Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Hydroxymethylated imidazolidinones

Evaluation statement

14 December 2023

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AICIS evaluation statement

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Hydroxymethylated imidazolidinones

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Reason for the evaluation

Evaluation Selection Analysis indicated a potential environmental risk.

Parameters of evaluation

This evaluation considers the environmental risks associated with the industrial uses of hydroxymethylated imidazolidinones. These chemicals have been assessed for:

- default Australian introduction volume of 100 tonnes per annum
- industrial uses listed in the ‘Summary of Use’ section
- expected emission into sewage treatment plants (STPs) due to consumer and commercial uses.

The following acronyms and abbreviations have been used in this evaluation:

- MDM hydantoin (2,4-Imidazolidinedione, 1-(hydroxymethyl)-5,5-dimethyl-; CAS RN 116-25-6)
- DMEU (2-Imidazolidinone, 1,3-bis(hydroxymethyl)-; CAS RN 136-84-5)
- DMDHEU (2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-; CAS RN 1854-26-8)
- TMAD (Imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)-; CAS RN 5395-50-6)
- DMDM hydantoin (2,4-Imidazolidinedione, 1,3-bis(hydroxymethyl)-5,5-dimethyl-; CAS RN 6440-58-0)
- Imidazolidinyl urea (Urea, N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-; CAS RN 39236-46-9)
- Diazolidinyl urea (Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-; CAS RN 78491-02-8)

Summary of evaluation

Summary of introduction, use and end use

Hydroxymethylated imidazolidinones are used in a wide variety of consumer, household and industrial products including:

- adhesives,
- arts and crafts products,
- automotive care products,
- cleaning products,
- construction products, including resins for particle board manufacture,
- cosmetics and personal care products,
- laundry and dishwashing products,
- lubricants, including metal cutting fluids,
- paints and coatings,
- plastics, rubber and polymers,
- textile and leather finishing agents.

Some chemicals may also have use as intermediates in the manufacturing of polymers and textile dyes.

Limited Australian use information is available for chemicals in this evaluation.

Some chemicals in this group were reported to have high international use volumes in the United States of America and in the European Economic Area.

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds (DCCEEW n.d.) and based on the available data these chemicals are:

- Not Persistent (not P)
- Not Bioaccumulative (not B)
- Not Toxic (not T)

Environmental hazard classification

Sufficient information for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is available for some chemicals in this evaluation (UNECE 2017).

Chemicals TMAD and diazolidinyl urea satisfy the GHS criteria for classification as Aquatic Acute Category 2 (H401):

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 2	H401: Toxic to aquatic life

Chemicals DMDM hydantoin and DMDHEU satisfy the GHS criteria for classification as Aquatic Acute Category 3 (H402):

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 3	H402: Harmful to aquatic life

Summary of environmental risk

Hydroxymethylated imidazolidinones are present in a variety of products. These chemicals are expected to be released to wastewater through the use of these products. Ultimately, these chemicals are released to the aquatic environment after treatment in sewage treatment plants (STP).

Hydroxymethylated imidazolidinones are not persistent in the environment and have a low potential for bioaccumulation. These chemicals are not toxic according to domestic threshold values.

Based on the worst case exposure scenario, the concentrations of these chemicals in STP effluent are expected to be below the level of concern. The calculated risk quotient value (RQ) for these chemicals is less than 1. Therefore, current use of these chemicals is not expected to pose a significant risk to the environment.

Conclusions

The Executive Director is satisfied that the identified risks to the environment from the introduction and use of the industrial chemicals can be managed.

Note:

1. Obligations to report additional information about hazards under *Section 100* of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Grouping rationale

This evaluation considers the environmental risk of 10 hydroxymethylated imidazolidinone chemicals. The evaluation has been performed as a group, as these chemicals are structurally similar, share similar uses, and are expected to undergo similar primary degradation.

The 10 chemicals in this evaluation contain imidazolidinone rings that are substituted with hydroxymethyl groups. These chemicals hydrolyse and release formaldehyde (CAS RN: 50-00-0), a chemical with biocidal activity.

The evaluation selection analysis for this group of chemicals indicated a potential risk to aquatic organisms.

