NEG and NIOSH basis for an occupational health standard:

Propylene Glycol Ethers and Their Acetates

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

CDC
CENTERS FOR DISEASE CONTROL

Arbete och Hälsa 1990:32

NEG and NIOSH Basis for an Occupational Health Standard:

Propylene Glycol Ethers and Their Acetates

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The contents of this document originally appeared in
Arbete Och Halsa 1990:32,
which was published in Solna, Sweden

Publications Dissemination, DSDTT
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DHHS (NIOSH) Publication No. 91-103

PREFACE

A memorandum has been signed between the Centers for Disease Control, National Institute for Occupational Safety and Health (NIOSH), USA, and the Nordic Expert Group for Documentation of Occupational Exposure Limits (NEG). The purpose of the memorandum is to exchange information and expertise in the area of occupational safety and health. One product of this agreement is the development of documents to provide scientific basis for establishing recommended occupational exposure limits. The exposure limits will be developed separately by each country according to the different national policies.

This document on the health effects of occupational exposure to propylene glycol ethers and their acetates is the first product of that agreement. The document was written by Gunnar Johanson, Dr Med Sc (Department of Occupational Medicine, University Hospital, Uppsala, and Swedish National Institute of Occupational Health, Solna), and was reviewed by NEG and the Division of Standards Development and Technology Transfer (DSDTT), NIOSH.

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CONTENTS

ABBREVIATIONS

CNS	central nervous system
DPGME	dipropylene glycol methyl ether
DSDTT	Division of Standards Development and Technology Transfer (NIOSH, USA)
FID	flame ionization detection
FTIR	Fourier transform infrared (spectrometry)
GC	gas chromatography
MS	mass spectrometry
NEG	Nordic Expert Group for Documentation of Occupational Exposure Limits
NIOSH	National Institute for Occupational Safety and Health (USA)
NMR	nuclear magnetic resonance (spectroscopy)
PGME	1-methoxy-2-propanol (alpha isomer)
PGMEA	1-methoxy-2-propyl acetate (alpha isomer)
ßPGME	2-methoxy-1-propanol (beta isomer)
ßPGMEA	2-methoxy-1-propyl acetate (beta isomer)

1 INTRODUCTION

This document deals with the propylene glycol ethers most commonly used in industry, namely methoxypropanol, methoxypropyl acetate and dipropylene glycol monomethyl ether. Both alpha and beta isomers are present in commercial methoxypropanol and methoxypropyl acetate. These isomers differ in toxicity and are therefore treated separately.

The propylene glycol ethers are colorless liquids at room temperature. They have a sweet, etherlike odor and are completely miscible with water and a number of organic solvents.

2 PHYSICAL AND CHEMICAL PROPERTIES

2.1 Methoxypropanol, alpha isomer

Chemical name:	1–methoxy–2–propanol
CAS number:	107–98–2 (alpha isomer) 1320–67–8 (unspecified isomer)
Synonyms:	propylene glycol monomethyl ether, propylene glycol methyl ether, PGME
Molecular formula:	$C_4H_{10}O_2$
Structural formula:	CH_3 - O OH CH_2 - CH - CH_3
Molecular weight:	90.1
Boiling point (101.3 kPa):	119.6 °C (41)
Melting point:	-96 °C (3)
Vapor pressure (25°C):	1.6 kPa (11.8 mm Hg) (41)
Saturation concentration (25°C):	15500 ppm (41)
Relative evaporation rate: (n–butyl acetate=1)	0.7 (47)
Vapor density (25°C, air=1):	3.11 (41)
Liquid density (25°C/4°C):	0.917 (41)
Flash point:	38°C (100°F) (41)
Miscibility with water:	∞
Conversion factors:	1 ppm = 3.68 mg/m^3 1 mg/m^3 = 0.272 ppm

Propylene glycol ethers are commercially prepared by reacting propylene oxide with methyl alcohol in the presence of a catalyst. Two isomers, often designated by alpha (1–methoxy–2–propanol) and beta (2–methoxy–1–propanol, ßPGME), are obtained. The commercial product (PGME) contains mainly alpha (95–99 %), the remainder (1–5 %) being beta isomer. One report, for example, states that 95 % is alpha isomer (12). In another report the manufacturer's declaration of 98.2 % alpha and 1.8 % beta isomer was confirmed by gas chromatography - mass spectrometry (GC–MS). The purity was > 99.9 % (24). The commercial product Dowanol® PM contains at least 97.5 % alpha isomer and no more than 2.5 % beta isomer, according to the manufacturer (3). The product used in human experiments conducted by Stewart *et al.* (51) was stated to contain 98 % PGME, 0.4 % water and 1.6 % corrosion inhibitors.

