
Paraffin wax (fume)

(CAS No: 8002-74-2)

Health-based Reassessment of Administrative
Occupational Exposure Limits

Committee on Updating of Occupational Exposure Limits,
a committee of the Health Council of the Netherlands

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1 Introduction

The present document contains the assessment of the health hazard of paraffin wax fume by the Committee on Updating of Occupational Exposure Limits, a committee of the Health Council of the Netherlands. The first draft of this document was prepared by KJ van den Berg, Ph.D. and H Stouten, M.Sc. (TNO Nutrition and Food Research, Zeist, the Netherlands).

The evaluation of the toxicity of paraffin wax (fume) has been based on the review by the American Conference of Governmental Industrial Hygienists (ACG91). Where relevant, the original publications were reviewed and evaluated as will be indicated in the text. In addition, literature was retrieved from the on-line databases Medline, Toxline, and Chemical Abstracts covering the period 1966 to November 1997, 1965 to October 1997, and 1967 to November 1997, respectively, and using (combinations of) the following key words: paraffin, wax, fume, and 8002-74-2. HSDB (no record) and RTECS, databases available from CD-ROM, were consulted as well (NIO97, NLM97). The final literature search was carried out in November 1997.

In February 1999, the President of the Health Council released a draft of the document for public review. The committee received no comments.

An additional literature search in May 2002 did not result in information changing the committee's conclusions.

2 Identity

name	:	paraffin wax (fume)
synonyms	:	hydrocarbon waxes; Ceratak; Gatch; hard paraffin; Slopvox; paraffin
molecular formula	:	C_nH_{2n+2} (C_{20} to C_{50})
CAS number	:	8002-74-2

Data from ACG91, EC00.

3 Physical and chemical properties

molecular weight	:	350-420
boiling point	:	-
melting point	:	46-68°C
flash point	:	>215°C
vapour pressure	:	not volatile
solubility in water	:	insoluble
log P _{octanol/water}	:	>6 (estimated)
conversion factors (20°C, 101.3 kPa)	:	-

Data from ACG91, EC00.

Paraffin wax is a white or slightly yellow, odourless solid, obtained from petroleum (ACG91). Generally, petroleum waxes are rarely characterised in terms of boiling range and autoflammability. They are very non-volatile materials, almost totally insoluble in water, and do not contain any oxidising constituent. Petroleum waxes consists of high-molecular-weight alkanes and cycloalkanes. There are 3 classifications, viz., paraffin, intermediate, and microcrystalline waxes. Paraffin waxes, the subject of this evaluation, typically contain C₂₀-C₅₀ *n*-alkanes with smaller quantities of iso-alkanes. They form visible crystalline structures, and are also known as macrocrystalline waxes (EC00).

4 Uses

Paraffin wax is used for making candles; as a sealant or coating for paper and food products; in extracting perfumes from flowers; as a chewing gum base; as a stiffening ingredient in pharmaceutical ointment and salve bases; in paraffin-wax baths for the relief of pain (ACG91, Moo84, Ric94). In cosmetics, paraffin wax is used in baby products, eye and facial makeup preparations, fragrance products, colouring and non-colouring hair preparations, manicuring products, personal cleanliness preparations, shaving and skin care products, and suntan preparations (Moo84).

5 Biotransformation and kinetics

Paraffin is considered to be neither absorbed nor digested (ACG91).

The skin is impermeable to hydrocarbons with a molecular structure above 20 carbon atoms, e.g., paraffin substances (WHO82).

6 Effects and mechanism of action

Human data

Pure paraffin wax and paraffin-wax-containing products were tested for their potential skin irritation by 24-hour single applications under occlusion to the forearm or upper back and readings immediately after removal of patches. Testing 2 samples of 100% pure paraffin wax in 20 volunteers each resulted in only one case of a barely perceptible erythema at one sample and one case of a pink uniform erythema at the other sample, all the others being negative. Three 8% paraffin-wax-containing products and one 15% paraffin-wax-containing product produced no irritation in 18, 19, 20, and 19 subjects, respectively. Out of four 16% paraffin-wax-containing formulations, one produced a mild erythema in 1/17 subjects, the second erythema in 2/18 subjects, and the third erythema in 9/18 (maximum score observed: 0.75) while application of the fourth formulation resulted in a maximum irritation score of 0.35 out of a maximum possible score of 40 (all unpublished studies, cited by Moo84).

