Annex 15 Report
Proposal for identification of a substance of very high concern (SVHC)

Melamine

EC Number: 203-615-4

CAS Number: 108-78-1

November 2026

Contents

1 Proposal **5**

2 Justification **8**

2.1 Identity of the substance and physical and chemical properties 8

2.2 Mandatory classification and labelling 10

2.3 Human health hazard assessment 11

2.4 Environmental fate properties 11

2.5 Conclusions on the SVHC properties 30

3 Information on use, exposure and alternatives **32**

3.1 UK and EU REACH registration status and tonnage 32

3.2 General description of uses and exposure 32

3.3 Alternatives 33

References **34**

Tables

Table 1: Substance identity....8
Table 2: Constituents other than impurities/additives....9
Table 3: Overview of physicochemical properties of melamine....10
Table 4: Mandatory classification in the GB MCL list....10
Table 5: Summary of abiotic degradation data....11
Table 6: Summary of screening test results for melamine....13
Table 7: Summary of aquatic biodegradation data....13
Table 8: Summary of soil biodegradation data....15
Table 9: Summary of soil biodegradation data....16
Table 10: Summary of log K_{OC} values....17
Table 11: EFSA conclusion adsorption parameters for melamine....18
Table 12: Properties and adsorption coefficient values for soils....19
Table 13: Summary of Henry's law constant values....20
Table 14: Environmental distribution pattern of melamine....21
Table 15: Modelled melamine removal for different drinking water processes....22
Table 16: Summary of field data including concentration and detection frequency (DF)....23
Table 17: Environment Agency monitoring results for melamine....25

Figures

Figure 1: Concentration of melamine (µg/L) in surface water with sampling time....14
Figure 2: Relationship between log K_{foc} for melamine and soil pH....19

List of abbreviations

CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
CREED	Criteria for reporting and evaluating exposure datasets
CTD	Characteristic travel distance
DFOP	Double first order in parallel
DOC	Dissolved organic carbon
DT_{50}	Time taken for 50% decline in mass or concentration. If the decline is described by first order kinetics then this is also called the half-life
$DegT_{50}$	Degradation half-life or transformation half-life (days)
DWI	Drinking Water Inspectorate
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EC	European Community
EC_{50}	50% effect concentration
EU	European Union
FOMC	First order multi-component
GAC	Granular activated carbon
GB	Great Britain
GLP	Good laboratory practice
HLC	Henry's law constant
HS	Hockey stick
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	Organic carbon normalised adsorption coefficient
K_f	Freundlich adsorption coefficient
K_{foc}	Organic carbon normalised Freundlich adsorption coefficient
K_{ow}	n-Octanol–water partition coefficient
LC_{50}	50% lethal effect concentration
LoQ	Limit of quantification

LRTP	Long-range transport potential
MCL	Mandatory classification and labelling
MDL	Method detection limit
MSC	Member State Committee
NOEC	No observed effect concentration
OECD	Organisation for Economic Cooperation and Development
P	Persistent
P_{ov}	Overall half-life in the environment
QSAR	Quantitative structure-activity relationship
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
SFO	Single first order
SMILES	Simplified Molecular Input Line Entry System
STOT RE	Specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
TG	Test guideline
UK	United Kingdom
vP	Very persistent
WWTP	Wastewater treatment plant

1 Proposal

Substance name: Melamine

EC number: 203-615-4

CAS number: 108-78-1

Melamine has been identified as a substance of very high concern (SVHC) in accordance with the requirements set out in Annex 15 of EU REACH (Regulation (EC) No 1907/2006). This is owing to it being identified as equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57.

This technical report documents an independent scientific assessment by the Agency on whether melamine should be identified as an SVHC under UK REACH. This report only considers studies and data presented in the equivalent document produced by the European Chemicals Agency (ECHA), the EU Member State Committee (MSC) support document (ECHA, 2022), unless stated otherwise. Relevant observations on studies made in the support document have been summarised and Agency comments have been added where appropriate. Unpublished study reports were not available and have not been examined, unless stated otherwise. A literature search was not performed because the existing information is considered to be sufficient for decision making.

It is proposed to identify melamine as a SVHC in accordance with Article 57(f) of UK REACH as it is a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57.

Summary of how the substance meets the criteria set out in Article 57 of the UK REACH Regulation

Melamine is proposed to be identified as a SVHC in accordance with Article 57(f) of UK REACH as there is scientific evidence of possible serious effects to human health and the environment which give rise to an equivalent level of concern to those of other hazards listed in points (a) to (e) of Article 57 of UK REACH. Its key properties can be summarised as follows:

- There is no evidence for abiotic degradation of melamine. The substance screens as potentially persistent (P) and very persistent (vP) based on modelling results and the lack of ready or inherent biodegradability in screening tests. There was no notable degradation of melamine in freshwater during an OECD TG 309 study, with a half-life much longer than 60 days at 13°C. The half-lives for melamine in aerobic soil degradation studies ranged from 255 to 448 days when extrapolated to 12°C. Melamine fulfils the P and vP criteria under Annex 13 of UK REACH for both freshwater (half-life > 60 days) and soil (half-life > 180 days).

- Experimental log K_{fOC} values for melamine ranged from 1.51 to 2.84, indicating a relatively low adsorption potential in sediments, sewage sludges and soils. Melamine has a high water solubility (3,840 mg/L), and a low tendency to volatilise from water (estimated Henry's law constant (HLC) is 1.89×10^{-8} Pa.m^3/mol). Melamine will remain in the aqueous phase and as it has limited adsorption potential it will be mobile in the aqueous environment.
- Melamine has a mandatory classification in accordance with GB CLP for carcinogenicity category 2 (H351: Suspected of causing cancer) and specific target organ toxicity by repeated exposure (STOT RE) category 2 (urinary tract) (H373: May cause damage to organs through prolonged or repeated exposure)[1]. Owing to the STOT RE 2 (urinary tract) classification, melamine meets the toxicity (T) criterion under Annex 13 of UK REACH.

These properties lead to the following concerns if melamine is released to the environment:

- *Widespread presence in the environment*

  The combination of persistence and mobility gives rise to the potential for melamine to travel far from the source of emission via water and to migrate between and through environmental compartments, such as from soil to groundwater, leading to widespread presence in the environment. Environment Agency monitoring data for England provides evidence of extensive contamination, with melamine detected in 33 to 71% of surface water samples and in 8.8 to 23.8% of groundwater samples between 2019 and 2022. Additional evidence from national monitoring programmes and academic studies indicates that melamine is present in surface water, including drinking water resources and groundwater in multiple countries.

- *Difficulty in removal from drinking water sources*

  Part 3 of the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (UK Government, 2017) requires that for water bodies used for abstraction, measures are implemented 'with the aim of avoiding deterioration in water quality in order to reduce the level of purification treatment required for the production of drinking water'.

  The ability of melamine to persist and its tendency to remain in the aqueous environment, together with its relatively low adsorption potential to organic matter, indicate that it may be difficult to remove through conventional drinking water treatment processes. Evidence from peer-reviewed studies outside the UK and modelling suggests that removal using standard treatment methods is incomplete. Even with advanced treatment technologies, complete removal may not be achieved. Melamine has been detected in drinking water in Europe.

[1] Classification in accordance with Annex 1 to the retained Regulation (EC) No 1272/2008 as amended for Great Britain (hereinafter referred to as GB CLP)

- *Potential for toxic effects*

  There is likely to be long-term exposure of humans and wildlife to melamine from its presence and likely slowly increasing concentrations in the environment. Given its hazard profile, this indicates a potential to cause harm.

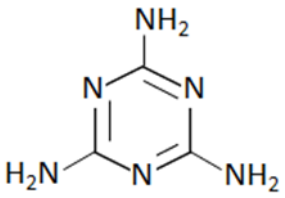
  This combination of concerns gives rise to the potential for long-term impacts that are difficult to reverse. Melamine is therefore proposed to be identified as an SVHC in accordance with Article 57(f) of the UK REACH Regulation as there is scientific evidence of possible serious effects to the environment and human health which give rise to an equivalent level of concern to those of other hazards listed in points (a) to (e) of Article 57.

2 Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	203-615-4
EC name:	Melamine
SMILES[a]:	n(c(nc(n1)N)N)c1N
CAS number:	108-78-1
IUPAC[b] name:	1,3,5-triazine-2,4,6-triamine
Index number in GB mandatory classification and labelling (MCL) list[c]	613-345-00-2
Molecular formula:	$C_3H_6N_6$
Molecular weight:	126.123 g/mol
Synonyms:	-
Structure:	

[a] SMILES: Simplified Molecular Input Line Entry System
[b] IUPAC: International Union of Pure and Applied Chemistry
[c] GB MCL list in accordance with the retained Regulation (EC) No 1272/2008 as amended for Great Britain

2.1.2 Composition of the substance

Substance type: Mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
Melamine	≥ 80% w/w

2.1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

No transformation products were considered in ECHA (2022). It is not necessary to consider transformation products since there are adequate data for melamine.

2.1.4 Identity and composition of structurally related substances (used in grouping or read-across approach)

No structurally related substances were considered in ECHA (2022). It is not necessary to consider structurally related substances since there are adequate data for melamine.