An odor threshold for PGME of 10 ppm (36 mg/m^3) is given in two reports (1, 39). The origin of this value may be a study in which male volunteers placed in a truck cab in a controlled exposure situation reported detectable odor at 10 ppm PGME (51).

2.2 Methoxypropanol, beta isomer

Chemical name:	2–methoxy–1–propanol
CAS number:	not available for beta isomer 1320–67–8 (unspecified isomer)
Synonyms:	propylene glycol monomethyl ether, propylene glycol methyl ether, ßPGME
Molecular formula:	$C_4H_{10}O_2$
Structural formula:	OH O - CH_3 CH_2 - CH - CH_3
Molecular weight:	90.1
Conversion factors:	1 ppm = 3.68 mg/m^3 1 mg/m^3 = 0.272 ppm

Small amounts (1–5 %) of the beta isomer 2–methoxy–1–propanol (ßPGME) are present in technical methoxypropanol, the main component of which is the alpha isomer (1–methoxy–2–propanol).

There are no data on the odor threshold of ßPGME.

2.3 Methoxypropyl acetate, alpha isomer

Chemical name:	1–methoxy–2–propyl acetate
CAS number:	108–65–6 (alpha isomer) 84540–57–8 (unspecified isomer)
Synonyms:	propylene glycol monomethyl ether acetate, propylene glycol methyl ether acetate, PGMEA
Molecular formula:	$C_6H_{12}O_3$
Structural formula:	$\begin{array}{l} \qquad\qquad\quad O \\ CH_3 - O \quad O - C - CH_3 \\ \quad\; CH_2 - CH - CH_3 \end{array}$
Molecular weight:	132.1
Boiling point (101.3 kPa):	145.8°C (4)
Melting point:	< -67°C (4)
Vapor pressure (20°C):	0.5 kPa (3.7 mm Hg) (4)
Vapor density (air=1):	4.55 (4)
Liquid density:	0.97 (4)
Flash point:	42.2°C (4)
Miscibility with water:	≈ 19 % (w/w) (4)
Conversion factors:	1 ppm = 5.40 mg/m^3 1 mg/m^3 = 0.185 ppm

Technical methoxypropyl acetate (PGMEA) consists mainly of the alpha isomer (1–methoxy–2–propyl acetate). In one study it was stated that the alpha isomer of PGMEA used was of at least 95 % purity (28). The remainder is largely beta isomer (2–methoxy–1–propyl acetate, ßPGMEA).

There are no data on the odor threshold of PGMEA.

2.4 Methoxypropyl acetate, beta isomer

Chemical name:	2–methoxy–1–propyl acetate
CAS number:	70657–70–4 (beta isomer) 84540–57–8 (unspecified isomer)
Synonyms:	propylene glycol monomethyl ether acetate, propylene glycol methyl ether acetate, ßPGMEA
Molecular formula:	$C_6H_{12}O_3$
Structural formula:	O CH_3 - C - O O - CH_3 CH_2 - CH - CH_3
Molecular weight:	132.1
Conversion factors:	1 ppm = 5.40 mg/m^3 1 mg/m^3 = 0.185 ppm

Small amount of the beta isomer 2-methoxy-1-propyl acetate (ßPGMEA) are present in technical grade methoxypropyl acetate.

There are no data on the odor threshold of ßPGMEA.

2.5 Dipropylene glycol methyl ether

Chemical name (main isomer):	1–(2–methoxy–1–methylethoxy)–2–propanol (additonal isomers are given in Table 1)
CAS number:	34590–94–8 (unspecified isomer)
Synonyms:	dipropylene glycol monomethyl ether, dipropylene glycol methyl ether, DPGME
Molecular formula:	$C_7H_{16}O_3$
Structural formula:	CH_3 - O CH_3 CH_2 - CH - O OH CH_2 - CH - CH_3
Molecular weight:	148.2
Boiling point (101.3 kPa):	189.6°C (41)
Melting point:	-80°C (41)
Vapor pressure (25°C):	0.05 kPa (0.38 mm Hg) (41)
Saturation concentration (25°C):	510 ppm (41)
Vapor density (air=1):	5.14
Liquid density (25°C/4°C):	0.948 (41)
Flash point:	85°C (185°F) (41)
Miscibility with water:	∞
Conversion factors:	1 ppm = 6.06 mg/m^3 1 mg/m^3 = 0.165 ppm

Four structural isomers can theoretically be formed in the propylene oxide based production of dipropylene glycol methyl ether. The main isomer as well as the technical product are abbreviated as DPGME in this document. There are two asymmetrical carbon atoms in the molecule, hence configurational isomers may also exist.

