11 DOSE-EFFECT AND DOSE-RESPONSE RELATIONSHIPS

11.1 Short-term exposure

Table 7. *Dose-effect relationships for short-term inhalation exposures to PGME.*

Exposure (ppm)	Number of subjects/animals	Exposure schedule	Reference	Effects
			Man	
2050	1 man	1 to 2050 in 2 hr	(51)	severe lacrimation and blepharospasm, pain and congestion of nose
1000	2 men	1 to 2050 in 2 hr	(51)	severe eye irritation in 1 man
750	? men	5 min, single	(51)	extremely irritating
700	2 men	1 to 2050 in 2 hr	(51)	lacrimation, rhinorrhea
300	? men	5 min, single	(51)	irritation of eyes, nose and throat
240	23 men	1–7 hr, single	(51)	irritation of eyes, nose and throat
95	6 men	3.5 hr, single	(51)	strongly objectionable odor initially, odor tolerance within 25 min, slight eye irritation in 2 men after 2 hr
47	1 man	1 hr, single	(51)	flushing of cheeks after 7 min
10	? men	5 min, single	(51)	odor detected
5	? men	5 min, single	(51)	odor not detected
			Monkey	
10000	1 male	6 hr, single	(40)	CNS depression, eye and nasal irritation
			Rabbit	
15000	8 both sexes	4–7 hr, single	(40)	CNS depression, unconsciousness, death
10000	8 both sexes	4–7 hr, single	(40)	CNS depression
3000	33 females	6 hr/d, d 6–18 of gestation	(19)	CNS depression, decreased weight gain, no embryotoxic or teratogenic effects
			Guinea pig	
15000	45 both sexes	6–10 hr, single	(40)	CNS depression, unconsciousness, death
			Mouse	
3000	5 females 5 males	6 hr/d, 2 wk	(29)	CNS depression, increased liver weight in females

Table 7 (continued). *Dose-effect relationships for short-term inhalation exposures to PGME (selected data).*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
		Rat		
15000	40 both sexes	2–8 hr, single	(40)	CNS depression, unconsciousness, death
15000	75 both sexes	1 hr, single	(40)	CNS depression
10000	105 both sexes	3–8 hr, single	(40)	CNS depression, unconsciousness, death
10000	15 females 15 males	6 hr, single	(40)	increased liver, kidney and lung weight, lung irritation
10000	5 males	2 hr, single	(40)	increased liver weight
10000	50 both sexes	1.5–2 hr, single	(40)	CNS depression
7000	40 both sexes	4–6 hr, single	(40)	CNS depression, unconsciousness, death
7000	30 both sexes	3 hr, single	(40)	CNS depression
6000	10 males	7 hr/d, 4 d in 5 d	(40)	1 died, increased liver and kidney weights, changes in liver and lung histology
5000	8–10 females	4 hr/d, 2 wk	(14)	transient CNS depression, no effect on conditioned avoidance-escape behavior
3000	10 males	7 hr, single	(40)	no observed effects
3000	28 females	6 hr/d, d 6–15 of gestation	(19)	CNS depression, decreased weight gain, delayed sternebral ossification, no embryotoxic or teratogenic effects
3000	5 females 5 males	6 hr/d, 5+4 d in 11 d[a]	(29)	CNS depression, increased liver weight, decreased urine specific gravity, increased urine pH, elevated platelet count, lowered alkaline phosphatase activity
1000	5 females 5 males	6 hr/d, 5+4 d in 11 d[a]	(29)	lowered alkaline phosphatase activity in females
600	20 females	6 hr/d, d 6–17 of gestation	(11)	no effect on offspring
600	10 males	6 hr/d, 10 d	(11)	no effect on testicles or hematology
300	5 females 5 males	6 hr/d, 5+4 d in 11 d[a]	(29)	lowered alkaline phosphatase activity

[a]5 d of exposure first week, 4 d second week, 2 d interruption during weekend

Table 8. *Dose-effect relationships for short-term inhalation exposures to PGMEA.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
			Rat	
3000	5 females 5 males	6 hr/d, 2 wk 5+4 d in 11 d[a]	(32)	increased liver weight in females, changes in kidney histology, degeneration of olfactory epithelium
1000	idem	idem	(32)	degeneration of olfactory epithelium
300	idem	idem	(32)	no observed effects
			Mouse	
3000	idem	idem	(32)	degeneration of olfactory epithelium
1000	idem	idem	(32)	no observed effects
300	idem	idem	(32)	no observed effects