2.1.5 Physicochemical properties

Physicochemical properties of melamine presented in ECHA (2022) are summarised in Table 3. No comments on the reliability of the data were made. The experimental values for melting point, density, water solubility, and the n-octanol–water partition coefficient (log K_{OW}) are all presented in the EU REACH registration dossier (ECHA, 2010) but limited details are reported beyond the method used and so could not be assessed directly by the Agency.

The Agency has considered quantitative structure-activity relationships (QSARs) as supporting evidence to check the data reported in ECHA (2010). The KOWWIN v1.69 programme of EPISuite™ v4.1 (US EPA, 2026) report an experimental log K_{OW} value of -1.37 (Hansch *et al.*, 1995) and an estimated value of -0.38. Melamine is within the molecular weight range of the training set of the model and as its structural features are all represented by the model fragments is therefore within the applicability domain of the model. The WSKOWWIN v1.43 programme reported an experimental water solubility of 3,230 mg/L at 20°C. In conclusion, given the similarity between different sources, the values for log K_{OW} and water solubility presented in Table 3 can be used in the assessment.

The vapour pressure of melamine presented in Table 3 was measured using a dynamic method in the temperature range of 144 to 341°C by Hirt *et al.* (2003). It is extrapolated to standard conditions and presented in MPBPVPWIN v1.44 of EPISuite™ v4.1. The values from the three estimation methods in this model are somewhat higher (7.05×10^{-6} to 1.19×10^{-5} Pa at 25°C) but all suggest a relatively low vapour pressure.

The pK_b values indicate that melamine is likely to be approximately 50% ionised around pH 7.

Table 3: Overview of physicochemical properties of melamine

Property	Description/value	Method
Physical state at 20°C and 101.3 kPa	White powder	-
Melting/freezing point (°C)	361	EU Method A.1
Boiling point (°C)	Not available (decomposition and sublimation close to the melting point)	-
Vapour pressure (Pa at 20°C)	4.79×10^{-8}	Dynamic method (Hirt *et al.*, 2003)
Density (kg/m^3 at 20°C)	1,570 (a relative density of 1.57)	EU Method A.3
Water solubility (mg/L at 20°C)	3,480 (at pH 7)	OECD TG 105
n-Octanol–water partition coefficient (log K_{OW})	-1.22 (at pH 8)	OECD TG 107
Base dissociation constant (pK_b)	pK_{b1}: 7.3 pK_{b2}: 11.4	OECD TG 112

2.2 Mandatory classification and labelling

Table 4: Mandatory classification in the GB MCL list

Index No	International Chemical Identification	EC No	CAS No	GB MCL list Classification		Aligned with EU CLH[a]
				Hazard Class and Category Code(s)	Hazard statement code(s)	Yes/No
613-345-00-2	1,3,5-triazine-2,4,6-triamine; melamine	203-615-4	108-78-1	Carc. 2 STOT RE 2	H351 H373 (urinary tract)	Yes

[a] EU CLH is harmonised classification and labelling in accordance with Regulation (EC) 1272/2008

2.3 Human health hazard assessment

Melamine is a suspected carcinogen and has the potential to damage the urinary tract through prolonged or repeated exposure.

2.4 Environmental fate properties

2.4.1 Degradation

2.4.1.1 Abiotic degradation

The information on abiotic degradation presented in ECHA (2022) is summarised in Table 5.

Table 5: Summary of abiotic degradation data

Abiotic degradation process	Information presented	Results
Hydrolysis	QSAR estimation using Vega Hub models Reliability is limited	Estimated half-life: 29.2 days
Oxidation	No information available	-
Phototransformation	QSAR modelling using the AOPWIN v1.92 model (EPISuite™ v4.10), assuming 12 h daylight, OH radical concentration of 1.5×10^6 OH/cm^3	Estimated half-life: 16.22 days

Hydrolysis: ECHA (2022) stated that melamine is not within the applicability domain of the HYDROWIN model of EPISuite™ (US EPA, 2026). A hydrolysis half-life was estimated using the Vega Hub model in the MSC support document but it states that reliability was limited because a prominent number of atom centred fragments of melamine are not present in the compounds of the training set or are rare fragments. ECHA (2022) considered a report by Gong et al. (2016) that examined hydrolytic conversion rates of melamine after 2 hours at 200°C and pH values from 1 to 13.26. Conversion was lowest at environmentally relevant pH values (28.43% at pH 5, 13.50% at pH 7) and it was concluded that hydrolysis was likely to be very low at environmentally relevant temperatures. There is no evidence presented to indicate that hydrolysis is likely to be a relevant degradation process for melamine in the environment.

Oxidation: No information on oxidation was presented in ECHA (2022).

Phototransformation in air: The estimated half-life in air of 16.22 days (12-h day, 1.5×10^6 OH/cm^3) was checked and it is agreed with ECHA (2022) that the half-lives presented may underestimate lifetimes in air because of sorption of melamine to airborne particles.

Phototransformation in water: No data are available. This process usually has limited impact on overall persistence due to attenuation of light with depth and turbidity, presence of quenching agents in aquatic media, etc.

Phototransformation in soil: No data are available. This process is expected to have limited impact on overall persistence as the substance is unlikely to occur on soil surfaces due to its low adsorption potential.

2.4.1.2 Biodegradation

2.4.1.2.1 Biodegradation in aqueous media or aqueous environment

2.4.1.2.1.1 Estimated data

Estimated biodegradation data from the BIOWIN v4.11 models of EPISuite™ v4.1 are summarised as follows:

- BIOWIN 2: 0.000 (does not biodegrade fast)
- BIOWIN 3: 2.2697 (recalcitrant)
- BIOWIN 6: 0.0000 (does not biodegrade fast)

The triazine ring and aromatic amine fragments of melamine are recognised by all three BIOWIN models. The datasets used for deriving the BIOWIN 2 and 3 models include several structurally similar substances to melamine. The BIOWIN 6 model training set includes melamine, and both the training and validation set include several similar substances. The Agency concludes that melamine is within the applicability domains of the three models.

2.4.1.2.1.2 Screening tests

ECHA (2022) briefly summarised a ready biodegradability study and two inherent biodegradability tests (Table 6). The GLP status is not specified for any of the studies in the EU REACH registration dossier. ECHA (2022) described the reliability of the ready biodegradability study as high and that of the two inherent biodegradation tests as limited because adaptation of the inoculum could not be excluded. There is very little information presented in the EU REACH registration dossier and therefore an opinion on reliability cannot be formed.

ECHA (2022) also stated that based on the results of a micro-organism toxicity test conducted according to test guideline DIN 38412-8 (0.5 h EC_{10} > 10,000 mg/L), it can be concluded that the test concentration of melamine in these three tests was not toxic to the inoculum used.

In conclusion, there is no evidence from these studies that melamine is readily biodegradable or inherently biodegradable.

Table 6: Summary of screening test results for melamine

Reference	Study type	Results
Anonymous (2010)	14-day study to OECD test guideline (TG) 301C. Inoculum source: activated sludge (30 ppm); melamine test concentration (100 ppm). GLP compliance not specified. Reliability of data described as high.	Degradation by biological oxygen demand: 0%
Anonymous (1993)	28-day OECD TG 302B study. Inoculum source: industrial activated sludge (adaptation not specified); melamine test concentration 100 mg/L. GLP compliance not specified. Reliability: limited as adaption of the inoculum cannot be excluded.	Degradation by dissolved organic carbon (DOC) removal: < 10%
Anonymous (1991)	20-day OECD TG 302B study. Inoculum source: industrial activated sludge; melamine test concentration 400 mg/L (non-adapted) and 1,400 mg/L (adapted). Reliability limited as adaption of the inoculum cannot be excluded.	Degradation by DOC removal: Non-adapted: 16% (after 20 days) Adapted: 10% (after 14 days)

2.4.1.2.1.3 Biodegradation studies (simulation tests)

ECHA (2022) considered an aerobic mineralisation study, details of which are presented in Table 7.

Table 7: Summary of aquatic biodegradation data

Reference	Study type	Results
Hofman-Caris and Claßen (2020)	60-day OECD TG 309 aerobic mineralisation study. Sub-surface spring water Melamine at 5 µg/L Reliability considered to be high.	Degradation: Melamine: little degradation after 60 days. Reference substance aniline: > 98% after 30 days.

- Hofman-Caris and Claßen (2020)

This was an aerobic mineralisation study conducted to OECD TG 309 that investigated the degradation of melamine in water from a sub-surface spring used as a drinking water source (no added suspended sediment). The test substance was non-radiolabelled melamine (purity 99.8%) added at 5 µg/L to test vessels containing 300 mL of water. The vessels were incubated in the dark at 13 ± 1°C and duplicate samples taken after 0, 7, 15, 30, 45, and 60 days. The microbial activity of the water was investigated using aniline (1 µg/L) as a reference substance and also by determination of adenosine triphosphate (ATP) present.