Landry and Yano isolated four isomers in the commercial product Dowanol® DPM and were able to identify the structure of two of them (Table 1) (25). The main isomer was a mixture of two enantiomers constituting 35.4 % and 49.1 %, respectively. Radiolabelled DPGME containing 93.2 % of the main isomer was used in a metabolic study (30). The same authors found four isomers in Dowanol® DPM but reported the identity only of the main isomer. In Table 1 the identities of the other three isomers are assumed to be the same as those reported by Landry and Yano. In other studies the composition of DPGME was not reported.

The odor threshold for DPGME was reported in a review to be 35 ppm (210 mg/m^3) (44).

Table 1. *Composition of commercial DPGME (Dowanol ® DPM).*

Isomer[a]	Relative proportion (%)	
	GC–FID[b]	GC–MS[c]
1–(2–methoxy–1–methylethoxy)–2–propanol	84.5	87.4
2–(2–methoxy–1–methylethoxy)–1–propanol	0.5 or 1.6[d]	0.1 or 1.3[e]
2–(2–methoxy–2–methylethoxy)–1–propanol	0.5 or 1.6[d]	0.1 or 1.3[e]
1–(2–methoxy–2–methylethoxy)–2–propanol	13.0	11.2[e]
Purity (%)	99.2	>98

[a]identity established with NMR (25)
[b]proportion and purity determined by GC–FID (25)
[c]proportion determined by GC–MS (30)
[d]structure not identified
[e]identity not reported

3 USES AND OCCURRENCE

3.1 Uses

Propylene glycol ethers are used industrially as solvents for paints, lacquers, resins, oils and fat. DPGME is often used in cosmetics (41). About 329000 employees (100000 of them females) are potentially exposed to PGME in the United States. About 306000 employees (36000 females) are potentially exposed to PGMEA and 184000 (17000 females) to DPGME (National occupational exposure survey, 1981-1983: Estimated total and female employees, actual observation and trade-named exposure to PGME. Unpublished provisional data as of January 1, 1990. NIOSH, Cincinnati, Ohio).

According to the Products Register at the Swedish Chemicals Inspectorate, PGME occurred in 421 chemical products present on the Swedish market in July 1989 (Table 2). The estimated annual use was 480–5800 tons. PGMEA occurred in 187 products (280–4500 tons/year) and DPGME in 123 products (240–2500 tons/year).

The use of propylene glycol ethers appears to have increased considerably from 1985 to 1989. One important reason for the increase is probably the replacement of ethylene glycol ethers by propylene glycol ethers because of the reproductive toxicity associated with the former group of solvents.

The beta isomers of the propylene glycol ethers were declared to be present in a few products only. According to the register ßPGME and ßPGMEA occurred in 4 products each in 1989 (Table 2). The estimated annual quantity ranged between 9 and 150 tons for ßPGME. The beta isomers are treated in this document as they are present as impurities in technical PGME and PGMEA.

Table 2. *Occurrence of propylene glycol ethers in Swedish chemical products (source: Ulf Rick, The Products Register, Swedish Chemicals Inspectorate).*

Glycol ether	October 1985			July 1989		
	number[a] of products	min[b] (ton/year)	max[c] (ton/year)	number[a] of products	min[b] (ton/year)	max[c] (ton/year)
PGME	112	90	290	421	480	5800
PGMEA	0	-	-	187	280	4500
ßPGME	0	-	-	4	9	150
ßPGMEA	0	-	-	4	-	-
DPGME	42	50	170	123	240	2500

[a]number of products in the register with a declared content of the compound
[b]estimated minimum annual use [c]estimated maximum annual use

3.2 Ambient air levels at the workplace

Only a few records of occupational exposure measurements have been published.

