



Waterschap Limburg.

t.a.v. Dagelijks Bestuur
Postbus 2207
6040 CC Roermond

Datum.
1 juli 2025

Kenmerk.
2025_WTW_IAZI0051
Zaaknummer.

Onderwerp.
Wijzigingsaanvraag voor de
lozing van formaldehyde

Beste dagelijks bestuur,

Met uw schrijven, kenmerk 2020-D125315 van 18 december 2020, hebben wij de vergunning in het kader van de Waterwet ontvangen voor het verrichten van handelingen in een watersysteem. Het besluit is gedateerd 15 december 2020 onder nummer 2019-Z4532.

Bijgevoegd een wijzigingsaanvraag van de vigerende Watervergunning voor de opname in bijlage 4 van de stof formaldehyde CAS# 50-00-0.

Hopende u voldoende te hebben geïnformeerd,

In afwachting van uw reactie.

Namens Circle Wastewater Services B.V.

CEO



Wijzigingsaanvraag stof formaldehyde

1. Inleiding

Voor de rapportage van voorschrift 25 lid 4 (voldoen aan immissietoets van de in bijlage 4 als Eco, B en C gelabelde stoffen) is onderzoek verricht naar de aanwezigheid in het effluent van de stof Formaldehydecyaanhydrine. Hierbij is ook gekeken naar afbraakproducten waaronder formaldehyde. Uitvloeisel hiervan is analyse van het effluent op formaldehyde vanaf 2023 met een hiervoor ontwikkelde doelstofanalyse. Omdat formaldehyde (CAS# 50-00-0) in het effluent vanaf de metingen in 2023 structureel aangetoond wordt en deze stof volgens de nieuwe inzichten altijd aanwezig moet zijn geweest in het effluent van de IAZI, vraagt Circle Wastewater Services B.V. om formaldehyde alsnog op te nemen in bijlage 4.

2. Gevraagde wijziging

Deze aanvraag betreft de stof Formaldehyde (CAS# 50-00-0).

Middels deze aanvraag wordt verzocht om formaldehyde op te nemen op bijlage 4 op basis van de in tabel 2.1 gegeven ABM indeling, (i)JG-MKE norm, drinkwaterrichtwaarde en alerteringswaarde.

Tabel 2.1: Normen en alerteringswaarde

Component	CAS#	ABM2016	(indicatieve) MAC-MKE µg/l	(indicatieve) JG-MKE µg/l	Drinkwater richtwaarde µg/l	Alerterings- waarde* µg/l
Formaldehyde	50-00-0	Z2	1800	180	900	67

Als alerteringswaarde wordt aangevraagd de gemiddelde concentratie + tweemaal de standaarddeviatie genomen (95% betrouwbaarheidsinterval).

Bijlage: Aanvullende toelichting op de wijzigingsaanvraag formaldehyde



Bijlage: aanvullende toelichting op de wijzigingsaanvraag formaldehyde

1. Inleiding

Voor de rapportage van voorschrift 25 lid 4 (voldoen aan immissietoets van de in bijlage 4 als Eco, B en C gelabelde stoffen) is onderzoek verricht naar de aanwezigheid in het effluent van de stof Formaldehydecyaanhydrine. Bij het ontwikkelen van een doelstofanalyse voor Formaldehydecyaanhydrine is besloten om ook meteen een doelstofanalyse voor de mogelijke restcomponent formaldehyde te laten ontwikkelen. Reden hiervoor is dat niet duidelijk was of een stabiele standaard van Formaldehydecyaanhydrine beschikbaar was. De doelstofanalyse voor formaldehyde is vanaf begin 2023 beschikbaar en vervolgens is gestart met reguliere analyse van het effluent op formaldehyde, zie bijlage B. Op basis van de structurele aanwezigheid van formaldehyde in het effluent is gezocht naar de mogelijke herkomst van formaldehyde. Formaldehyde wordt niet als grond- of hulpstof gebruikt en is ook niet bekend als een (bij)product. Mogelijk is formaldehyde een afbraakproduct van de stof Formaldehydecyaanhydrine (CAS# 107-16-4; ABM = B1) of van de stof formaldehyde copolymeer met 1-naftol (CAS# 25359-91-5; ABM = A2) in de IAZI. Ervan uitgaande dat formaldehyde een afbraakproduct is van voornoemde stoffen en met name Formaldehydecyaanhydrine, kan gesteld worden dat formaldehyde in het effluent aanwezig moet zijn geweest en betreft het geen nieuwe stof en dient deze alsnog (corrigerende actie op basis van nieuw inzicht) opgenomen te worden op bijlage 4 van de watervergunning.

2. ABM2016

De stof formaldehyde is via de ABM2016 toets ingedeeld als Z2, de onderliggende gegevens zijn te vinden in bijlage A.

3. Sommatie

Sommatie is voor Formaldehyde niet van toepassing omdat het als stof niet geloosd wordt door de fabrieken. In tabel 3.1 is de effluentconcentratie en vracht gegeven op basis van de analyses in 2023, 2024 en begin 2025.

Tabel 3.1: Vracht en effluentconcentratie formaldehyde

Stof	ABM stof	CAS#	Jaarvracht via inname geflocculeerd kanaalwater* (kg/jaar)	Jaarvracht effluent** (kg/jaar)	Effluent concentratie gemiddeld (µg/l)	Effluent concentratie gemiddeld+2S (µg/l)
Formaldehyde	Z2	50-00-0	0	717	29 (n= 37)	67

* Door zowel RWS als WML wordt het oppervlaktewater niet geanalyseerd op deze stoffen, jaarvracht is gebaseerd op eigen metingen Circle.