Degradation of aniline was 52% after 15 days and > 98% after 30 days of incubation. ATP concentration was 86 ± 1.2 pg/mL at day 0 in the surface water (no melamine added) and 92 ± 16 pg/mL at day 2 in the presence of melamine, indicating no loss of microbial activity and no negative effect from melamine in that early time frame. The concentration of melamine at each sampling time in the study is presented in Figure 1: Concentration of melamine (µg/L) in surface water with sampling time.

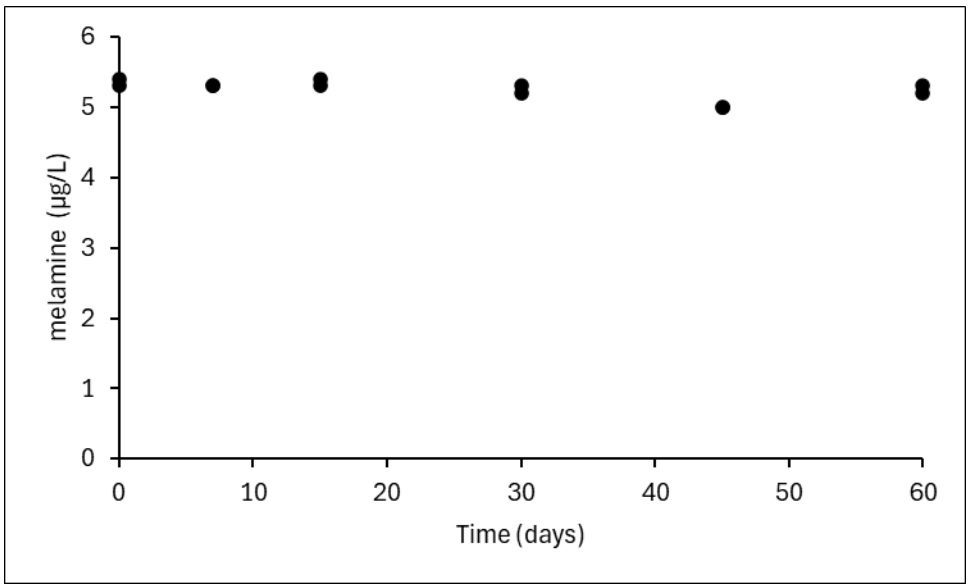


Figure 1: Concentration of melamine (µg/L) in surface water with sampling time

A kinetic assessment was carried out as part of the study by fitting the data with single first order (SFO), double first order in parallel (DFOP), hockey stick (HS), and first order multi-component (FOMC) kinetics. However, it is clear that no notable degradation had occurred and as can be seen from the report, degradation rate constants were not statistically different from zero (where available). The study is well described but it is not stated whether it is conducted to GLP. In conclusion, the study is reliable with restrictions (Klimisch score 2) and the half-life of melamine in freshwater is much longer than 60 days

at 13°C.

2.4.1.2.2 Biodegradation in soil

ECHA (2022) considered a non-standard soil degradation study, details of which are presented in Table 8.

Table 8: Summary of soil biodegradation data

Author / year	Study	Results
Hauck and Stephenson (1964)	196-d soil degradation Melamine (2,000 mg/kg) incubated at 32°C and 60% soil humidity. Reliability limited because of missing information on study conditions.	Degradation followed by nitrate formation: 0.7% after 70 days 0% after 196 days

- Hauck and Stephenson (1964)

This was a non-standard study where the degradation of melamine in a Webster silty clay loam soil (100 g) at pH 8.2 was followed by nitrate formation. The concentration of melamine in the soil was 2,000 mg/kg and the soil was incubated at 32°C and 60% soil humidity for 196 days. Degradation of melamine was reported as 0.7% after 70 days and 0% after 196 days. The degradation half-life in soil was estimated to be two to three years using the data from the original study by ECETOC (1983). ECHA (2022) stated that there is information missing (e.g. light regime during incubation, microbial activity of the soil used, negative control, soil history with regard to adaptation) and therefore the reliability is considered to be 'limited'. The Agency has not accessed the original study but concludes that its reliability is unassignable (Klimisch score 4) given the missing data and the lack of substance-specific analysis.

Melamine is a degradation product formed in soil from the pesticide cyromazine. The EFSA conclusion for cyromazine (EFSA, 2008) included degradation DT_{50} values for melamine from 3 studies, all conducted to OECD TG 307 or similar guidelines using ^{14}C radiolabelled cyromazine as test substance (briefly summarised in Table 9). These findings were agreed when the UK was a member of the European Union, so are considered reliable and do not need further review for the purposes of this assessment. The $DegT_{50}$ values were all determined from SFO kinetics and ranged from 120 to 211 days (geometric mean: 155 days) at 20°C. The Agency has calculated the $DegT_{50}$ values at 12°C using an activation energy (E_a) of 65.4 KJ/mol; these ranged from 255 to 448 days (mean: 314 days). For the two soils where no DT_{50} value was calculated, the concentration of melamine was still increasing at the end of the study and no statistically acceptable kinetic assessment was possible.

Table 9: Summary of soil biodegradation data

Reference[a]	Study	Soil	pH	$DegT_{50}$ (days)	
				20°C	12°C
Glänzel (2000)	120-day aerobic degradation of cyromazine in two soils at 20°C in the dark. Study conducted according to SETAC (1995).	Gartenacker (loam/silt loam)	7.3	125	266
Aalderink et al (2003)	Aerobic degradation of cyromazine in three soils at 20 ± 2°C in the dark. Incubation times ranged from 121 to 206 days. Study conducted according to OECD TG 307 (draft form).	Horst (loamy sand)	5.7	135[b]	287
		Westmass (loam)	7.5	211	448
		Naaldwijk (loamy sand)	6.8	120	255
Adam (2003)	120-day aerobic degradation of cyromazine in two soils at 20 ± 2°C in the dark. Study conducted according to OECD TG 307.	Marsillargues (silty clay loam)	8.1	Not calculated[c]	-
		18 Acres (sandy clay loam)	5.6	Not calculated[c]	-

[a] References taken from the draft assessment report available on the EFSA website (EFSA, 2026; accessed 08 May 2026).
[b] Reported as 88 days, but this was for 25°C (value corrected to 20°C reported as 135 days in the draft assessment report).
[c] The values reported in the EFSA conclusion are maximum percentage formation values, not DT_{50} values. For these soils, the percentage of melamine was still increasing at the end of the study, and no kinetic assessment was carried out.

2.4.1.3 Summary and discussion of degradation

Hydrolysis and oxidation are unlikely to be relevant degradation processes for melamine in the environment. Phototransformation in air is suggested by modelling, but the half-life of 16.22 days may be an underestimate because of sorption to airborne particles. No information is available on phototransformation in water or soil, but these processes are unlikely to have a significant impact on overall persistence.

Melamine is not predicted to degrade rapidly based on the BIOWIN v4.11 model of EPISuite™. It is not readily biodegradable (no degradation after 28 days), nor inherently biodegradable (< 10% and 16% degradation from two tests) in standard tests.

There are two simulation studies that provide direct evidence for the persistence of melamine:

- There was no notable degradation of melamine in surface water during an OECD TG 309 study by Hofman-Caris and Claßen (2020). The half-life of melamine in freshwater was much longer than 60 days at 13°C.

- The half-lives for melamine in aerobic soil degradation studies reported as part of the active substance approval of the pesticide cyromazine (EFSA, 2008) ranged from 120 to 211 days at 20°C (extrapolated to 255 to 448 days at 12°C).

In conclusion, melamine is likely to degrade slowly in the environment.

2.4.2 Environmental distribution

2.4.2.1 Adsorption/desorption

ECHA (2022) included a number of log K_{OC} values from different sources (summarised in Table 10). Melamine has a pK_{b1} of 7.3 and therefore non-ionic and ionic forms of the molecule occur under environmentally relevant conditions and log K_{OC} may be to some extent pH dependent.

The reported KOCWIN value from the molecular connectivity index (MCI) approach of EPISuite™ v4.1 was checked by the Agency. The estimation using log K_{OW} gave a log K_{OC} of 1.00. The molecular weight of melamine is within that of the training set and its molecular features are represented in the correction factor descriptors. Un-ionised melamine is within the applicability domain of the models. The other estimated log K_{OC} values have not been examined in detail, but it is noted that they are similar to the KOCWIN values, ranging from 1.13 to 1.37.

ECHA (2022) concluded based on the log K_{OC} values that melamine 'will not adsorb to organic matter and clay minerals in relevant quantities'.

Table 10: Summary of log K_{OC} values

Source	Study type	Results
Estimated value using KOCWIN v2.00	Estimated data	1.51 (MCI method)
ECB Technical Guidance Document (2000)	Estimated data from a specific equation for triazines: Log K_{OC} = 0.30.log K_{OW} + 1.5	1.13 (using a log K_{OW} of 1.22)
INERIS database	References the FOOTPRINT Pesticide Properties Database for the estimated value. No details of test method or conditions were provided for the experimental test method.	1.16 (estimated value) 1.81 (experimental value)
CompTox Chemicals Dashboard (US EPA, 2021)	Estimated data	1.37 (average value)
Risk assessment for the active substance cyromazine (EFSA, 2008).	Determined through 3 adsorption studies, all conducted to OECD TG 106.	K_{foc} = 54 to 423 (1/n = 0.7414 to 0.83)

Source	Study type	Results
		Equivalent to a log K_{fOC} of 1.74 to 2.63
Wang *et al.* (2014)	Study of adsorption on 5 typical Chinese agricultural soils (pH 5.56 to 7.45).	Log K_f range: 1.63 to 2.55[a] Log K_{fOC} range: 1.51 to 2.83 (Agency estimated values – see text)

[a] ECHA (2022) incorrectly reported these values as K_{OC} values when they are in fact Freundlich partition coefficient (K_f) values

There are experimental values from two sources which give higher values than the predicted values, with log K_{fOC} values ranging from of 1.51 to 2.83.