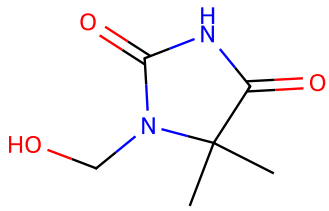
Chemical identity

Five chemicals in this group have the core structure of 2,4-imidazolidinone (hydantoin) (CAS RN: 461-72-3) with differences in the positions of one or several hydroxymethyl groups and other substitutions on the carbon in the 5th ring position. One chemical (CAS RN: 39236-46-9) has two hydantoin rings linked by two urea molecules.

The other five chemicals have the structure of 2-imidazolidinone (ethylene urea) (CAS RN: 120-93-4), where the 5 membered ring has only one ketone group between the two nitrogen atoms. The positions of the hydroxymethyl groups and other substitutions differentiate these chemicals. One chemical (CAS RN: 5395-50-6) has a fused bicyclic structure.

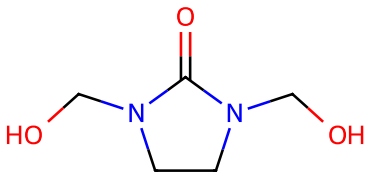
Chemical name	2,4-Imidazolidinedione, 1-(hydroxymethyl)-5,5-dimethyl-
CAS RN	116-25-6
Synonyms	MDM hydantoin 1-(hydroxymethyl)-5,5-dimethylhydantoin 1-(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione
Molecular formula	$C_6H_{10}N_2O_3$
Molecular weight (g/mol)	158.16
SMILES (canonical)	O=C1NC(=O)C(N1CO)(C)C
Chemical description	-

Structural formula:

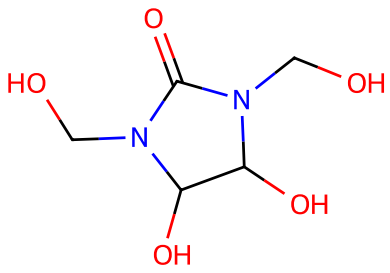


Chemical name	2-Imidazolidinone, 1,3-bis(hydroxymethyl)-
CAS RN	136-84-5
Synonyms	dimethylol ethylene urea
	DMEU
	1,3-bis(hydroxymethyl)imidazolidin-2-one
	1,3-dimethylol-2-imidazolidinone
Molecular formula	$C_5H_{10}N_2O_3$
Molecular weight (g/mol)	146.14
SMILES (canonical)	O=C1N(CO)CCN1CO
Chemical description	-

Structural formula:



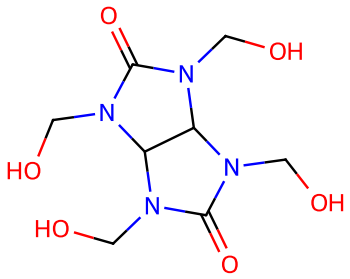
Chemical name	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-
CAS RN	1854-26-8
Synonyms	dimethyloldihydroxyethyleneurea
	DMDHEU

	4,5-dihydroxy-1,3-bis(hydroxymethyl)imidazolidin-2-one
	N,N'-dimethylol-4,5-dihydroxyethyleneurea
Molecular formula	$C_5H_{10}N_2O_5$
Molecular weight (g/mol)	178.14
SMILES (canonical)	O=C1N(CO)C(O)C(O)N1CO
Chemical description	-
Structural formula:	

Chemical name	Imidazo[4,5-d]imidazole-2,5(1H,3H)-dione, tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)-
CAS RN	5395-50-6
Synonyms	tetramethylol acetylenediurea
	TMAD
	tetramethylolglycoluril
	1,3,4,6-tetrakis(hydroxymethyl)tetrahydroimidazo[4,5-d]imidazole-2,5(1H,3H)-dione
	tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione
	tetramethylol acetylene diuriene
Molecular formula	$C_8H_{14}N_4O_6$
Molecular weight (g/mol)	262.22