In a 21-day cumulative irritancy test, patches with a 5% paraffin-wax-containing formulation were applied daily to the same site on the backs of each of 10 subjects for 4 consecutive days. Patches remained in contact with the skin for 23 hours and scores were read just before the next patch application. This procedure resulted in an irritation score of 18 out of a maximum possible score of 630 (unpublished study, cited by Moo84). No irritation was reported in 187 women after 2-week daily use of a 5% paraffin-wax-containing cosmetic product (unpublished study, cited by Moo84).

When an undiluted 15% paraffin-wax-containing product was applied under occlusion to the back or arm of 48 subjects, every other day for a total of 9-15 induction results, followed by a challenge application to an adjacent untreated site after a 10-21-day rest, no irritation or sensitisation was observed. Reactions were scored immediately, and 24, 48, and 72 hours after removing patches (unpublished study, cited by Moo84).

No irritation and no sensitisation was observed in 3 different groups of 25, 30, and 39 subjects, respectively, when testing a 5% paraffin-wax-containing formulation. The test material was applied under occlusion to the same site of the volar forearm for five 48-hour periods. The patch sites were pre-treated for 24 hours with 2.5% aqueous sodium lauryl sulphate under occlusion. After a 14-day rest, challenge patches were applied and sites were read immediately after and 24 hours after patch removal (unpublished studies, cited by Moo84).

Paraffin fumes (exposure levels not reported) are stated to be mildly irritating to the human eye, nose, and throat (Ric94).

Work around molten paraffin is reported to be uncomfortable and nauseating as is the use of paraffin sprays in printing shops. Concentrations of paraffin fume of 0.6 to 1.0 mg/m³ were found mildly disagreeable by workers in one plant, but in other plants, no complaints or discomfort were recorded at levels up to 2 mg/m³ (ACG91).

A possible association has been observed between a decrease in lung function (forced expiratory volume in one second, FEV₁) and occupational exposure to waxes, estimated by job exposure matrices. In women, FEV₁ was reported to be significantly decreased with the level of exposure, but no information is given on the actual exposure levels (LeM95).

The effects of using ski waxes, containing mostly paraffins but also, in some cases, silicone compounds and, in one case, polytetrafluoroethylene have been examined in 5 male professional waxers (40-50-year old; 2 smokers; 3 non-smokers) after waxing for 2-3 hours. The components were stated to vaporise on heating and to condense rapidly on cooling in air to smoke consisting of particles less than 1 µm in diameter. Exposure levels ranged from 0.62-2.36 and from 0.18-1.60 mg/m³, when determined by personal sampling and stationary measurements, respectively. These total dust concentrations, consisting of C₁₇ to C₄₀ straight aliphatic hydrocarbons, were found to correlate with the intensity of ski waxing. The main findings were an increase in complaints including itching eyes, rhinitis, coughing, and breathlessness and a decrease in lung function as indicated by an average decrease of 15% of the diffusion capacity. This decrease occurred immediately after waxing, varied between 10 and 25%, and tended to increase upon repeated exposure. There was some recovery after a night's break. It was found both in smokers and in non-smokers, and therefore attributed to ski waxing rather than to smoking. From results from blood samples taken one to 2 days after waxing, there were no indications of systemically toxic effects, including inflammation and

immunological responses (parameters: haemoglobin, mean cell haemoglobin concentration, volume fraction of erythrocytes, white blood cell counts, red blood cell counts, platelet counts, acute inflammatory protein, liver function tests, immunoglobulins) (Dah92).

