o-, *m*-, *p*-Terphenyl (mixture)

(CAS reg no: 26140-60-3)

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 terphenyls 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 RN Hooftman, M.Sc. and H. Stouten, M.Sc. (TNO Nutrition and Food Research, Zeist, the Netherlands).

The evaluation of the toxicity of terphenyls has been based on the review by the American Conference of Governmental Industrial Hygienists (ACG96). Where relevant, the original publications were reviewed and evaluated as will be indicated in the text. In addition, literature was retrieved from the online data bases Medline, Toxline, and Chemical Abstracts covering the period 1966 to 24 October, 1997 (19971024/UP), 1965 to 20 October 1997 (19971020/ED), and 1967 to 28 October, 1997 (971028/ED); vol 127 iss 18), respectively, and using the following key words: terphenyls, triphenyl and terphenyl compounds, Delowax OM, Delowax, diphenyl benzene, terbenzene, $C_{18}H_{14}$, and 26140-60-3, 84-51-1, 92-06-8, 92-94-4. HSDB and RTECS, data bases available from CD-ROM, were consulted as well (NIO98, NLM98). The final literature search has been carried out in October 1997, followed by an additional search in May 2001.

In July 2001, the President of the Health Council released a draft of the document for public review. Comments were received from the following individuals and organisations: AJ Aarts (Solutia Services International Comm.VA/SCA, Louvain-la-Neuve, Belgium). These comments were taken into account in deciding on the final version of the document.

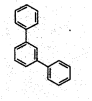
2 Identity

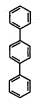
name	:	terphenyl
synonyms	:	terphenyl mixture; diphenylbenzene; terbenzene; triphenyl
molecular formula	:	$C_{18}H_{14}$
CAS reg no	:	21640-60-3

Data from ACG96, EC96, Ric94a, Ric94b.

Terphenyls are commercial mixtures of the three isomers, *i.e.*, *o*-terphenyl, *m*-terphenyl, and *p*-terphenyl, with registered trade names such as Delowax OM,

name	:	*o*-terphenyl
synonyms	:	*ortho*-terphenyl; 1,2-diphenylbenzene; 1,1':2',1"-terphenyl; 2-phenylbiphenyl
structure	:	
CAS reg no	:	84-15-1

name	:	*m*-terphenyl
synonyms	:	*meta*-terphenyl; *m*-diphenylbenzene; 1,3-diphenylbenzene, *iso*diphenylbenzene; 3-phenyldiphenyl; *m*-triphenyl; 1,3-terphenyl; 1,1':3',1"-terphenyl
structure:	:	
CAS reg no	:	92-06-8

name	:	*p*-terphenyl
synonyms	:	*para*-terphenyl; *p*-diphenylbenzene; 1,4- diphenylbenzene; 4-phenylbiphenyl; p-triphenyl; 1,1':4',1"-terphenyl
structure	:	
CAS reg no	:	92-94-4

3 Physical and chemical properties

The properties of the terphenyl isomers and mixtures are summarised in Table 1.

Pure terphenyl is a white crystalline solid; commercial grades are light yellow. Commercial terphenyl mixtures are crumbly, waxy-like flakes at room temperature, and light amber liquids above the melting point, with a faint, pleasant odour.

Data from ACG96, EC96, Ric94a, Ric94b, http://esc.syres.com.

Table 1 Physical and chemical properties of terphenyl isomers and mixtures.

	o-terphenyl	*m*-	*p*-	mixture
molecular weight	230.31	id	id	id
melting point/range	56.2°C	87.5°C	212.7°C	60-145°C[a]
boiling point/range	332°C	365°C	376°C	10% over 364°C , 90% over 418°C[a]
vapour pressure	at 25°C: 2.5×10^{-5} kPa[b]	at 25°C: 0.18×10^{-5} kPa[b]	-	at 149°C: 0.16×10^{-2} kPa[a]
flash point (open cup)	163°C	191°C	207°C	191°C[a]
solubility in water	not soluble	not soluble	not soluble	0.11 mg/L[c]
log $P_{octanol/water}$	5.52 (estimated)	5.52 (estimated)	6,03 (experimental) 5.52 (estimated)	5.86[c]
Conversion factors (20°C, 101.3 kPa)	1 ppm = 9.6 mg/m^3 1mg/m^3 = 0.10 ppm			

[a] Commercial mixture consisting of 2-10% *o*-, 45-49% *m*-, and 25-35% *p*-terphenyl with trace amounts of diphenyl plus higher polyphenyls normally in the 2 to 18% range.
[b] Stated to be extrapolated from experimentally-derived coefficients.
[c] Mixture of unknown composition.