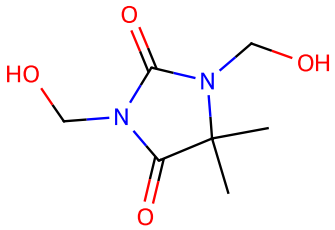
SMILES (canonical)	O=C1N(CO)C2N(C(=O)N(CO)C2N1CO)CO
Chemical description	-

Structural formula:



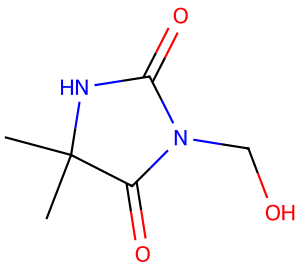
Chemical name	2,4-Imidazolidinedione, 1,3-bis(hydroxymethyl)-5,5-dimethyl-
CAS RN	6440-58-0
Synonyms	DMDM hydantoin Dimethyloldimethyl hydantoin 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione 1,3-di(hydroxymethyl)-5,5-dimethylhydantoin
Molecular formula	$C_7H_{12}N_2O_4$
Molecular weight (g/mol)	188.18
SMILES (canonical)	O=C1N(C(=O)C(N1CO)(C)C)CO
Chemical description	-

Structural formula:



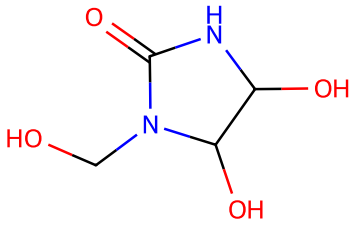
Chemical name	2,4-Imidazolidinedione, 3-(hydroxymethyl)-5,5-dimethyl-
CAS RN	16228-00-5
Synonyms	2,4-imidazolidinedione, 3-(hydroxymethyl)-5,5-dimethyl- 3-(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione 3-hydroxymethyl-5,5-dimethylhydantoin
Molecular formula	$C_6H_{10}N_2O_3$
Molecular weight (g/mol)	158.16
SMILES (canonical)	O=C1NC(C(=O)N1CO)(C)C
Chemical description	-

Structural formula:

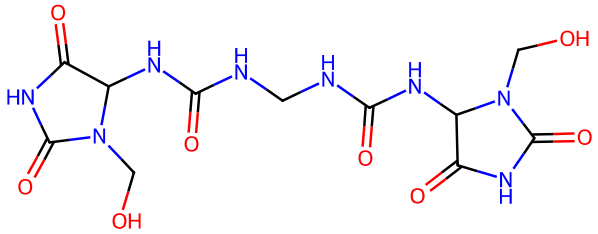


Chemical name	2-Imidazolidinone, 4,5-dihydroxy-1-(hydroxymethyl)-
CAS RN	20662-57-1
Synonyms	4,5-dihydroxy-1-(hydroxymethyl)imidazolidin-2-one
Molecular formula	$C_4H_8N_2O_4$
Molecular weight (g/mol)	148.12
SMILES (canonical)	O=C1NC(O)C(O)N1CO
Chemical description	-

Structural formula:



Chemical name	Urea, N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-
CAS RN	39236-46-9
Synonyms	imidazolidinyl urea 1,1'-methylenebis(3-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea) 1-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-3-[[[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]carbamoylamino]methyl]urea N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
Molecular formula	$C_{11}H_{16}N_8O_8$
Molecular weight (g/mol)	388.29
SMILES (canonical)	O=C(NCNC(=O)NC1C(=O)NC(=O)N1CO)NC2C(=O)NC(=O)N2CO
Chemical description	-



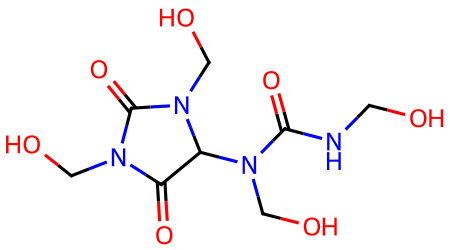
Structural formula:

Chemical name	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated

CAS RN	68411-81-4
Synonyms	dihydroxydimethylolethyleneurea, methylated 4,5-dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidinone, methylated
Molecular formula	$C_6H_{12}N_2O_5$
Molecular weight (g/mol)	192.18
SMILES	N/A
Chemical description	UVCB substance with the same structure as 1854-26-8 with any of the hydroxymethyl groups methylated.