In a Swiss study, pulmonary function, determined as CO-diffusion capacity, was decreased for at least 24 hours in 5 healthy volunteers exposed to hot ski wax, containing paraffin and Cera-F. No changes were observed in the dynamic and static lung volumes. No information was given on the actual exposure levels (Knö92).

It should be kept in mind that ski wax in the form of a spray can contain appreciable levels of organic solvents, i.e., toluene and benzene. During waxing procedures, also exposure to the solvents can occur as can be observed from markedly elevated levels of urinary hippuric acid (Sug87).

Hydrocarbons with 21-23 carbon atoms, e.g., paraffins, were found to be non-dermatotoxic (WHO82).

Animal data

Irritation

No irritation was observed when rabbits (n=9) were treated for 24 hours applying 3 x 0.5 mL of the test substance to the clipped intact skin and covering with a closed patch. Treating 6 rabbits for 24 hours applying 3 x 0.5 mL of a 50/50 blend of paraffin wax and petrolatum to the clipped intact skin and covering with an open patch caused slight irritation consisting of a 3-day-lasting erythema produced by 2 samples (out of 3 tested) in 4 animals and of a 2-day-lasting erythema in a single animal produced by the third sample. Closed- and open-patch testing of 4 cosmetic formulations containing 8% paraffin wax resulted in minimal to severe and no to minimal irritation, respectively. The tests were repeated 3 times. A 15% paraffin-wax-containing formulation was minimally irritating in a single, open insult patch test while single, closed-patch testing of three 16% paraffin-wax-containing formulations resulted in scores indicative of mild to minimal irritation (no more information available) (all unpublished studies, cited by Moo84).

Instillation of 0.1 mL of a 50/50 blend of paraffin wax and petrolatum into the eyes of rabbits (n=6) was found slightly irritating. Of the 4 samples tested, 2 caused mild irritation in one animal at the 24-hour observation point. All other observations were negative (no rinsing; observation time: 3 days). No signs of

irritation or corneal damage was observed up to 72 hours following instillation of 0.1 mL of a 5% paraffin-wax-containing cosmetic product into the left eyes of monkeys (n=6). Three treated eyes were washed 30 minutes after instillation while the other eyes were not rinsed. When 0.1 mL of another, similar product was instilled into the eyes of monkeys (n=6) and albino rabbits (n=9; rinsing in 3), no irritation or damage was seen in monkeys. In rabbits, there was minimal conjunctival redness at 48 hours after instillation in 4/6 and 2/3 animals with unrinsed and rinsed eyes, respectively (observation points: 24, 48, and 72 hours, and 4 and 7 days). Testing of four 8% and three 16% paraffin-wax-containing products in rabbits (n=6/product) caused mild irritation 24 or 48 hours after instillation in one animal in each test while a 15% paraffin-wax-containing formulation caused mild irritation in 3/6 animals at 24 hour (observation time: 3 days) (all unpublished studies, cited by Moo84). Paraffin wax, implanted in eyes of rabbits (to study its use as an implant material for substitution of silicone sponges), elicited an intense foreign body response but had no adverse effects on the ciliary and conjunctival epithelial and the retina (Mur83).

Acute toxicity

A dermal LD₅₀ of >3600 mg/kg was reported in rabbits when one single dose of 50% paraffin wax of 4 mL/kg bw was applied under occlusion for 24 hours. There were no systemic effects or abnormalities at necropsy (no more details available) (unpublished study, cited by Moo84).

In 2 separate tests, single oral (gavage) doses of 5000 mg/kg bw of pure (100%) paraffin and a 75% solution in corn oil, respectively, were not lethal to rats (n=5 and 6, respectively) (no more details available) (unpublished study, cited by Moo84). Administration of an amount of a cosmetic product containing 5% paraffin wax did not cause toxic effects or abnormalities at necropsy in 4/4 dogs (dose: 25 mL/kg bw) but mortality in 1/10 rats (dose: 60 mL/kg bw), the other animals being unaffected. Findings in the dead animal included urinary staining of the abdomen and intestines filled with red fluid (observation time: 14 days). No deaths were found when cosmetic products containing 8 or 16% paraffin wax were given to rats at amounts of 10,000 and 8000 mg/kg bw, respectively (observation time: 7 days) (no more details available) (unpublished studies, cited by Moo84).