4 Uses

Terphenyl mixtures are used industrially as heat storage and transfer agents, as textile dye carriers, and as intermediates in the production of non-spreading lubricants (ACG96, Ric94a, Ric94b)

The individual isomers are used as solvents. Furthermore, *m*-terphenyl is used in thermal printing material and as a coolant in nuclear reactors, and *p*-terphenyl as a laser dye and a sunscreen lotion component (ACG96, Ric94a, Ric94b).

5 Biotransformation and kinetics

There were no toxicokinetic data found following exposure by inhalation to the terphenyl isomers or to mixtures.

When 80 mg radiolabelled *o*-terphenyl/kg were orally (gavage) given to male rats and rabbits, approximately 80% and 90% of the radiolabel administered were eliminated in the first 24 hours by rats and rabbits, respectively, while elimination was almost complete within 48 hours (>94%). In rats, the main excretion route was the faeces from which approximately 75% of the radioactivity was recovered in the first 24 hours. Of this radioactive fraction, 10% were parent compound,

86% were metabolites containing free phenol groups or conjugated products, while the remaining 4% was highly polar, probably conjugated compounds that could not be hydrolysed by ß-glucuronidase or arylsulphatase. It was shown that approximately 50% of the radioactivity administered was excreted via the bile within the first 24 hours, indicating the involvement of enterohepatic circulation. Approximately 6% of the radioactivity was excreted in the first 24-hour urine, consisting mostly of ß-glucuronide conjugates. Upon sacrifice at 24 hours, 12.5%, 1.5%, and 0.2% of the radiolabel were recovered from the gastrointestinal tract, the adipose tissue, and the blood, respectively, while only very low amounts (<0.03%) were found in the liver, the kidneys, and the brains. In rabbits, the urine was the most important excretion route accounting for approximately 76% of the amount of radiolabel excreted within the first 24 hours. Of this, 12% were parent compound, 79% were metabolites containing free or conjugated phenol groups, and 9% conjugates that could not be hydrolysed by ß-glucuronidase or arylsulphatase. Approximately 12% was excreted in the faeces within the first 24 h (Sco71). In male rabbits, 15 and 45% of a single oral dose of 1 g of *o*-terphenyl were excreted within 4 days in the urine as free phenolic and glucuronide derivatives, respectively, while another 8% was found unchanged in the faeces. Following oral administration of *m*- or *p*-terphenyl, these figures were 18% (urinary free phenols), 20% (urinary glucuronides), and 15% (faecal unchanged compound), and 0% (urinary free phenols), 4% (urinary glucuronides), and 30% (faecal unchanged compound), respectively. There were no indications for the excretion of ethereal sulphates or mercapturic acids (Cor62).

In a chronic toxicity experiment in which rats were orally given a commercial terphenyl mixture for 188 days followed by an exposure-free period of 47 days (see section: Animal data: repeated-dose toxicity), thin layer chromatography of benzene extracts of kidney homogenates showed the presence of *o*- and *m*-terphenyl (the latter in trace amounts only) (You69), indicating that accumulation occurs at repeated dosing.

When investigating the potency of the 3 isomers to induce drug-metabolising enzyme activity (4,4'-dimethylaminoantipyrine *N*-demethylase; benzo(a)pyrene hydroxylase; ethoxyresorufin *O*-deethylase) by giving rats oral doses of 300 µmol/kg (69 mg/kg), there were no increases in liver weight or in the liver protein content. The only effect seen was an induction of the dimethylamino-antipyrine N-demethylase activity by *o*-terphenyl (Lee86).

The three isomers were investigated for their potency to induce liver regeneration in rats by dietary or subcutaneous exposure. Both *o*- and *m*-terphenyl induced liver regeneration in hepatectomised animals and a significant increase in liver weight in hepatectomised and intact animals (Ger75).

6 Effects and mechanism of action

Human data

Referring to a Russian study (published in 1972), transient headaches and sore throat from spills with short-term exposure were mentioned. Chronic inhalation to 0.01-0.94 ppm (0.1-9 mg/m^3) was stated to have not affected blood pressure, to have improved pulmonary function, and to have induced borderline (not statistically significantly) elevated isocitric dehydrogenase levels. Furthermore, 6 out of 200 workers chronically exposed to these levels developed nonspecific, readily reversible skin rashes, but there were no indications for skin sensitisation (Cav94). These data were summarised in a table without further details.

From the statement that workers in a reactor room had to wear dust proof masks and goggles at concentrations of a terphenyl mixture (12% *o*-, 60% *m*- and 28% *p*-terphenyl) above 10 mg/m^3 (Tes64), it may be concluded that this level may cause ocular and respiratory tract irritation.