Chemical name	Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-
CAS RN	78491-02-8
Synonyms	diazolidinyl urea 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea
Molecular formula	$C_8H_{14}N_4O_7$
Molecular weight (g/mol)	278.22
SMILES (canonical)	O=C(NCO)N(CO)C1C(=O)N(C(=O)N1CO)CO
Chemical description	-

Structural formula:



Relevant physical and chemical properties

Information on the properties of these chemicals was taken from the ECHA registration dossiers for four substances (REACH n.d.-a; n.d.-b; n.d.-j; n.d.-k) and a SIDS report (OECD 2000). All calculated values are from EPI Suite (US EPA 2017). No information on properties is available for the remaining five chemicals.

Chemical	DMDHEU	TMAD	DMDM Hydantoin	Imidazolidinyl urea	Diazolidinyl urea
Physical form	liquid	liquid	solid	solid	solid
Melting point (in °C)	-35 (exp.)	-13 (exp.)	90 (exp.)	240.5 (exp.)	157.8 (exp.)
Boiling point (in °C)	106 (exp.)	100.2 (exp.)	198 - 200 (exp.)	>380°C (calc.)	>380°C (calc.)
Vapour pressure (Pa)	1,440 (calc.)	1,990 (calc.)	1.2×10^{-5} (exp.)	$<1.3 \times 10^{-7}$ (calc.)	2.3×10^{-8} (exp.)
Water solubility (g/L)	>1,000 (calc.)	>1,000 (calc.)	140* (exp.)	>1,000 (exp.)	>1,000 (exp.)
Henry's law constant ($Pa \cdot m^3/mol$ at 25 °C)	$<1.0 \times 10^{-3}$ (calc.)	$<1.0 \times 10^{-3}$ (calc.)	$<1.0 \times 10^{-3}$ (calc.)	$<1.0 \times 10^{-3}$ (calc.)	$<1.0 \times 10^{-3}$ (calc.)
Ionisable in the environment?	No	No	No	No	No
log K_{ow}	-2.2 (exp.)	-2.0 (exp.)	-2.9 (exp.)	< 0.9 (exp. read across)	< 0.9 (exp.)

*Value taken from the hydrolysis product

Chemicals in this evaluation are readily soluble in water. These chemicals are not expected to ionise at environmental pH. The very low Henry's law constants for all chemicals suggest that these chemicals are unlikely to volatilise from water surfaces.

Introduction and use

Australia

Limited Australian use information is available for chemicals in this evaluation.

The total volume of TMAD introduced into Australia, reported under previous mandatory and/ or voluntary calls for information, was less than 100 tonnes. Use information was not specified (NICNAS 2016).

Information collected from industry in the year 2000 indicated that 16 tonnes of DMDM hydantoin were imported in Australia. Smaller amounts of imidazolidinyl urea were also imported in the year 2000 (NICNAS 2006). The reported uses of these chemicals included preservatives, biocides in industrial emulsions, and as hardeners in the manufacture of phenolic based refractory binders.

Consolidated information provided by Accord Australasia and their Members (in 2023) indicated that only DMDM hydantoin and imidazolidinyl urea were in current use in personal care products, cosmetics, or cleaning products in Australia. For these uses, the reported annual use volumes were <250 kg/year for DMDM hydantoin and <150 kg/year for imidazolidinyl urea.

International

International use information for chemicals in this evaluation has been gathered from registration dossiers submitted under REACH (REACH n.d.-a; n.d.-b; n.d.-j; n.d.-k), PubChem compound summaries (NCBI n.d.-a; n.d.-b; n.d.-c; n.d.-d; n.d.-e; n.d.-f; n.d.-g; n.d.-h; n.d.-i), information provided under the United States of America Chemical Data Reporting rule (US EPA n.d.), and from OECD assessment dossiers (OECD 2000).