Repeated-dose toxicity

Daily dermal application (site and conditions not reported) of a 8% paraffin-containing cosmetic product, 5 days/week, for 13 weeks, to groups of female albino rats (strain and number not reported) at dose levels of at least 100 times the normal use concentration (not further specified) did not cause systemic toxic or abnormal cumulative dermal effects (no more information available; unpublished study, cited by Moo84).

Subchronic feeding studies with paraffin waxes (10-3000 mg/kg/day) in Fischer 344 rats have been reported to result in accumulation of paraffin wax in tissues and a dose-dependent increase in inflammatory responses consisting of histiocytosis of the mesenteric lymph nodes, liver microgranulomas, and inflammatory thickening at the base of the mitral valve of the heart. These findings are probably a specific property of the Fischer strain of rats, because in other rat strains (Sprague-Dawley and Long-Evans), and in dogs, these inflammatory responses have not been observed (Mil96). In a later study in which female Fischer 344 and Sprague-Dawley (SD) rats were given 2% of low-melting-point paraffin wax in the diet (i.e., 1000 mg/kg bw/day, assuming a body weight of 200 mg and a food intake of 10 g/day) for 60 days, the aforementioned findings were confirmed. In Fischer 344 rats only, effects on the liver were found consisting of granuloma formation/lymphoid cell aggregates with small areas of necrosis and significant increases in serum alanine and aspartate transferase as well as γ -glutamyltransferase activities. In addition, detectable amounts of this paraffin wax were present only in the livers of the treated Fischer 344 rats. Further, in Fischer 344 rats only, paraffin wax was present in Kupfer cells. These cells were markedly activated or otherwise altered both functionally and morphologically (presence of large, irregularly shaped, membrane-associated vacuoles; increased phagocytic activity and nitric oxide and superoxide anion production; decreased LPS-stimulated production of TNF and LTB₄) when compared to Kupfer cells from SD or control rats. Through the altered production of inflammatory mediators, the Kupfer cells were thought to play a direct role in paraffin wax-induced formation of granulomas (Hog98).

Carcinogenicity

Different samples of petroleum wax, when applied by repeated skin application to mice, did not result in carcinogenic effects. When 5 petroleum waxes were

subcutaneously implanted in disc form in mice, fibrosarcomas developed around the implants with incidences that correlated to the melting points of the waxes. It was concluded that the sarcomas developed as a result of the physical rather than the chemical properties of the substance (WHO82).

In a long-term study, the incidence of tumours following a diet containing 10% ground wax was similar to that in control animals (Eke93).

In a series of 180-day feeding studies in rats with chewing-gum bases containing hydrocarbon wax in proportions ranging from 2-57% of the gum base, no compound-related effects were observed (Eke93).

Implantation of paraffin wax pellets in the bladder of Fischer 344 rats promoted the formation of tumours in the bladder. Tumour formation was found to be strictly dependent on the simultaneous presence of urine. The authors concluded that the presence of an (unidentified) factor or substance in the urine together with a foreign body (the pellet) was responsible for the induction of tumours (Cha73). In this respect, the bladder model resembles the solid state carcinogenesis process in the skin implantation test (see above).

In another study, paraffin wax pellets were surgically implanted into the bladder lumen of mice. The tumour response to paraffin wax significantly depended on the type of pellet used. Paraffin wax pellets made in Leeds, UK, induced 10.6, 26.7, and 53.8% bladder tumours after approximately 45, 75, and 105 weeks, respectively; paraffin wax pellets prepared in Vancouver, Canada, 0 and 33.3% tumours after approximately 45 and 75 weeks, respectively. The progressions of lesions in time and the presence of mucosal inflammation in the majority of bladders suggest a non-genotoxic mechanism for the induction of bladder tumours. Incorporation of known carcinogens into the pellet enhanced the proliferative response somewhat. Unresolved questions are rate of diffusion of the carcinogen from the pellet and its stability (Jul79).

