Gezondheidsraad **Voorzitter**
Health Council of the Netherlands

Aan de Staatssecretaris van Sociale Zaken en Werkgelegenheid

Onderwerp : Aanbieding adviezen herevaluatie bestuurlijke MAC-waarden
Uw kenmerk : ARBO/AMIL/97/00648
Ons kenmerk : U 2706/CB/MP/563-O3
Bijlagen : 18
Datum : 14 december 2000

Mijnheer de staatssecretaris,

Op verzoek van uw ambtsvoorganger bied ik u hierbij de eerste adviezen aan van een reeks over de gezondheidskundige basis van uit het buitenland overgenomen grenswaarden voor beroepsmatige blootstelling aan stoffen. Het verzoek om deze adviezen is in algemene zin vervat in brief nr ARBO/AMIL/97/00648 en in latere stadia door uw departement toegespitst op afzonderlijke stoffen. De adviezen zijn opgesteld door een daartoe door mij geformeerde internationale commissie van de Gezondheidsraad en beoordeeld door de Beraadsgroep Gezondheid en Omgeving.

De beoogde reeks van in het Engels gestelde adviezen zal losbladig worden gepubliceerd onder ons publicatienummer 2000/15OSH en, conform de aan de Gezondheidsraad voorgelegde toespitsingen van de adviesaanvraag, betrekking hebben op 168 stoffen. Het u thans aangeboden eerste pakket bestaat uit een Algemene Inleiding (publicatienummer 2000/15OSH/000) en uit de adviezen genummerd 2000/15OSH/001 tot en met 2000/15OSH/017, respectievelijk betrekking hebbend op:
cesiumhydroxide, cyclopentaan, diboraan, dimethoxymethaan, dipropylketon, fenylfosfine, germaniumtetrahydride, hexachloornaftaleen, methaanthiol, methylcyclohexanol, methylisopropylketon, mica, natriumhydroxide, octachloornaftaleen, silaan, tetrachloornaftaleen, en yttrium en yttriumverbindingen.

Bij afronding van de werkzaamheden van de hierboven bedoelde commissie ontvangt u een Nederlandstalige samenvatting van de in de gehele reeks van adviezen neergelegde bevindingen.

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Gezondheidsraad
Health Council of the Netherlands

Onderwerp : Herevaluatie uit het buitenland overgenomen grenswaarden
Ons kenmerk : U
Pagina : 2
Datum : 14 december 2000

De u thans aangeboden adviezen heb ik vandaag ter informatie doen toekomen aan de Minister van Volksgezondheid, Welzijn en Sport en aan de Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer.

Hoogachtend,

prof. dr JJ Sixma

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Hexachloronaphthalene

(CAS reg. nr: 1335-87-1)

Health-based Reassessment of Administrative Occupational Exposure Limits

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

No. 2000/15OSH/007, The Hague, 14 December 2000

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1 Introduction

The present document contains the assessment of the health hazard of hexachloronaphthalene 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 mrs MA Maclaine Pont, M.Sc. (Wageningen University, the Netherlands).

Literature was retrieved from the data bases Medline, Toxline and Chemical Abstracts, covering the periods 1966 until March 1998, 1981 until October 1997 and 1937 until December 1997, respectively, and using the following key words: hexachloronaphthalene, 1335-87-1, Halowax, Nibren, naphthalene or hexachloro- (all isomers). Data considered to be critical were evaluated by reviewing the original publications. The final literature search has been carried out in March 1998, followed by an additional search in May 1999.

In February 1999, the President of the Health Council released a draft of the document for public review. Comments were received by the following individuals and organizations: dr P Wardenbach (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Dortmund, Germany). These comments were taken into account in deciding on the final version of the document.

2 Identity

name	:	hexachloronaphthalene
synonyms	:	-
CAS reg nr	:	1335-87-1
molecular formula	:	$C_{10}H_2Cl_4$
structural formula	:	

Data from How92.

The technical product Halowax 1014 can often erroneously be found under the same CAS reg nr as the original mixture. The theoretical chlorination degree is 63.5%, the actual degree varies from 62 to 64% (Aho80, Bel53). Halowax 1014 (CAS reg nr 12616-36-3) is said to be a mixture of penta- and hexachloronaphthalenes (Ham57) or of tetra- to octachloronaphthalenes (Asp86).

3 Physical and chemical properties

molecular weight	:	334.8
melting point	:	137°C
boiling point	:	343 - 388°C
vapour pressure	:	20°C: < 133 Pa
solubility in water	:	insoluble
log $P_{oct/water}$	:	7.59
conversion factors (20°C, 101.3 kPa)	:	not applicable

Data from ACG91, DFG97.