- EFSA (2008)

The risk assessment for the pesticide cyromazine included determination of a number of K_{fOC} values for melamine from three studies following OECD TG 106. ECHA (2022) stated that the pH values of the soils used for determination of K_{OC} values were not provided in the EFSA conclusion. However, they are present in the conclusion and in the current lead EU REACH registration dossier for melamine (ECHA, 2010). The findings were accepted for use when the UK was a member of the European Union. They are therefore considered reliable and do not need further review for the purposes of this assessment. A summary of the results is reproduced in Table 11.

Table 11: EFSA conclusion adsorption parameters for melamine

Soil	Organic carbon (%)	Soil pH (H_2O)	K_f (mL/g)	K_{fOC} (mL/g)	Log K_{fOC}	1/n
Loamy sand	1.3	5.9	5.50	423	2.62	0.80
Loam	1.5	7.5	1.45	97	1.99	0.80
Loamy sand	1.8	6.8	2.77	154	2.19	0.83
Loamy sand	1.5	4.2	5.57	371	2.57	0.72
Silt loam	1.8	7.3	0.96	54	1.73	0.74

There is a good correlation between pH and log K_{fOC} for this dataset as stated in the EFSA conclusion (see Figure 2). This reflects the partial ionisation of melamine at environmentally relevant pH values (pK_{b1} = 7.3), with the extent of ionisation increasing and K_{fOC} values decreasing with increasing pH values.

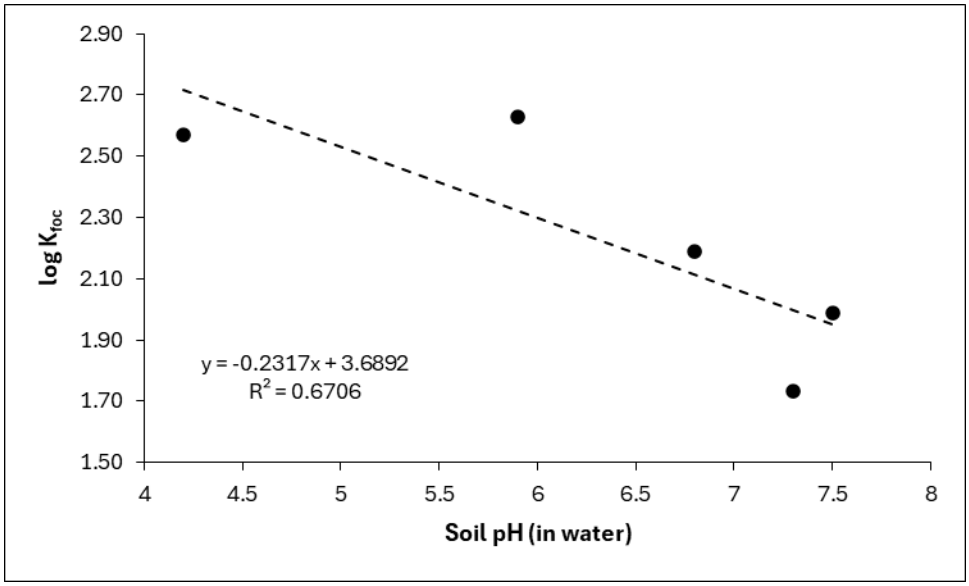


Figure 2: Relationship between log K_{foc} for melamine and soil pH

- Wang *et al.* (2014)

This was a batch equilibrium study conducted according to OECD TG 106 using 5 typical agricultural soils from China. The melamine concentrations used were either 0, 1, 2, 3, 4, and 5 mg/L with a 0.01 M $CaCl_2$:soil ratio of 25:1, or 0, 0.2, 0.5, 1, 2, and 2.5 mg/L with a 0.01 M $CaCl_2$:soil ratio of 5:1. The samples were shaken for 24 hours at 25°C in the dark and after centrifugation, the concentration of melamine was measured in the supernatant only (the indirect method). The reliability of this study is unassignable (Klimisch score 4) because no mass balance was reported and there was a lack of detail concerning how data were processed. Log K_f values were reported but not log K_{OC} values. Log K_{fOC} values were calculated from the K_f values, assuming a conversion factor from organic carbon to organic matter of 1.724 (EFSA, 2017), summarised in Table 12.

Table 12: Properties and adsorption coefficient values for soils

Soil	Organic matter (%)	Soil pH	Log K_f	Organic carbon (%)[a]	K_{fOC} (mL/g)[b]	Log K_{fOC}[b]
Argosols	9.93	7.45	1.63	0.57	74.6	1.87
Cambosols	5.36	7.38	1.64	0.31	141.4	2.15
Ferrosols	26.41	5.56	1.70	1.53	32.6	1.51
Anthrosols	45.89	5.57	2.42	2.66	98.6	1.99
Isohumosols	8.88	7.05	2.55	0.51	688.9	2.84

[a] Calculated by the Agency assuming a conversion factor from organic carbon to organic matter of 1.724.

[b] Calculated by the Agency.

An EU proposal to amend the hazard classification of melamine (ECHA, 2026) included additional experimental studies that were not presented in ECHA (2022), for example Hubert and Arp (2025). However, given the availability of a sufficient set of reliable adsorption data, further review is considered unnecessary as the additional data do not affect the overall conclusion for this endpoint.

2.4.2.2 Volatilisation

ECHA (2022) reported two estimated Henry's law constants (HLC; summarised in Table 13). The Agency checked the HENRYWIN value using version 3.21 of the model in EPISuite™ v4.1. Melamine was adequately represented by the bond contribution descriptions and there were a number of structurally similar substances in the chemical dataset used to derive the regressions for bond descriptions and correction factors. It is therefore likely to be within the model applicability domain. A separate calculation using equation R.16-4 of Guidance Document R.16 (ECHA, 2016) gave a similarly low HLC value. The inputs used in the equation were a vapour pressure of 2.69 × 10^{-8} Pa, molecular weight of 126.12 g/mol, and water solubility of 3.101 g/L (all values taken from Table 3 and adjusted to a temperature of 12°C using the Arrhenius equation). The pH will affect the degree of ionisation of melamine in water, but this is considered unlikely to significantly affect the HLC.

Table 13: Summary of Henry's law constant values

Source	HLC estimation method	Results
Estimated value using HENRYWIN (version not stated)	Estimated data from the bond	1.89 × 10^{-8} Pa.m^3/mol
Guidance document R.16 (ECHA, 2016)	Equation R.16-4: $HENRY = \frac{Vapour\ pressure\ x\ MWt}{Solubility}$	1.09 × 10^{-9} Pa.m^3/mol
INERIS database	References the FOOTPRINT Pesticide Properties Database for the estimated value. No details of test method or conditions were provided for the experimental test method.	1.16 (estimated value) 1.81 (experimental value)

It is agreed given the estimated HLC values between 1 × 10^{-8} and 1 × 10^{-9} Pa.m^3/mol, that melamine is of low volatility and will remain in the aqueous phase under environmental conditions.

2.4.2.3 Modelling of distribution between environmental compartments

ECHA (2022) presented modelling according to MacKay Level III, part of EPISuite™ v4.1, that showed if melamine is released to water, it will remain in that compartment. If melamine is released to soil, much will remain in the soil, but it is noted that the limited potential for adsorption means that melamine has the potential to leach from soil to groundwater. The data are summarised in Table 14.

Table 14: Environmental distribution pattern of melamine

Environmental compartment	Mass amount (%)			
	Equal release	Release to air	Release to water	Release to soil
Air	1.85×10^{-7}	4.45×10^{-7}	1.42×10^{-16}	1.18×10^{-14}
Water (surface)	25	14.5	99.7	11.6
Soil	74.9	85.4	2.73×10^{-8}	88.3
Sediment	0.086	0.05	0.343	0.04

2.4.2.4 Distribution and removal during water treatment

2.4.2.4.1 Distribution in sewage treatment plants

ECHA (2022) presented distribution modelling according to SimpleTreat (version 3.0) that shows that 99.2% of melamine entering a municipal sewage treatment works will be emitted to surface water and 0.8% to sludge; no melamine is predicted to be degraded. It acknowledges that sewage treatment plants specifically designed to treat sewage predominantly from industrial sites might achieve a higher removal efficiency.

ECHA (2022) stated that research by Piai *et al.* (2021) and references therein reflect that melamine is poorly removed from water in conventional wastewater treatment plants. One cited study reported removal efficiencies of 14 ± 10% and 20 ± 15% from synthetic wastewater influent in two laboratory-scale activated sludge systems (Xu *et al.*, 2013). In contrast, another cited study reported removal efficiencies greater than 90% by comparing effluent to synthetic wastewater influent concentrations between 0.01 to 0.10 mg/L in sequencing batch reactors containing activated sludge (An *et al.*, 2017). It was concluded that the mechanism of removal was primarily by adsorption to the biomass.

