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Schweizerisches Zentrum für angewandte Ökotoxikologie
Centre Suisse d'écotoxicologie appliquée

# CQC (AA-EQS), AQC (MAC-EQS) and SQC ($EQS_{sed}$) – Proposal by the Ecotox Centre for: *Gadolinium*

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Please note that the suggested EQS and contents of this dossier do not necessarily reflect the opinion of the external reviewer.



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## Executive summary


| | |
|---|---|
| **CQC (AA-EQS):** | **0.084 µg/L (dissolved $Gd^{3+}$)** |
| **AQC (MAC-EQS):** | **0.84 µg/L (dissolved $Gd^{3+}$)** |
| **SQC ($EQS_{sed}$):** | **1.607 mg/kg d.w., preliminary** |

The chronic quality criterion (CQC) and the acute quality criterion (AQC) for surface waters and the sediment quality criterion (SQC) were derived according to the TGD for EQS of the European Commission (EC 2018). To ensure that the dossiers are internationally comparable, the English terminology of the TGD will be used in the remainder of the dossier. The AQC corresponds to the MAC-EQS ("maximum allowable concentration environmental quality standard") and the CQC corresponds to the AA-EQS ("annual average environmental quality standard"). The SQC corresponds to the $EQS_{sed}$. According to the Swiss Water Protection Ordinance (The Swiss Federal Council 2020), the CQC should not be compared with an annual average value but with the averaged concentration over two weeks.


## Zusammenfassung


| | |
|---|---|
| **CQK (AA-EQS):** | **0.084 µg/L (gelöstes $Gd^{3+}$)** |
| **AQK (MAC-EQS):** | **0.84 µg/L (gelöstes $Gd^{3+}$)** |
| **SQK ($EQS_{sed}$):** | **1.607 mg/kg d.w., vorläufig** |

Das chronische Qualitätskriterium (CQK) und das akute Qualitätskriterium (AQK) für Oberflächengewässer und das Qualitätskriterium für Sediment (SQK) wurden nach dem *TGD for EQS* der Europäischen Kommission (EC 2018) hergeleitet. Damit die Dossiers international vergleichbar sind, wird im Weiteren die englische Terminologie des TGD verwendet. Der AQK entspricht dabei dem MAC-EQS ("maximum allowable concentration environmental quality standard") und der CQK entspricht in der Herleitung dem AA-EQS ("annual average environmental quality standard"). Das SQK entspricht dem $EQS_{sed}$. Das CQK soll aber gemäss Schweizer Gewässerschutzverordnung (Der Schweizerische Bundesrat 2020) nicht mit einem Jahresmittelwert sondern mit der gemittelten Konzentration über 2 Wochen verglichen werden.


## Résumé


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|---|---|
| **CQC (AA-EQS) :** | **0.084 µg/L ($Gd^{3+}$ dissout)** |
| **CQA (MAC-EQS) :** | **0.84 µg/L ($Gd^{3+}$ dissout)** |
| **CQS ($EQS_{sed}$) :** | **1.607 mg/kg p.s., provisoire** |

Le critère de qualité chronique (CQC) et le critère de qualité aiguë (AQC) pour les eaux de surface et le

critère de qualité pour les sédiments (CQS) ont été dérivés selon le *TGD for EQS* de la Commission européenne (EC 2018). Afin que les dossiers soient comparables au niveau international, la terminologie anglaise du TGD est utilisée ci-dessous. La CQA correspond à la MAC-EQS (“maximum allowable concentration environmental quality standard”) ou NQE-CMA ("norme de qualité environnementale de la concentration maximale admissible") et la CQC correspond à la AA-EQS (“annual average environmental quality standard”) ou NQE-MA ("norme de qualité environnementale de la moyenne annuelle"). Le CQS correspond à l’$EQS_{sed}$. Selon l'ordonnance suisse sur la protection des eaux (Le Conseil fédéral suisse 2020), la CQC ne doit cependant pas être comparée à une valeur moyenne annuelle, mais à la concentration moyenne sur deux semaines.

## Sommario

**CQC (AA-EQS) :** **0.084 µg/L ($Gd^{3+}$ disciolto)**

**CQA (MAC-EQS) :** **0.84 µg/L ($Gd^{3+}$ disciolto)**

**CQS ($EQS_{sed}$) :** **1.607 mg/kg p.s., provvisorio**

Il criterio di qualità cronica (CQC) e il criterio di qualità acuta (CQA) per le acque superficiali ed il criterio di qualità per i sedimenti (QCS) sono stati derivati secondo il *TGD for EQS* della Commissione Europea (EC 2018). Per garantire che i dossier siano comparabili a livello internazionale, viene utilizzata la terminologia inglese del TGD. Il CQA corrisponde al MAC-EQS (“maximum allowable concentration environmental quality standard”) oppure SQA-CMA ("standard di qualità ambientale a concentrazione massima ammissibile") e il CQC corrisponde al AA-EQS (“annual average environmental quality standard”) oppure SQA-MA ("standard di qualità ambientale medio annuo"). Il CQS corrisponde al $EQS_{sed}$. Secondo l'ordinanza svizzera sulla protezione delle acque (Il Consiglio federale svizzero 2020), tuttavia, il CQC non deve essere confrontato con un valore medio annuo, ma con la concentrazione media su due settimane.

# Table of content

# 1 General Information

The aim of this dossier is to derive quality standards for gadolinium (Gd)[1] in surface waters and sediments. As explained below, the most important anthropogenic source is contrast agents in medical applications (see 1.3). The Swissmedic database lists six active Gd-based ingredients (acidum gadotericum (CAS No. 135326-11-3), dinatrii gadoxetas (salt of gadoteric acid, no CAS No. identified), gadobutrolum (CAS No. 770691-21-9), gadopiclenolum (CAS No. 933983-75-6), gadoteridolum (CAS No. 120066-54-8), meglumini gadoteras (CAS No. 92943-93-6)).
As the free $Gd^{3+}$ ion exerts toxicity to aquatic organisms, data on other Gd compounds releasing $Gd^{3+}$ in aqueous media are also included in this dossier. The compounds gadolinium trinitrate (CAS No. 10168-81-7), gadoliniumsulfite trihydrate (CAS No. 51285-81-5), and Tris[oxalato(2-)]digadolinium (CAS No. 867-64-1) have REACH registered substances factsheets. Elemental Gd, oxides and oxide nanoparticles were excluded from the assessment.