Hexachloronaphthalene is a white or yellow wax-like compound, with a typical odour. The compound decomposes upon heating and combustion, forming corrosive and very toxic fumes, e.g. hydrochloric acid (NIA98).

4 Uses

Hexachloronaphthalene has been used in the manufacture of electric wire insulation and also as an additive to special lubricants (ACG91). The manufacturing of chlorinated naphthalenes (Halowax) has been discontinued in the USA since 1977 (Ben94).

5 Biotransformation and kinetics

After a single oral dose of Halowax 1014 (containing mainly penta- and hexachloronaphthalene) at 20 mg/kg bw to rats, one component (hexachloronaphthalene) concentrated in the liver. The concentration ratio between the liver and adipose tissue was about 140 after 10 days, and 5 after 4 months. The component was characterised by comparison with GC/MS data of

all available chloronaphthalenes. It was shown that the bioaccumulating compound was 1,2,3,5,6,7-hexachloronaphthalene (Asp86). Later it was shown that the retained compound actually was a mixture of two hexachloronaphthalenes: the 1,2,3,4,6,7- and 1,2,3,5,6,7-isomers (Asp94). Also when rats were orally dosed with a mixture of the identified isomers of hexachloronaphthalene, the isomers were strongly retained in the liver. The half lives were calculated to be 41 days in adipose tissue and 36 days in the liver (Asp94).

After a single intra peritoneal injection with Halowax 1014 in rats, the activity of several drug metabolizing enzymes in the liver was increased: aryl hydrocarbon hydroxylase, ethoxycoumarine deethylase and UDP glucuronosyltransferase (Aho80).

6 Effects and mechanism of action

Human data

A quantity of 2 ml of a 3% solution of either Halowax 1014 or hexachloronaphthalene was applied on the skin of six Caucasian and four Negro male volunteers, daily for a minimum of 6 weeks to a maximum of 12 weeks. With both compounds dermal effects developed, from increase in number of epidermal cells (day 5), follicular involvement without erythema (day 10), follicular accentuation (day 14), small comedones (week 3 - 5), to large comedones (week 6 - 12). Pretreatment with vitamin A did not result in any amelioration of the effect (Ham57).

Acne was also produced on the skin of several volunteers: seven areas of skin in 3 to 5 white and Negro male adults were investigated by applying a 50% suspension of Halowax 1014 daily for 35 days. Five subjects were treated daily for 2 months with Halowax 1014 on their back and biopsies were taken at regular intervals, up to 16 weeks. Fulminant inflammatory acne developed, which was not confined to the sites of application, but also appeared on areas to which the wax was transferred by the hands or clothing. The disease slowly resolved over the next half year. Residual scarring, hyperpigmentation and other characteristic symptoms remained evident at one year (She57). Several cases are described of persons who died from liver cirrhosis, liver atrophy, toxic jaundice or related diseases. All were exposed to Halowax, but its composition is not known (Str44).

A group of 9,028 workers, exposed to a mixture of polychlorinated naphthalenes, was investigated for work-related causes of mortality and morbidity. In this group 460 individuals were diagnosed with chloracne (5%). There was an elevated mortality due to liver cirrhosis. After leaving out the cases which could be associated with alcohol abuse, 83 cases with liver cirrhosis were observed, resulting in a SMR of 1.67 (no confidence limits were given, $p<0.01$). Although exposure to chlorinated naphthalenes ceased in 1945, the elevated mortality from cirrhosis persisted through the 80s. Furthermore, the workers were probably also exposed to other chlorinated hydrocarbons (War96). Although the authors tried to relate the incidence of chloracne with causes of death, no such relationship was found. In the total cohort (not corrected for alcohol abuse) an increase in death from ischemic heart disease, digestive system diseases, and all cancers, was also found; this increase was not found in the subcohort of individuals with chloracne.

In a group of 16 workers for many years occupationally exposed to a mixture of chlorinated naphthalenes, six had liver dysfunctions, especially elevated levels of the enzyme gamma-glutamyltransferase (GGT). None of them had chloracne. The naphthalene waxes contained in some cases a mixture of 40% pentachlorinated and 35% hexachlorinated naphthalenes (Pop97). In view of the fact that 10 of the 16 workers were not available for examination, that the workers were exposed to a mixture of compounds and that data are lacking concerning occupational circumstances, this study gives only weak support to the hypothesis that hexachloronaphthalene can induce liver toxicity.

Animal data

Halowax 1014 (according to the authors hexachloronaphthalene) was investigated for dermal effects. A quantity of 29 mg was topically applied three times per week for two weeks on hairless mice. Within 14 days hyperkeratotic scaly skin was observed. Histologically hyperkeratosis, epidermal hyperplasia, sebaceous gland involution and intraepidermal keratinous cyst formation were evident (Puh82).