Hydroxymethylated imidazolidinones are used worldwide in a variety of consumer, commercial and industrial products including:

- adhesives and sealants
- arts, crafts and hobby products
- automotive care products
- cleaning products
- construction products, including resins for particle board manufacture
- cosmetics and personal care products
- laundry and dishwashing products
- lubricants, including hydraulic fluids
- paints and coatings
- plastics, rubber and polymers.

Four chemicals (MDM hydantoin, DMEU, TMAD, and DMDM hydantoin) are also used as intermediates in the production of amino resins and polymer products (NCBI n.d.-f; n.d.-g; REACH n.d.-a; n.d.-j; US EPA n.d.).

DMDM hydantoin, DMEU and DMDHEU also have use in textile and leather finishing (NCBI n.d.-g; OECD 2000; Stuart et al. 2001).

Six chemicals in this evaluation have reported use volumes in the United States of America (USA) under the Chemical Data Reporting rule. DMDM hydantoin and diazolidinyl urea have reported volumes of 454–9,070 tonnes per year. DMDHEU has a reported use volume of 1,050 tonnes per year. TMAD and imidazolidinyl urea have reported use volumes up to 454 tonnes per year. MDM Hydantoin is reported at 26 tonnes per annum (US EPA n.d.).

Four chemicals are registered under the REACH legislation for use in the European Economic Area. DMDM hydantoin is registered for use at 1,000–10,000 tonnes per year. Imidazolidinyl urea and diazolidinyl urea are each registered for use at 100–1,000 tonnes per annum. TMAD is registered for use as an intermediate only (REACH n.d.-a; n.d.-b; n.d.-j; n.d.-k). These volumes may not include uses regulated under the EU Biocidal Products Regulation.

Existing Australian regulatory controls

Environment

There are no specific environmental regulatory controls for chemicals in this evaluation.

International regulatory status

United Nations

None of these chemicals in this evaluation are listed as Persistent Organic Pollutants (UNEP 2001), ozone depleting substances (UNEP 1987), or hazardous substance for the purpose of international trade (UNEP & FAO 1998).

OECD

DMDHEU was assessed under the OECD HPV program and concluded to be a substance of low priority for further work (OECD 2000).

European Union

DMDM hydantoin, imidazolidinyl urea, and diazolidinyl urea are allowed for use in cosmetics at concentrations up to 0.5–0.6% under the EU Cosmetics Products Regulation (European Commision n.d.).

Applications for approval for TMAD and DMDM hydantoin under the EU Biocidal Products Regulation are ongoing. Proposed uses are as preservative of products during storage (PT06), preservatives for liquid cooling and processing systems (PT11), slimicides (PT12), and working or cutting fluid preservatives (PT13) (ECHA n.d.).

Environmental exposure

Chemicals in this evaluation are found in household and industrial products available for use in Australia. Products for the Australian market are assumed to be similar to those available internationally.

Chemicals in this evaluation will be released into the environment when products containing the chemicals are used. During or after product use, these chemicals are released to wastewaters that will be treated at sewage treatment plants (STPs). A proportion of these chemicals will be removed during treatment, with the remainder released into the aquatic environment.

The amount of chemical released to wastewater depends on the specific end use of each product. Cosmetics and personal care products are expected to be fully disposed “down the drain” to wastewater streams. Comparatively, chemicals used in products such as hydraulic fluids, cutting fluids, sealants, coatings, and resins are expected to have low releases to

wastewater streams. Use in textile and leather finishing will result in moderate releases to the sewer.

When used in water based products or processes, chemicals in this evaluation are not expected to be volatile and releases to air are expected to be minimal.

Resins and polymers containing hydroxymethylated imidazolidinones can also release the formaldehyde product directly to air. However, the short atmospheric lifetime of formaldehyde suggests that this route of exposure will not result in significant risk to the environment (NICNAS 2006).

Environmental fate

Dissolution, speciation and partitioning

Hydroxymethylated imidazolidinones will predominately partition to water, with negligible amounts partitioning to air, soil, or sediments.

Chemicals in this group are readily soluble in water. Water solubilities range from 140 g/L to being miscible in water. The volatilisation of these chemicals from water is unlikely, as demonstrated by calculated Henry's law constant values below 1.0 x 10^{-3} Pa·m^3/mol.