Selected information relevant for the aquatic environment is presented in this chapter. Registration information and risk assessments referred to are:

- REACH registered substances factsheets retrieved from the ECHA database:
  - Gadolinium trinitrate, https://echa.europa.eu/de/registration-dossier/-/registered-dossier/22802/4/18 (ECHA 2025a)
  - Gadolinium sulfite trihydrate, https://echa.europa.eu/de/registration-dossier/-/registered-dossier/23801/4/9 (ECHA 2025b)
  - Tris[oxalato(2-)]digadolinium, https://echa.europa.eu/de/registration-dossier/-/registered-dossier/23010/4/9 (ECHA 2025c)
- Sneller FEC, Kalf DF, Weltje L, Van Wezel AP. Maximum Permissible Concentrations and Negligible Concentrations for Rare Earth Elements (REEs) (RIVM 2000)

Please note that REACH registered substances factsheets in the ECHA database were announced to be no longer be updated after May 19, 2023. However, we have noted that information is still added. The new database “ECHA CHEM” has been released but is not yet complete. We have relied on the older ECHA database but have verified that no additional information was available in the new database. European Public Assessment Reports (EPAR) could not be identified in the European Medicines Agency (EMA) database.

## 1.1 Identity and physico-chemical properties

Essential information on Gd and its compounds is summarized in Greenwood *et al.* (1997). It is the eighth element in the lanthanide series (atomic number 64, atomic mass of 157) and considered as one of the rare-earth elements (REE). Greenwood *et al.* (1997) reported that Gd exists in one main oxidation state, Gd(III), and six naturally occurring isotopes ($^{154}Gd$, $^{155}Gd$, $^{156}Gd$, $^{157}Gd$, $^{158}Gd$ and $^{160}Gd$) and one radioisotope ($^{152}Gd$). According to (Rogowska *et al.* 2018), natural Gd consists of 7 stable isotopes, and 30 radioisotopes were characterized until 2003. It can be found in minerals like samarskite, monazite and bastnasite. After conversion into gadolinium chloride (GdCl3) or gadolinium fluoride (GdF3), Gd can be extracted through electric currents or reduction of the bonded fluoride with metallic calcium (Rogowska *et al.* 2018). Gd has a permanent electron in the 5d orbital. Therefore, it’s 4f shell is half filled. This property makes it a strong paramagnet that shortens the relaxation times of water molecules against an external magnetic field (Blomqvist *et al.* 2022).

Table 1 summarizes identity and physico-chemical parameters for gadolinium, gadolinium trinitrate, gadoliniumsulfite trihydrate and tris[oxalato(2-)]digadolinium required for EQS derivation according to

[1] Gadolinium is abbreviated as Gd when not used in the name of a compound.

the EU TGD for EQS (EC 2018). Where available, experimentally collected data is identified as (exp.) and estimated data as (est.). When not identified, no indication is available in the cited literature. Test methods are indicated in brackets when available in the cited document.

**Table 1** Information required for EQS derivation according to the EU TGD for EQS (EC 2018). Where available, experimentally collected data is identified as (exp.) and estimated data as (est.). When not identified, no indication is available in the cited literature. Test methods are indicated in brackets when available in the cited document.

| Parameter | Substance | | | Reference |
|---|---|---|---|---|
| Common name | Gadolinium trinitrate | Gadoliniumsulfite trihydrate | Tris[oxalato(2-)]digadolinium | ECHA Database |
| Chemical group | inorganic | inorganic | inorganic | ECHA Database |
| Molecular formula | $Gd(NO_3)_3$ | $Gd_2(SO_3)_3*3H_2O$ | $C_6Gd_2O_{12}$ | ECHA Database |
| CAS No. | 10168-81-7 | 51285-81-5 | 867-64-1 | ECHA Database |
| EC No. | 233-437-2 | 456-900-2 | 212-766-5 | ECHA Database |
| Molecular weight [g/mol] | 343.26 (PubChem 2025a) | 608.73 | 578.55 (PubChem 2025b) | ECHA Database or as indicated |
| Melting point [°C] | 350 – 575 | > 400 | 275 - 325 (OECD Guideline 102 and EU Methid A.1, exp.) | ECHA Database |
| Boiling point [°C] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Vapour pressure [Pa] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Henry's law constant [$Pa \cdot m^3 \cdot mol^{-1}$] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Water solubility | 1455 g/L (20 °C, pH 0) (key value for chemical safety assessment); 1407 g/L (19,3 °C, pH 4,94) by adding NaOH; exp. | 2.72 g/L (10 °C, pH ca. 5.6)<br>1.86 g/L (20 °C, pH ca. 5.8)<br>0.77 g/L (30 °C, pH ca. 3.9) | 13 mg/L (20 °C, pH 7/pH 9, OECD Guideline 102 and EU Method A.1, exp.) | ECHA Database |
| Dissociation constant ($pK_a$) | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Octanol-water partition coefficient (log $K_{ow}$) | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Suspended matter/ sediment- water partition coefficient (Log $K_p$) | Suspended matter log Kp 5.78 (geomean)<br>Sediment log Kp 5.28 (geomean) | | | Annex 1 |
| Aqueous hydrolysis $DT_{50}$ | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Aqueous photolysis $DT_{50}$ | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Biodegradation in aqueous environment $DT_{50}$ [d] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Biodegradation in sediment $DT_{50}$ [d] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |
| Biodegradation in soil $DT_{50}$ [d] | Not applicable to metals according to REACH Annex VII | | | ECHA (2008) |

## 1.2 Regulatory context and environmental limits

Existing regulatory and environmental limits in Switzerland, Europe and elsewhere for Gd and PNEC/environment quality standards for freshwater are listed in Table 2. No values for secondary poisoning were identified. Please note that the information provided in Table 2 may have changed since finalization of this dossier.

