study using mice, a mixture of phenols, cresols, and xlenols at concentrations approximately equal to those expected in Coal Tar extracts produced regionally selective effects, with a rank order of corpus striatum > cerebellum > cerebral cortex. Coal Tar applied to the backs of guinea pigs increases epidermal thickness. Painting female rabbits with tar decreases the absolute and relative weights of the ovaries and decreased the number of interstitial cells in the ovary. Four therapeutic Coal Tar preparations used in the treatment of psoriasis were mutagenic in the Ames assay. Urine and blood from patients treated with Coal Tar were genotoxic in bacterial assays. Coal Tar was genotoxic in a mammalian genotoxicity assay and induced DNA adducts in various tissue types. Chronic exposure of mice to Coal Tar significantly decreased survival and liver neoplasms were seen in a significant dose-related trend; in other studies using mice lung tumors and perianal skin cancers were found. Coal Tar was comedogenic in three small clinical studies. Folliculitis is associated with the prolonged use of some tars. Several published reports describe cases of contact sensitivity to Coal Tar. Polycyclic aromatic hydrocarbons, which make up Coal Tar, are photosensitizers and cause phototoxicity by an oxygen-dependent mechanism. A retrospective study of the reproductive toxicity of Coal Tar in humans compared exposed women to controls and found little difference in spontaneous abortion and congenital disorders. Cancer epidemiology

studies of patients who have received Coal Tar therapy of one form or other have failed to link treatment with an increase in the risk of cancer. Although the Cosmetic Ingredient Review (CIR) Expert Panel believes that Coal Tar use as an antidandruff ingredient in OTC drug preparations is adequately addressed by the FDA regulations, the Panel also believes that the appropriate concentration of use of Coal Tar in cosmetic formulations should be that level that does not have a biological effect in the user. Additional data needed to make a safety assessment include product types in which Coal Tar is used (other than as an OTC drug ingredient), use concentrations, and the maximum concentration that does not induce a biological effect in users.

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MeSH Terms, Substances



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