Since 1985 the Norwegian National Institute of Occupational Health has collected in a data base the results of their analyses of volatile organic compounds in personal air samples (Tables 3 and 4). As of 1988, 5500 samples had been analyzed. PGME was detected in 687, or 12 % of them. The sample with the highest level of PGME, 1030 ppm, was collected during solvent cleaning in a paint factory. The highest average levels were associated with paint manufacturing, printing and silk screen printing. PGMEA was detected in 260 samples, or 5 %. The highest average levels were measured around metal production and air-craft lacquering. Relatively low levels were measured in silk screen printing. The beta isomer of methoxypropanol was detected in 2 %, or 127 of the samples. Samples collected around manufacturing of paint, metal and plastics had average levels of 2–3 ppm. The highest level of ßPGME, 14 ppm, was associated with cleaning in a paint factory. The other propylene glycol ethers discussed in this document were not identified. These data should be interpreted with caution, as the number of analyses aimed at finding propylene glycol ethers is not documented. In addition, the detection limits are not given and may vary.

Peak levels of 0.5–7 ppm (2–26 mg/m^3) PGME were reached in apartments painted with water-based alkyd and acrylate paints (23).

In a survey covering several work places parquet fitters in Finland were exposed to approximately 35–39 ppm PGME during undercoat varnishing and 10–63 ppm during varnishing with urea-formaldehyde based products (Riita Riala, personal communication).

Table 3. *Propylene glycol ethers found in 5500 personal air samples collected in Norway 1985–1988 (source: Per Einar Fjeldstad, Norwegian National Institute of Occupational Health).*

Glycol ether	Number of samples with presence of glycol ether					
	> det. limit	> 1 ppm	> 5 ppm	> 10 ppm	> 50 ppm	> 100 ppm
PGME	687	419	174	79	20	5
PGMEA	260	89	50	40	8	1
ßPGME	127	39	4	1		
ßPGMEA	0					
DPGME	0					

3.3 Analytical methods for air monitoring

Standardized methods for sampling and analysis of ambient air levels specific for propylene glycol ethers have not been published. However, the methods used for ethylene glycol ethers might be applicable. Samples are taken either actively with adsorption tubes or passively with diffusive samplers containing either activated charcoal or Amberlite XAD–7. Diethyl ether or a mixture of methanol and methylene chloride is used for desorption, and analysis is made by gas chromatography with flame ionization detection (GC–FID) (2, 5, 13). In the presence of other gaseous polar substances, for example water vapor, the adsorption and/or desorption efficiency may be reduced (36). Langhorst analyzed PGME in the range 0.2–300 ppm and DPGME in the range 0.7–57 ppm after adsorption on activated charcoal and desorption by a mixture of water and carbon disulfide. The yield for PGME was 96–99 % in the solvent phase and 1.7–3.1 % in the aqueous phase; for DPGME yields were 79–84 % and 9–14 %, respectively (26).

Propylene glycol ether vapors may also be monitored by infrared spectrophotometry (24, 51). The detection limits for ethylene and diethylene glycol ethers monitored by this method range from 0.03–0.08 ppm according to one instrument manufacturer (Foxboro, Redhill Surrey, Great Britain). Another manufacturer (Brüel & Kjær, Nærum, Denmark) states that its instrument, which is equipped with a photoacoustic detector, has detection limits of 0.1–0.3 ppm for various ethylene glycol ethers. Fourier transform infrared (FTIR) spectrometry may improve resolution, component identification and analytical sensitivity. Ying *et al.* reported detection limits of about 0.01–0.1 ppm for various solvent vapors measured by FTIR with a spectral resolution of 2 cm^{-1}. The detection limit for 2–ethoxyethanol was 0.012 ppm (55).

Table 4. *Job activities associated with exposure to propylene glycol ethers (source: Per Einar Fjeldstad, Norwegian National Institute of Occupational Health).*

Job activity	Maximum concentration (ppm)	Average concentration (ppm)	Standard deviation (ppm)	Number of samples
		PGME		
Paint manufacturing	1030	20	98	157
Printing	80	10	18	87
Silk screen printing	61	9	13	132
		PGMEA		
Metal production	103	18	33	21
Air-craft lacquering	91	12	19	83
Silk screen printing	12	0.9	1.9	94
		βPGME		
Solvent cleaning	13.9	2.0	3.6	24

4 TOXICOKINETICS

4.1 Uptake

Due to the solubility of the propylene glycol ethers a high uptake may be expected for all routes of exposure. The relative respiratory uptake in anesthetized rats was 87 % for PGME (exposure level 1000 ppm) and 85 % for PGMEA (exposure level 1000 ppm) (52). For comparison, the relative respiratory uptake of the ethylene glycol ethers 2–butoxyethanol, 2–ethoxyethanol, 2–ethoxyethyl acetate, 2–methoxyethanol and 2–propoxyethyl acetate ranged between 50 and 79 % in man and dog (15–18, 21).