Gadolinium arsenide (CAS No. 12005-89-9) is part of the substance group "arsenic compounds" listed in Annex XVII to REACH with use restrictions for biofouling, wood treatment, and industrial wastewater treatment[2].

**Table 2** PNEC/quality standards available from authorities and reported in the literature. MPA: maximum permissible addition; MPC: maximum permissible concentration

| Description | Value | Development method | References |
|---|---|---|---|
| MPA freshwater | 6.8 µg/L $Gd^{3+}$ | *D. magna* 6.8 mg/L EC50, AF 1000 | RIVM (2000) |
| MPA sediment | 1.8 g/kg d.w. | Equilibrium Partitioning, from MPA of 6.8 µg/L $Gd^{3+}$ and $logK_p$ of 5.42 L/kg | RIVM (2000) |
| PNEC | 56.9 µg/L dissolved Gd | SSD (freshwater and saltwater organisms) based on EC10 from a mix of acute and chronic tests | (González *et al.* 2015) |

## 1.3 Use and emissions

Gwenzi *et al.* (2018) have provided a comprehensive summary of Gd uses and emissions. While Gd is widely used in different industrial and household applications, the most significant application regarding release into the environment is in magnetic resonance imaging (MRI). Early use of Gd in medical imaging involved Gd salts, but these proved toxic due to the release of free gadolinium ions in the body. To reduce toxicity, researchers developed chelated forms of gadolinium, where the metal is bound to organic ligands to improve stability and safety. Gd shortens the longitudinal relaxation time of nearby water protons, producing areas of high signal intensity and thereby improving tissue contrast. This property is particularly valuable for detecting tumors, vascular lesions, and inflammatory processes. Other applications include nuclear technology, where Gd oxides and salts serve as neutron absorbers in reactor control rods and shielding. Gd oxysulfide phosphors are used in X-ray screens and scintillators, while gadolinium gallium garnet functions as a substrate in microwave and magneto-optical devices. Certain Gd alloys exhibit magnetocaloric effects, and gadolinium-doped crystals are applied in solid-state lasers. Gd compounds are being investigated in neutron capture therapy and as fluorescent probes in bioimaging.

Chelated Gd complexes are excreted unchanged by patients and enter wastewater systems. Conventional wastewater treatment plants are generally ineffective at removing these due to their high stability, resulting in their persistence in surface waters, groundwater, and even drinking water (Brünjes & Hofmann 2020). This leads to the so-called "anthropogenic gadolinium anomaly", observed as elevated gadolinium concentrations relative to natural REE patterns. Additional anthropogenic sources include nuclear industry, industrial activities, mining and processing of REE-bearing minerals, contributing to local soil and water contamination.

[2] https://www.echa.europa.eu/documents/10162/a798c758-371f-41e5-a38d-5f8dc9ba739d

### 1.4 Mode of action

According to available information, Gd has no known biological role in humans and animals. Gd (and other lanthanides) exerts adverse biological effects mainly by resemblance to calcium (Sherry *et al.* 2009). This similarity enables replacement of calcium in biomolecules without substituting for it functionally. Gd has been shown to interact with proteins (including ion channels), nucleic acids, carbohydrates and lipids (Unruh *et al.* 2020). Inhibitory effects on calcium and magnesium-dependent physiological processes (such as those involved in the blood clotting cascade as well as in neuronal and muscular functions) of REE are well documented (Adeel *et al.* 2019, Barker *et al.* 2022, Jakupec *et al.* 2005). REEs can also react with proteins in which Ca/Mg are not usually involved and substitute other elements. These mechanisms have been reported in micro-organisms, nematodes, crustaceans, insects, mammals, and plants. REEs can also cause phosphate deficiency due to precipitation of phosphate-REEs. Precipitation of phosphate from test media can occur (reviewed by Herrmann *et al.* (2016) for lanthanum), which is why phosphate deficiency may be the reason for measured effects or add to effects exerted by REEs for primary producers.

Examples of reported sub-lethal effects of Gd are reduced sperm motility in mussels (Spampinato *et al.* 2024), increased swimming in amphipods (Riedel *et al.* 2024), changed brain activity in zebra fish (Piarulli *et al.* 2024). Biofilm communities in wastewater treatment simulations showed changed community composition (Ontita *et al.* 2025).

## 2 Environmental fate

### 2.1 Speciation and bioavailability

As reviewed for example in (Hatje *et al.* 2024, Trapasso *et al.* 2021), (Rogowska *et al.* 2018), REEs like Gd exhibit distinct speciation behaviors in freshwater versus saltwater due to differences in ionic composition, pH, and complexing agents. In freshwater, Gd typically exists as free $Gd^{3+}$ ions or forms complexes with carbonate (e.g., $GdCO_3^+$, $Gd(CO_3)_2^-$), hydroxide ($GdOH^{2+}$, $Gd(OH)_2^+$), and dissolved organic carbon (DOC). Increasing pH shifts speciation toward hydroxo- and carbonate complexes, while lower pH favors the free ion. Elevated DOC enhances complexation, forming stable Gd–humic or Gd–fulvic complexes that increase solubility and mobility. Water hardness—especially higher $Ca^{2+}$ and $Mg^{2+}$ concentrations—can suppress Gd complexation with DOC due to competition for binding sites.