Halowax 1014 (according to the authors a mixture of penta- and hexachloronaphthalene) and hexachloronaphthalene were applied as a 3% solution on the ear canal skin of rabbits daily for 5 days; each time 1 ml was applied, the rabbits received thus 5 times 30 mg. In both cases mild dermatitis, thickening of the epidermis, and proliferation of the follicles and sebaceous gland ducts were observed. The effects gradually receded upon discontinuation

of the applications. Pretreament with vitamin A did not result in any amelioration of the effect (Ham57).

Daily inhalation of a mixture of penta- and hexachloronaphthalene in a concentration of 1.16 mg/m^3 for 16 hours/day during 134 days (4.5 months) induced liver injury in rats: swollen cells, more granules in the cells, and hyaline droplets in the cytoplasm. No significant advances of the effects were observed between the 72nd and 134th day of exposure. Daily inhalation of the same mixture in a concentration of 1.44 mg/m^3 for 8 hours/day during 143 days (4.8 months) induced similar liver injury as that seen in rats exposed 16 hours daily. A higher concentration of 8.88 mg/m^3 for 16 hours/day induced weight loss in all 80 rats, and 4 died by the end of the first month, 55 within 52 days. Liver injury was more marked compared with the lower dosed groups. Rats removed from exposure between the 3rd and 5th week continued to die, the longest survival time being 35 days. Microscopic examination of the livers of these animals revealed no recovery (Ben38). Feeding experiments with the same mixture of penta- and hexachloronaphthalene to rats resulted in the same liver injury as after inhalation exposure. Daily feeding of 3 g per animal led to the death of all 10 animals within 33 days. Daily feeding of 1 g per animal led to the death or a moribund state of all 10 animals within 55 days.

Rats were given 0.02%, 0.0063%, or 0.002% hexachloronaphthalene in the diet for 12 weeks. The group size was 39 - 40 animals 39-days old (older rats) and 62 - 64 animals 32-days old (younger rats) at the start of the study; interim kills were performed at 4 days and at 1, 4, 8, and 12 weeks. Therefore, only 8 - 16 animals received the diet for 12 weeks. The parameters measured were body, liver and kidney weight and the sleeping time after a single intra peritoneal injection of hexobarbital or pentylenetetrazol. A treatment- and dose-related decrease in food consumption and body weight and an increase in relative liver weight was observed within one week of treatment. The treatment of half of the number of rats from the top dose was discontinued after 4 weeks. A recovery was observed, but after 4 weeks the parameters were not yet comparable with those of the control group. At the lowest dose the increase in relative liver weight of the combined groups was significant after 1 week ($0.05>p>0.01$) and after 4, 8 and 12 weeks ($p<0.001$). After 12 weeks the body weights of the older and the younger rats were not significantly different from the control group, as were the kidney weights and the sleeping times of the combined groups (Wei62).

A technical mixture of hexachloronaphthalene (chlorination degree 62%) was given per os to swine and pigs for several days. A total dose of 50 mg/lb

(110 mg/kg) after 10 days did not induce any effects in swine. After a total dose of 90 or 100 mg/lb (198 or 220 mg/kg) after 8 or 9 days pigs became moribund or died after 33 to 40 days. Gross lesions were swelling and haemorrhage in the liver, mild gastritis, slight thickening of the intestinal wall, oedema of the eyelids in some animals and swelling of the epididymis. The plasma vitamin A did not remain low after the administration was discontinued. There was a temporary drop into the deficiency range 14 days after the initial dose of 70 mg/lb (145 mg/kg) or more was given to the pigs. However, levels did not remain in the deficiency range, and pigs which were severely poisoned later on had normal plasma vitamin A values (Lin58).

After daily oral dosing of 10 mg hexachloronaphthalene/lb body weight (22 mg/kg) to 6 pigs for 8 or 9 days, they were moribund or had died after 31 to 40 days. Symptoms before death were depression, anorexia, ataxia, retarded weight gain or weight loss. They did not develop other signs characteristic of bovine hyperkeratose. Histopathological lesions were observed in liver and kidneys. After 14 days the plasma vitamin A levels were decreased ($p<0.001$). No significant differences in the plasma vitamin A levels were observed at necropsy (Hub62).

Five calves received doses of hexachloronaphthalene in the range of 2.5 - 11.6 mg/lb (5.6 - 25.6 mg/kg) as a total dose, given in small doses for 5 to 10 days. Symptoms developed by the fifth day, consisting of hyperkeratosis, lacrimation, nasal discharge, salivation, red areas on the oral mucosa, anorexia, depression, indentation of horn, and finally extreme weakness or prostration. They had to be killed between the 15th and 29th day. Upon autopsy the animals had lesions in kidneys, liver, pylorus, gall bladder and small intestine (Bel53).