The blood/air partition coefficient of PGME is 12400 according to one study (20) and 403 according to another (52). The high affinity to blood suggests that pulmonary ventilation, and not the equilibration between air and blood, is the rate-limiting factor for the uptake of PGME. This hypothesis is supported by experiments in which the blood PGME concentration in rats increased continuously during 6 hr of exposure to 300–3000 ppm (35).

The percutaneous uptake of neat PGME *in vitro* (isolated human epidermis) of 1.2 $mg \cdot cm^{-2} \cdot hr^{-1}$ (12) is relatively high compared with other organic solvents. Among the glycol ethers studied only 2–methoxyethanol had a higher percutaneous uptake rate. No data regarding *in vivo* skin uptake of propylene glycol ethers were found in the literature. Skin uptake was indirectly indicated by toxic effects observed in rabbits and rats after dermal application of PGME and DPGME (40, 48).

4.2 Probable routes of human exposure

The propylene glycol ethers may enter the body by the respiratory as well as the dermal route. For DPGME with its lower vapor pressure the respiratory route may be of less importance relative to the dermal route. Both exposure routes are of special concern in cases of aerosol formation during spray painting with products containing propylene glycol ethers.

4.3 Distribution

PGME was detected in blood from rats exposed for 6 hours to 300–3000 ppm (35); concentrations ranged from 1.2 to 23.4 mM (109–2113 µg/g).

No studies on the distribution of propylene glycol ethers in the body were found in the literature. The low olive oil/blood partition coefficient of 0.056 (20) suggests that PGME does not accumulate in adipose tissue.

In a number of studies Miller and coworkers have investigated the distribution of radioactivity in rats following oral administration or vapor exposure to ^{14}C–labeled PGME (31), PGMEA (32), ßPGME (34) and DPGME (30). In general, major fractions of the radioactivity remaining in the body 48 hours after exposure were recovered in the skin and the liver. There were no indications of accumulation of radioactivity in adipose tissue, testes or main body tissues.

4.4 Biotransformation

The major metabolic pathways of propylene glycol ethers can be summarized as follows: 1) acetate esters are rapidly hydrolyzed to the corresponding ether alcohol, 2) ether alcohols, both alpha and beta isomers, are conjugated with sulphate and glucuronic acid, 3) beta isomers, being primary alcohols, are also oxidized to carboxylic acids, 4) alpha isomers, being secondary alcohols, are also oxidized to carbon dioxide after cleavage of the ether bond (Figures 1–3).

PGME

When rats were given an oral dose of ^{14}C–labeled PGME (1 mmol/kg body weight), 11 % of the administered radioactivity was found in the urine and 0.9 % in the feces within 48 hours after the dosage. Most (66 %) of the given dose was recovered in the expired air. Most of the exhaled radioactivity (63 %) was carbon dioxide. After a higher dose of PGME (8.7 mmol/kg) the recovery in urine increased to 19–25 %. The predominant urinary metabolite was the glucuronic acid conjugate of PGME, followed by the sulphate conjugate, propylene glycol (1,2–propanediol) and unchanged PGME (31). It is known from previous studies that propylene glycol is oxidized to lactic and pyruvic acids, and subsequently enters the normal carbohydrate metabolism of the body to finally end up as carbon dioxide (42, 43, 54). The metabolism of PGME is depicted in Figure 1.

PGMEA

Rats given an oral dose (8.7 mmol/kg body weight) of ^{14}C–labeled PGMEA excreted 24 % of the radioactivity in urine, 1.8 % in feces, and 66 % in expired air (64 % as carbon dioxide) within 48 hours. The half time of the radioactivity in the urine was 5.5 hr after an oral dose and 7.0 hr after 6 hr of exposure to 3000 ppm. The urinary metabolite pattern was in agreement with that observed for PGME (32). The metabolism of PGMEA is summarized in Figure 1.

Acetate esters of aliphatic alcohols are rapidly hydrolyzed by enzymes in the respiratory epithelium, lungs, liver and blood (10, 53). PGMEA in the body would therefore be rapidly converted to PGME. A comparison of the metabolism of PGME (31) and PGMEA (32) supports this hypothesis. Hence, at equimolar doses the two compounds may be expected to act similarly with respect to kinetics as well as toxicity. At very high doses of PGMEA, however, the acetic acid formed in the hydrolysis may have adverse effects.