** De jaarvracht is berekend op basis van de gemiddelde effluentconcentratie en het gemiddelde jaardebiet 2023/2024 van 24730627 m³.

Er is geen Formaldehyde aangetoond in het geflocculeerd kanaalwater. Het betreft nog maar enkele resultaten, allen beneden de detectiegrens, maar vooralsnog wordt ervan uitgegaan dat geen Formaldehyde wordt ingetrokken met het kanaalwater. Daarnaast is geen Formaldehyde aangetoond in de CZV-bronnen welke aan de IAZI gedoseerd worden.

4. Verwijdering in IAZI en restemissie

Op basis van de stofgegevens is formaldehyde gemakkelijk biologisch afbreekbaar waardoor conform aanvraag gerekend kan worden met 95% verwijdering in de IAZI. De influentvracht is niet bekend omdat de formaldehyde als metaboliet in de IAZI gevormd wordt uit een groter molecuul. Uitgaande van het formaldehyde aandeel in de twee formaldehyde-bevattende producten zou 25.680 kg "formaldehyde equivalent" geloosd worden, dit is berekend op basis van de gemiddelde opgave stamkaarten 2022/2023. Een verwijderingsrendement van 95% is op basis van voornoemde berekende jaarvracht en effluentanalyses een conservatieve benadering en geeft aan dat formaldehyde in de IAZI zeer goed wordt afgebroken en IAZI als BBT kan worden beschouwd.



5. Immissietoets

In de tabellen 5.1 en 5.2 zijn voor de immissietoets de uitgangspunten en normen gegeven.

Tabel 5.1: Parameters immissietoets

Parameter	Waarde
Maasdebiet 90-%	20 m3/s
Maximale lozing (scenario 1)	1,4 m3/s effluentdebiet
Gemiddelde lozing (scenario 2)	0,95 m3/s effluentdebiet
Toetsing ecologie acuut (MAC-MKE) =PEC15	Concentratie op 15 meter na lozingspunt
Toetsing ecologie chronisch (JG-MKE) =PEC600	Concentratie op rand mengzone = 600 meter na lozingspunt
Toetsing op waterlichaam (KRW)	Concentratie na volledige menging op monitoringspunt
Drinkwatertoets	Indien geen drinkwaterrichtwaarde bekend dan toetsing tegen signaleringswaarde voor overige antropogene stoffen van 1 µg/l

In tabel 5.2 zijn de ecologienormen, de drinkwaterrichtwaarde en de achtergrondconcentratie voor formaldehyde gegeven.

Tabel 5.2: Normen gebruikt in immissietoets

Component	CAS#	MAC-MKE µg/l	JG-MKE µg/l	Drinkwater richtwaarde µg/l	Gemiddelde achtergrond concentratie Maas** µg/l
Formaldehyde	50-00-0	1800 (RIVM)	180 (RIVM)	900 (WHO)*	Niet aanwezig in database RWS

* De onderbouwing van deze WHO-drinkwaternorm is gegeven in bijlage D.

** Door zowel RWS als WML wordt het oppervlaktewater niet geanalyseerd op deze stoffen.

Getoetst is met de gemiddelde formaldehyde concentratie in het effluent van 29 µg/l, bij deze concentratie voldoet de lozing van formaldehyde aan de effluenttoets (stap 1a en 1b) van de immissietoets. Indien getoetst wordt aan de aangevraagde alerteringswaarde (X gemiddeld + 2S; 95% betrouwbaarheidsinterval) dan wordt nog steeds voldaan aan de effluenttoets. In bijlage C zijn als aanvullende informatie de rekenbladen gegeven (stap 3 en verder van de immissietoets).

6. Advies drinkwaterproductie bedrijf

De wijzigingsaanvraag is in concept naar de drinkwaterbedrijven gestuurd voor advies. De terugkoppeling vanuit de drinkwaterbedrijven betrof de relatief hoge drinkwater richtwaarde voor formaldehyde van de WHO. Uit navraag bij het RIVM over beschikbare Nederlandse drinkwaterrichtwaarde voor formaldehyde is de volgende reactie van het RIVM ontvangen:

“Op dit moment is er geen specifieke i-DWR voor deze stof. Er lijkt ook geen geldige Nederlandse kwaliteitseis voor drinkwaterproductie specifiek voor deze stof te zijn. In dat geval kan de richtwaarde van de WHO (900 µg/L) als uitgangspunt worden gebruikt. Voor formaldehyde is in 2019 in het kader van biociden een Aanvaardbaar Effect Niveau (AEL) bepaald. Wanneer deze waarde wordt vertaald naar een drinkwater richtwaarde, komt deze op ongeveer 1050 µg/L. Dit suggereert dat de WHO-richtwaarde aan de veilige kant is en kan dienen voor een immissietoets.”

Naar aanleiding van bovenstaande reactie van het RIVM is aanvullend door WML onderstaande terugkoppeling ontvangen:

“Naar aanleiding van het gesprek dat we een paar weken geleden hebben gevoerd over de te hanteren drinkwaterrichtwaarde voor formaldehyde, en de twijfels die we hadden bij het gebruik van deze richtwaarde op basis van de WHO norm, laat ik je weten dat, gezien de reactie van RIVM (zie bijgevoegde email), het gebruik van deze waarde akkoord te zijn voor het RIVM. Ik stel daarom voor om dit dan ook als uitgangspunt te beschouwen.”