In saltwater, the much higher ionic strength (mainly $Na^+$, $Cl^-$, $SO_4^{2-}$, $Mg^{2+}$) promotes the formation of inorganic chloride complexes such as $GdCl^{2+}$ and $GdCl_2^+$, which dominate over carbonate species. These chloride complexes are generally more stable, reducing free $Gd^{3+}$ activity and influencing bioavailability. The higher ionic strength also weakens Gd–organic complexation through competitive ion interactions and electrostatic screening. Temperature increases can slightly favor complex dissociation but usually have minor effects compared to salinity and pH. Overall, Gd remains more soluble and mobile in saltwater due to stable chloride complexes, while in freshwater its speciation is more sensitive to pH, carbonate, hardness, and organic matter. **Due to the differences in speciation in freshwater and saltwater, toxicity data for saltwater species are not considered here** (see section 5).

With respect to bioavailability, recent studies have indicated that the REEs seem to share common biological binding sites (Aharchaou *et al.* 2021, Lachaux *et al.* 2023), which suggests that there is limited interaction between the REEs, resulting in reduced mixture effects compared to the individual effects.

In acute tests with algae, crustaceans, and fish, the presence of DOC decrease bioaccumulation and toxicity of Gd and two other REEs (Lachaux *et al.* 2023). The authors suggest that this was due to the formation of non-bioavailable complexes. del Buono *et al.* (2024) and Revel *et al.* (2025) have demonstrated a competitive behaviour in phytoplankton and *Daphnia magna* between $Gd^{3+}$ and $K^{+}$, $Mg^{2+}$ and $Ca^{2+}$, in particular. The impact of $Al^{3+}$ and $Fe^{3+}$ on $Gd^{3+}$ uptake was not measurable. Costa et al. have observed an increase in bioavailability of potentially toxic elements, namely Pb in most macroalgae at high salinity driven by the high affinity of $Gd^{3+}$ to carbonate (Costa *et al.* 2020).

Gadolinium-based contrast agents (GBCAs) have been reported to be nonreactive and stable in the environment, suggesting that Gd complexes are mostly nonbioavailable (Gwenzi *et al.* 2018, Le Goff *et al.* 2019, Trapasso *et al.* 2021, Zhang *et al.* 2024), thus unable to enter the food chain. However, GBCAs have also been shown to undergo slow dissociation in the presence of competing ions, including $Fe^{3+}$, $Zn^{2+}$, and $Cu^{2+}$ (Ognard *et al.* 2021). Linear chelates have been reported to be particularly susceptible, with excess iron shown to promote their degradation and dissociation (Oluwasola *et al.* 2022). In seawater or mixed effluents, partial removal of $Gd^{3+}$ from ligands has been observed due to competition from $Mg^{2+}$ and $Ca^{2+}$ ions. This process, referred to as transmetallation, involves displacement of $Gd^{3+}$ from its ligands by competing metal ions such as $Cu^{2+}$, $Ca^{2+}$, $Fe^{3+}$, and $Zn^{2+}$ (Trapasso *et al.* 2021).

For risk assessments, determination of the free ion concentration of metals in general is thought to be essential as these will permeate biological membranes and exert toxicity (Pesavento *et al.* 2009). According to the authors, the determination in environmental samples is difficult because of the very low concentrations and of the presence of interferences. Recent research in *Daphnia magna* indicates that total concentrations could be a more accurate descriptor of chronic toxicity of Gd (and La) in this species as metal precipitates could be taken up through feeding (Revel *et al.* 2024). After exposure to uncontaminated food and spiked water, the highest concentrations of Gd (and La) were detected in the gut of *D. magna*. Also, slow depuration was observed. A TKTD (toxicokinetic-toxicodynamics) model to describe the relation between uptake and observed toxicity was established. A recently published biotic-ligand model for Gd and *Daphnia magna* focuses on linking bioavailable concentrations and toxicity (Revel *et al.* 2025). In *Mytilus galloprovincialis*, the presence of an uncontaminated food source reduced bioaccumulation of Gd from Gd-spiked saltwater (Andrade *et al.* 2023, Trapasso *et al.* 2021) indicating that exposure routes differ among different groups of organisms. **As these differences are not yet understood, we focus on the effects of dissolved $Gd^{3+}$ defined as filtered fraction of aqueous samples as a proxy for the bioavailable fraction of Gd.**

## 2.2 Partitioning between water and sediment and suspended matter

In sediment and soil, REEs with higher atomic numbers (also referred to as heavy REEs) have an affinity to residual and carbonate fractions while REEs with lower atomic numbers (also referred to as light REEs) tend to bind with reducible and oxidizable proportions (Adeel *et al.* 2019, Brito *et al.* 2021, Trapasso *et al.* 2021). Light REEs have been observed to absorb clay, in contrast to heavy REEs, there is no affinity for particle sizes or silt. In the aquatic environment, it appears that sediment is the primary sink for REEs, with a significant impact on bioavailability (Hao *et al.* 1998, Yang *et al.* 1999). Gd is positioned between light and heavy REEs (González *et al.* 2015).

Partitioning coefficients available from the literature for Gd are listed in Annex 1. As explained in (RIVM 2000), experimental results from field studies are prioritized over those derived from laboratory experiments for determining partitioning coefficients for REE due to oxidation processes in sediment samples in the laboratory resulting in higher REE concentrations in pore water. Values from estuarine and marine sites are in the same range as those from freshwater sites and were thus included in the calculation of the geometric mean; studies based on soils could not be identified.