Animal data

Irritation

Instillation of 0.1 mL of a terphenyl mixture (45% *o*-, 29.2% *m*-, 5.6% *p*-terphenyl, 17% biphenyl, 2.9% other aromatics) into the eye of rabbits (2 animals) caused immediate strong conjunctival irritation and oedema of the nictitating membrane, which prevented its relaxation. The mixture did not produce corneal or iris damage (Hal59).

The aforementioned terphenyl mixture caused moderate skin irritation (average score: 2.7; maximum possible score: 8.0) to rabbits (intact and abraded skin; 6 animals per group); average scores of 1.1, 0.9, and 0.8 were obtained for *o*-, *m*-, and *p*-terphenyl, respectively (Hal59). No skin irritation was reported following application of alcohol solutions of the 3 separate isomers (concentrations not

mentioned) to the shaved skin of rabbits (24-hour contact; lightly covered) (Cor62).

In guinea pigs, intradermal injection of the terphenyl mixture (0.05 mL; 3 times weekly; 10 injections) caused severe irritation. The individual isomers also caused necrosis and scarring under the same conditions. Multiple injections of a 10% solution did not increase the skin irritation over that seen on the initial injection. A final 1% test injection caused development of a wheal and flare response of about 22-28 mm compared to an initial response of 12-16 mm, which indicated the development of sensitivity to the test substance. Eosinophilic infiltration was considered further indicative of sensitisation to the test chemical (Hal59).

In contrast, in an unpublished study, terphenyl (composition unknown) was reported to be not irritating to the skin and slightly irritating to the eyes of rabbits (EC96).

Nasal (congestion with rhinitis) and eye (lachrimation with eyes closed) irritation and laboured breathing as well as erythema of the ears and paws was observed in rats exposed to 2550-3870 mg/m^3 of mixed terphenyl (composition: see above) or *o*- or *m*-terphenyl, for 1 hour. Apart from the nasal effects, these effects were also seen at 1-hour exposures to levels of 660-1070 mg/m^3. *p*-Terphenyl induced erythema of the ears and paws only at an exposure level of 1030 mg/m^3 (the only level tested) (no data on particle size or method of generating vapours or aerosols) (Hal59).

When guinea pigs were exposed to homogeneous aerosols of *m*-terphenyl of diameters of 0.30, 0.65, 1.0, and 2.0 µm (mass concentrations between 9 and 81 mg/m^3) at equal mass concentrations, an increase of the irritant potency (parameter: pulmonary-flow resistance) was observed as the particle size decreased and the number of particles increased. A small increase in mass concentration for the smaller particles caused a greater increase in response than occurred when the larger particles were used (Amd66).

Acute toxicity

Following exposure by inhalation to a terphenyl mixture or to the separate isomers for 1 hour (see also previous paragraphs), lungs and trachea were histologically examined in each two rats sacrificed at 1and 3 hours and 1, 3, 7, and 14 days after ending exposure. Particle sizes and method by which aerosols or vapours were generated were not presented. Exposure to 3560 mg/m^3 *o*-terphenyl caused early asphyxial death by formation of crystalline plugs in the

trachea near its entrance to the pharynx in 5/8 animals (4/8 within 1 hour). Acute tracheal oedema persisting for 1 week, acute tracheal necrosis, and chronic tracheitis were observed. Exposure to 3390 mg/m^3 *m*-terphenyl caused mortality in 4/8 animals (all within 1 hour). There were acute tracheal necrosis, chronic tracheitis, and acute tracheobronchitis. Following exposure to 2550 mg/m^3 of the mixture, mortality in 1/8 animals and acute mediastinal oedema were found. All induced a number of additional lesions, but these were found in the hot-air and unexposed control animals as well - albeit at the end of the experiment at day 14 - and could, therefore, not be attributed to exposure to the terphenyls with certainty (Hal59).

A dermal LD_{50} of > 12,500 mg/kg has been estimated in rats for a terphenyl mixture of unknown composition (EC96).

Following oral administration, LD_{50}s of 13,200 and >50,000 mg/kg have been reported for terphenyl (nonspecified mixture) in mice and rats, respectively (EC96, NIO98, Ric94b). An oral LD_{50} in rats of 1400 mg/kg for a commercial mixture consisting of approximately 64% *o*-, 25% *m*-, 6% *p*-terphenyl, and 5% biphenyl has been reported as well (Pet65). Concerning the individual isomers, LD_{50}s in rat were 1900, 2400, and >10,000 mg/kg for *o*-, *m*-, and *p*-terphenyl, respectively (Cor62).