The committee did not find data on the irritation, acute and repeated-dose toxicity, including carcinogenicity or reproduction toxicity, and genotoxicity or mutagenicity of paraffin wax fumes or on the genotoxicity, mutagenicity, and reproduction toxicity of paraffin waxes.

7 Existing guidelines

The current administrative occupational exposure limit (MAC) of paraffin wax fume in the Netherlands is 2 mg/m³, 8-hour TWA.

Existing occupational limits in some European countries and in the USA are summarised in the annex.

8 Assessment of health hazard

Paraffin wax and paraffin-wax-containing products were at most slightly irritating but not sensitising to human skin. There is some information that these fumes can cause irritation of the eyes and the respiratory tract and impairment of lung function. There is only one study available in which both exposure levels and effects were reported. In this study, an increase in subjective symptoms and a decrease in pulmonary lung function was observed in 5 professional ski waxers after exposure for 2 to 3 hours to mean dust levels of approximately 0.6 to 2.4 mg/m³. However, since waxes containing other compounds such as silicones and polytetrafluoroethylene were used as well, it cannot be assessed to what extent the effects found can be attributed to paraffins. The committee did not find data on effects following long-term occupational exposure to paraffin wax fumes.

In experimental animals, undiluted pure paraffin wax did not cause irritation to the skin of rabbits while application of a 50/50 mixture of paraffin wax in petrolatum or of products containing 8-16% paraffin wax produced minimal to severe irritation. Instillation of 50% solutions or of products containing 5-16% paraffin wax caused no or minimal irritation to the eyes of rabbits.

A single dermal application of a dose of 4 mL/kg bw or a single oral dose of 5000 mg/kg bw did not affect rabbits or rats, respectively. Upon subchronic oral administration of 10 to 3000 mg/kg bw, there were no effects in dogs or Long-Evans or Sprague-Dawley rats, while in Fischer 344 rats, dose-dependent inflammatory responses were seen in lymph nodes, the liver, and the heart. No increased tumour incidence was observed after topical, subcutaneous, or oral administration to rats. Bladder tumours reported in rats and mice following implantation of paraffin-wax-containing pellets in the bladder are not considered to be compound related.

The committee did not find experimental animal data on the irritation, acute and repeated-dose toxicity, including carcinogenicity or reproduction toxicity, and genotoxicity or mutagenicity of paraffin wax fumes or on the genotoxicity, mutagenicity, and reproduction toxicity of paraffin waxes.

The committee considers the toxicological database on paraffin wax fume too poor to justify recommendation of a health-based occupational exposure limit.

The committee concludes that there is insufficient information to comment on the level of the present MAC-value.

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* This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No 793/93 on the Evaluation and Control of the Risks of Existing Substances' to allow a risk assessment by member states of the EC. However, the data in this dossier have not undergone any evaluation by any EC member state yet.

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Annex

Occupational exposure limits for paraffin wax fume in various countries.

country -organisation	occupational exposure limit		time-weighted average	type of exposure limit	note ^a	reference ^b
	ppm	mg/m ³				
the Netherlands -Ministry of Social Affairs and Employment	-	2	8 h	administrative		SZW02
Germany -AGS	-	-				TRG00
-DFG MAK-Kommission	-	-				DFG02
Great-Britain -HSE	-	2 6	8 h 15 min	OES		HSE02
Sweden	-	-				Swe00
Denmark	-	2	8 h			Arb02
USA -ACGIH	-	2	8 h	TLV		ACG02b
-OSHA	-	-				ACG02a
-NIOSH	-	2	10 h	REL		ACG02a
European Union -SCOEL	-	-				EC02

^a S = skin notation; this means that skin absorption may contribute considerably to body burden; sens = substance can cause sensitisation.

^b Reference to the most recent official publication of occupational exposure limits.