Bijlagen

- A. Stoffenlijst update 15 april 2025, wijzigingsaanvraag formaldehyde
- B. Resultaten formaldehyde bepaling effluent IAZI (2023, 2024 en 2025)
- C. Rekenbladen Immissietoets.
- D. Document WHO; WHO/SDE/WSH/03.04/48, "Formaldehyde in Drinking-water", 2003



BIJLAGE B Overzicht van de analyse resultaten van formaldehyde effluent 2023, 2024 en begin 2025

Datum	Formaldehyde in effluent IAZI (µg/l)
09-01-2023	22
13-02-2023	60
13-03-2023	19
10-04-2023	23
08-05-2023	31
12-06-2023	<5*
10-07-2023	28
14-08-2023	36
11-09-2023	19
09-10-2023	52
13-11-2023	39
11-12-2023	29
08-01-2024	62
12-02-2024	73
19-02-2024	30
26-02-2024	28
04-03-2024	34
11-03-2024	36
18-03-2024	48
25-03-2024	51
01-04-2024	17
08-04-2024	17
15-04-2024	18
22-04-2024	18
29-04-2024	48
06-05-2024	38
13-05-2024	24
10-06-2024	7,9
08-07-2024	72
12-08-2024	45
09-09-2024	<5*
14-10-2024	<5*
11-11-2024	5,6
09-12-2024	17
13-01-2025	9,5
10-02-2025	<5*
10-03-2025	<5*

* de S is berekend met 4,3 (5 µg/l x vb-factor)

Formaldehyde in effluent IAZI (µg/l)	
max	73
min	<5
det grens	5
gemiddeld	29
n	37
n <dg	5
vb-factor	0,86
Standaarddeviatie S	19
X gemiddeld + 2S	67

BIJLAGE C Rekenbladen Immissietoets

De lozing van formaldehyde voldoet aan de effluenttoets (stap 1a en 1b) van de immissietoets op ecologie en drinkwater toetsing. De rekenbladen van de immissietoetsen zijn alleen als aanvullende informatie toegevoegd.

Qmax_JG.

RESULTATENBLAD IMMISSIE TOETS O.B.V. VERDUNNINGSFACTOREN UIT WEBAPPLICATIE IMMISSIE TOETS

Vindt de lozing plaats op zee? ☒ nee

Vindt de lozing plaats op haven? ☒ nee

Resultaten van immissie toets:
dimensies watersysteem:
(breedte en diepte) en
Q₅₀ lage afvoer en lozingsgebied

Resultaten van immissietoets:
mengfactoren op X_{max} en X_L en ter
hoogte van drinkwaterinnamepunt

Wilt u de invloed van hechting aan zwevend stof meenemen bij beoordeling? (dit kan bij lozing van metalen en stoffen die aan zwevend stof hechten van belang zijn?) ☒ ja

Wilt u in geval van metalen corrigeren voor natuurlijke achtergrondconc. ? ☒ ja

Geef zwevend stof concentratie van oppervlaktewater [µg/l] 0.00

aangegeven afvoer in kolom G

dimensies watersysteem:
breedte (m) 50
diepte (m) 0.83
afvoer (m³/s) 50-percentil lage afvoer:
gemiddelde afvoer (m³/s) ter hoogte van monitoringpunt 221
lozingsgebied (m³/s) 1750
Type lozing **bestaand**
is er benedenstrooms sprake van beschermde gebieden (drinkwater, zwembad, natuura 2000, schelpdierwater of overgangswater) ? ☒ ja
geef verdunningsfactor ter hoogte van drinkwaterinnamepunt 15

Verdunningsfactor X-L 600 [m] 3.2284
X-max 15 [m] 2.0652

berekende mengfactor (volledige menging) op monitoringpunt 159

Invoer

resultaten immissietoets (mengzone)

resultaat beschermde gebieden

beoordeling op waterlichaamniveau

overall oordeel

Kp (alleen van belang bij aan zw- stof adsor- berende stoffen)	F- verdunni ng op afst. l	F- verdunni ng op afst. Xmax	F- volledig mon- punt	Natuur- lijke C _{achter- grond} [µg/l]	C _{achter- grond} [µg/l]	eenheid waarin MKN is vastgesteld	Waarde MKN (*)	norm voor norm- toets [µg/l (*)]	meet- nauw- keurig- heid (%)	C _L (rand meng- zone) [µg/l]	AC _L /MKN [%]	C _L [µg/l]	Resultaat van immissietoets	geef achter- grondcon- centratie ter hoogte van drinkwater- innamepunt [µg/l]	Concen- tratie ter hoogte van beschermde gebied [µg/l]	drink- water- norm [µg/l]	oordeel bescherm- de gebieden	C-mon- torings- punt [µg/l]	C-mon > MKN?	AC-mon > meet-nauw- keurig- heid?	Resultaat van toetsing aan prin- cipe van geen achter- uitgang (KRW)	overall oordeel	
Geloopte stof	1	3.22	2.07	158.86	6800.00	29.20	up/l	180	180	10	1000	NEE	9.067	0.04%	2111.57	444.86	900	volledig	42.806	NEE	NEE	volledig	volledig
zwevend stof	1	3.22	2.07	158.86	6800.00	29.20	up/l	180	180	10	1000	NEE	9.067	0.04%	2111.57	444.86	900	volledig	42.806	NEE	NEE	volledig	volledig
Formaldehyde	3	2.07	158.86																				