Seitz and Winzenbacher (2017) examined inlet/outlet concentration values at four different wastewater treatment plants (WWTPs) in Germany. All included mechanical and biological treatment and removal processes for phosphorus and nitrogen but no specialist additional treatment except for one case of sand filtration. The median elimination rate for melamine was 27% for one WWTP and < 20% for the other three.

ECHA (2022) also considered a number of published reports of techniques available for removal of melamine from sewage water but concluded that their implementation is hardly likely to occur in municipal and industrial sewage treatment because of a lack of evidence for verification in a laboratory setting or at real installations.

2.4.2.4.2 Removal during drinking water treatment

ECHA (2022) reported information in Winzenbacher *et al.* (2015) that indicated the removal rates of melamine achieved by applying ozonisation or adsorption on granular activated carbon (GAC) will be lower under real life conditions than at laboratory scale. This might serve as an explanation for the findings of melamine in purified drinking water (see Section 2.4.2.52.4.2.5). Sangjung and Ihnsup (2015) found the removal efficiency of melamine from distilled water was 69% at an ozone concentration of 10 mg/L and also determined breakthrough times for removal using GAC (this study was not discussed in ECHA (2022)).

A Drinking Water Inspectorate report (DWI, 2023) modelled the removal of a number of persistent and potentially mobile substances in different drinking water treatment scenarios. Estimated melamine removal varied between 74 and 95% (Table 15).

Table 15: Modelled melamine removal for different drinking water processes

Drinking water source	Treatment process	Description	Melamine removal (%)
Surface water	Conventional	Coagulation/flocculation/filtration and chlorination	74
	Advanced	Coagulation/flocculation/filtration, ozonation, activated carbon and chlorination	95
Groundwater	Filtration	Sand filtration plus disinfection	74
	Membrane	Ultrafiltration plus disinfection	74

2.4.2.5 Field data

ECHA (2022) discussed the presence of melamine in drinking water and the aquatic environment. A summary of the papers cited and results are presented in Table 16Table 16. No reports of melamine in drinking water in the UK were available. The support document did not comment on the reliability of the field data. The Agency is aware of recent developments in the reliability assessment of monitoring data using Criteria for Reporting and Evaluating Exposure Datasets (CREED; Merrington *et al.* (2024)). It would normally be appropriate to use this approach to carry out an assessment of the studies but, given the volume of data and general consistency in findings, it was not considered necessary in this case. The Agency considered the quality and reporting of the monitoring

evidence presented in this dossier for a selection of references using the CREED framework. Overall, the studies were generally well reported, relevant to the assessment, and included the required reporting elements, although some recommended elements were not consistently reported. Consequently, the monitoring evidence is considered to be broadly consistent with the CREED silver level ("usable with restrictions").

ECHA (2022) also included comments from a report by Broneder *et al.* (2022) for the European Melamine Producers Association (EMPA) that indicated that melamine was detected in nearly all surface water samples in the rivers Rhine and Maas or in North-Rhine Westphalia. The same report considered the NORMAN Empodat database data and summarised that melamine was not detected in 61 out of 673 surface water samples (9.1%) in Germany and not detected in 8 out of 325 surface water samples (2.5%) in the Netherlands.

ECHA (2022) concluded from these studies that melamine can be found in surface waters and groundwater bodies in a widespread manner. It stated that melamine, irrespective of its origin, enters the aquatic environment and persists there. The presence of melamine in surface water may result from continuous environmental release. Nevertheless, the available data indicate that melamine is widespread in surface waters and is also present in some groundwaters. No studies have examined changes in melamine concentrations over extended periods; therefore, it is not possible to determine whether concentrations are increasing or whether accumulation is occurring in different water bodies.

Table 16: Summary of field data including concentration and detection frequency (DF)

Reference	Study details	Concentration (µg/L) and DF (%)
Groundwater and drinking water		
Kolkman *et al.* (2021)	The Netherlands and Flanders (Belgium). Drinking water samples (n = 12)	0.70 and 1.93 in two samples DF = 17% (MDL[a] = 0.19)
Zhu and Kannan (2020)	New York State, USA (2015 and 2019) Tap water (n = 70)	Median: 0.019 Mean = 0.033 Maximum = 0.188 DF = 91% (MDL = 0.005)
Kiefer *et al.* (2021)	Switzerland (2018) Groundwater (n = 60)	Above LoQ[b] (0.005) in 14 samples. Maximum: 690
Neuwald *et al.* (2022)	Various sites in Germany, two campaigns in 2020 and 2021. Groundwater: 2020 (n = 7); 2021 (n = 4)	2020 sampling campaign: < 0.010 to 5.94 (DF: 14%) 2021 sampling campaign: < 0.010 to 3.24 (DF: 25%)

Reference	Study details	Concentration (µg/L) and DF (%)
Surface waters		
Smit (2018)	The Netherlands (2016) River Rhine and Meuse (drinking water companies monitoring of intake points)	Rhine: Annual average: 0.97 to 1.36 Maximum individual: 2.8 Meuse: Maximum individual: 5.8
Been *et al.* (2021)	The Netherlands 2018 and 2019) River water (Meuse and Rhine) Sampled three times each year	Found at all three samplings; range from 0.7 to 2.3
Alhelou *et al.* (2019)	The Netherlands (2016 to 2017) River Mulde, downstream of WWTP discharges; n = 4)	Concentration range: 0.4 to 19.90
Seitz and Winzenbacher (2017)	Germany (2012 to 2014); areas around Ulm and Neu-Ulm. Run-off waters Groundwater (hotspots) Surface water	Highest median concentration: Run-off from roads: 0.25 Groundwater hotspots: 0.36 Stream water: 0.61
Park and Jeon (2021)	South Korea (2016) Surface water (Nakdong river)	Maximum: 94 Minimum: 1.23 Median: 11 DF = 100% (LoQ = 0.070)
Kolkman *et al.* (2021)	The Netherlands and Flanders (Belgium) Surface water (n = 7).	1.49 to 3.49 in 5 samples DF = 71% (MDL = 0.19)
Neuwald *et al.* (2022)	Various sites in Germany, two campaigns in 2020 and 2021. Surface water (SW; n = 16) Bank filtrate (BF; n = 16) Raw water (RW; n = 7)	2020 sampling campaign: SW: < 0.010 to 2.14 (DF: 81%) BF: < 0.010 to 4.18 (DF: 43%) RW: < 0.010 to 0.96 (DF: 57%) 2021 sampling campaign: SW: < 0.010 to 4.84 (DF: 81%) BF: < 0.010 to 3.92 (DF: 31%)
Zhu and Kannan (2020)	New York State, USA (2015 and 2019). River water (n = 35) Lake water (n = 39) Seawater (n = 10)	River water: min: 0.017; max 3.65; median: 235 Lake water: min: 0.005; max 1.75; median: 0.205 Seawater: min: 0.014; max 0.086; median: 0.028 DF: 100% (in all waters)

[a] MDL is method detection limit

[b] LoQ is the limit of quantification

Monitoring data are available from the Environment Agency. The analytical method was liquid chromatography-mass spectroscopy (LC-MS), the data are semi-quantitative, and

the sites are distributed throughout England and include rural and urban locations. The results are summarised in

Table 17 for freshwater and groundwater. The data show a high level of detection in freshwater (32.76 to 71.35% of samples analysed between 2019 and 2022) and a lower but still significant level of detections in groundwater (8.8 to 23.8%).

Table 17: Environment Agency monitoring results for melamine

Year	Total analyses	Total detections	% detection	Total sites detected	Concentration (µg/L)[a]			
					Min.	Max.	Mean	Median
Freshwater detections								
2019	407	213	52.33	83	0.0058	13.0	0.902	0.360
2020	116	38	32.76	14	0.0290	3.9	0.483	0.195
2021	380	248	65.26	21	0.0110	4.9	0.479	0.225
2022	534	381	71.35	32	0.0048	19.0	0.854	0.280
Groundwater [b]								
2019	216	38	17.59	38	0.0058	1.20	0.107	0.031
2020	91	8	8.79	8	0.0140	2.50	0.391	0.054
2021	21	5	23.81	5	0.0110	0.12	0.049	0.036
2022	161	19	11.80	19	0.0073	1.00	0.099	0.039

[a] These reported values should only be considered an approximation for actual levels
[b] Groundwater quality monitoring network data

2.4.2.6 Summary of environmental distribution

The experimental log K_{foc} values ranged from 1.73 to 2.62 (EFSA, 2008) and from 1.51 to 2.84 (Wang *et al.*, 2014). This indicates that melamine has limited potential to adsorb to environmental matrices. Melamine is partially ionised around neutral pH values; the potential for adsorption appears to be pH dependent and therefore there is more potential for adsorption to soils and sediments at higher but still environmentally relevant pH values.