## 2.3 Bioaccumulation and biomagnification

According to field studies retrieved from public literature, Ce followed by La are the most abundant REEs in fish, crustaceans and shellfish, accounting for 60 to more than 80% of the total REEs bioaccumulated concentrations (Wang *et al.* 2022, Wang *et al.* 2019). As observed in laboratory experiments, REEs accumulate to a greater extent in organs, viscera, and bone compared to muscle (fillet) tissues (Mayfield & Fairbrother 2015). A comparative study of fish samples collected from local markets of the Shandong Province (China) have shown that average concentrations in freshwater species are relatively lower compared to those of marine species (Yang *et al.* 2016). Benthic feeding species (exposed to sediments) show greater concentrations of REEs than pelagic omnivorous or piscivorous fish species ((Mayfield & Fairbrother 2015, Yang *et al.* 2016) and references cited herein). The concentrations of REE for several freshwater species (except rainbow trout) have shown a decreasing trend with increasing age, total length or weight (Mayfield & Fairbrother 2015). Based on the observed trend of REE not increasing significantly with size (length or weight) or trophic position (Mayfield & Fairbrother 2015) and the absence of correlation between muscle concentrations with fat content or trophic level (Wang *et al.* 2022), there is indication that REEs have limited potential for biomagnification. Additional information supporting the conclusion that Gd has limited or no bioaccumulation potential at higher levels in the food chain and does not tend to biomagnify is the mesocosm study performed by Yang *et al.* (1999), which reported no accumulation in daphnids, shellfish and fish over 16 days of exposure to a mixture of REEs spiked to waters (but deposited in sediments by the end of exposure). As discussed in Kosak née Röhder *et al.* (2018), for algae for cerium, it cannot be said whether reported values are based on adsorption or actual uptake. However, for consumption by the next trophic level, this difference is not relevant.

The ECHA registration dossiers do not contain bioaccumulation data. The applicants state that "a bibliographical review based on ca. 60 publications (1964-2016), containing information on the accumulation of lanthanides (including gadolinium, the rare earth element under consideration in this registration dossier), yttrium and/or zirconium in aquatic organisms, was written to cover this endpoint. […] This has led to the following conclusions: A considerable decrease of bioaccumulation was observed when ascending the trophic levels, this being obvious when comparing data in fish to those in lower trophic levels. Lanthanides, yttrium and zirconium do not biomagnify through the aquatic food web." (ECHA 2025c). We noted that it was also concluded that "the bioaccumulation thresholds (e.g. for classification) used for organic substances are considered not applicable" while for cerium and lanthanum compounds, for example, bioaccumulation data were submitted to the ECHA database (Kroll *et al.* 2023a, Kroll *et al.* 2023b). Only few bioaccumulation data from laboratory and field studies for Gd in freshwater organisms are available in the public literature (Table 3). Laboratory data indicate negligible accumulation in fish but BCFs above 100 in algae, aquatic plants, and mussels, with the highest reported BCF in the mussel *Corbicula fluminea* (249 L/kg) (Lachaux *et al.* 2023). Data from field studies indicate large variability of accumulation in algae, aquatic plants, and mussels. Available Biota Sediment Accumulation Factor (BSAF) values for a sediment dwelling amphipod and water spinach rooted in sediment were below 1 (Moermond *et al.* 2001). Bioaccumulation dynamics and tissue-specificity have been studied (e.g., (Gwenzi *et al.* 2018, Revel *et al.* 2024, Zhang *et al.* 2024)) but are not discussed in detail here.

Some laboratory and field studies have investigated the relationship of REE tissue concentrations of freshwater organisms compared to that of the water column or sediment to understand whether a Gd anomaly (section 1.3) would be detectable and indicate uptake of Gd originating from contrast agents and whether ratios of REE tissue concentrations resemble those in sediment or water. Barber *et al.* (2006) described REE concentrations in mosquitofish (*Gambusia affinis*) and tilapia (*Tilapia mossambica*) tissues in a wetland with a Gd anomaly consistent with the presence of effluent from a wastewater treatment plant. When tilapia liver samples were normalized to sediment concentrations, the Gd anomaly in this system was absent, suggesting that the REE composition of the fish was more strongly influenced by sediment exposure (through ingestion) than by uptake from the aqueous phase. The ratios of REE among each other in marine fish (Barber *et al.* 2006, Squadrone *et al.* 2019, Wang *et al.* 2022), seaweed and marine bivalves (Ma *et al.* 2019, Squadrone *et al.* 2019) also resembled those in sediments and suspended particles more than those in water samples. Zocher *et al.* (2022) could not detect a Gd anomaly in duckweed in a field study and concluded that contrast agents would not contribute to Gd uptake by duckweed. The same was reported by (Zhang *et al.* 2024) in freshwater *Anodonta anatina* field samples, while a positive Gd anomaly was observed in marine *Mytilus* spp. and *Tapes* spp. (Castro *et al.* 2023).

In laboratory experiments, (Braun *et al.* 2018) did not find detectable update of Gd by duckweed species from complex-based contrast agents. Using higher exposure concentrations, Lingott *et al.* (2016) detected concentrations-dependent uptake in both, duckweed species and *D. magna*. In summary, uptake of Gd directly from complex-based contrast agents seems to be of minor importance. However, as discussed in section 2.1, release of Gd from these complexes can occur depending on environmental conditions over time.

Table 3 lists information on bioaccumulation and biomagnification for freshwater organisms retrieved from scientific literature. Values based on nominal concentrations or measured total concentrations were considered non-reliable as described in section 5.

**Table 3** Bioconcentration factors (BCF), bioaccumulation factors (BAF) and measured concentrations (MC) of Gd in freshwater organisms based on wet weight (w.w.) or dry weight (d.w.). Values based on d.w. were recalculated based on Table 7 in (EC 2018). Non-relevant/non-reliable studies are in grey font.