Qgem_JG

RESULTATENBLAD IMMISSIE TOETS O.B.V. VERDUNNINGSFACTOREN UIT WEBAPPLICATIE IMMISSIE TOETS

Vindt de lozing plaats op zee? ☒ nee

Vindt de lozing plaats op haven? ☒ nee

Resultaten van immissie toets:
dimensies watersysteem:
(breedte en diepte) en
Q₅₀ lage afvoer en lozingsgebied

Resultaten van immissietoets:
mengfactoren op X_{max} en X_L en ter
hoogte van drinkwaterinnamepunt

Wilt u de invloed van hechting aan zwevend stof meenemen bij beoordeling? (dit kan bij lozing van metalen en stoffen die aan zwevend stof hechten van belang zijn?) ☒ ja

Wilt u in geval van metalen corrigeren voor natuurlijke achtergrondconc. ? ☒ ja

Geef zwevend stof concentratie van oppervlaktewater [µg/l] 12662.00

aangegeven afvoer in kolom G

dimensies watersysteem:
breedte (m) 50
diepte (m) 0.83
afvoer (m³/s) 50-percentil lage afvoer:
gemiddelde afvoer (m³/s) ter hoogte van monitoringpunt 221
lozingsgebied (m³/s) 1750
Type lozing **bestaand**
is er benedenstrooms sprake van beschermde gebieden (drinkwater, zwembad, natuura 2000, schelpdierwater of overgangswater) ? ☒ ja
geef verdunningsfactor ter hoogte van drinkwaterinnamepunt 22

Verdunningsfactor X-L 600 [m] 4.1304
X-max 15 [m] 2.1349

berekende mengfactor (volledige menging) op monitoringpunt 234

Invoer

resultaten immissietoets (mengzone)

resultaat beschermde gebieden

beoordeling op waterlichaamniveau

overall oordeel

Kp (alleen van belang bij aan zw- stof adsor- berende stoffen)	F- verdunni ng op afst. l	F- verdunni ng op afst. Xmax	F- volledig mon- punt	Natuur- lijke C _{achter- grond} [µg/l]	C _{achter- grond} [µg/l]	eenheid waarin MKN is vastgesteld	Waarde MKN (*)	norm voor norm- toets [µg/l (*)]	meet- nauw- keurig- heid (%)	C _L (rand meng- zone) [µg/l]	AC _L /MKN [%]	C _L [µg/l]	Resultaat van immissietoets	geef achter- grondcon- centratie ter hoogte van drinkwater- innamepunt [µg/l]	Concen- tratie ter hoogte van beschermde gebied [µg/l]	drink- water- norm [µg/l]	oordeel bescherm- de gebieden	C-mon- torings- punt [µg/l]	C-mon > MKN?	AC-mon > meet-nauw- keurig- heid?	Resultaat van toetsing aan prin- cipe van geen achter- uitgang (KRW)	overall oordeel	
Geloopte stof	1	4.13	2.13	233.63	6800.00	29.20	up/l	180	180	10	1000	NEE	7.069	0.01%	11242.78	12396.18	900	volledig	1263.600	NEE	NEE	volledig	volledig
zwevend stof	1	4.13	2.13	233.63	6800.00	29.20	up/l	180	180	10	1000	NEE	7.069	0.01%	11242.78	12396.18	900	volledig	1263.600	NEE	NEE	volledig	volledig
Formaldehyde	4	2.13	233.63																				



BIJLAGE D Document WHO; WHO/SDE/WSH/03.04/48, "Formaldehyde in Drinking-water", 2003



WHO/SDE/WSH/03.04/48
English only

Formaldehyde in Drinking-water

Background document for development of
WHO *Guidelines for Drinking-water Quality*

Originally published in **Guidelines for drinking-water quality**, 2nd ed. Vol.2. *Health criteria and other supporting information*. World Health Organization, Geneva, 1996.

© World Health Organization 2003

All rights reserved. Publications of the World Health Organization can be obtained from Marketing and Dissemination, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel: +41 22 791 2476; fax: +41 22 791 4857; email: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to Publications, at the above address (fax: +41 22 791 4806; email: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

The World Health Organization does not warrant that the information contained in this publication is complete and correct and shall not be liable for any damages incurred as a result of its use.

Preface

One of the primary goals of WHO and its member states is that “all people, whatever their stage of development and their social and economic conditions, have the right to have access to an adequate supply of safe drinking water.” A major WHO function to achieve such goals is the responsibility “to propose regulations, and to make recommendations with respect to international health matters”

The first WHO document dealing specifically with public drinking-water quality was published in 1958 as International Standards for Drinking-Water. It was subsequently revised in 1963 and in 1971 under the same title. In 1984–1985, the first edition of the WHO Guidelines for drinking-water quality (GDWQ) was published in three volumes: Volume 1, Recommendations; Volume 2, Health criteria and other supporting information; and Volume 3, Surveillance and control of community supplies. Second editions of these volumes were published in 1993, 1996 and 1997, respectively. Addenda to Volumes 1 and 2 of the second edition were published in 1998, addressing selected chemicals. An addendum on microbiological aspects reviewing selected microorganisms was published in 2002.

