Compound	Propylene glycol monomethyl ether (PGME)	*Data collection sheet (1/2)*
N°CAS 107-98-2 **1 ppm = 3.71 mg/m³**	**CLP: STOT SE 3**	

Organisation name	**ACGIH**	**AgBB**	**ANSES**	**DFG**	**German IAGV**	**REACH Registrants**
Risk value name	TLV-TWA	NIK (=LCI)	CLI (=LCI)	MAK	IAGV (RW I/RW II)	DNEL(general population, long-term, inhalation)
Risk value	184 mg/m³	3.7 mg/m³	2 mg/m³	375 mg/m³	1/10 mg/m³	43.9 mg/m³
Risk value	50 ppm	1 ppm	0.53 ppm	100 ppm	0.27/2.7 ppm	11.8 ppm
Reference period	Chronic (worker)	Chronic	Chronic	Chronic (worker)	Chronic	Chronic
Year	2013	2015	2004	1984	2013	2011, updated 2017
Key study	Stewart et al., 1970	NIK derivation based on the review performed by the Committee on Hazardous Substances (AGS)	Landry et al., 1983	Stewart et al., 1970	Cieszlak et al., 1998 (Spencer et al., 2002)	DNEL derived based on SCOEL OEL
Study type	Acute inhalation study		Subchronic inhalation study	Acute inhalation study	Chronic whole-body inhalation study	Inhalation study
Species	Humans		Rats/rabbits	Humans	Fischer 344 rats	
Duration of exposure in key study	7 hours at concentration range up to 250 ppm or 2 hours at concentration ranges up to 2050 ppm		6 h/d, 5 d/w for 13 weeks	7 hours at concentration range up to 250 ppm or 2 hours at concentration ranges up to 2050 ppm	6 h/d, 5 d/w for 104 w	
Critical effect	Eye irritation		Mild reversible sedation	Eye irritation	Eosinophilic foci of altered hepatocytes in male rats	Repeated dose toxicity as most sensitive endpoint
Critical dose value		370 mg/m³	NOAEC: 3678 mg/m³ (1000 ppm)			
	LOAEC: 100 ppm (after 1 h exposure)		LOAEC: 11060 mg/m³ (3000 ppm)	LOAEC: 100 ppm (after 1 h exposure)	LOAEC: 3600 mg/m³ (1000 ppm)	

Adjusted critical dose			$NOAEC_{HEC}$: 658 mg/m^3			
			$LOAEC_{HEC}$: 1975 mg/m^3		643 mg/m^3 = 3600 mg/m^3 x 6h/24h x 5d/7d	
Single assessment factors		100	UF_H 10 x UF_S 10 x UF_A 3 = 300		UF_H 10 x UF_A 2.5 x UF_{sen} 2 x UF_L 10 = 500	
Other effects	After one hour of exposure to 100 ppm, one subject noted mild eye irritation. After two hours, two of the six were complaining of slight eye irritation. However, during the 3.5 hours of exposure, there was no decrement in visual acuity, coordination, neurological responses, or brake reaction time.			After one hour of exposure to 100 ppm, one subject noted mild eye irritation. After two hours, two of the six were complaining of slight eye irritation. However, during the 3.5 hours of exposure, there was no decrement in visual acuity, coordination, neurological responses, or brake reaction time.		
UF_H Intraspecies variability; UF_A Interspecies variability; UF_L Used LOAEL; UF_{sen} Sensitive population; UF_S Used subchronic study; UF_D Data deficiencies						

Compound	Propylene glycol monomethyl ether (PGME)	*Data collection sheet (2/2)*
N°CAS 107-98-2 **1 ppm = 3.71 mg/m³**	**CLP: STOT SE 3**	

Organisation name	**NIOSH**	**OEHHA**	**RIVM**	**SCOEL**	**U.S. EPA (IRIS)**
Risk value name	REL-TWA	REL	OEL-TWA	OEL-TWA	RfC
Risk value	360 mg/m³	7 mg/m³	375 mg/m³	375 mg/m³	2 mg/m³
Risk value	100 ppm	2 ppm	100 ppm	100 ppm	0.53 ppm
Reference period	Chronic (worker)	Chronic	Chronic (worker)	Chronic (worker)	Chronic
Year	1992	2000	1996	1999	1991
Key study	No information available	Cieszlak et al., 1998	No information available	Emmen et al., 1997 (Emmen et al., 2003)	Landry et al., 1983
Study type		Chronic whole-body inhalation study		Subacute inhalation study	Subchronic inhalation study
Species		Fischer 344 rats		Human	Rats/rabbits
Duration of exposure in key study		6 h/d, 5 d/w for 104 w		2.5 h	6 h/d, 5 d/w for 13 w
Critical effect	No information available	Eosinophilic foci of altered hepatocytes in male rats	No information available	Eye irritation	Mild reversible sedation
Critical dose value		NOAEC: 300 ppm		NOAEC: 563 mg/m³ (150 ppm)	NOAEC: 3678 mg/m³ (1000 ppm)
		LOAEC: 1000 ppm			LOAEC: 11060 mg/m³ (3000 ppm)
Adjusted critical dose		$NOAEC_{HEC}$: 54 ppm			$NOAEC_{HEC}$: 658 mg/m³
					$LOAEC_{HEC}$: 1975 mg/m³
Single assessment factors		UF_S 1 x UF_A 3 x UF_H 10 = 30			UF_H 10 x UF_S 10 x UF_A 3 = 300
Other effects				In order to protect against exposure to concentrations that could	

				result in irritation, the SCOEL recommended an 8-hour TWA of 100 ppm (375 mg/m^3).	
UF_H Intraspecies variability; UF_A Interspecies variability; UF_S Used subchronic study; UF_D Data deficiencies					

