

Stofdocument deel A

CAS-nr: 111-30-8

Glutaaraldehyde



VN-nr: 3265

GEVI: 80

Synoniemen: 1,5-pentaandial, succinaldehyde, glutaaral (Engels: Glutaraldehyde)

Interventiewaarden		10 min.	30 min.	1 uur	2 uur	4 uur	8 uur
Voorlichtingsrichtwaarden	VRW (mg/m³)	0,42	0,42	0,42	0,42	0,42	0,42
Alarmeringsgrenswaarden	AGW (mg/m³)	9,7	6,7	5,3	4,2	3,4	1,7
Levensbedreigende waarden	LBW (mg/m³)	27	18	15	12	9,2	4,6
Datum vaststelling: 31-10-2017		1 mg/m ³ = 0,240 ppm; 1 ppm = 4,16 mg/m ³					
Explosiegrens: 1,5 vol% ≈ 62.000 mg/m ³			Geur: Groene appel, stekende geur				
			LOA: 0,016 mg/m ³				

Fysisch-chemische eigenschappen		Overige informatie
Uiterlijk: Kleurloze tot gele viskeuze oplossing	Molecuulmassa: 100,1 g/mol	Publieke grenswaarde: niet afgeleid MAK: 0,21 mg/m ³ TLV-ceiling: 0,21 mg/m ³
Brand: moeilijk tot niet brandbaar	Zuurgraad: 3,7 (bij 10g / 100 ml)	
	LogKow: -0,4	
Relatieve dichtheid van verzadigd damp-lucht mengsel: 1,00	Wateroplosbaarheid: volledig	
	Verzadigde dampdruk: 0,6 mbar	

Toxicologische eigenschappen

Effecten bij inhalatoire blootstelling <u>Onder VRW:</u> Geen effect <u>VRW → AGW:</u> Irritatie van ogen, neus en keel, tranende ogen, keelpijn en hoesten <u>AGW → LBW:</u> Irritatie van ogen, neus en keel, hoofdpijn, kortademigheid <u>Boven LBW:</u> Ademnood, sufheid, bloeddrukdaling, bewusteloosheid, sterfte	Toxiciteit bij eenmalige, inhalatoire blootstelling <ul style="list-style-type: none"> ▪ Glutaaraldehyde is als vloeistof en damp sterk irriterend tot bijtend voor alle contactwegen. ▪ Inademing kan tot een heftige astmatische reactie leiden die wordt veroorzaakt door hetzij een bronchiële hyperreactiviteit dan wel door een respiratoire allergie (de stof is ook een huidallergeen). ▪ Hoge concentraties kunnen zwellingen in de keel (larynx- en glottisoedeem) veroorzaken, met gevaar op verstikking. ▪ In zeer hoge (dodelijke) concentraties worden effecten op het centrale zenuwstelsel merkbaar (spiertrekkingen, sufheid tot bewusteloosheid)
Effecten bij blootstelling aan vloeistof <u>Huidcontact:</u> prikkeling, roodheid en pijn, bijtend, branderig gevoel, brandwonden. <u>Oogcontact:</u> prikkeling, roodheid en pijn, tranenvloed, branderig gevoel, hoornvliesbeschadiging.	Carcinogeniteit IARC classificatie: niet geclassificeerd CRP: niet afgeleid

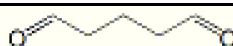
Beknopte medische informatie

Ontsmetting damp <i>algemeen:</i> frisse lucht, rust, halfzittende houding, direct spoedeisende medische hulp inzetten
Ontsmetting vloeistof <i>huid:</i> verontreinigde kleding uittrekken, minimaal 20 min. spoelen met veel water of douchen, arts raadplegen. <i>ogen:</i> minimaal 15 min. spoelen met water (evt. contactlenzen verwijderen), dan naar oogarts brengen, blijven spoelen tijdens vervoer. <i>inslikken:</i> mond laten spoelen (uitspugen!), GEEN braken opwekken, 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: 111-30-8

Glutaraldehyde



UN-nr: 3265

Basis for the Dutch Intervention Values

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

Date: 31-10-2017

ERPG, 2015

Dutch Intervention Values (mg/m³)

	10 min	30 min	1 h	2 h	4 h	8 h	End point
VRW	0.42	0.42	0.42	0.42	0.42	0.42	Sensory irritation in human volunteers
AGW	9.7	6.7	5.3	4.2	3.4	1.7	Symptoms of ocular irritation in rats
LBW	27	18	15	12	9.2	4.6	No lethality in rats