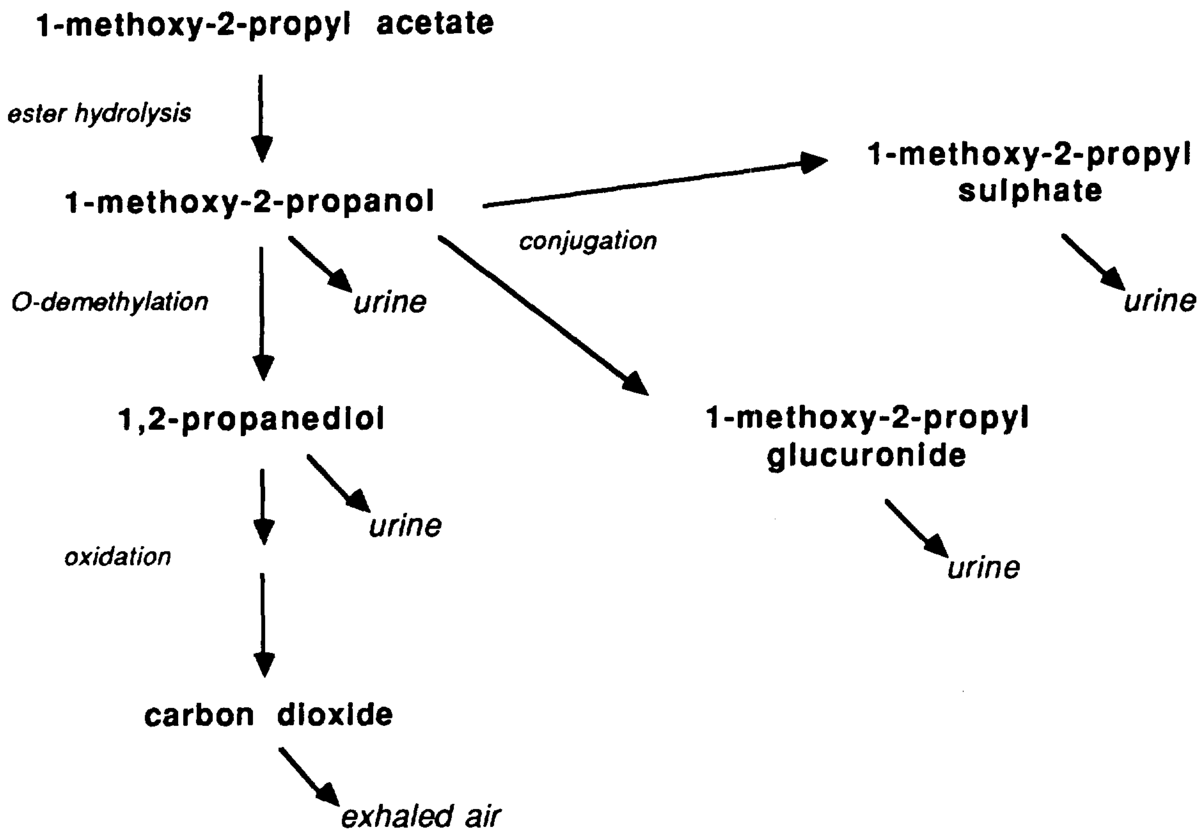

Figure 1. *The metabolism of the alpha isomers of methoxypropanol and methoxypropyl acetate.*

ßPGME

Rats given an oral dose (1 mmol/kg body weight) of ^{14}C–labeled ßPGME excreted 70 % of the radioactivity in urine, 1.6 % in feces and 16.7 % in expired air (16.6 % as carbon dioxide) within 48 hours. After a higher dose (8.7 mmol/kg) the recovery in urine increased to 77 %. The major metabolite was 2–methoxypropionic acid. The glucuronic acid conjugate and unchanged ßPGME were also found (34). The metabolism of ßPGME is summarized in Figure 2.

DPGME

When rats were given an oral dose (8.7 mmol/kg body weight) of ^{14}C–labeled DPGME 60 % of the radioactivity was recovered in urine, 2.7 % in feces and 27.2 % in expired air (26.6 % as carbon dioxide) within 48 hours. The half time of radioactivity in the urine was 5.9 hr. The predominant urinary metabolite was dipropylene glycol, but sulphate and glucuronic acid conjugates, propylene glycol , PGME and unchanged DPGME were also identified (30). The metabolism of DPGME is given in Figure 3.

