

Stofdocument deel A

CAS-nr: 64-17-5

Ethanol

CH₃CH₂OH

VN-nr: 1170

GEVI: 33

Synoniemen: ethylalcohol, alcohol (Engels: ethanol)

Interventiewaarden		10 min.	30 min.	1 uur	2 uur	4 uur	8 uur
Voorlichtingsrichtwaarden	VRW (mg/m³)	640	640	640	640	640	640
Alarmeringsgrenswaarden	AGW (mg/m³)	6.700*	6.700*	6.700*	6.700*	6.700*	6.700*
Levensbedreigende waarden	LBW (mg/m³)	NA	NA	NA	NA	NA	NA
Datum vaststelling: 31-10-2017		1 mg/m ³ = 0,521 ppm; 1 ppm = 1,918 mg/m ³					
Explosiegrens: 3,1 vol% ≈ 59.000 mg/m ³ * berekende interventiewaarde hoger dan 10% LEL			Geur: zoete, typerende geur LOA: 15,6 mg/m ³				
Fysisch-chemische eigenschappen				Overige informatie			
Uiterlijk: kleurloze vloeistof Brand: zeer brandgevaarlijk		Molecuulmassa: 46,1 g/mol Zuurgraad: - LogKow: -0,3		Publieke grenswaarde: 260 mg/m ³ MAK: 960 mg/m ³ TLV-TWA: 1918 mg/m ³			
Relatieve dichtheid van verzadigd damp-lucht mengsel: 1,03		Wateroplosbaarheid: volledig Verzadigde dampdruk: 59 mbar					
Toxicologische eigenschappen							
Effecten bij inhalatoire blootstelling <i>Onder VRW:</i> prikkeling, hoesten <i>VRW → AGW:</i> hoofdpijn, opwinding, warmtegevoel <i>Boven AGW:</i> coördinatiestoornissen, bewustzijnsdaling, branderig gevoel achter het borstbeen, onderkoeling, ernstige bloeddrukdaling, sterfte				Toxiciteit bij eenmalige, inhalatoire blootstelling ▪ De stof kan irritatie van de luchtwegen veroorzaken. ▪ De stof kan inwerken op het centrale zenuwstelsel. ▪ Na inademen van hoge concentraties kan de stof aanleiding geven tot o.a. ontremming en opwinding gevolgd door bewustzijnsverlaging.			
Effecten bij blootstelling aan vloeistof <i>Huidcontact:</i> droge huid. <i>Oogcontact:</i> prikkeling, roodheid, branderig gevoel, pijn.				Carcinogeniteit IARC classificatie: 1 CRP: niet afgeleid			
Beknopte medische informatie							
Ontsmetting damp <i>algemeen:</i> frisse lucht, rust, en arts raadplegen.							
Ontsmetting vloeistof <i>huid:</i> verontreinigde kleding uittrekken, afspoelen met water. <i>ogen:</i> minimaal 15 min. spoelen met water (evt. contactlenzen verwijderen), dan naar oogarts brengen. <i>inslikken:</i> mond laten spoelen (uitspugen!), GEEN braken opwekken en direct spoedeisende medische hulp inzetten.							
Specifieke behandeling en materialen: geen.							
Neem contact op met het NVIC (Tel:+31 (0)30 274 8888) voor informatie met betrekking tot medisch handelen							

Stofdocument deel B

CAS-nr: 64-17-5

Ethanol

CH₃CH₂OH

UN-nr: 1170

Basis for the Dutch Intervention Values

VRW: Based on additional information to that described in ERPG-document, different values are derived, other time-points added

AGW: Based on information as described in ERPG-document, different values are derived, other time-points added

LBW: Not recommended, in accordance with the ERPG.

Date: 31-10-2017

ERPG 2010

Dutch Intervention Values (mg/m³)

	10 min	30 min	1 h	2 h	4 h	8 h	End point
VRW	640	640	640	640	640	640	Respiratory irritation in humans
AGW	6,700*	6,700*	6,700*	6,700*	6,700*	6,700*	Lacrimation and marked coughing in humans
LBW	NR	NR	NR	NR	NR	NR	Not recommended

* value higher than 10% of LEL

Derivation of the Dutch Intervention Values

VRW: VRW levels were based on results from a human volunteer study (see below under “additional toxicological information”) in which 8 female and male volunteers were exposed in an inhalation chamber for 4 hour to up to 1000 ppm (1918 mg/m³). No adverse systemic or local effects were observed, whereas repeatedly changing the concentration from 1900 to 100 ppm (3643 and 192 mg/m³) (one hour for each exposure level, for 4 hours in total) in a second experiment caused temporary irritation. Symptoms included tickling in the throat; irritation of the eyes, nose, throat, skin; blurred vision; unpleasant taste and discomfort. These data are supported by a human volunteer study in which healthy subjects inhaled an aerosol of 25% ethanol in water for 30 min via a micronebulizer with ethanol air concentrations in inspired air varying from 0.18 to 0.20% (corresponding to 3452-3835 mg/m³). All subjects had initial coughing which subsided, and a dry throat. Three of the six complained of chest tightness at the end of the 30-min period. There was no change in FEV₁. Subjects had a statistically significant decrease in flow rates on partial expiratory flow volume curves that lasted up to 90 minutes following inhalation.