Compound	**Propylene glycol monomethyl ether (PGME)**		***Factsheet***
Parameter	**Note**	**Comments**	**Value / descriptor**
EU-LCI value and status			
EU-LCI value	1	Mass/volume [µg/m^3]	7900
EU-LCI status	2	Draft/final	Final
EU-LCI year of issue	3	Year when the EU-LCI value has been issued	2018
General information			
CLP-INDEX-No.	4	INDEX	603-064-00-3
EC-No.	5	EINECS – ELINCS - NLP	203-539-1
CAS-No.	6	Chemical Abstracts Service number	107-98-2
Harmonised CLP classification	7	Human Health Risk related classification	STOT SE 3
Molar mass and conversion factor	8	[g/mol] and [ppm – mg/m^3]	90.12 1 ppm = 3.71 mg/m^3
Key data / database			
Key study, author(s), year	9	Critical study with lowest relevant effect level	Spencer et al., 2002
Read across compound	10	Where applicable	
Species	11	Rat, human, etc.	Rat
Route/type of study	12	Inhalation, oral feed, etc.	Inhalation
Study length	13	Days, subchronic, chronic	Chronic
Exposure duration	14	Hrs/day, days/week	6 h/d, 5 d/wk for 104 weeks
Critical endpoint	15	Effect(s), site of	Eosinophilic foci of altered hepatocytes in male rats
Point of departure (POD)	16	LOAEC*L, NOAEC*L, NOEC*L, Benchmark dose, etc.	NOAEC
POD value	17	[mg/m^3] or [ppm] or [mg/kg$_{BW}$×d]	300 ppm
Assessment factors (AF)	**18**		
Adjustment for exposure duration	19	Study exposure hrs/day, days/week	5.6
Study length	20	sa→ sc→ c *(R8-5)*	1
Route-to-route extrapolation factor	21		1
Dose-response	22 a	Reliability of dose-response, LOAEL → NOAEL	1
	22 b	Severity of effect *(R 8-6d)*	1
Interspecies differences	23 a	Allometric Metabolic rate *(R8-3)*	1
	23 b	Kinetic + dynamic	2.5
Intraspecies differences	24	Kinetic + dynamic Worker - general population	10
AF (sensitive population)	25	Children or other sensitive groups	1
Other adjustment factors Quality of whole database	26	Completeness and consistency Reliability of alternative data *(R8-6 d,e)*	1

Result			
Summary of assessment factors	27	Total Assessment Factor (TAF)	140
POD/TAF	28	Calculated value (µg/m³ and ppb)	7950 µg/m³ and 2143 ppb
Molar adjustment factor	29	Used in read-across	
Rounded value	30	[µg/m³]	7900
Additional comments	31		
Rationale section	32		

Data compilation and evaluation for propylene glycol monomethyl ether are based on a project funded by the European Commission and carried out by Ramboll Environment & Health GmbH (formerly BiPRO GmbH).

Several organisations or national agencies have published comprehensive assessments of propylene glycol monomethyl ether (PGME) (Johansson, 1990; OECD, 2001, 2003; ACGIH, 2013). These assessment reports, along with limit values derived by European or national authorities including the German DFG, the French ANSES, ECHA, the US EPA and the European SCOEL (see data collection sheet for more information), were evaluated and considered for the EU-LCI derivation of PGME.

Rationale for key study/POD

Human volunteers exposed to PGME experience eye irritation. PGME concentrations greater than 150 ppm are expected to be self-limiting for humans due to irritation effects (Stewart et al., 1970; Emmen et al., 1997; Emmen et al., 2003). Since existing human studies only observed acute exposure (up to 7 hours) and had small sample sizes, however, they were not deemed suitable for the EU-LCI derivation.

Derivation of the EU-LCI for PGME is based on the chronic 2-year inhalation PGME study conducted in Fischer 344 rats and B6C3F1 mice (Spencer et al., 2002). Animals of both sexes were exposed to 0, 300, 1000 or 3000 ppm PGME for durations ranging from 1 week to 2 years. Effects observed in animals chronically exposed over 2 years to 3000 ppm include induction of hepatic mixed function oxidase activity and S-phase DNA synthesis, elevated mortality in male rats and mice, elevated alpha 2U-globulin deposition and associated nephropathy and S-phase DNA synthesis in male rat kidneys, and increased occurrence and/or severity of eosinophilic foci of altered hepatocytes in male rats.

The increased incidence of eosinophilic foci in the livers of PGME-exposed male rats is considered the most critical effect observed in this study, and was therefore selected for the EU-LCI derivation. Alpha 2U-globulin-associated nephropathy is an effect specific to male rats and so is not considered suitable as a key critical effect for the EU-LCI derivation. Since a significant increase in eosinophilic foci in the liver was also observed in male rats chronically exposed to 1000 ppm, 300 ppm (the established NOAEC for this hepatic effect) is set as the point of departure for the EU-LCI derivation.

Assessment factors (AF)

Standard default assessment factors for exposure duration and interspecies as well as intraspecies difference were applied. The assessment factors applied are:

- adjustment for exposure duration: 5.6
- interspecies differences: 2.5
- intraspecies differences: 10

The total assessment factor is 140.

This resulted in a calculated value of 7950 µg/m³ and a derived EU-LCI for PGME of 7900 µg/m³. This EU-LCI value (7900 µg/m³ or ~2 ppm) is below the reported odour threshold level of 10 ppm (Stewart et al., 1970).

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