Fugacity modelling indicates that after release to water and soil, melamine is likely to remain in that environmental compartment. After release to water, it has a very low potential to volatilise from water and adsorption to sediment is likely to be limited. After release to soil there is some potential, depending on soil pH, to move through the soil to groundwater.

Modelling indicates that there will be no retention in WWTWs and most melamine will be emitted to surface water. There is some experimental evidence to confirm that removal during wastewater treatment is limited. Modelling and experimental evidence indicates that removal during drinking water treatment is likely to be incomplete.

The widespread presence of melamine in surface waters and its presence in groundwaters is confirmed by Environment Agency monitoring and a number of peer reviewed studies.

2.4.3 Data indicating potential for long-range transport

Melamine has an estimated half-life in air of 16.22 days and so screens for long-range environmental transport via the air (half-life > 2 days) according to the Stockholm Convention (UNEP, 2025). However, given that melamine volatilisation from water is low, long-range transport of melamine is more likely to occur via the water phase.

ECHA (2022) reported the use of the OECD P_{OV} and Long-Range Transport Potential (LRTP) screening tool (v2.2) to evaluate the LRTP of melamine. Two sets of results were presented, one using 'pragmatic worst case' $DegT_{50}$ values for water and soil and the other using 'upper limit' values.

As transport is predicted to occur via the water phase, the model is particularly sensitive to the half-life of water parameter. The values used in the support document modelling are a 'pragmatic worst case' of 1,500 days and an 'EUSES upper limit' of 10,000 days. Although there was little degradation seen in the aerobic mineralisation study, the study duration was only 60 days and determination of half-lives beyond the length of the study introduces considerable uncertainty.

In conclusion, as a definitive bound experimental half-life in water is not available, the results of any LRTP modelling will not be reliable and so no further consideration is given to long-range transport modelling as part of this assessment.

2.4.3.1 Summary of long-range transport potential

It is concluded that it is possible that melamine could be subject to long-range transport as it is persistent in water with limited potential for removal by either volatilisation or adsorption.

2.4.4 Bioaccumulation

Bioaccumulation is not considered in this assessment of melamine. ECHA (2022) concluded that melamine was not bioaccumulative in aquatic organisms. Melamine does not screen as bioaccumulative in terrestrial organisms as the log K_{OW} value is less than 2.

2.4.5 Ecotoxicity information

ECHA (2022) briefly reported a range of studies that are used to assess the environmental hazard of melamine. The support document makes no comments on reliability of the studies but does report the Klimisch score assigned in the EU REACH registration dossier. Brief summaries of the most relevant studies are provided below.

2.4.5.1 Aquatic compartment (including sediment)

2.4.5.1.1 Fish

2.4.5.1.1.1 Short-term toxicity to fish

There were ten acute toxicity to fish studies reported in ECHA (2022). Eight are rated as Klimisch score 3 or 4 and not considered any further except to say that they generally do not contradict the conclusions of the two studies assigned Klimisch score 2.

- Pirarat *et al.* (2012)

This was a 14-d flow-through study and not following any specific guideline. *Clarius batrachus* (Walking catfish) were fed either 5 or 20 g of melamine/kg of feed (nominal concentration, purity not specified) and were sacrificed at 7 and 14 days (post feeding) and examined for gross abnormalities. Fish body weight was 80 to 140 g and there were 10 fish per treatment. No mortality was seen at either feed concentration. There was darkening of the skin in fish exposed to 20 g/kg feed, effects on the skin (melanophore hyperplasia) and kidney (degeneration of the renal tubular epithelium with hyaline droplet accumulation or vacuolation of tubular epithelial cells) at 5 and 20 g/kg feed, and effects on the liver (ingle cell necrosis) at 20 g/kg feed.

- EU REACH registration dossier; unpublished report (1984)

This was a non-GLP 28-d semi-static study of the acute toxic effects of melamine on *Oncorhynchus mykiss* (Rainbow trout) that didn't follow any specific guideline. The test concentrations were 0, 750, and 3,000 mg/L (nominal concentration) and there were 10 fish (fingerlings) per treatment. The test temperature was 14.3 to 14.4°C (range 10.6 to 16°C). The reported 96-h LC_{50} was > 3,000 mg/L based on mortality and nominal concentration. It was observed that 30% mortality did occur in the 3,000 mg/L exposure group, the first mortality occurring after 10 days. The 3,000 mg/L test concentration is near to the solubility limit of melamine and some precipitation was seen at this concentration, although it was not confirmed to be melamine.

2.4.5.1.1.2 Long-term toxicity to fish

There were 12 studies of long-term exposure to fish reported in ECHA (2022). One study was conducted to a recognised test guideline, and this also gave the lowest recorded endpoint (see below). It was assigned a Klimisch score of 1 by the registrant. None of the other studies were considered in detail by the Agency.

- EU REACH registration dossier; report dated 2015

A 36-d flow-through study with was *Pimephales promelas* (Fathead minnow) conducted to OECD TG 210 and following GLP. . There were 100 eggs (< 4 hours) added to each test vessel and measured test concentrations were 0 (< LoQ), 0.618, 1.18, 2.30, 5.25, and 10.1 mg/L. The test temperature was 25 ± 1°C. At 10.1 mg/L there were two deformed fish

recorded from 31 days and a decrease in body length. The 36-d mean measured NOEC was 5.25 mg/L (based on length). There was a statistically significant decrease in fish survival from end of swim-up (day 6) until the end of exposure (day 36) at 10.1mg/L compared to the control.

2.4.5.1.2 Aquatic invertebrates

2.4.5.1.2.1 Short-term toxicity to aquatic invertebrates

There were two short-term toxicity to aquatic invertebrate studies reported in ECHA (2022), rated by the registrant as either Klimisch score 1 (report dated 1988) or 2 (report dated 1978).

- EU REACH registration dossier; report dated 1988

A 48-h static study conducted to EU Method C.2 and to GLP. The test species was *Daphnia magna* (Water flea) and the nominal test concentrations were 0, 56, 100, 180, 320, 560, and 1,000 mg/L. The reported 24-h LC_{50} was > 1,000 mg/L and the 48-h EC_{50} based on mobility was 200 (95% C.I.: 160 to 250) mg/L (based on nominal concentrations).

- EU REACH registration dossier; report dated 1978

A 48-h non-GLP static study conducted to Dutch proposed standards NEN 6501 and 6502. The test species was *D. magna* (Water flea) and the nominal test concentrations were 180, 320, 560, 1000, 1,800, and 2,000 mg/L. The 48-h LC_{50} was > 2,000 mg/L and based on behaviour the 48-h EC_{50} was < 180 mg/L (both based on nominal concentrations). The condition of the daphnids was described as poor at test concentrations as low as 180 mg/L.

2.4.5.1.2.2 Long-term toxicity to aquatic invertebrates

There were three long-term toxicity to aquatic invertebrate studies reported in ECHA (2022). The two studies presented in the EU REACH registration dossier are summarised below. The third study examined the effect of feeding *Litopenaeus vannamei* (Pacific white shrimp) with melamine at 10.1 g/kg of feed and qualitatively described a number of effects (Nuntapong, 2019).

- EU REACH registration dossier; report dated 2014

This was a 21-d semi-static study conducted to OECD TG 211 and to GLP. The test species was *D.magna* (Water flea) and the measured test concentrations were 0.7, 1.4, 2.6, 5.5, and 11.0 mg/L. There were no indications of mortality, reduced reproduction, or behavioural effects up to 11 mg/L. The 21-d NOEC was ≥ 11 mg/L (geometric mean measured concentration). The study was assigned as Klimisch score 1 by the registrant.

- EU REACH registration dossier; report dated 1978

A 21-d semi-static study conducted to Dutch proposed standards NEN 6501 and 6502 (not to GLP). The test species was *D. magna* (Water flea) and the nominal test concentrations were 10, 18, 32, 56, and 100 mg/L (mortality test) and 5.6, 10, 18, 32, and 56 mg/L (reproduction test). The 21-d LC_{50} was between 32 and 56 mg/L and the 21-d NOEC (reproduction) was 18 mg/L based on reproduction and mortality. The registrant assigned the mortality test as Klimisch 1 and the reproduction test as Klimisch score 3 (because of a less sensitive study design as more sensitive animals were excluded from examination of reproduction).

2.4.5.1.3 Algae and aquatic plants

There were two algal studies available and both are summarised briefly below. ECHA (2022) concluded that melamine has a low toxicity to algae. There were no data on aquatic plants.

- EU REACH registration dossier; report dated 1988

A 96-h algal growth inhibition test conducted to the stated guideline PRO/FT Algae AC090-6 (details of this guideline could not be found) and to GLP. The test species was *Pseudokirchneriella subcapitata* and the nominal test concentrations were 10, 32, 100, 320, and 1000 mg/L. The study reports a 96-h EC_{50} = 325 mg/L based on the area under the growth curve and a 96-h NOEC of 98 mg/L (basis not specified), both determined from nominal concentrations. The registrant assigned Klimisch score 1 to the study. .