The GDWQ are subject to a rolling revision process. Through this process, microbial, chemical and radiological aspects of drinking-water are subject to periodic review, and documentation related to aspects of protection and control of public drinking-water quality is accordingly prepared/updated.

Since the first edition of the GDWQ, WHO has published information on health criteria and other supporting information to the GDWQ, describing the approaches used in deriving guideline values and presenting critical reviews and evaluations of the effects on human health of the substances or contaminants examined in drinking-water.

For each chemical contaminant or substance considered, a lead institution prepared a health criteria document evaluating the risks for human health from exposure to the particular chemical in drinking-water. Institutions from Canada, Denmark, Finland, France, Germany, Italy, Japan, Netherlands, Norway, Poland, Sweden, United Kingdom and United States of America prepared the requested health criteria documents.

Under the responsibility of the coordinators for a group of chemicals considered in the guidelines, the draft health criteria documents were submitted to a number of scientific institutions and selected experts for peer review. Comments were taken into consideration by the coordinators and authors before the documents were submitted for final evaluation by the experts meetings. A “final task force” meeting reviewed the health risk assessments and public and peer review comments and, where appropriate, decided upon guideline values. During preparation of the third edition of the GDWQ, it was decided to include a public review via the world wide web in the process of development of the health criteria documents.

During the preparation of health criteria documents and at experts meetings, careful consideration was given to information available in previous risk assessments carried out by the International Programme on Chemical Safety, in its Environmental Health

Criteria monographs and Concise International Chemical Assessment Documents, the International Agency for Research on Cancer, the joint FAO/WHO Meetings on Pesticide Residues, and the joint FAO/WHO Expert Committee on Food Additives (which evaluates contaminants such as lead, cadmium, nitrate and nitrite in addition to food additives).

Further up-to-date information on the GDWQ and the process of their development is available on the WHO internet site and in the current edition of the GDWQ.

Acknowledgements

The work of the following coordinators was crucial in the development of this background document for development of WHO *Guidelines for drinking-water quality*:

J.K. Fawell, Water Research Centre, United Kingdom
(inorganic constituents)
U. Lund, Water Quality Institute, Denmark
(organic constituents and pesticides)
B. Mintz, Environmental Protection Agency, USA
(disinfectants and disinfectant by-products)

The WHO coordinators were as follows:

Headquarters:

H. Galal-Gorchev, International Programme on Chemical Safety
R. Helmer, Division of Environmental Health

Regional Office for Europe:

X. Bonnefoy, Environment and Health
O. Espinoza, Environment and Health

Ms Marla Sheffer of Ottawa, Canada, was responsible for the scientific editing of the document.

The efforts of all who helped in the preparation and finalization of this document, including those who drafted and peer reviewed drafts, are gratefully acknowledged.

The convening of the experts meetings was made possible by the financial support afforded to WHO by the Danish International Development Agency (DANIDA), Norwegian Agency for Development Cooperation (NORAD), the United Kingdom Overseas Development Administration (ODA) and the Water Services Association in the United Kingdom, the Swedish International Development Authority (SIDA), and the following sponsoring countries: Belgium, Canada, France, Italy, Japan, Netherlands, United Kingdom of Great Britain and Northern Ireland and United States of America.

GENERAL DESCRIPTION

Identity

CAS no.: 50-00-00

Molecular formula: CH₂O

The IUPAC name for formaldehyde is methanal.

Physicochemical properties (1–4) [Conversion factor in air: 1 ppm = 1.2 mg/m³ at 25 °C]

<i>Property</i>	<i>Value</i>
Physical state	Colourless gas
Boiling point	-19.2 °C
Melting point	-118 °C
Relative density	1.04 (air = 1)
Vapour pressure	52.6 kPa at -33 °C
Water solubility	Freely miscible at 25 °C
Log octanol–water partition coefficient	-1

Organoleptic properties

Formaldehyde has a pungent, suffocating, hay- or straw-like odour. Taste and odour thresholds are 50 and 25, respectively (3,4).

Major uses

Formaldehyde's main industrial use is in the production of urea–formaldehyde, phenolic, melamine, pentaerythritol, and polyacetal resins. Its second largest use is in the industrial synthesis of a number of organic compounds. It is also used in cosmetics, fungicides, textiles, and embalming fluids (1).

ANALYTICAL METHODS

Formaldehyde in drinking-water is generally determined by a high-performance liquid chromatographic method following derivatization with 2,4-dinitrophenylhydrazine and liquid–solid extraction. The detection limit is 6.2 µg/litre (5).

ENVIRONMENTAL LEVELS AND HUMAN EXPOSURE

Air

Formaldehyde is emitted into air from plastics and resin glues. Low levels in air may also result from the photo-oxidation of hydrocarbons derived from fossil fuel. Typical levels in air are a few µg/m³. Smokers are exposed to high levels of formaldehyde (1,6,7).

Water

Formaldehyde in drinking-water is formed mainly by the oxidation of natural organic (humic) matter during ozonation (8) and chlorination (9). It also enters drinking-water via industrial effluents and leaching from polyacetal plastic fittings. Concentrations of up to 30 µg/litre have been found in ozonated drinking-water (10,11).