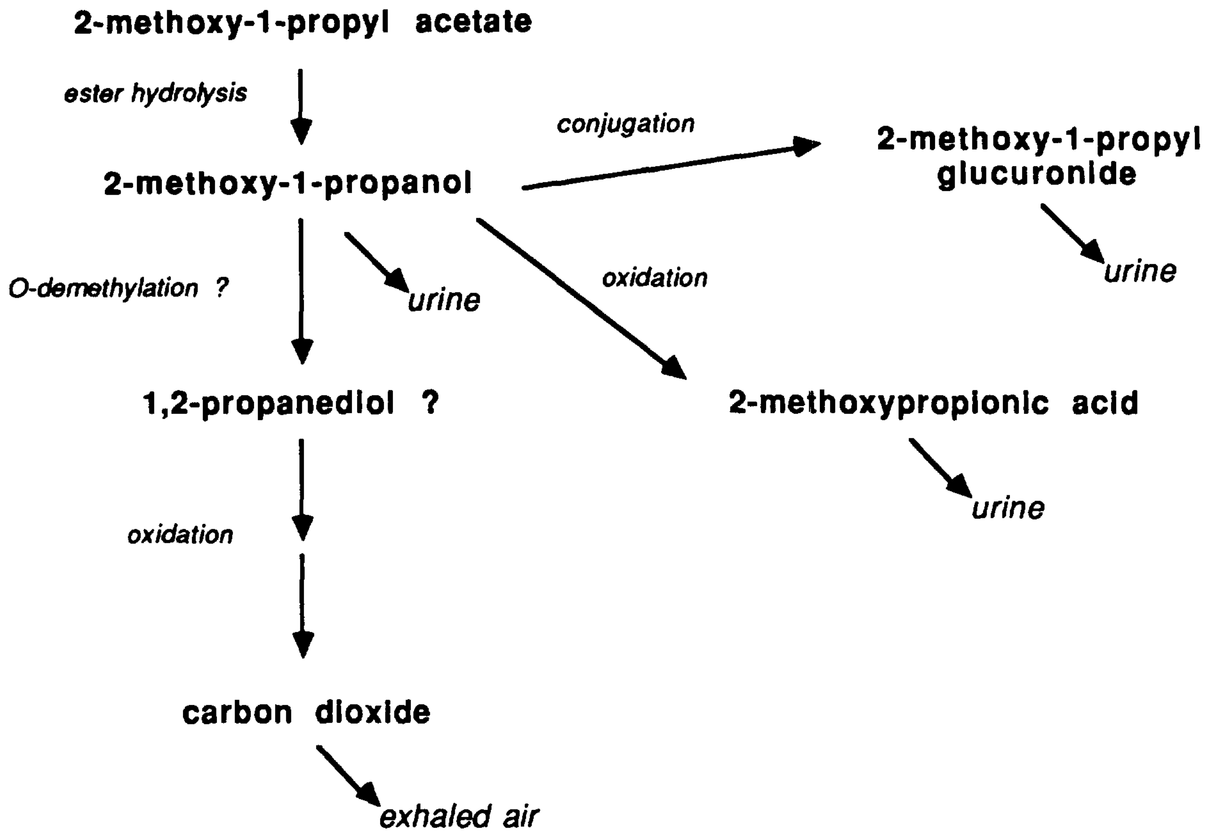

Figure 2. *The metabolism of the beta isomers of methoxypropanol and methoxypropyl acetate.*

4.5 Elimination

In rats of both sexes exposed to 300–3000 ppm PGME for 6 hours the elimination kinetics were nonlinear. At a tenfold increase in exposure level the blood levels increased 20 times. The half time of the blood PGME concentration was 2.4 hr after the lowest exposure level and 15.7 hr after the highest. Assuming a constant volume of distribution of 0.9 l/kg body weight, the total blood clearance of PGME was calculated to 3.1 $ml \cdot min^{-1} \cdot kg^{-1}$ at the lowest and 0.5 $ml \cdot min^{-1} \cdot kg^{-1}$ at the highest level. The post exposure decay of blood PGME levels followed zero order rather than first order kinetics (35). These results indicate saturation of the PGME metabolism.

4.6 Biological exposure indicators

No studies on biological monitoring of exposure to propylene glycol ethers are available.

Unchanged PGME or DPGME as well as a number of metabolites in urine and/or blood are candidates for biological exposure indicators. Morgott and Nolan analyzed by gas chromatography the parent compound and the metabolite 1,2–propanediol in rats exposed to PGME (35). Using ion exclusion chromatography - mass spectrometry Miller and coworkers identified the sulphate and glucuronic acid conjugates of PGME, 1,2–propanediol and unchanged PGME in the urine of rats given high doses of PGME or PGMEA (31, 32). Rats dosed with DPGME excreted dipropylene glycol, 1,2–propanediol, PGME, sulphate and glucuronic acid conjugates, and unchanged DPGME (30). Rats given ßPGME excreted 2–methoxypropionic acid, ßPGME-glucuronide and unchanged ßPGME (34).