Chemicals in this group are very mobile in soil. They are expected to have very low adsorption to organic matter and are very soluble. Estimated KOC values for these chemicals are all below 18 L/kg (US EPA 2017).

Fugacity modelling (level III) for direct releases into wastewaters suggests that these chemicals will stay in water (>99%), with negligible amounts going to sediment (0.2%), air or soil (<0.01% each) (US EPA 2017).

All the chemicals in this evaluation will release formaldehyde through hydrolysis. Formaldehyde is readily water soluble and highly volatile, although its volatility from water is considered moderate (Henry's Law constant 0.022–0.034 Pa.m^3 /mol). Most of the formaldehyde released into water is expected to stay dissolved in water. Formaldehyde that is released to air is expected to stay in the air (NICNAS 2006).

Degradation

Hydroxymethylated imidazolidinones are not persistent in the environment. Chemicals in this evaluation hydrolyse quickly in water to form formaldehyde and other biodegradable products.

Hydrolysis is the initial degradation pathway of hydroxymethylated imidazolidinones in aquatic and soil compartments. The hydrolytic half-life is approximately 12 hours for diazolidinyl urea at pH 7 and 20.4°C (REACH n.d.-k), and <1 day for DMDM hydantoin at pH 7 and 25°C (REACH n.d.-a). The rate of hydrolysis is expected to be rapid for all chemicals in this evaluation. Hydrolysis of these chemicals produces formaldehyde along with other byproducts.

Formaldehyde is not expected to persistent in water, air, soils or sediments (NICNAS 2006).

The other hydrolysis products are hydantoin, imidazolidinone, glycoluril or urea derivatives such as:

- hydantoin (CAS RN: 461-72-3)
- 5,5-dimethylhydantoin (CAS RN: 77-71-4)
- 2-imidazolidone (CAS RN: 120-93-4)
- 4,5-dihydroxyimidazolidin-2-one (CAS RN: 3720-97-6)
- glycoluril (CAS RN: 496-46-8)
- allantoin (CAS RN: 97-59-6)
- urea (CAS RN: 57-13-6).

Available information suggests that these chemicals are readily biodegradable, inherently degradable, or naturally occurring biological waste products (REACH n.d.-c; n.d.-d; n.d.-e; n.d.-f; n.d.-g; n.d.-h). As such, none of these hydrolysis products are expected to be persistent.

Biodegradation screening tests are available for some chemicals in this evaluation with mixed results and reliability.

Reported test results, using procedures comparable to OECD TG 301A, include 95% degradation after 28 days for DMDM hydantoin and 70–80% degradation after 28 days for TMAD (REACH n.d.-a; n.d.-j). However, there are some reliability concerns about these results. The DMDM hydantoin test used a lower test substance concentration than specified by the guideline, and very little information is available to judge the reliability of the TMAD test.

Other reported biodegradation test results, using procedures similar to OECD TG 301B, include 24% in 28 days for diazolidinyl urea and 40% in 25 days for imidazolidinyl urea (REACH n.d.-b; n.d.-k).

Two aerobic sewage treatment simulation tests are available for diazolidinyl urea. One study performed according to OECD TG 303A found that an average of 55% of the chemical was mineralised during each sludge retention period (11.3 days), with average total removal of 86.4% per sludge retention period. Another simulation study, using environmentally relevant test concentrations, found that 85% of the chemical was mineralised to CO2 after 8 days (REACH n.d.-k).

Bioaccumulation

The hydroxymethylated imidazolidinones are not expected to bioaccumulate in organisms. Chemicals in this evaluation all have experimental or estimated log K_{OW} values <1.0, which is below the domestic threshold for bioaccumulation (DCCEEW n.d.).

Environmental transport

Chemicals in this evaluation are unlikely to undergo long range environmental transport as they are not persistent in the aquatic environment. Transport through other environmental compartments is not expected to be relevant.

Predicted environmental concentration (PEC)

The PEC for chemicals in the evaluation is estimated at 12.73 µg/L based on available use information and conservative worst-case assumptions.