Food

Concentrations of formaldehyde ranging from 3 to 23 mg/kg have been reported in a variety of foods (6).

Estimated total exposure and relative contribution of drinking-water

The general population is exposed to formaldehyde mainly by inhalation, smokers receiving about 0.38 mg/day by this route (1,7). People are also exposed by ingesting contaminated drinking-water and food, and from the use of urea–formaldehyde foam in housing insulation, and of cosmetics containing formaldehyde.

KINETICS AND METABOLISM IN LABORATORY ANIMALS AND HUMANS

Ingested formaldehyde is readily absorbed by the gastrointestinal tract. In dermal studies, it was absorbed less readily in monkeys than in rats or guinea-pigs (12). It appears to be distributed mainly to muscle, lower levels being found in the intestines, liver, and other tissues (13).

Formaldehyde is rapidly oxidized to formic acid; the subsequent oxidation to carbon dioxide and water is slower in monkeys than in rats (14). Other metabolic products, such as *N,N*-bis(hydroxymethyl)urea and *N*-(hydroxymethyl)urea, have been reported in rats (15). Metabolites are eliminated in the urine, faeces, and expired air, the relative amounts depending on the route of administration (1,16,17).

EFFECTS ON LABORATORY ANIMALS AND *IN VITRO* TEST SYSTEMS

Acute exposure

Oral LD₅₀s of 800 and 260 mg/kg of body weight have been reported for the rat and guinea-pig, respectively (18).

Short-term exposure

In a 4-week study, Wistar rats (10 per sex per dose) received formaldehyde in drinking-water at doses of 0, 5, 25, or 125 mg/kg of body weight per day. Rats receiving the highest dose showed lowered food and liquid intake, histopathological changes in the stomach (i.e., focal hyperkeratosis of the forestomach, moderate papillomatous hyperplasia), and, in males only, lowered total protein and albumin levels in plasma. The NOAEL was 25 mg/kg of body weight per day (1,19).

Oral doses of 0, 50, 100, or 150 mg/kg of body weight per day in rats and 0, 50, 75, or 100 mg/kg of body weight per day in dogs for 91 days had no effect on haematology, clinical chemistry, urinalysis, or gross microscopic pathology. Depression in body weight gain was observed in both species at the highest dose levels and in male rats given 100 mg/kg of body weight per day (20).

Long-term exposure

In a 2-year study, Wistar rats were exposed to formaldehyde in drinking-water at mean doses of 0, 1.2, 15, or 82 mg/kg of body weight per day for males and 0, 1.8, 21, or 109 mg/kg of body weight per day for females. Adverse effects were observed only in animals receiving the highest dose and included lower food and liquid intake, lower body weights, and pathological changes in the stomach, characterized by thickening of the mucosal wall. Relative kidney weights were increased in high-dose females, and an increased incidence of renal papillary

necrosis was found in both sexes. Exposure did not appear to affect survival, haematology, or clinical chemistry. The NOAEL was 15 mg/kg of body weight per day (21).

In a similar study, Wistar rats were given formaldehyde in drinking-water at 10, 50, or 300 mg/kg of body weight per day. At the end of 12 months, rats of both sexes in the high-dose group were observed to have gastric erosions, ulcers, squamous cell hyperplasia, hyperkeratosis, and basal cell hyperplasia. Only one male and one female from the mid-dose group showed hyperkeratosis (1,22).

Reproductive toxicity, embryotoxicity, and teratogenicity

No teratogenic effects were reported in mice given formaldehyde at oral doses of 0, 74, 148, or 185 mg/kg of body weight per day on days 6–15 of gestation (23). Growth and viability of neonates from mice given oral doses of 540 mg/kg of body weight per day on days 8–12 of gestation were unaffected (24). No effects on reproductive performance or on the health of offspring were observed in beagle dogs fed 0, 3.1, or 9.4 mg of formaldehyde per kg of body weight per day in their diet on days 4–56 after mating (25). Sperm abnormalities were observed in male rats given single oral doses of 100–200 mg/kg of body weight (26). Intraperitoneal injection of formaldehyde at 8 or 16 mg/kg of body weight per day for 10 days resulted in degeneration of testicular tissue, inhibition of spermatogenesis, and lowered male reproductive organ weights in rats (27).

Mutagenicity and related end-points

Formaldehyde has shown evidence of mutagenicity in prokaryotic and eukaryotic cells *in vitro*. It has also been shown to be genotoxic in *Drosophila melanogaster*. Formaldehyde binds readily to proteins, RNA, and single-stranded DNA to induce DNA–protein cross-links and breaks in single-stranded DNA. It reacts readily with macromolecules in cells, mainly at the point of exposure (28). *In vivo*, formaldehyde increases both DNA synthesis in rats (29) and the number of micronuclei and nuclear anomalies in epithelial cells in rats (30).

Carcinogenicity

There is little evidence that formaldehyde is carcinogenic by the oral route. In a 2-year study in which Wistar rats were exposed to formaldehyde in drinking-water at mean doses of 0, 1.2, 15, or 82 mg/kg of body weight per day for males and 0, 1.8, 21, or 109 mg/kg of body weight per day for females, exposure did not appear to affect tumour incidence (21). In a 2-year study in which Sprague-Dawley rats were exposed to formaldehyde in drinking-water at dose levels of 0, 1, 5, 10, 50, 100, or 150 mg/kg of body weight per day, a dose-dependent increase in the incidence of leukaemia (mainly lymphoblastic) and lymphosarcoma was reported at dose levels of 5 mg/kg of body weight per day or greater. The increase in the incidence of gastrointestinal neoplasms was not dose-related. Tumours of this type were rare in historical controls and not detected in concurrent controls (31).