- EU REACH registration dossier; report dated 1982

A 90.5-h algal growth inhibition test conducted to Dutch proposed standard NEN 6506 (not to GLP) guideline. The test species was *Scenedesmus pannonicus* and the nominal test concentrations were 10, 32, 100, 320, 1,000, and 2,000 mg/L. The reported E_rC_{50} was 940 (95% C.I.: 880 to 1,000) mg/L (based initial measured concentration) and the NOE_rC was 320 mg/L (based on nominal concentrations). The registrant assigned Klimisch score 2 to the study.

2.4.5.2 Terrestrial compartment

2.4.5.2.1 Toxicity to birds

Suchý *et al.* (2014) studied egg-laying hens (*Gallus gallus*) which were fed melamine at a rate of 100 mg/kg feed which resulted in significantly decreased eggshell strength and weight. Haemoglobin concentration was significantly decreased, whereas the number of erythrocytes was significantly increased. The NOEC is therefore below 100 mg/kg feed.

2.4.5.3 Summary and discussion of the ecotoxicity information

The lowest acute endpoint for fish was a 96-h LC_{50} > 3,000 mg/L in *O. mykiss* (Rainbow trout) while for aquatic invertebrates it was a 48-h EC_{50} < 180 mg/L for *D. magna* (based on nominal concentrations). The lowest chronic endpoint for fish was a 36-d mean

measured NOEC of 5.25 mg/L for *P. promelas* (based on length) and for aquatic invertebrates it was a 21-d NOEC ≥ 11 mg/L for *D. magna* (geometric mean measured concentration). For aquatic plants, the lowest endpoints were a 96-h EC_{50} of 325 mg/L and a 96-h NOEC of 98 mg/L for *Ps. subcapitata.*

ECHA (2022) did not assess the reliability of the studies. There is insufficient information available for most of the studies to enable an independent assessment of reliability, but a full assessment of each study is unnecessary as ecotoxicity is not central to the justification for identifying melamine as an SVHC. Several of the endpoints are based on nominal concentrations without analytical confirmation, although given the high water solubility, low vapour pressure, low adsorption potential and slow rate of degradation, there is no reason to expect the exposure concentrations to have declined over time.

ECHA (2022) concluded that melamine has a low acute toxicity and a moderate chronic toxicity to fish, it has a low acute and chronic toxicity to aquatic invertebrates, and toxicity to algae is low. The Agency agrees with these conclusions based on the evidence presented and noting that study reliability is uncertain in some cases.

Additionally, a study with egg-laying hens resulted in significantly decreased eggshell strength and weight, along with other clinical effects. The R.11 PBT/vPvB assessment guidance states that a NOEC of ≤ 30 mg/kg food in a long-term bird study should be considered as a strong indicator for fulfilling the T criterion. In this case the study was a limit test and the NOEC was below 100 mg/kg feed so a firm conclusion cannot be drawn.

2.5 Conclusions on the SVHC properties

2.5.1 Equivalent level of concern under Article 57(f)

Melamine is proposed to be identified as an SVHC in accordance with Article 57(f) of UK REACH as there is scientific evidence of possible serious effects to human health and the environment which give rise to an equivalent level of concern to those of other hazards listed in points (a) to (e) of Article 57. Its key properties can be summarised as follows:

- There is no evidence for abiotic degradation of melamine. The substance screens as potentially persistent (P) and very persistent (vP) based on modelling results and the lack of ready or inherent biodegradability in screening tests. There was no notable degradation of melamine in freshwater during an OECD TG 309 study, with a half-life much longer than 60 days at 13°C. The half-lives for melamine in aerobic soil degradation studies reported as part of the active substance approval of the pesticide cyromazine ranged from 255 to 448 days when extrapolated to 12°C. Melamine fulfils the P and vP criteria under Annex 13 of UK REACH for both freshwater (half-life > 60 days) and soil (half-life > 180 days).
- Experimental log K_{fOC} values for melamine ranged from 1.51 to 2.84, indicating a relatively low adsorption potential in sediments, sewage sludges and soils. Melamine has a high water solubility (3,840 mg/L), and a low tendency to volatilise from water

(estimated Henry's law constant (HLC) is 1.89×10^{-8} Pa.m^3/mol). Melamine will remain in the aqueous phase and as it has limited adsorption potential it will be mobile in the aqueous environment.

- Melamine has a mandatory classification in accordance with GB CLP for carcinogenicity category 2 (H351: Suspected of causing cancer) and STOT RE 2 (urinary tract) (H373: May cause damage to organs through prolonged or repeated exposure). Owing to the STOT RE 2 (urinary tract) classification, melamine meets the toxicity (T) criterion under Annex 13 of UK REACH.

These properties lead to the following concerns if melamine is released to the environment:

- *Widespread presence in the environment*

  The combination of persistence and mobility gives rise to the potential for melamine to travel far from the source of emission via water and to migrate between and through environmental compartments, such as from soil to groundwater, leading to widespread presence in the environment. Environment Agency monitoring data provide evidence of extensive contamination, with melamine detected in 33 to 71% of surface water samples and in 8.8 - 23.8% of groundwater samples between 2019 and 2022. Additional evidence from national monitoring programmes and academic studies indicates that melamine is present in surface water, groundwater and drinking water sources in multiple countries.

- *Difficulty in removal from drinking water sources*

  Part 3 of the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (UK Government, 2017) requires that, for water bodies used for abstraction, measures are implemented 'with the aim of avoiding deterioration in water quality, in order to reduce the level of purification treatment required for the production of drinking water'.

  The persistence of melamine, its tendency to remain in the aqueous environment, and its relatively low adsorption potential to organic matter indicate that it may be difficult to remove through conventional drinking water treatment processes. Evidence from peer-reviewed studies and modelling suggests that removal using standard treatment methods is incomplete. Even with advanced treatment technologies, complete removal may not be achieved. Melamine has been detected in drinking water in Europe.

- *Potential for toxic effects*

  There is likely to be long-term exposure of humans and wildlife to melamine from its presence and likely slowly increasing concentrations in the environment. Given its hazard profile, this indicates a potential to cause harm.

This combination of concerns gives rise to the potential for long-term impacts that are difficult to reverse. Melamine is therefore proposed to be identified as an SVHC in accordance with Article 57(f) of the UK REACH Regulation as there is scientific evidence of possible serious effects to the environment and human health which give rise to an equivalent level of concern to those of other hazards listed in points (a) to (e) of Article 57 of the Regulation.

3 Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

Under UK REACH, the substance is registered with an aggregated tonnage in the range of 1000 to <10,000 tonnes per annum (tpa).

A total 258 Downstream User Import Notifications (DUINs[2]) have been submitted under UK REACH.

Under EU REACH, the substance is registered in the range of 100 000 to 1 000 000 tpa (51 active registrants and one intermediate Article 18 registration).

3.2 General description of uses and exposure

Melamine is a starting material in the production of melamine-based resins. The main reported use is the manufacture of formaldehyde based resins for the production of wood-based panels and other composite wood products. These resins are also used to impregnate papers and foils for decorative surface applications including furniture, worktops and laminate flooring. In addition, melamine-based resins are used as amino crosslinkers in coating systems to provide durable surface finishes, with applications in the automotive sector for example. Other uses include the production of moulding compounds for consumer articles, including tableware and other household products.

It is also used in fire protection applications, both as an intermediate in the production of flame retardants and also as the substance itself incorporated into intumescent coating systems that are used for passive protection of building structures. Other uses include as

[2] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to the Agency.

an additive in polyurethane foams to improve fire performance and flame-retardant properties, including applications in furniture and furnishings that are required to meet certain fire safety standards.

Exposure and environmental release may occur during industrial and professional uses of melamine-containing products. Releases from articles containing melamine cannot be excluded based on the information currently available.

3.3 Alternatives

No information on specific alternatives is available.

References

Alhelou, R., Seiwert, B. & Reemtsma, T. (2019). Hexamethoxymethylmelamine - A precursor of persistent and mobile contaminants in municipal wastewater and the water cycle. *Water Research,* 165, 114973. https://doi.org/10.1016/j.watres.2019.114973

An, H., Li, X., Yang, Q., Wang, D., Xie, T., Zhao, J., Xu, Q., *et al.* (2017). The behavior of melamine in biological wastewater treatment system. *Journal of Hazardous Materials,* 322(Pt B), 445-453. https://doi.org/10.1016/j.jhazmat.2016.10.036

Been, F., Kruve, A., Vughs, D., Meekel, N., Reus, A., Zwartsen, A., Wessel, A., *et al.* (2021). Risk-based prioritization of suspects detected in riverine water using complementary chromatographic techniques. *Water Research,* 204, 117612. https://doi.org/10.1016/j.watres.2021.117612

Broneder, C., Strauss, F. & Höhne, D. (2022). Melamine in the environment. Ramboll Deutschland GmbH.