1,2,3,4,5,6-hexachloronaphthalene was intra peritoneally injected into immature male rats (n=4) on day 1 and day 3, with a dose of 30 and 150 µmol/kg (10 and 50 mg/kg). A control group (n=10) was injected with corn oil. On day 6 there was a dose-related increase in the relative liver weight ($p<0.05$ in both cases), in the induction of the enzymes B[a]P hydroxylase ($p<0.05$ at the high dose), ethoxyresorufine O-deethylase ($p<0.05$ in both cases), cytochrome b_5 ($p<0.05$ at the high dose) and cytochrome P450 ($p<0.05$ in both cases) (Cam83).

A very old study reports that after exposure to 1 mg/m^3 hexachloronaphthalene 16 hours/day, for 6 weeks, rats showed only damage to the liver (Dri37).

No data on carcinogenicity, genotoxicity or mutagenicity of hexachloronaphthalene have been found.

Reproduction toxicity

A 1 year old Holstein bull administered 1.8 g of penta- and hexachloronaphthalene became aspermatozoal for 6 months, but recovered in 10 months following treatment (Ben94).

7 Existing guidelines

The current administrative occupational exposure limit (MAC) for hexachloronaphthalene in the Netherlands is 0.2 mg/m^3, 8 h TWA.

Existing occupational exposure limits for hexachloronaphthalene in some European countries and in the USA are summarized in the annex.

8 Assessment of health hazard

Occupational exposure to a mixture of polychlorinated naphthalenes is associated with liver dysfunctioning and liver cirrhosis in humans. However, the workers were probably also exposed to other chlorinated hydrocarbons (Pop97, War96).

Hexachloronaphthalene and Halowax 1014 are acnegenic in humans (Ham57, She57), and in rabbits and hairless mice (Ham57, Puh82) after dermal application. The lowest dose applied on humans was 2 ml of a 3% solution, that is 60 mg per day.

After oral dosing calves developed hyperkeratosis, but pigs and swine did not, even at doses which were lethal to the animals.

Inhalation studies in rats to hexachloronaphthalene (1 mg/m^3, for 6 weeks) or with a mixture of this compound and the pentachloronaphthalene (1.2 - 1.4 mg/m^3, approx. 20 weeks) resulted in effects in the livers (Dri37, Ben38).

Dosing of 0.002% hexachloronaphthalene via the diet increased the relative liver weights in rats after 12 weeks, but not the body weights and the relative kidney weights. These were the only parameters measured, histopathology was not performed (Wei62). Using default values the consumption of hexachloronaphthalene was estimated by the committee to be 1 mg/kg body weight per day.

No data on carcinogenicity, genotoxicity, mutagenicity and reproduction toxicity studies have been found.

The activity of several enzymes was increased in the liver of rats after intra peritoneal injection of the technical product (Aho80).

The 1,2,3,5,6,7- and 1,2,3,4,6,7-isomer can accumulate in the liver of rats after oral dosing the technical product (Asp94).

The limited data available indicate that the target organ for toxicity is probably the liver.

The committee considers the toxicological data base on hexachloronaphthalene too poor to recommend a health-based occupational exposure limit.

Considering the effects found in the inhalation studies in rats, the committee concludes that the present MAC value for hexachloronaphthalene of 0.2 mg/m^3, as an 8 h time weighted average, is too high.

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Annex

Occupational exposure standards for hexachloronaphthalene in various countries.

country -organisation	occupational exposure limit		time-weighted average	type of exposure limit	note[a]	lit ref[b]
	ppm	mg/m^3				
the Netherlands						
- Ministry	-	0.2	8 h	administrative	S	SZW00
Germany						
- AGS		0.2[c]	8 h	administrative		TRG00
- DFG MAK-Kom.	-	-[d]				DFG99
Great Britain						
- HSE	-	-				HSE99
Sweden	-	[e]				NBO96
Denmark	-	0.2	8 h		S	Arb96
USA						
- ACGIH	-	0.2	8 h	TLV	S	ACG00
- OSHA	-	0.2	8 h	PEL	S	
- NIOSH	-	0.2	10 h	REL	S	
European Union						Hun97
- SCOEL	-	-				

[a] S = skin notation; which means that skin absorption may contribute considerably to the body burden
sens = substance can cause sensitization

[b] reference to the most recent official publication of occupational exposure limits

[c] the inhalable fraction of the aerosol

[d] substance for which no MAK value can be established at present

[e] Sweden has a Level Limit Value for chlorinated naphthalenes of 0.2 mg/m^3 8 h TWA and a STEL (10 min) of 0.6 mg/m^3 with a skin notation. However, the CAS reg nr assigned to this mixture is the same as that for trichloronaphthalene.