In a carcinogenicity study, a group of 10 rats was given drinking-water containing 0.5% formalin (0.2% formaldehyde) for 32 weeks. Histopathological changes were observed in the stomach, as well as neoplastic changes in the forestomach and papillomas. In addition, the authors reported evidence that formaldehyde had tumour-promoting activity. However, because of the presence of high levels of methanol in formalin, the usefulness of this information is limited (32). In another study, formaldehyde induced ornithine decarboxylase activity (an indication of tumour-promoting activity) in rats given a single oral formaldehyde dose of up to 100 mg/kg of body weight (29). There is no evidence that formaldehyde acts as a carcinogen or promoter when applied to mouse skin (33).

There is some evidence that inhalation exposure to formaldehyde causes cancer in rats and mice by irritating the nasal epithelium. Rats exposed to 17 mg of formaldehyde per m³, 6 h per day, 5 days per week for 2 years, exhibited an increased incidence of squamous cell carcinoma of the nasal cavity. Tumours were also noted in mice at the same level of exposure, but this species was less sensitive than the rat (34,35).

EFFECTS ON HUMANS

Irritation and allergic contact dermatitis have been associated with exposure of the skin to formaldehyde at levels higher than those encountered in drinking-water (36). Its presence in some types of water filters has been associated with the occurrence of haemolytic anaemia in dialysis patients (1,37).

There is some evidence that formaldehyde is a carcinogen in humans exposed by inhalation. Epidemiological investigations of the mortality of factory workers following prolonged occupational exposure to formaldehyde showed a slight excess of lung cancer that was not related to formaldehyde exposure (2,38). An increase in the incidence of nasopharyngeal cancer was also noted but again did not appear to be related to formaldehyde (39).

GUIDELINE VALUE

Rats and mice exposed to formaldehyde by inhalation exhibited an increased incidence of carcinomas of the nasal cavity at doses that caused irritation of the nasal epithelium (34,35). Ingestion of formaldehyde in drinking-water for 2 years caused stomach irritation in rats (21,22). Papillomas of the stomach associated with severe tissue irritation were observed in one study (32).

On the basis of studies in which humans and experimental animals were exposed to formaldehyde by inhalation, IARC has classified formaldehyde in Group 2A (40). The weight of evidence indicates that formaldehyde is not carcinogenic by the oral route. A guideline value has been derived, therefore, on the basis of a TDI. A TDI of 150 µg/kg of body weight was calculated based on the NOAEL of 15 mg/kg of body weight per day in a 2-year study in rats (21), incorporating an uncertainty factor of 100 (for intra- and interspecies variation). No account was taken of potential carcinogenicity from the inhalation of formaldehyde from various indoor water uses, such as showering. With an allocation of 20% of the TDI to drinking-water, the guideline value is 900 µg/litre.

REFERENCES

1. *Formaldehyde*. Geneva, World Health Organization, 1989 (Environmental Health Criteria, No. 89).
2. Acheson ED et al. Formaldehyde process workers and lung cancer. *Lancet*, 1984, 1(8385):1066-1067 (letter).
3. Bills TD, Marking LL, Chandler JH. *Investigation in fish control. 73. Formalin: Its toxicity to nontarget aquatic organisms, persistence and counteraction*. Washington, DC, US Department of the Interior, Fish and Wildlife Service, 1977:1-7.
4. Verschueren K. *Handbook of environmental data on organic chemicals*, 2nd ed. New York, Van Nostrand Reinhold, 1983:678-679.
5. Environmental Monitoring Systems Laboratory. *Method 554. Determination of carbonyl compounds in drinking water by DNPH derivatization and high performance liquid chromatography (HPLC)*. Cincinnati, OH, US Environmental Protection Agency, 1991.
6. International Agency for Research on Cancer. *Some industrial chemicals and dyestuffs*. Lyon, 1982:345-389 (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Volume 29).