The compounds listed above were detected in experimental animals after high doses of propylene glycol ether. To detect these compounds at levels expected after occupational exposure, more sensitive methods will probably be needed.

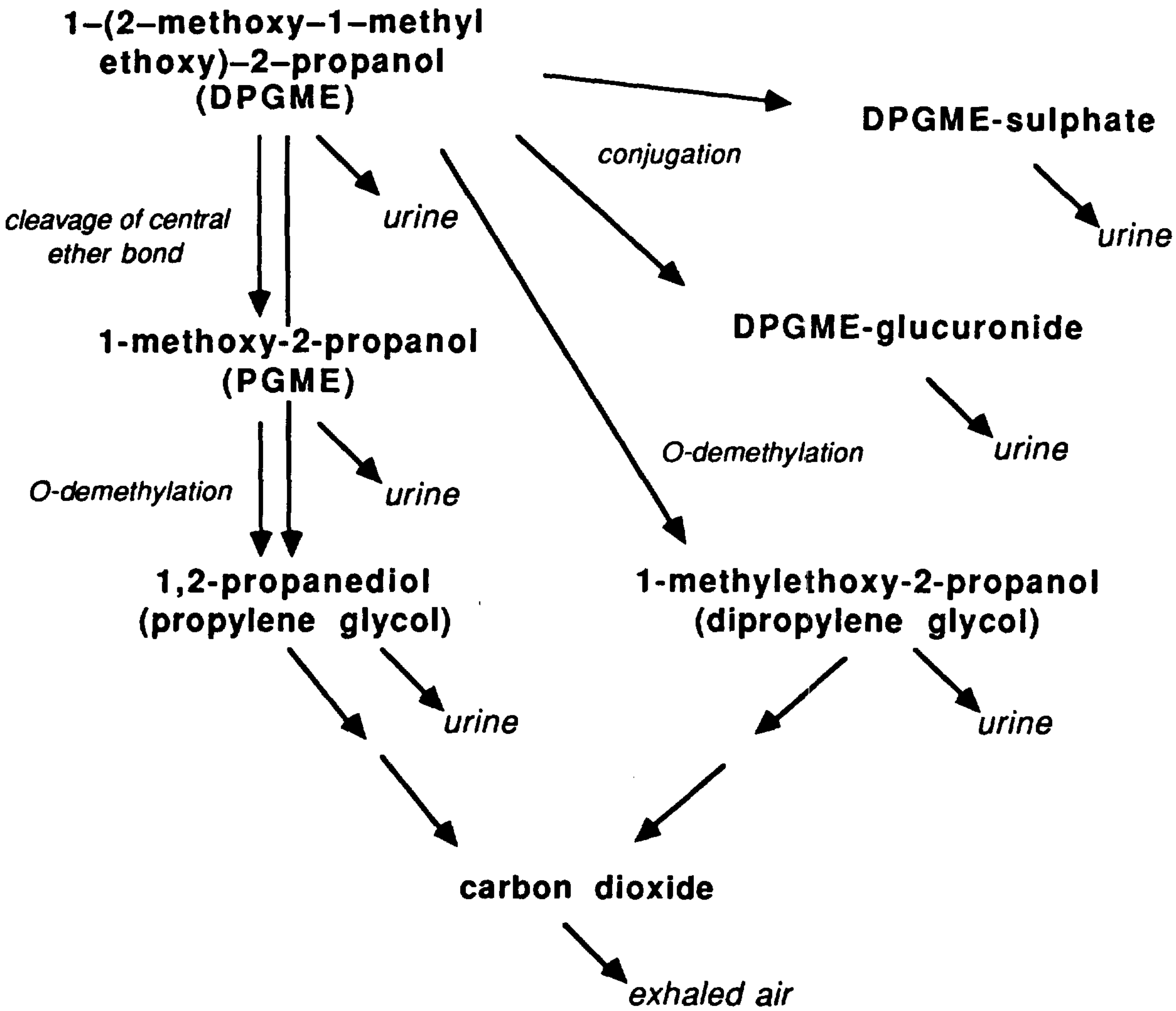

Figure 3. The metabolism of dipropylene glycol methyl ether.