| Species | BCF/BAF/BSAF/MC/BMF | Comments | Reference |
|---|---|---|---|
| **Bioconcentration Factors (BCF) from laboratory exposures** | | | |
| Algae (*Chlorella vulgaris,* log-phase growth cultures) | BCF<br><br>water soluble species: 157.6 (no unit provided)<br>acid extractable species: 181.4 (no unit provided)<br>organic/sulphides bound species: 10.35 (no unit provided) | test substance: $Gd_2O_3$<br>analytics: ICP-AES<br>N = unknown<br>laboratory experiment with natural sediment<br>water:sediment ratio of 50:1<br>24 h exposure<br>pH 6.0<br>exposure concentration: 0.24-1 mg/kg<br>temperature: 25 ± 1 °C<br>reference: not reported | (Hao *et al.* 1998) |
| Mussel (*Corbicula fluminea*) | BCF<br><br>Gd-exposure: 249 ± 75 L/kg w.w.<br>Gd-DOM-exposure: 110 ± 57 L/kg w.w. | test substance: $GdCl_3$ 6 $H_2O$<br>analytics: ICP-MS<br>N = 30<br>cultured in reconstituted water<br>96 h exposure<br>pH 7.3 ± 0.1 (monitored for 24 h)<br>exposure concentrations: 8 mg/L DOM and 5 g/L $GdCl_3$<br>temperature: n.r.<br>in tissues: gills, digestive gland and rest of soft tissues<br>reference: wet weight | (Lachaux *et al.* 2023) |

| Species | BCF/BAF/BSAF/MC/BMF | Comments | Reference |
|---|---|---|---|
| Fish<br>(*Cyprinus carpio*, first-year juveniles) | BAF<br><br>Skeleton: 5 µg/g w.w.; 10 L/kg w.w.<br>Muscles: 3.5 µg/g w.w.; 7 L/kg w.w.<br>Gills: 7 µg/g w.w.; 14 L/kg w.w.<br>Inner organs: 105 µg/g w.w.; 210 L/kg w.w.<br>(provided as "maximum values")<br>(own calculations based on measured concentrations in tissue and water) | test substance: $Gd(NO_3)_3$<br>analytics: ICP-AES<br>N = 40 individuals (in two groups à 20 individuals as duplicate)<br>45 d exposure<br>pH 6<br>exposure: 0.5 mg/L, $GdNO_3$<br>temperature: 11-14 °C<br>reference: wet weight | (Qiang *et al.* 1994) |
| Aquatic plant (*Spirodela polyrrhiza*) | BCF<br><br>103.7 L/kg | test substance: $Gd_2O_3$<br>analytics: ICP-AES<br>N = 20 g duckweed, N = 400 daphnids, N = 30 shellfish, N = 15 goldfish<br>0.5 – 16 d (duckweed and daphnids);<br>2 – 16 d (shellfish and goldfish)<br>pH 6.5 – 6.8<br>exposure concentration: 1 mg/L<br>temperature: 22 ± 1 °C<br>reference: wet weight | (Yang *et al.* 1999) |
| Fish (*Carassius auratus*) | BAF<br><br>1.27 L/kg | | |
| **Bioconcentration[3] or bioaccumulation Factors (BCF/BAF) from field organisms** | | | |
| Aquatic plants (duckweed, *different species*) | BCF<br><br>215-21309 L/kg d.w.<br><br>(own calculations based on measured concentrations in duckweed and water; no standard moisture fraction available for recalculation) | ditches and ponds in Joure (The Netherlands), Hanover and Bremen (Germany)<br>freshwater samples<br>analytics: ICP-OES and ICP-MS<br>N = 9 samples<br>2 sites (Spiegelteich and Morrweiher) were sampled a second time after 10 and 8 months<br>no $Gd_{geo}$ and $Gd_{anthr.}$ for Spiegelteich (1018) available<br>reference: dry weight | (Zocher *et al.* 2022) |
| Mussel (*Anodonta anatina*) | BAFs for Danube/Vistual<br><br>Gills 481/591 L/kg d.w.<br>38.5/47.3 L/kg w.w.<br>Internal organs 326/151 L/kg d.w.<br>26.1/12.1 L/kg w.w.<br>Mantles 273/224 L/kg d.w.<br>21.8/18 L/kg w.w.<br>Adductor muscles 257/13 L/kg d.w.<br>20.6/1 L/kg w.w.<br>Feet 13/63 L/kg d.w.<br>1/5 L/kg w.w.<br><br>(own calculations based on measured concentrations in duckweed and water) | Danube River (Hungary) and Vistual River (Poland)<br>soft tissues and shell<br>analytics: ICP-MS; 0.2-µm CA filters<br>N = 3 individuals (2 mussels from Danube River and 1 mussel from Vistual River)<br>reference: dry weight | (Zhang *et al.* 2024) |
| Mussel (*Corbicula fluminea*) | BAF<br><br>Natural Gd 1020 L/kg d.w.<br>81.6 L/kg w.w.<br>Anthropogenic Gd 83 L/kg d.w.<br>6.6 L/kg w.w.<br><br>(calculated based on regression analysis) | Jalle River, Bordeaux (France)<br>cage in-situ experiment, downstream WWTP<br>soft tissues<br>analytics: ICP-MS<br>N = 5 individuals (caged)<br>85 d<br>reference: dry weight | (Pereto *et al.* 2020) |

[3] Bioconcentration Factors (BCF) from field measurements are calculated only for species that are exposed solely through the water phase and food does not contribute to exposure (e.g., plants).

| Species | BCF/BAF/BSAF/MC/BMF | Comments | Reference |
|---|---|---|---|
| Amphipods | BAF<br>13183 L/kg | Based on porewater concentrations, field data, no further details available | Stronkhorst and Yland (1998) cited in (RIVM 2000) |
| Fish *(Tilapia mossambica)* | BAF<br>460 L/kg (liver) d.w.<br>119.6 L/kg (liver) w.w. | Constructed wetlands<br>analytics: ICP-MS<br>N = 17 (according to Barber et al. 2003, Table 2-15)<br>reference: dry weight | (Barber *et al.* 2006)<br>(Barber *et al.* 2003) |

# 3 Analytics

Gd can be quantified in water and sediment samples with inductively coupled plasma-mass spectrometry (ICP-MS), inductively coupled plasma-optical emission spectrometry (ICP-OES), laser ablation ICP-MS, neutron activation analysis, High pressure liquid chromatography-inductively coupled plasma-mass spectrometry (HPLC-ICP-MS), hydride generation-gas chromatography-quartz tube flame atomic absorption spectrometry (HGGC-QFAAS), hydrophilic interaction chromatography (ZIC-cHILIC) plus ICP-MS as summarized in (Gwenzi *et al.* 2018, Trapasso *et al.* 2021). Different combinations of acids, digestion times and temperatures may be required to extract total REEs from sediments, depending on the sediment matrix (Weltje *et al.* 2002). For extraction of total concentrations in sediments, acid digestion in Teflon vessels at high temperatures is required, e.g., using $HNO_3$, HF, $HClO_4$ and $H_2SO_4$ at 200 ◦C (Liu et al. 2023). When measuring dissolved concentrations in water, it is likely that filtration at 0.45 µm overestimate the true dissolved concentration according to the presence of colloids (Weltje *et al.* 2002).

