Compound	Diethylene glycol	*Data collection sheet*
N°CAS 111-46-6	**CLP:** Acute Tox. 4 (H302: Harmful if swallowed)	
Organisation name	**MAK**	**REACH registrants**
Risk value name	MAK	DNEL worker/consumer
Risk value (µg/m³)	44000	60000 worker / 12000 consumer
Risk value (ppb)	10000	14000
Reference period		
Year	2012	2014
Key study	Gaunt et al., 1976	Read across ethylene glycol (CAS 107-21-1), Wills et al., 1974.
Study type	chronic feeding study	clinical study
Species	rat	human
Duration of exposure in key study	225 days	20-22h/day, for 30 days
Critical effect	kidney effects	respiratory tract irritation
Critical dose value	NOEL 50 mg/kg bw/day	NOAEC (EG)
		67 mg/m³
Adjusted critical dose	6 mg/kg$_{bw}$/day	60 mg/m³ (worker), 12 mg/m³ (consumer)
Single assessment factors (see table R.8.6)	intraspecies rat-human 10	"general factor" 2 (workers), 10 (consumer)
Other effects		

Compound	Diethylene glycol		*Factsheet*
Parameter	**Note**	**Comments**	**Value / descriptor**
EU-LCI value and status			
EU-LCI value	1	Mass/volume [µg/m^3]	5700
EU-LCI status	2	Draft/final	Final
EU-LCI year of issue	3	Year when the EU-LCI value was issued	2016
General information			
CLP Index No	4	INDEX	603-140-00-6
EC No	5	EINECS – ELINCS - NLP	203-872-2
CAS No	6	Chemical Abstracts Service number	111-46-6
Harmonised CLP classification	7	Human health risk-related classification	Acute Tox. 4 (H302: Harmful if swallowed)
Molar mass and conversion factor	8	[g/mol] and [ppm – mg/m^3]	106.12 1 ppm = 5.23mg/m^3
Key data / database			
Key study, author(s), year	9	Critical study with lowest relevant effect level	
Read-across compound	10	Where applicable	Ethylene glycol CAS 107-21-1
Species	11	Rat etc. / human	
Route/type of study	12	Inhalation, oral feed, etc.	
Study length	13	Days, subchronic, chronic	
Exposure duration	14	Hours/day, days/week	
Critical endpoint	15	Effect(s), site of	
Point of departure (POD)	16	LOAEC*L, NOAEC*L, NOEC*L, benchmark dose, etc.	POD/TAF in EU-LCI factsheet for ethylene glycol
POD value	17	[mg/m^3] or [ppm] or [mg/kg$_{BW}$×d]	3.35 mg/m^3 or 1.3 ppm
Assessment Factors (AF)	**18**		
Adjustment for exposure duration	19	Study exposure hours/day, days/week	-
Study Length	20	sa→ sc→ c *(R8-5)*	-
Route-to-route extrapolation factor	21		-
Dose-response	22 a	Reliability of dose-response, LOAEL → NOAEL	-
	22 b	Severity of effect *(R 8-6d)*	-
Interspecies differences	23 a	Allometric Metabolic rate *(R8-3)*	-
	23 b	Kinetic + dynamic	-
Intraspecies differences	24	Kinetic + dynamic Worker - general population	-
AF (sensitive population)	25	Children or other sensitive groups	-
Other adjustment factors Quality of whole database	26	Completeness and consistency Reliability of alternative data *(R8-6 d,e)*	-

Result			
Summary of assessment factors	27	Total Assessment Factor (TAF)	-
POD/TAF	28	Calculated value (µg/m³ and ppb)	3350 µg/m³ and 1300 ppb
Molar adjustment factor	29	Used in read-across	1.7 (= 106/62)
Rounded value	30	[µg/m³]	5700
Additional comments	31		
Rationale section	32		

Toxicity profile

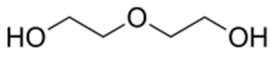
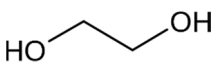
Diethylene glycol (DEG) is not classifiable for skin or mucosal irritation based on guideline animal assays. Nephrosis is the most sensitive systemic health effect following repeated oral intake.

Two studies in rats are available, one of lower quality resulting in a NOAEL of 100 mg/kg bw/day following a feeding period of 7.5 months (Gaunt, 1976) and one resulting in a NOAEL at the limit dose of 1000 mg/kg bw/day following a feeding period of 4 weeks (BASF SE, 1988). Compared with ethylene glycol (EG), DEG does not result in effects on development.

As for EG, irritation of the upper respiratory tract is anticipated to be the most relevant health effect for inhalation exposure to DEG. Both levels of upper respiratory tract irritation are similar for EG and DEG and therefore, in absence of reliable data for local irritation, a read-across from EG is performed. Nephrotoxicity and other acute systemic effects occur at lower dose levels compared to EG, underlining the conservative character of this approach.

Rationale for read-across

- Data-poor compound: no adequate toxicological data for DEG; *de novo* derivation of EU-LCI is not possible.
- Read-across candidate compounds for starting value: within the chemical class of glycols, EG is the closest homologue with an EU-LCI value.
- Toxicological critical endpoints for homologue compound:
  - EG: irritation of upper respiratory tract.
- The key assumption underlying the read-across of the EU-LCI value from EG is that the two compounds have a similar toxicity profile.
- The chemical structure and molecular weight of DEG and EG are listed in the table below:

Compounds	Structure	MW [g/mol]	EU-LCI value
Diethylene glycol		106.12	
Ethylene glycol		62.07	3400 µg/m³ (*de novo* protocol) Unrounded value: 3350 µg/m³ or 1300 ppb

- No cut-off rule in place: difference in change length between the two homologue compounds is two CH_2 groups per aliphatic chain.
- Thus, after molar weight conversion at 23 °C and 1 atm: EU-LCI diethylene glycol = 3350 µg/m³ x 1.7 = 5695 µg/m³ → to be rounded to 5700 µg/m³.

References

Gaunt (1976): Studies of the toxicity of diethylene glycol in rats. ACC Chemstar report No 5/1976.

BASF SE (1988): Pruefung der oralen Toxizitaet von Diethylenglykol an Ratten; Verabreichung im Futter über 4 Wochen und 3 Wochen Nachbeobachtung. Report No. 30S0036/8526.