Monitoring data have not been identified for any chemicals in this group. Environmental concentrations in surface waters can be calculated based on estimated discharges from sewage treatment plants (STPs) according to the various uses of the products.

The potential uses of chemicals in this evaluation can be categorised according to their expected release scenarios:

- Use in personal care products, cosmetics, or cleaning products is assumed to fully release these chemicals to sewer during use (release factor = 1).
- Use in leather and textiles processing is assumed to result in moderate releases to sewer (release factor = 0.4).
- Use in construction products, such as resins, will result in smaller releases over their use lifetime (release factor = 0.2).
- All other uses in lubricants, adhesives, paints and coatings and other similar products are conservatively assumed to result in much lower releases to sewer (release factor = 0.05).

Except for cosmetics and personal care products, specific volumes for the above uses are unknown, and as such, the default introduction volume of 100 tonnes per year was assumed for each chemical as a conservative estimate.

The worst case exposure scenario occurs when the highest release uses have the highest volumes of use.

Information provided by Accord Australasia (in 2023) indicates that only DMDM hydantoin and imidazolidinyl urea are currently used in personal care products, cosmetics or cleaning products. A maximum volume of 250 kg/year was reported for these uses. To cover the worst-case scenario, the exposure scenario assumes that all chemicals in this evaluation have these high release uses up to 250 kg/year.

As the overall release volume is small compared to the default introduction volume, the releases from these uses have conservatively been added to the releases from the next highest release use (release factor = 0.4 uses).

Assuming inherent biodegradability for all chemicals and estimated STP removal (Struijs 1996), the highest predicted concentration expected in effluents of STPs is:

Use Volume (release factor = 1 uses)	250	kg/year
Proportion expected to be released to sewer	100%	-
Annual quantity of chemical released to sewer (release factor = 1 uses)	**250**	**kg/year**
Use Volume (release factor = 0.4 uses)	100,000	kg/year

Proportion expected to be released to sewer	40%	-
Annual quantity of chemical released to sewer (release factor = 0.4 uses)	**40,000**	**kg/year**
Total annual quantity of chemical released to sewer	**40,250**	**kg/year**
Days per year where release occurs	365	days/year
Daily chemical release	2.74	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	41%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor	1	-
PEC – Surface Waters	**12.73**	**µg/L**

This PEC does not consider any hydrolysis occurring before these chemicals enter the water treatment facilities.

Environmental effects

Effects on aquatic life

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

Ecotoxicity information is available for formaldehyde (NICNAS 2006; OECD 2002; REACH n.d.-i), the common hydrolysis product to all hydroxymethylated imidazolidinones.

Information is also available for the other hydrolytic breakdown products of chemicals in this group (see degradation section). These hydrolysis products are not harmful to aquatic life and have previously been assessed as posing low risk to the environment (AICIS 2023).

Therefore, formaldehyde is expected to have a significant contribution to the ecotoxicity of chemicals in this evaluation.

Acute toxicity

Acute toxicity data are available for four chemicals in this group: DMDHEU, TMAD, DMDM hydantoin and diazolidinyl urea. Toxicity of the other compounds is assumed to be similar based on their common mode of action (production of formaldehyde) and similar chemical structures.

The following are the most sensitive acute endpoints sourced from the REACH registration dossiers for the respective compounds (OECD 2000; REACH n.d.-a; n.d.-j; n.d.-k). Endpoints for the 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	Diazolidinyl urea	96h LC50 > 67 mg/L	*Lepomis macrochirus* juveniles (bluegill) Flow-through, measured concentrations EPA OPP 72-1
Fish	Formaldehyde	96h LC50 = 6.7 mg/L	*Morone saxatilis* (striped bass) Semi-static, nominal concentrations
Invertebrate	DMDM hydantoin	48h EC50 = 29.1 mg/L	*Daphnia magna* (water flea) Immobilisation Semi-static, measured concentrations OECD TG 202
Invertebrate	Formaldehyde	48h EC50 = 5.8 mg/L	*Daphnia pulex* (water flea) Static, nominal concentrations OECD TG 202
Algae	TMAD	72h EC50 = 3.85 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate Static, measured concentrations OECD TG 201
Algae	Diazolidinyl urea	72h EC50 = 5.78 mg/L	*Selenastrum capricornutum* (green algae) Growth rate Static, measured concentrations EU method C.3
Algae	DMDM hydantoin	72h EC50 = 11 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate Static, measured concentrations OECD TG 201
Algae	DMDHEU	72h EC50 = 36.9 mg/L	*Scenedesmus subspicatus* (green algae) Growth rate Static, measured concentrations
Algae	Formaldehyde	72h EC50 = 4.89 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate Static, nominal concentrations OECD TG 201