Derivation of the Dutch Intervention Values

VRW: VRW values are based on an experimental study on the detection of odour and sensory irritation from exposure to glutaraldehyde vapour in human volunteers. Fifty female volunteers (aged 18 – 35 years) were exposed to 35, 50, 75 or 100 ppb (0.146, 0.208, 0.312 or 0.416 mg/m³) during 15 minutes in an exposure chamber, either in ascending or descending order of concentration (25 subjects each) and with intervals of 45 – 75 minutes between subsequent exposures. In addition, exposure to clean air and an odour control (heptane) were included in the exposure setup. Exposure up to 0.416 mg/m³ was tolerated without eye, nose or throat irritation. Other human volunteer studies reported irritation thresholds of 0.26 ppm (1.08 mg/m³) and 0.3 ppm (1.25 mg/m³). In hospital workers, irritation of the eyes and upper respiratory tract was reported at glutaraldehyde vapour concentrations of 0.2 ppm (0.833 mg/m³), while no symptoms were reported at 0.1 ppm (0.416 mg/m³). Therefore, 0.416 mg/m³ is used as point of departure for the VRW values. An intraspecies uncertainty factor was not applied given the absence of irritation effects in the volunteer study. Time scaling was not applied as respiratory irritation is considered to be concentration-dependent rather than concentration x time-dependent.

AGW: AGW values are based on an acute inhalation study in rats. Groups of 10 rats (5 male, 5 female) were exposed to dynamically generated saturated glutaraldehyde vapour atmosphere in an exposure chamber for 4 hours at ambient temperatures (17°C – 23°C) followed by a 14-days post-exposure observation. Air sampling inside the exposure chambers showed that glutaraldehyde concentrations ranged from 8.1 ppm (33.7 mg/m³) to 22.2 ppm (92.4 mg/m³). At 33.7 mg/m³, blepharospasm (involuntary closing of the eyes) and lacrimation were noted. At higher concentrations also periocular wetness, hyperactivity and audible breathing were noted. All symptoms resolved within a day after exposure. The exposure concentration of 33.7 mg/m³ was used as the point of departure for derivation of the AGW values. The default uncertainty factor of 10 (3x3) was considered sufficient to account for inter- and intraspecies differences. Time scaling was performed using $C^n \cdot t = k$, with the default values of $n = 1$ and $n = 3$ for extrapolation to longer and shorter exposure durations, respectively

LBW: Acute inhalation studies were available with glutaraldehyde vapour generated at ambient temperature under dynamic (concentrations of 22.2 ppm (92 mg/m³)) and static conditions (concentrations up to 48.1 ppm (200 mg/m³)). The six and four hour exposures to static and dynamic generated saturated concentrations, respectively did not result in mortality in rats. Acute inhalation toxicity studies were also performed, in which rats were exposed to glutaraldehyde vapour generated at elevated temperature (60°C or 65°C) and cooled before exposure. Mortality was observed in these studies. As heating of glutaraldehyde appears to increase the toxicity of the vapour these studies

were not used as point of departure for derivation of the LBWs. The dynamically generated highest concentration of 92 mg/m³, for a 4 hr exposure, causing no mortality was used as PoD. The default uncertainty factor of 10 (3x3) was considered sufficient to account for inter- and intraspecies differences. Time scaling was performed using $C^n * t = k$, with the default values of $n = 1$ and $n = 3$ for extrapolation to longer and shorter exposure durations, respectively

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

The primary effect of inhalation exposure to glutaraldehyde is irritation of the eyes and upper respiratory tract. Glutaraldehyde is usually used in aqueous solutions, which contain a mixture of chemical species including the dialdehyde, hemihydrate, dehydrate, and cyclic hemiacetal forms. Depending on temperature and pH, several polymers may also be present. The chemical composition of the mixture affects toxicity and may change with temperature. Exposure to glutaraldehyde vapours generated under elevated temperature appears to result in more severe toxicity than exposure to similar concentrations of the vapour at ambient temperature. Vapour concentrations above approximately 28 ppm (approximately 120 mg/m³) require heating of the solution.

No evidence for reproductive toxicity upon inhalation of glutaraldehyde was found.

H330: Fatal if inhaled; H301: Toxic if swallowed; H314: Causes severe skin burns and eye damage; H317: May cause an allergic skin reaction; H335: May cause respiratory irritation; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Carcinogenicity and derivation of the CRP value

IARC classification: not classified.

No carcinogenic risk potency (CRP) was derived.

Odour and derivation of the LOA value

Odour: pungent, green apple-like

OT: 0.001 mg/m³ [Cain et.al., 2007]
LOA = 11.8 * 0.001 * 1.33 = 0.016 mg/m³

(The concentration Level leading to distinct Odour Awareness (I=3) is calculated using the formula: $I = 2.33 * \log(C/OT_{50}) + 0.5$. A correction factor of 1.33 is applied to this value)

The LOA lies well below VRW level.

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

VRW level 0.42	AEGL-1 -	ERPG-1 0.82	IDLH: not derived
AGW level 5.3	AEGL-2 -	ERPG-2 4.1	
LBW level 15	AEGL-3 -	ERPG-3 20.5	

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