Repeated dose toxicity

There were no data from studies in which experimental animals were repeatedly exposed by inhalation to the terphenyl isomers or their mixture.

When young male rats (Wistar; n=not reported) were fed diets containing 0.2% (200-250 mg/kg bw/day*) *o*-, *m*-, or *p*-terphenyl for 14 days, *m*-terphenyl treatment resulted in decreases in food uptake. Body weight gain was decreased in animals receiving *o*- and *m*-terphenyl. All isomers caused increased plasma cholesterol concentrations, while liver cholesterol levels were not affected. Treatment with *o*- and *m*-terphenyl induced increases in relative adrenal and kidney, and in liver and kidney weights, respectively. *p*-Terphenyl did not cause relative weight changes in any of the organs examined (*i.e.*, liver, spleen, heart, kidneys, adrenals) (Kir74).

When fed 250 or 500 mg/kg bw/day in the diet of male rats (Sprague Dawley: Holtzman strain; n=5) for 30 days, *o*-terphenyl induced decreases in body weights and increases in relative liver and kidney weights. At these levels,

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* Calculated from data presented by Kir74; depending on the isomer, 120-127.5 g was taken as an average body weight over the experimental period and 175-215 g as the amount of food taken up during this period.

m-terphenyl caused decreased body weight and increased relative liver weights. When fed either of these isomers at doses of 100 mg/kg bw/day, no such effects were observed. The only changes seen following feeding *p*-terphenyl were decreases in body weight in the animals of the high-dose group. Histological examinations did not show treatment-realated changes in any of the exposed animals (Cor62).

A commercial terphenyl mixture (approx 64% *o*-, 25% *m*-, 6% *p*-terphenyl, 5% biphenyl) was fed to rats ("black hooded"; n=9/sex/group) at doses of 0.01, 0.1, and 1.0 % (by weight), for 235 days. Control groups receiving chow pellets (n=5 males; 6 females) or chow pellets and corn oil (2:1 w/w) (n=9/sex), equivalent to that fed to the test groups, were included. Three animals per sex of each group were sacrificed on the 130th, 188th, and 235th day (the end of the study), respectively (chow-pellet-only group: 5, 2, 4 animals, resp). The last third of the high-dose group was put back on the control diet from the 189th day on. Parameters investigated included body weights, organ weights (liver, kidneys, lungs), and haematology (haemoglobin, haematocrit, total white blood cell counts). Furthermore, brain, lungs, heart, stomach, intestines, liver, spleen, pancreas, kidneys, adrenals, bladder, gonads, and bone were examined histologically. Some animals (1, 2, 1 in low-, mid-, and high-dose groups, resp) died during the course of the study, but no autopsy was performed and the cause of death was not assessed. In the animals of the high-dose group, receiving 350 (males) to 409 (females) mg/kg bw/day, nephrotoxicity (degenerative kidney changes and interstitial nephritis with fibrosis), decreased body weight, increased relative liver weights, and reduced haemoglobin values (the latter based on combining the results of all sacrifices) were observed. The kidney lesions were partly still present after the exposure-free period of 47 days. No histological lesions were observed in the other organs investigated. In the mid-dose group, fed approximately 30 mg/kg bw/day (males: 31, females: 37 mg/kg) for 235 days, only changes in the renal tubules (accumulations of unidentified golden-yellow granules) were seen. These changes were present at the first interim sacrifice at day 130, and progressively increased in number of cells involved at the subsequent sacrifices at day 188 and 235. Growth curves suggested a decrease in body weight gain of the male animals. There were no effects observed in the low-dose group receiving daily oral doses of approximately 3 mg/kg (males: 3.0, females: 3.5 mg/kg) (Pet65, You69).

From this study, the committee concludes that oral administration of daily amounts of approximately 30 and 350 mg/kg induces kidney effects, 3 mg/kg bw/d being the no-observed-adverse-effect level (NOAEL).

Mutagenicity and genotoxicity

A terphenyl mixture of unknown composition was negative when tested in *S. typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA100 and in *S. cerevisiae* strain D4 at concentrations up to 500 µg/plate, with and without metabolic activation (EC96). Of the individual isomers, *o*- and *m*- terphenyl were negative in *S. typhimurium* strain TM677 when tested with and without metabolic activation at concentrations up to 900 µmol/L (2100 mg/L; upper limit of solubility) (Kad79).

The aforementioned mixture was negative in a DNA damage and repair assay in rat hepatocytes at concentrations up to 100 µg/mL and in two mutation assays in Chinese hamster ovary cells (HGPRT assay and an unspecified assay; concentrations: up to 500 and 150 µg/mL, resp; with and without S9) (EC96).