DWI (2023). Persistent, mobile and toxic substances - Risk to drinking water in England and Wales (Phase 2). [DWI 70/2/341]. Drinking Water Inspectorate. https://dwi-content.s3.eu-west-2.amazonaws.com/wp-content/uploads/2023/01/18144553/DWI70_2_341.pdf

ECETOC (1983). Joint assessment of commodity chemicals: No. 1 Melamine CAS: 108-78-1. European Chemical Industry Ecology & Toxicology Centre. Available at: https://www.ecetoc.org/wp-content/uploads/2021/10/JACC-001.pdf

ECHA (2010). EU REACH registration for melamine; last updated May 2023. Available at: https://chem.echa.europa.eu/100.003.288/dossier-list/reach/dossiers/active?searchText=108-78-1

ECHA (2016). Chapter R.16: Environmental Exposure Assessment. *Guidance on Information Requirements and Chemical Safety Assessment.* European Chemicals Agency. Helsinki, Finland. https://data.europa.eu/doi/10.2823/515110

ECHA (2022). Member State Committee support document for identification of melamine as a substance of very high concern. European Chemicals Agency. Available at: https://chem.echa.europa.eu/api-activity-list/v1/svhcIdentification/documents?name=640c895f30a00c6faf0a40ac97d9daee_svhc_supdoc_melamine_en.pdf

ECHA (2026). Harmonised classification and labelling activity details for melamine. Available at: https://chem.echa.europa.eu/100.003.288/activities/clhProcess/ddf6db98e11c15a830cff4ad960cba53?searchText=108-78-1

EFSA (2008). Conclusion regarding the peer review of the pesticide risk assessment of the active substance cyromazine. *EFSA Journal,* 6(10). https://doi.org/10.2903/j.efsa.2008.168r

EFSA (2017). EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil: This guidance published on 19 October 2017 replaces the earlier

version published on 28 April 2015. *EFSA Journal,* 15(10), e04982. https://doi.org/10.2903/j.efsa.2017.4982

EFSA (2026). Public consultations. Available at: https://www.efsa.europa.eu/en/calls/consultations

Gong, H., Tang, S. & Zhang, T. (2016). Catalytic hydrolysis of waste residue from the melamine process and the kinetics of melamine hydrolysis in NaOH solution. *Reaction Kinetics, Mechanisms and Catalysis,* 118(2), 377-391. https://doi.org/10.1007/s11144-016-1014-9

Hansch, C., Leo, A. & Hoekman, D. (eds.) (1995). *Exploring QSAR. Hydrophobic, Electronic, and Steric Constants.* Washington, DC: American Chemical Society.

Hauck, R. D. & Stephenson, H. F. (1964). Fertilizer nitrogen sources, nitrification of triazine nitrogen. *Journal of Agricultural and Food Chemistry,* 12(2), 147-151. https://doi.org/10.1021/jf60132a014

Hirt, R. C., Steger, J. E. & Simard, G. L. (2003). Vapor pressure of 2,4,6-triamino-s-triazine (melamine). *Journal of Polymer Science,* 43(142), 319-323. https://doi.org/10.1002/pol.1960.1204314204

Hofman-Caris, R. & Claßen, D. (2020). Persistence of gabapentin, 1H-benzotriazole, diglyme, DTPA, 1,4-dioxane, melamine and urotropin in surface water. Testing of chemicals according to the OECD 309 guideline. [KWR 2020.118]. Available at: https://edepot.wur.nl/539038

Hubert, M. & Arp, H. P. H. (2025). Determination of log K_{OC} values according to OECD TG 106: for melamine (CAS: 108-78-1). Dessau-Roßlau: German Environment Agency. https://doi.org/10.60810/openumwelt-7998

Kiefer, K., Du, L., Singer, H. & Hollender, J. (2021). Identification of LC-HRMS nontarget signals in groundwater after source related prioritization. *Water Research,* 196, 116994. https://doi.org/10.1016/j.watres.2021.116994

Kolkman, A., Vughs, D., Sjerps, R., Kooij, P. J. F., van der Kooi, M., Baken, K., Louisse, J., *et al.* (2021). Assessment of highly polar chemicals in Dutch and Flemish drinking water and Its sources: Presence and potential risks. *ACS Environmental Science and Technology Water,* 1(4), 928-937. https://doi.org/10.1021/acsestwater.0c00237

Merrington, G., Nowell, L. H. & Peck, C. (2024). An introduction to Criteria for Reporting and Evaluating Exposure Datasets (CREED) for use in environmental assessments. *Integrated Environmental Assessment and Management,* 20(4), 975-980. https://doi.org/10.1002/ieam.4899

Neuwald, I. J., Hubner, D., Wiegand, H. L., Valkov, V., Borchers, U., Nodler, K., Scheurer, M., *et al.* (2022). Occurrence, distribution, and environmental behavior of persistent, mobile, and toxic (PMT) and very persistent and very mobile (vPvM) substances in the sources of German drinking water. *Environmental Science & Technology,* 56(15), 10857-10867. https://doi.org/10.1021/acs.est.2c03659

Park, N. & Jeon, J. (2021). Emerging pharmaceuticals and industrial chemicals in Nakdong River, Korea: Identification, quantitative monitoring, and prioritization. *Chemosphere,* 263, 128014. https://doi.org/10.1016/j.chemosphere.2020.128014

Piai, L., van der Wal, A., Boelee, N. & Langenhoff, A. (2021). Melamine degradation to bioregenerate granular activated carbon. *Journal of Hazardous Materials,* 414, 125503. https://doi.org/10.1016/j.jhazmat.2021.125503

Pirarat, N., Katagiri, T., Chansue, N., Ponpornpisit, A., Endo, M. & Maita, M. (2012). The pathological effects of melamine and cyanuric acid in the diet of walking catfish (*Clarius batrachus*). *Journal of Comparative Pathology,* 147(2-3), 259-266. https://doi.org/10.1016/j.jcpa.2011.12.008

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.: European Commission. Available at: http://data.europa.eu/eli/reg/2006/1907/2022-12-17

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). European Commission. Available at: http://data.europa.eu/eli/reg/2008/1272/2026-05-01

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). UK Government. Available at: https://www.legislation.gov.uk/eur/2008/1272/contents

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). UK Government. Available at: https://www.legislation.gov.uk/eur/2006/1907/contents

Sangjung, L. & Ihnsup, H. (2015). The analysis of melamine and the removal efficiencies in the advanced oxidation process (AOP) and granular activated carbon (GAC) processes. *Desalination and Water Treatment,* 53(6), 1565-1577. https://doi.org/10.1080/19443994.2013.855665

Seitz, W. & Winzenbacher, R. (2017). A survey on trace organic chemicals in a German water protection area and the proposal of relevant indicators for anthropogenic influences. *Environmental Monitoring and Assessment,* 189(6), 244. https://doi.org/10.1007/s10661-017-5953-z

Smit, C. E. (2018). Water quality standards for melamine A proposal in accordance with the methodology of the Water Framework Directive. RIVM. Available at: https://rivm.openrepository.com/server/api/core/bitstreams/53efb912-ae9f-4e5f-9c29-0620aa4a4f1d/content

Suchý, P., Novák, P., Zapletal, D. & Straková, E. (2014). Effect of melamine-contaminated diet on tissue distribution of melamine and cyanuric acid, blood variables, and egg quality in laying hens. *British Poultry Science,* 55(3), 375-379. https://doi.org/10.1080/00071668.2014.911815

UK Government (2017). The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 [2017 No. 407]. Available at: https://www.legislation.gov.uk/uksi/2017/407/data.pdf

UNEP (2025). Stockholm Convention on persistent organic pollutants (POPS). Text and Annexes. Revision 2025. Available at: https://www.pops.int/Portals/0/download.aspx?e=UNEP-POPS-COP-CONVTEXT-2025.English.pdf

US EPA (2021). CompTox Chemicals Dashboard v.2.8.0. Available at: https://comptox.epa.gov/dashboard/

Wang, H. Y., Wang, H., Tang, L. L., Dong, Y. H., Zhao, L. & Toor, G. (2014). Sorption characteristics of cyromazine and its metabolite melamine in typical agricultural soils of China. *Environmental Science and Pollution Research,* 21(2), 979-985. https://doi.org/10.1007/s11356-013-1956-7

US EPA (2026). EPI Suite™ - Estimation Programs Interface Suite™ for Microsoft® Windows. Version: v 4.11. Washington, DC, USA: United States Environmental Protection Agency. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface; accessed 13 May 2026

Winzenbacher, R., Seitz, W. & Schulz, W. (2015). Bedeutung der Spurenstoffanalytik für die Wasserversorgung - Was, Wie, Warum? 35, 66-75. Available at: https://www.lw-online.de/fileadmin/lwonline/redaktion/pdf-dateien/publikationen/schriftenreihe/Beitrag_6_Winzenbacher_2015.pdf

Xu, S., Zhang, Y., Sims, A., Bernards, M. & Hu, Z. (2013). Fate and toxicity of melamine in activated sludge treatment systems after a long-term sludge adaptation. *Water Research,* 47(7), 2307-2314. http://dx.doi.org/10.1016/j.watres.2013.01.048

Zhu, H. & Kannan, K. (2020). Occurrence and distribution of melamine and its derivatives in surface water, drinking water, precipitation, wastewater, and swimming pool water. *Environmental Pollution,* 258, 113743. https://doi.org/10.1016/j.envpol.2019.113743

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit the HSE website.

You can order HSE priced publications at the HSE books website.

HSE priced publications are also available from bookshops.

This publication is available on the HSE website here.

© Crown copyright If you wish to reuse this information visit the HSE website for details. First published [11/26].

Published by the Health and Safety Executive [11/26].