[a]5 d of exposure first week, 4 d second week, 2 d interruption during weekend

Table 9. *Dose-effect relationships for short-term inhalation and dermal exposures to βPGMEA.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
		Rabbit, inhalation exposure (ppm)		
550	15 females	6 hr/d, d 6–18 of gestation	(28)	slightly reduced maternal weight gain, reduced fetal body weight, increased number of dead implantations, anomalies in all 63 fetuses
145	15 females	idem	(28)	no observed maternal effects, reduced fetal weight
36	15 females	idem	(28)	no observed maternal effects, anomalies in 3 of 65 fetuses
		Rat, inhalation exposure (ppm)		
2710	25 females	6 hr/d, d 6–15 of gestation	(28)	CNS depression, reduced maternal weight gain, reduced uterus weight, reduced fetal body weight, increased number of dead implantations, vertebral fusion defects
550	25 females	idem	(28)	CNS depression, reduced maternal weight gain
110	25 females	idem	(28)	no observed maternal or fetal effects
		Rabbit, dermal exposure ($mg \cdot kg^{-1} \cdot d^{1}$)		
2000	16 females	daily, d 6–18 of gestation	(28)	no observed maternal or fetal effects
1000	15 females	idem	(28)	no observed maternal or fetal effects

Table 10. *Dose-effect relationships for short-term inhalation exposures to DPGME.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
		Man		
74	not given	not given	(1)	irritation
35	not given	not given	(1)	odor threshold
		Rat		
500	9 males	7 hr, single	(40)	CNS depression

11.2 Long-term exposure

Table 11. *Dose-effect relationships for long-term inhalation exposures to PGME.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
			Monkey	
10000	1 females 2 males	4 hr/d, 5–13 wk	(40)	CNS depression, decreased final body weight, increased liver weight, changes in liver and lung histology
3000	2 females	7 hr/d, 29 wk	(40)	increased liver weight, changes in liver and lung histology
1500	1 female	7 hr/d, 29 wk	(40)	increased liver weight, changes in lung histology
800	1 female 1 male	7 hr/d, 29 wk	(40)	no observed effects
			Rabbit	
6000	1 female	7 hr/d, 16 wk	(40)	CNS depression, decreased weight gain, increased liver and lung weight, changes in lung histology
3000	7 females 6 males	6 hr/d, 13 wk	(24)	CNS depression first 2 wk, increased alkaline phosphatase activity
3000	?	6 hr/d, 13 wk	(33)	no observed effects
3000	1 female 1 male	7 hr/d, 26 wk	(40)	increased liver weight, changes in liver (female) and lung (male) histology
1500	2 females 2 males	7 hr/d, 26 wk	(40)	increased liver weight, changes in liver and lung histology in females
1000	7 females 6 males	6 hr/d, 13 wk	(24)	no observed effects
800	2 females 1 male	7 hr/d, 26 wk	(40)	no observed effects

Table 11 (continued). *Dose-effect relationships for long-term inhalation exposures (5 d/wk) to PGME.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
			Guinea pig	
6000	5 females 5 males	7 hr/d, 16 wk	(40)	CNS depression, decreased body weight, increased liver and kidney weight, changes in liver and lung histology
3000	8 females 8 males	7 hr/d, 26 wk	(40)	no observed effects
1500	idem	idem	(40)	no observed effects
			Rat	
10000	5 females 5 males	2 hr/d, 17 wk	(40)	increased liver and kidney weight
10000	idem	1 hr/d, 15 wk	(40)	CNS depression
10000	idem	0.5 hr/d, 15 wk	(40)	no observed effects
6000	10 females 10 males	7 hr/d, 16 wk	(40)	7 females and 4 males died, CNS depression, increased liver weight, increased kidney weight in males
3000	20 females 20 males	7 hr/d, 28 wk	(40)	CNS depression first week, increased liver weight
3000	10 females 10 males	6 hr/d, 13 wk	(24)	CNS depression first wk, increased liver weight, hepatocellular swelling in females, increased serum glutamic pyruvic transaminase activity in females, increased urine pH after 4 wk in males
3000	?	6 hr/d, 13 wk	(33)	CNS depression first wk, increased liver weight, reduced white cell count in females, hepatocellular swelling in females
1500	20 females 20 males	7 hr/d, 28 wk	(40)	no observed effects
1000	10 females 10 males	6 hr/d, 13 wk	(24)	no observed effects
1000	?	6 hr/d, 13 wk	(33)	no observed effects
300	?	6 hr/d, 13 wk	(33)	increased white cell count in females

Table 12. *Dose-effect relationships for long-term inhalation exposures (5 d/wk) to DPGME.*

Exposure (ppm)	Number of animals	Exposure schedule	Reference	Effects
			Monkey	
300–400	1 female 1 male	7 hr/d, 31 wk	(40)	changes in liver histology
			Rabbit	
300–400	2 females 2 males	7 hr/d, 31 wk	(40)	changes in liver histology
200	7 females 7 males	6 hr/d, 13 wk	(25)	increased kidney weight in females
50	idem	idem	(25)	increased body and kidney weight in females
15	idem	idem	(25)	no observed effects
			Guinea pig	
300–400	5 females 7 males	7 hr/d, 26 wk	(40)	changes in liver histology in females
			Rat	
300–400	17 females 13 males	7 hr/d, 28 wk	(40)	CNS depression first week, increased liver weight
200	10 females 10 males	6 hr/d, 13 wk	(25)	no observed effects
50	idem	idem	(25)	no observed effects
15	idem	idem	(25)	no observed effects

12 RESEARCH NEEDS

The irritant property of propylene glycol ethers to man is described in only one paper, and for PGME only (51). This effect needs to be studied in more detail and in the other propylene glycol ethers as well.