Reproduction toxicity

There were no data on the reproduction toxicity of terphenyl isomers or mixtures in experimental animals.

In *in vitro* fertilisation experiments using oocytes collected from superovulated B6D2F1 mice, incubation with 1 and 10 µg/mL of *o*-, *m*-, or *p*-terphenyl caused increased incidence in abnormal embryos and oocytes degeneration. Decreases in fertilisation rate were observed as well (Kho94).

7 Existing guidelines

The current administrative occupational exposure limit (MAC) for terphenyls in the Netherlands is 4.5 mg/m^3 (0.5 ppm), as a ceiling limit.

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

8 Assesment of health hazard

Some limited human information suggests that eye and respiratory tract irritation may occur at occupational exposure levels of above 10 mg/m^3.

Although the available animal data are not consistent, they indicate that the terphenyls have the potential to cause irritation of the eyes, skin, and respiratory tract, and sensitisation.

From acute inhalation mortality data, the terphenyls may be considered as harmful by inhalation. Exposures to approx. 2000-4000 mg/m^3 for 1 hour seem to induce local respiratory tract effects only. The acute oral mortality data on mixtures are conflicting. Acute data on the individual isomers indicate that the *o*- and *m*-isomer are more toxic than the *p*-isomer following oral administration; these isomers can be considered as harmful if swallowed. This may hold for the mixture as well. Following dermal exposure, terphenyl mixtures are probably of low toxicity.

No data on effects following repeated exposure by inhalation were found; data are limited to those from long-term oral administration. When male and female rats were given a commercial mixture consisting of 95% terphenyl isomers and 5% biphenyl during 235 days, changes in the kidneys (accumulations of unidentified golden-yellow granules in the tubules) were seen at a dose of 30 mg/kg bw/d, while there were no effects at a daily dose of 3 mg/kg bw (Pet65, You69).

A terphenyl mixture and the *o*- and *m*-isomers were negative in *in vitro* genotoxicity tests in bacteria. A mixture was negative upon testing in rat hepatocytes and Chinese hamster ovary cells.

No data were found on the potential carcinogenicity and reproduction toxicity.

The committee takes the NOAEL of 3 mg/kg bw/day from the oral study in which rats were repeatedly exposed to a commercial mixture consisting of 95% terphenyl isomers and 5% biphenyl (Pet65, You69) as a basis for deriving a health-based recommended occupational exposure limit (HBROEL). The committee is aware of the fact that a mixture containing 5% biphenyl was tested. However, no effects were reported in rats fed doses of biphenyl of 75 mg/kg bw/day, for 165 days while kidney lesions were seen in some animals fed 188 mg/kg bw/day (BUA91). In view of the minor biphenyl content of 5% in the mixture tested, the committee is of the opinion that biphenyl may not have contributed significantly to the kidney effects found and that, therefore, the dose (3 mg/kg bw) which is used as a starting point needs no correction. A factor of 4 for scaling from rat to human based on caloric demand is used. To account for inter- and intraspecies variation and the confidence in the data base, the committee considers an overall assessment factor of 18 to be appropriate for the extrapolation of a (sub)chronic oral NOAEL in rats to a working lifetime-exposed worker. Thus, applying the scaling factor of 4 and the assessment factor of 18 and assuming that a 70-kg worker inhales 10 m^3 during an 8-hour working day,

the committee recommends a preferred value of 0.5 mg/m^3, 8-hour TWA, for terphenyls, *i.e.*, for the individual isomers or for any isomer mixture.

The committee recommends a health-based occupational exposure limit for terphenyls (individual isomers or any isomer mixture) of 0.5 mg/m^3, as an 8-hour time-weighted average.

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040-15 *o*-, *m*-, *p*-Terphenyl (mixture)

Annex

Occupational exposure limits for terphenyls 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 of Social Affairs and Employment	0.5	4.5	ceiling	administrative		SZW01
Germany						
-AGS		5[c]	8 h			TRG00
-DFG MAK-Kommission	-	-				DFG01
Great-Britain						
-HSE	0.5	4.8	15 min	OES		HSE01
Sweden	-	-				Arb00b
Denmark	0.5	5	8 h			Arb00a
USA						
-ACGIH	0.53	5	ceiling	TLV		ACG01
-OSHA	1	9	ceiling	PEL		ACG00
-NIOSH	0.5	5	ceiling	REL		ACG00
European Union						
-SCOEL	-	-				CEC00

[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

[c] Measured as the inhalable fraction of the aerosol