A 4-hour exposure to 1918 mg/m³ was selected as point of departure for deriving the VRW. These data were considered more reliable with respect to the applied exposure. The default uncertainty factor of 3 was considered sufficient to account for intraspecies differences. Timescaling was not applied. This approach was considered appropriate because mild irritation effects are considered concentration-dependent rather than concentration x time dependent.

AGW: Data from a inhalation study in human volunteers (number, gender and exposure duration not stated) indicate that concentrations greater than 40,000 mg/m³ are intolerably irritating while at concentrations between 10,000 and 20,000 mg/m³ some coughing and smarting of the eyes and nose occurred (which disappeared in 5 to 10 minutes, suggesting adaptation), and at 30,000 mg/m³ continuous lacrimation and marked coughing occurred. The exposure to 20,000 mg/m³ was selected as point of departure for AGW-values. The default uncertainty factor of 3 was considered sufficient to account for intraspecies differences. In the second part of the study volunteers were exposed for 3 or 6 hours to 15000 mg/m³ ethanol to determine a.o. blood concentration levels. Though this part of the study was not designed to establish clinical effects it does demonstrate that this concentration is tolerable for 3 to 6 hours. Since no increase of the effect is expected by extension of the exposure duration time-scaling was not applied.

LBW: Appropriate data for deriving LBW-values are not available. Results of acute inhalation studies show that the lowest lethal concentration reported is 12,700 ppm (24,353 mg/m³) during a 22 hour exposure of rats, while rats exposed for 3.75 hours survived 45,000 ppm (86,291 mg/m³). A rat LC₅₀ was reported to be 20,000 ppm (38,352 mg/m³) for 10 hours. The lowest reported lethal exposure in mice is 29,000 ppm (55,610 mg/m³) after 7 hours of exposure, whereas the LC₅₀-value was 21,000

ppm (40,269 mg/m³) after 4 hours. It is noted that the outcome of the acute animal studies are derived from secondary literature sources (i.e. other than ERPG-document). Details on study methods are therefore not available. Moreover, selecting these animal data as point of departure would result in LBW-values that are in conflict with human data. Human exposure data (see AGW) show that one hour exposures to 30,000 mg/m³ and 40,000 mg/m³ cause marked eye and respiratory irritation, but did not result in systemic effects such as central nervous system depression. In absence of appropriate data, LBW-values were set at Not Recommended.

Additional toxicological information (including relevant results of a general literature search, if any)

Ethanol has an effect on the central nervous system and is irritating to the mucous membranes. Upon inhalation in humans, the irritating effects are more pronounced.

There are no data available on the effects on human reproduction after inhalation of ethanol. No clear effects of ethanol were observed in animal inhalation studies on reproduction (effects on fertility or on development).

Additional human data were derived from a report of the Health Council of the Netherlands (2006)¹. In a human volunteer study (Seeber et al., 1997)², healthy volunteers were exposed in an exposure laboratory to ethanol by inhalation; this included two experiments. The first experiment focused on neurobehavioural effects and included exposure of 12 male and female subjects to 80, 400 and 800 ppm (153, 767, 1534 mg/m³) ethanol for 4 hours. The second experiment included exposure of 8 male and female subjects to 1000 ppm (1918 mg/m³) for 4 hours under three exposure conditions: 1918 mg/m³ as a constant level and 1918 mg/m³ as the average exposure with hourly changes of 100/1900/100/1900 ppm (192/3643/192/3643 mg/m³) or 1900/100/1900/100 ppm (3643/192/3643/192 mg/m³). No adverse effects on well-being (rated on a 7 points scale comprising tension, tiredness, complaints, and annoyance) were (self)reported. Increasing the concentration directly from 0 or 192 to 3,643 mg/m³ caused temporary irritation. The female subjects gave a stronger response than the males. Symptoms included tickling in the throat; irritation of the eyes, nose, throat, skin; blurred vision; unpleasant taste and discomfort.

No harmonised H-sentences for human health.

Carcinogenicity and derivation of the CRP value

IARC classification: 1 (carcinogenic to human)
No carcinogenic risk potency (CRP) was derived. Reliable inhalation data were not available.

Odour and derivation of the LOA value

Odour: sweet
Odour threshold: 0.997 mg/m³ [Nagata, 2003]
LOA = 11.8 * OT * 1.33 = 15.6 mg/m³
(The concentration Level leading to distinct Odour Awareness (I=3) is calculated using the formula: I = 2.33 * log (C/OT) + 0.5. A correction factor of 1.33 is applied to this value)

The LOA is below the VRW.

Other standards and guidelines (1h values in mg/m³, unless otherwise indicated)³

VRW level 640	AEGL-1 -	ERPG-1 3384	IDLH: 6329 mg/m ³ (30 minutes)
AGW level 6,700	AEGL-2 -	ERPG-2 6204	
LBW level NR	AEGL-3 -	ERPG-3 NR	

¹ Health Council of the Netherlands. Ethanol (ethyl alcohol); Evaluation of the health effects from occupational exposure. The Hague: Health Council of the Netherlands, 2006; publication no. 2006/06OSH

² Seeber A, Blaszkewicz M, Golka K, Kiesswetter E. Solvent exposure and ratings of well-being: dose-effect relationships and consistency of data. Environ Res 1997; 73(1-2): 81-91

³ Note that the ERPG values as presented here (in mg/m³) are derived using the conversion factors of the ERPG.