Only one study concerning the reproductive toxicity of the beta isomers was found in the scientific literature (28). The study dealt with the effects of ßPGMEA in female rats and Himalayan rabbits. There is a need for additional investigations involving ßPGME, male reproductive toxicity of both beta isomers and testing in other animal species.

The toxicokinetics of the propylene glycol ethers have not been studied in humans. Such studies are valuable in order to assess respiratory and dermal uptake, distribution, metabolism and excretion. The possibility of dose-dependent kinetics in man should be investigated, as this has been observed for PGME in laboratory animals (35). Dermal uptake may contribute largely to the body burden of propylene glycol ethers. Methods for biological monitoring are therefore needed. The acid metabolite of ßPGME, 2–methoxypropionic acid, is a strong candidate for biological monitoring of exposure to ßPGME for the following reasons: 2–methoxypropionic acid is closely related to the teratogenic potential of ßPGME, it is to a large extent excreted in urine, and it probably has a long urinary half time.

To make possible toxicokinetic studies and to develop methods for biological monitoring sensitive analytical methods for the propylene glycol ethers and their metabolites in biological material will have to be developed.

13 DISCUSSION AND EVALUATION

The five propylene glycol monoalkyl ethers reviewed here are all of low acute toxicity. The main effect exerted at high doses is depression of the central nervous system. This effect has been clearly observed in animals exposed to PGME at 3000 ppm or more (14, 19, 24, 29, 40), to ßPGMEA at 550 ppm or more (28), and to DPGME at 300–400 ppm (40), but not at lower exposure levels. In the DPGME experiment a mist was present in the exposure chamber, and the internal dose may have been higher due to dermal deposition and uptake. One man acutely exposed to about 1000 ppm PGME exhibited a tendency to CNS effects, but exhibited no effects at lower exposure levels (51). There are no signs of subacute or chronic organ specific damage at levels below 1500 ppm PGME, 1000 ppm PGMEA and 300–400 ppm DPGME. Furthermore, there are no indications of mutagenicity or genotoxicity from any of the five glycol ethers, although such effects have only been studied to a limited extent. No carcinogenicity studies are reported. The alpha isomers of PGME and PGMEA, as well as DPGME, seem to lack reproductive toxicity. The critical effect of these three compounds appears to be irritation to the eyes and mucous membranes. Two of six men experienced eye, nose and throat irritation after 2 hr of exposure to 95 ppm PGME (51).

The beta isomer of PGMEA is embryotoxic and teratogenic in laboratory animals (28). The effects were seen in the offspring of rats after exposure at 2710 but not at 550 ppm and in rabbits at 550 but not at 145 ppm. Considering the metabolism of ßPGMEA, it is very likely that ßPGME is also teratogenic. The common metabolite of ßPGME and ßPGMEA is 2-methoxypropionic acid. The structural isomer 3-methoxypropionic acid caused growth retardation and abnormalities in post-implantation rat embryo cultures (37). These observations are analogous to those made for methoxyacetic acid, common metabolites of 2-methoxyethanol and 2-ethoxyethyl acetate (7, 38, 56). Thus, the critical effect of ßPGME and ßPGMEA appears to be the teratogenic potential. The teratogenic potential of beta isomers present in technical PGME and PGMEA must be kept in mind, and these impurities should be monitored and kept as low as possible.

14 SAMMANFATTNING

Arbete och Hälsa 1990:32, sid 1–47.
Kritisk genomgång och värdering av den litteratur som är relevant som underlag för fastställande av hygieniskt gränsvärde för propylenglykolmonometyleter och propylenglykolmonometyleteracetat inklusive deras betaisomerer, samt dipropylenglykolmonometyleter. Rekommendation av de effekter (irritation och reproduktionsstörning) som kan läggas till grund för ett sådant ställningstagande. 56 referenser.

Nyckelord: dipropylenglykolmonometyleter, hygieniskt gränsvärde, irritation, 1–metoxi–2–propanol, 2–metoxi–1–propanol, 1–metoxi–2–propylacetat, 2–metoxi–1–propylacetat, 1–(2–metoxi–1–metyletoxi)–2–propanol, propylenglykolmonometyleter, propylenglykolmonometyleteracetat, reroduktionsstörning, yrkesmässig exponering.

15 SUMMARY

Arbete och Hälsa 1990:32, p. 1–47.
Survey of the literature on propylene glycol monomethyl ether, propylene glycol monomethyl ether acetate, including their beta isomers, and dipropylene glycol monomethyl ether. The document is to be used as background for discussion of occupational exposure limits. The effects irritation and reproductive toxicity are recommended to be used in this discussion. 56 references.

Key words: dipropylene glycol methyl ether, irritation, 1–methoxy–2–propanol, 2–methoxy–1–propanol, 1–methoxy–2–propyl acetate, 2–methoxy–1–propyl acetate, 1–(2–methoxy–1–methylethoxy)–2–propanol, occupational exposure, occupational exposure limits, propylene glycol methyl ether, propylene glycol methyl ether acetate, reproductive toxicity

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