Recently reported limits of quantification and detection from scientific literature are listed in Table 4. The ECHA registration dossiers do not list analytical methods.

**Table 4** Methods for Gd analysis and corresponding limits of detection (LOD) and limits of quantification (LOQ). n.r. means not reported.

| LOD | LOQ | Analytical method | Reference |
|---|---|---|---|
| | | **Water** | |
| n.a. | 0.3 µg/L | ICP-MS/MS, surface water, aqua regia digestion (EN-ISO 15587-1) | (Tirez *et al.* 2025) |
| 0.01 ng/L | n.a. | ICP-MS; LOD = three times the standard deviation of the calibration blank measurements (n = 10) | (Inoue *et al.* 2022) |
| | | **Sediment** | |
| 0.1 µg/g d.w. | n.a. | ICP-MS, Microwave digestion: HF-HNO 3-HCl | (Di Leonardo *et al.* 2009) |

# 4 Environmental concentrations

Gd concentrations in surface water from rivers and streams worldwide are very low, typically well below 1 µg/L. Gd data correlate most closely with the other lanthanides (Sandström *et al.* 2005). The median concentration in European stream waters was 0.01 µg/L (filtered <0.45 µm, range: <0.002 – 0.97 µg/L, one outlier of 4.32 µg/L) and 5.06 mg/kg (range: 0.2 – 6.32 mg/kg) in stream sediments based on data available before 2005 (Salminen *et al.* 2005). Positive Gd anomalies – a higher concentration of Gd than expected based on the natural background (see section 1.3) - have been reported in the dissolved load of European rivers and attributed to the use of gadopentetic acid in magnetic resonance imagining as early as 1996 (Bau & Dulski 1996). In Japan, for example, a 7.7-fold increase of this anomaly has been detected between 1996 and 2000 (Kumasaka *et al.* 2024). When compared to the total sediment fraction, lanthanides concentrations seems to be dependent on grain size (Weltje *et al.* (2002), Zhang *et al.* 1998 cited in Weltje *et al.* (2002)). At uncontaminated sites, the concentrations measured in the fine fraction (<63 µm) are higher than those measured in the < 2 mm fraction, a difference that is due to the proportion of sand fraction which contains low lanthanide concentrations (e.g. (Consani *et al.* 2020, Weltje *et al.* 2002). Accordingly, the FOREGS-EuroGeoSurveys geochemical baseline value derived from European stream sediments is higher than that for floodplain sediment (Table 5). Measured environmental concentrations (MEC) of Gd in surface waters and sediments are summarized in Table 5.

**Table 5** Measured environmental concentrations (MEC) of Gd in waste water treatments plants (WWTP), surface waters and sediments. All concentrations expressed as µg/L and mg/kg d.w. if not indicated otherwise. $Gd_{Anth}$: Gd from anthropogenic sources; n.d.: not detected; n.a.: not available, not reported. *Additional studies not listed here can be found in (Rogowska et al. 2018)*

| Location | | MEC (min-max) | No. of sites | Comments | Reference |
|---|---|---|---|---|---|
| **Water [µg/L]** | | | | | |
| Osaka (Japan) | Yodo River | Gd: 0.0058 – 0.4920<br>$Gd_{Anth}$: 0.0013 – 0.0127<br>Gd/Gd*[1]: 0.0009 – 0.0013 | 5 | Filtered (<0.45 µm) and pre-concentrated water samples; reported as ng/L | (Inoue *et al.* 2025) |
| | Kanzaki River | Gd: 0.0022 – 0.0249<br>$Gd_{Anth}$: 0.0014 – 0.0027<br>Gd/Gd*[1]: 0.0015 – 0.0026 | 4 | | |
| | Shirinashi River | Gd: 0.0023 - 0.0029<br>$Gd_{Anth}$: 0.0005 – 0.0014<br>Gd/Gd*[1]: 0.0012 – 0.0024 | 2 | | |
| | Kizugawa River | Gd: 0.0041<br>$Gd_{Anth}$: 0.0018<br>Gd/Gd*[1]: 0.0018 | 1 | | |
| | Sumiyoshi River | Gd: 0.0018<br>$Gd_{Anth}$: 0.0018<br>Gd/Gd*[1]: 0.0026 | 1 | | |
| | Hirano River | Gd: 0.0024<br>$Gd_{Anth}$: 0.0024<br>Gd/Gd*[1]: 0.004 | 1 | | |
| | Daini Neya River | Gd: 0.0093 – 0.0225<br>$Gd_{Anth}$: 0.0044 – 0.0112<br>Gd/Gd*[1]: 0.002 | 2 | | |
| | Neya River | Gd: 0.0216<br>$Gd_{Anth}$: 0.0134<br>Gd/Gd*[1]: 0.0026 | 1 | | |
| | mean | Gd = 0.0524 (median: 0.0102)<br>$Gd_{Anth}$ = 0.0056<br>Gd/Gd*[1] = 0.0017 | 17 | | |
| WWTPs Osaka (Japan) | | Gd (influent): 0.0262 (mean) (0.0113 – 0.0623)<br>Gd (effluent): 0.0482 (mean) (0.0088 – 0.106) | 144 | | |
| | | Gd/Gd*[1] (influent): 0.0138 (mean) (0.0025 – 0.0406)<br>Gd/Gd* [1] (effluent): 0.0304 (mean) (0.0085 – 0.0854) | | | |

