Environmental effects

Effects on aquatic life

Chemicals in this evaluation undergo hydrolysis to form formaldehyde, ammonium cations and other products. Organisms in the aquatic environment will be exposed to a combination of these chemicals and their breakdown products.

Ecotoxicity information is available for formaldehyde (Eisentraeger et al. 2003; NICNAS 2006; OECD 2002; REACH n.d.-b). Ammonium cations are considered to be ubiquitous in the environment, although ammonia in solution can be harmful to fish at elevated pH > 8 (McCormick et al. 1984). Methylamine has previously been evaluated as low risk (NICNAS 2020), with acute aquatic ecotoxicity results >31 mg/L under buffered conditions (OECD 2011). Calculated acute endpoints for 3-chloroallylamine are all >15 mg/L (US EPA 2017b), which is above the pivotal endpoint for Quaternium-15.

Acute toxicity

Acute toxicity data are available for two chemicals in this group: methenamine and cis-Quaternium-15 (CAS RN 51229-78-8). The ecotoxicity of methenamine hydrochloride is expected to be similar to the ecotoxicity of methenamine. Quaternium-15 is expected to have higher ecotoxicity than methenammonium chloride due to its chlorallyl functional group.

The following acute endpoints are sourced from the REACH registration dossiers for the respective compounds (REACH n.d.-a; n.d.-c). Endpoints for the hydrolysis product formaldehyde (CAS RN 50 00 0) are also shown for comparison (Eisentraeger et al. 2003; NICNAS 2006; OECD 2002):

Taxon	Chemical	Endpoint	Method
Fish	Methenamine	96 h LC50 = 41,000 mg/L	*Lepomis macrochirus* (bluegill) Nominal concentrations US EPA 660
Fish	Quaternium-15 (cis-isomer)	96 h LC50 = 26 mg/L	*Unknown species* Semi-static OECD TG 203
Fish	Formaldehyde	96 h LC50 = 6.7 mg/L	*Morone saxatilis* (striped bass) Semi-static, nominal concentrations
Invertebrate	Methenamine	48 h EC50 = 36,000 mg/L	*Daphnia magna* (Water flea) Immobilisation Nominal concentrations ATSM
Invertebrate	Quaternium-15 (cis-isomer)	48 h EC50 = 25.8 mg/L	*Daphnia magna* (water flea) Immobilisation OECD TG 202
Invertebrate	Formaldehyde	48 h EC50 = 5.8 mg/L	*Daphnia pulex* (water flea) Immobilisation Static, nominal concentrations OECD TG 202
Algae	Methenamine	14 d EC50 = 3,000 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate Nominal concentrations US EPA
Algae	Quaternium-15 (cis-isomer)	72 h EC50 = 1.5 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201
Algae	Formaldehyde	72 h EC50 = 4.89 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate Static, nominal concentrations OECD TG 201

Chronic toxicity

Chronic endpoints for fish are not available for any chemical in this group. The only chronic toxicity available is a 21-d reproduction test for Quaternium-15 (cis-isomer) on an unspecified invertebrate species (REACH n.d.-c) and the no observed effect concentration (NOEC) values from the algae tests for methenamine and Quaternium-15 (cis-isomer), which can be used to evaluate the chronic toxicity to this taxon (EPHC 2009). Chronic toxicity data for formaldehyde are also shown for a comparison (OECD 2002; REACH n.d.-b):

Taxon	Chemical	Endpoint	Method
Invertebrates	Quaternium-15 (cis-isomer)	21 d NOEC = 19.8 mg/L	*Unknown sp.,* Reproduction Semi-static OECD TG 211
Invertebrates	Formaldehyde	21 d NOEC = 6.4 mg/L	*Daphnia magna* (water flea) Reproduction Semi-static, nominal concentrations OECD TG 211
Algae	Methenamine	14 d NOEC = 1,500 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate, nominal concentrations US EPA
Algae	Quaternium-15 (cis-isomer)	72 h NOEC = 0.35 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201

Effects on terrestrial life

Information about the toxicity of Quaternium-15 to birds is available. Quaternium-15 (mixed isomer) is slightly toxic to bird via oral exposures. Median lethal dose (LD50) values for acute oral toxicity were ≥1440 mg/kg for mallard duck (US EPA 1995). LD50 values for subacute dietary toxicity were ≥2,645 ppm for bobwhite quail and mallard duck (US EPA 1995).

Effects on sediment dwelling life

No ecotoxicity data are available for any of these chemicals in this group.

Endocrine effects/activity

No data were identified. Endocrine activity is not expected for any of these chemicals in this group, and none of their degradation products have known endocrine activity in aquatic organisms.

Predicted no-effect concentration (PNEC)

PNEC values have been calculated for methenamine and for the Quaternium-15 isomers.

The lowest chronic endpoints are for the algae *R. subcapitata* with endpoint values of 1,500 mg/L for methenamine and 0.35 mg/L for Quaternium-15.

Given that chronic ecotoxicity data for methenamine are available only for one trophic level, an assessment factor of 100 is used for this chemical. This results in a predicted no effect concentration (PNEC) of 15 mg/L for methenamine.

The toxicity of Quaternium-15 to algae is one order of magnitude lower than endpoints for other trophic levels. This suggests that algae are the most sensitive trophic level to Quaternium-15. As acute and chronic data are available for algae, an assessment factor of 10 has been used (EPHC 2009). This results in a PNEC of 0.035 mg/L (35 µg/L) for Quaternium-15.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to domestic environmental hazard thresholds is presented below:

Persistence

Not Persistent (Not P). Based on measured hydrolysis and evidence of biodegradation, all chemicals in this group are categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on log K_{OW} values <4.2, all chemicals in this group are categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available aquatic toxicity endpoints above domestic threshold values for these chemicals and their degradation products, all chemicals in this group are categorised as Not Toxic.

Environmental risk characterisation

The environmental risk assessment of these chemicals in this evaluation considers releases from their industrial uses into wastewater as the main release pathway. After treatment in STPs, the remaining chemicals in the effluent may be released into the aquatic environment.

The concentrations of releases in effluents of STPs were determined according to the exposure scenarios identified in the exposure section above.

The following Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for emissions of methenamine and Quaternium 15 isomers into the aquatic environment through STP effluents under these two scenarios:

Chemical	PEC	PNEC	RQ
Methenamine	63.6 µg/L	15,000 µg/L	<0.01
Quaternium-15 isomers	31.8 µg/L	35 µg/L	0.91

The RQs for methenamine hydrochloride and methenammonium chloride are expected to be lower than Quaternium-15 isomers.

Calculated RQ values less than 1 indicate that these chemicals in this evaluation are not expected to pose a significant risk to the aquatic environment. Environmental concentrations are expected to be below levels likely to cause harmful effects in typical environmental conditions.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in scope. Some relatively common data limitations can be addressed through use of conservative assumptions (OECD 2019) or quantitative adjustments such as assessment factors (OECD 1995). Others must be addressed qualitatively, or on a case-by-case basis (OECD 2019).

The most consequential areas of uncertainty for this evaluation are:

- The estimated RQ values are likely to be overestimates of risk. The PEC calculation did not consider the removal of these chemicals due to the hydrolytic breakdown of these chemicals or any removal to sludge, soil, or sediment through charge effects.
- Introduction volume data for all chemicals in this group except methenamine are unknown. The default introduction volume of 100 tonnes/year for the other chemicals could be an overestimate resulting in overestimated RQ values; and
- No environmental monitoring data for these chemicals or the non-formaldehyde degradants were identified. In their absence, standard exposure modelling was required to calculate a worst-case PEC.

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