7. National Research Council. *Formaldehyde: an assessment of its health effects*. Washington, DC, National Academy of Sciences, 1980.
8. Glaze WH, Koga M, Cancilla D. Ozonation by-products. 2. Improvement of an aqueous-phase derivatization method for the detection of formaldehyde and other carbonyl compounds formed by the ozonation of drinking water. *Environmental science and technology*, 1989, 23:838-847.
9. Becher G, Ovrum NM, Christman RF. Novel chlorination by-products of aquatic humic substances. *Science of the total environment*, 1992, 117/118:509-520.
10. Tomkins BA et al. Liquid chromatographic determination of total formaldehyde in drinking water. *Journal of the Association of Official Analytical Chemists*, 1989, 72:835-839.
11. Krasner SW et al. The occurrence of disinfection by-products in US drinking water. *Journal of the American Water Works Association*, 1989, 81:41-53.
12. Jeffcoat AR. *Percutaneous penetration of formaldehyde. Final report (July 1981-July 1983)*. Research Triangle Park, NC, Research Triangle Institute, 1983:59.
13. Bhatt HS, Lober SB, Combes B. Effect of glutathione depletion on aminopyrine and formaldehyde metabolism. *Biochemical pharmacology*, 1988, 37:1581-1589.
14. McMartin KE et al. Methanol poisoning. V. Role of formate metabolism in the monkey. *Journal of pharmacology and experimental therapeutics*, 1977, 201:564-572.
15. Mashford PM, Jones AR. Formaldehyde metabolism by the rat: a re-appraisal. *Xenobiotica*, 1982, 12:119-124.
16. Galli CL et al. Toxicological evaluation in rats and mice of the ingestion of a cheese made from milk with added formaldehyde. *Food chemistry and toxicology*, 1983, 21:313-317.
17. Upreti RK et al. Toxicokinetics and molecular interaction of [¹⁴C]-formaldehyde in rats. *Archives of environmental contamination and toxicology*, 1987, 16:263-273.
18. Smyth HF Jr, Seaton J, Fischer L. The single dose toxicity of some glycols and derivatives. *Journal of industrial hygiene and toxicology*, 1941, 23:259-268.
19. Til HP et al. Evaluation of the oral toxicity of acetaldehyde and formaldehyde in a 4-week drinking-water study in rats. *Food chemistry and toxicology*, 1988, 26:447-452.
20. Johannsen FR, Levinskas GJ, Tegeris AS. Effects of formaldehyde in the rat and dog following oral exposure. *Toxicology letters*, 1986, 30:1-6.
21. Til HP et al. Two-year drinking-water study of formaldehyde in rats. *Food chemistry and toxicology*, 1989, 27:77-87.
22. Tobe M, Naito K, Kurokawa Y. Chronic toxicity study of formaldehyde administered orally to rats. *Toxicology*, 1989, 56:79-86.
23. Marks TA, Worthy WC, Staples RE. Influence of formaldehyde and Sonacide (potentiated acid glutaraldehyde) on embryo and fetal development in mice. *Teratology*, 1980, 22:51-58.
24. Seidenberg JM, Anderson DG, Becker RA. Validation of an *in vivo* developmental toxicity screen in the mouse. *Teratogenesis, carcinogenesis and mutagenesis*, 1987, 6:361-374.
25. Hurni H, Ohder H. Reproduction study with formaldehyde and hexamethylenetetramine in beagle dogs. *Food and cosmetics toxicology*, 1977, 11:459-462.
26. Cassidy SL, Dix KM, Jenkins T. Evaluation of a testicular sperm head counting technique using rats exposed to dimethoxyethyl phthalate (DMEP), glycerol alpha-monochlorohydrin (GMCH), epichlorohydrin (ECH), formaldehyde (FA), or methyl methanesulphonate (MMS). *Archives of toxicology*, 1983, 53:71-78.
27. Shah BM et al. Formaldehyde-induced structural and functional changes in the testis of rats. *Journal of reproductive biology and comparative endocrinology*, 1987, 7:42-52.
28. Ma TM, Harris MM. Review of the genotoxicity of formaldehyde. *Mutation research*, 1988, 196:37-59.
29. Overman DO. Absence of embryotoxic effects of formaldehyde after percutaneous exposure in hamsters. *Toxicology letters*, 1985, 24:107-110.
30. Migliore L et al. Micronuclei and nuclear anomalies induced in the gastrointestinal epithelium of rats treated with formaldehyde. *Mutagenesis*, 1989, 4(5):327-334.

31. Soffritti M et al. Formaldehyde: an experimental multipotential carcinogen. *Toxicology and industrial health*, 1989, 5(5):699-730.
32. Takahashi M et al. Effects of ethanol, potassium metabisulfite, formaldehyde and hydrogen peroxide on gastric carcinogenesis in rats after initiation with *N*-methyl-*N*^l-nitro-*N*-nitrosoguanidine. *Japanese journal of cancer research (Gann)*, 1986, 77:118-124.
33. Krivanek ND, Chromey NC, McAlack JW. Skin initiation-promotion study with formaldehyde in CD-1 mice. In: Clary JJ, Gibson JE, Waritz RS, eds. *Formaldehyde: toxicology, epidemiology, mechanisms*. New York, Marcel Dekker, 1983:159-171.
34. Swenberg JA et al. Induction of squamous cell carcinomas of the rat nasal cavity by inhalation exposure to formaldehyde vapor. *Cancer research*, 1980, 40:3398-3402.
35. Kerns WD et al. Carcinogenicity of formaldehyde in rats and mice after long-term inhalation exposure. *Cancer research*, 1983, 43:4382-4392.
36. Cosmetic, Toiletry and Fragrance Association. Final report on the safety assessment of formaldehyde. *Journal of the American College of Toxicologists*, 1984, 3:157-184.
37. Beall JR. Formaldehyde in dialysis patients. A review. In: Turosk V, ed. *Formaldehyde: analytical chemistry and toxicology*. Washington, DC, Chemical Society, 1985:275-287 (Advances in Chemistry Series, Vol. 210).
38. Acheson ED et al. Formaldehyde in the British chemical industry. An occupational cohort study. *Lancet*, 1984, 1(8377):611-616.
39. Collins JJ et al. Formaldehyde exposure and nasopharyngeal cancer: re-examination of the National Cancer Institute study and an update of one plant. *Journal of the National Cancer Institute*, 1988, 80:376-377.
40. International Agency for Research on Cancer. *Overall evaluations of carcinogenicity: an updating of IARC Monographs volumes 1-42*. Lyon, 1987:211-216 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Suppl. 7).