Chronic toxicity

Limited chronic toxicity information is available for chemicals in this evaluation. Information on DMDHEU, TMAD and diazolidinyl urea is reported below

(OECD 2000; REACH n.d.-j; n.d.-k). Chronic toxicity data for formaldehyde are also shown for a comparison (OECD 2002; REACH n.d.-i):

Taxon	Chemical	Endpoint	Method
Invertebrate	DMDHEU	21d NOEC = 100 mg/L	*Daphnia magna* (water flea) Reproduction Nominal concentrations XI/681/86 EEC
Invertebrate	Formaldehyde	21d NOEC = 6.4 mg/L	*Daphnia magna* (water flea) Reproduction Semi-static, nominal concentrations OECD TG 211
Algae	TMAD	72h NOEC = 1.22 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate Static, measured concentrations OECD TG 201
Algae	Diazolidinyl urea	72h NOEC = 1.6 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate Static, measured concentrations EU method C.3

Effects on terrestrial life

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

Effects on sediment dwelling life

No ecotoxicity data for sediment dwelling life are available for any chemicals in this group.

Endocrine effects/activity

No data are available. Endocrine activity is not expected for any chemicals in this group.

Predicted no-effect concentration (PNEC)

The lowest endpoint is for TMAD with a NOEC value of 1.22 mg/L on the freshwater algae *Desmodesmus subcapitatus*.

Given that chronic ecotoxicity data are available for at least two trophic levels in the aquatic environment, an assessment factor of 50 is applied to the lowest endpoint for TMAD (EPHC 2009).

This results in a PNEC of 0.0244 mg/L (24.4 µg/L), which has been applied to the risk calculation for all chemicals in this evaluation.

Categorisation of environmental hazard

The categorisation of the environmental hazards of these assessed chemicals according to domestic environmental hazard thresholds (DCCEEW n.d.) is presented below:

Persistence

Not Persistent (Not P). Based on measured hydrolysis half-lives <1 day and the biodegradability of the hydrolysis products, 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 values above 1 mg/L for these chemicals and their hydrolysis products, all chemicals in this group are categorised as Not Toxic.

Environmental risk characterisation

The environmental risk assessment of hydroxymethylated imidazolidinones 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 such releases in effluents of STPs was determined according to the worst case scenario identified in the exposure section above.

The following Risk Quotient (RQ = PEC ÷ PNEC) was calculated for emissions of hydroxymethylated imidazolidinones into the aquatic environment through STP effluents under the worst case scenario:

Compartment	PEC	PNEC	RQ
Surface waters	12.73 µg/L	24.4 µg/L	0.52

A calculated RQ value less than 1 indicates that 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.

The above RQ is likely to be an overestimate of the risk. The exposure scenario assumed that all uses of a chemical were in a combination of high and moderate release uses. It is unlikely that all tonnage will be used in products with higher releases, especially as use in low release uses is known. Additionally, the exposure scenario did not consider the removal of these chemicals due to hydrolysis.

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 total introduction volumes for chemicals in this evaluation are unknown. The default introduction volume of 100 tonnes per annum for uses other than cosmetics and personal care products is expected to be a conservative overestimate.
- 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.
- The ecotoxicity testing of chemicals in this evaluation is complicated by the fast hydrolysis of these chemicals. The overall contributions of the parent chemicals and formaldehyde are unknown. However, this is not expected to affect the risk as the PNEC was calculated using the lowest available ecotoxicity endpoint between formaldehyde and the parent chemicals.

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