| Location | MEC (min-max) | No. of sites | Comments | Reference |
|---|---|---|---|---|
| **Water [µg/L]** | | | | |
| | $Gd_{Anth}$ (influent): 0.0237 (mean) (0.0072 – 0.0575)<br>$Gd_{Anth}$ (effluent): 0.0465 (mean) (0.0077 – 0.105) | | | |
| Tone River (Tokyo, Japan) | 0.1641 (mean) (0.0732 – 0.4285) | 15 | filtered < 0.22 µm; reported as ng/L | Kumasaka et al. (2024) |
| Weser River – Weser River Estuary – North Sea Bight (Germany) | Weser River:<br>Gd: 0.0204 (mean) (0.0180 – 0.0237)<br>$Gd_{SN}/Gd_{SN*}$[2]: 0.0010 (mean) (0.0008 – 0.0012) | 4 | filtered < 0.45 µm; reported as pM ($M_{Gd}$ = 157.25 g/mol) | Kulaksız and Bau (2007) |
| | Weser River Estuary:<br>Gd: 0.0124 (mean) (0.0071 – 0.0191)<br>$Gd_{SN}/Gd_{SN*}$[2]: 0.0008 (mean) (0.0006 – 0.0011) | 17 | | |
| | North Sea Bight:<br>Gd: 0.002 (mean) (0.0018 – 0.0022)<br>$Gd_{SN}/Gd_{SN*}$[2]: 0.0003 (mean) | 5 | | |
| Vene River (France) | Gd: 0.0013 – 0.003 | n.r. | filtered < 0.22 µm and preconcentrated; reported as pmol/L ($M_{Gd}$ = 157.25 g/mol) | Elbaz-Poulichet et al. (2002); cited by Rogowska et al. (2018) |
| WWTP Montbazin, Poussan, Pinet and Meze (France) | Gd: 0.0115 – 0.0896 | 4 | | |
| Saale River (Germany) | Gd: 0.012 – 0.181 | 3 | filtered < 0.45 µm and preconcentrated; reported as ng/L | Hennebrüder et al. (2004); cited by Rogowska et al. (2018) |
| Boulder Creek, Colorado (USA) | Gd: 0.0018 – 0.073 | 27 | filtered < 0.1 µm | Verplanck et al. (2005); cited by Rogowska et al. (2018) |
| Dommel basin (Belgium/The Netherlands) | Gd: 0.007 – 0.173 | 7 | filtered < 0.45 µm; reported as ng/L | Petelet-Giraud et al. (2009); cited by Rogowska et al. (2018) |
| WWTPs effluent Berlin (Germany) | Gd: 0.3722 (mean) (0.0316 – 1.1762)<br>Gd/Gd[1]: 0.1040 (mean) (0.0101 – 0.3167)<br>$Gd_{Anth}$: 0.3716 (mean) (0.0311 – 1.1756) | 7 | filtered < 0.2 µm; reported as pmol/kg ($M_{Gd}$ = 157.25 g/mol) | Knappe et al. (2005); cited by Rogowska et al. (2018) |
| Spree River (Berlin, Germany) | Gd: 0.0017 – 0.0154<br>Gd/Gd[1]: 0.0002 – 0.0003<br>$Gd_{Anth}$: 0.0008 – 0.0033 | 2 | | |
| Dahme River (Berlin, Germany) | Gd: 0.0012<br>Gd/Gd[1]: 0.0003<br>$Gd_{Anth}$: 0.0006 | 1 | | |
| Upper Havel River (Berlin, Germany) | Gd: 0.0441 (mean) (0.0030 – 0.1234)<br>Gd/Gd[1]: 0.0054 (mean) (0.0003 – 0.0184)<br>$Gd_{Anth}$: 0.0425 (mean) (0.0014 – 0.1223) | 7 | | |
| Teltow Canal (Berlin, Germany) | Gd: 0.2275 (mean) (0.0088 – 1.0710)<br>Gd/Gd[1]: 0.0385 (mean) (0.0016 – 0.1513)<br>$Gd_{Anth}$: 0.2261 (mean) (0.0079 – 1.0704) | 8 | | |
| Lake Tegel (Berlin, Germany) | Gd: 0.0820 (mean) (0.0629 - 0.1300)<br>Gd/Gd[1]: 0.0085 (mean) (0.0035 – 0.0137) | 5 | | |

| Location | MEC (min-max) | No. of sites | Comments | Reference |
|---|---|---|---|---|
| **Water [µg/L]** | | | | |
| | $Gd_{Anth}$: 0.0803 (mean) (0.0613 – 0.1285) | | | |
| Teltow Canal (Berlin, Germany) | Gd: 0.3081 (mean) (0.050 – 0.990), 0.099 ± 0.016 (constant measured concentration); ∑(Gd-DOTA + Gd-BT-DO3A): 0.2789 (mean) (0.034 – 0.926) | 10 | reported as ng/L | Lindner et al. (2013) |
| Vltava River (Czech Republic) | $Gd_{Anth}$: 0.0014 (mean) (0.0006 – 0.0031) | 7 | filtered < 0.2 µm; reported as nmol/m³ ($M_{Gd}$ = 157.25 g/mol) | Morteani et al. (2006); cited by Rogowska et al. (2018) |
| Ontario and Erie Lakes (USA) | Gd: 0.0014 – 0.0027 | 6 | filtered < 0.2 µm and spiked; reported as pmol/L ($M_{Gd}$ = 157.25 g/mol) | Bau et al. (2006); cited by Rogowska et al. (2018) |
| Pennsylvania Rivers (USA) | Gd: 0.0041 – 0.0148 | 7 | | |
| Hérault River (South France) | Gd: 0.0017 (mean) (0.0012 – 0.0039) Gd/Gd³: 0.0002 (mean) (0.0002 – 0.0003) | 14 | filtered < 0.22 µm and preconcentrated; reported as pM ($M_{Gd}$ = 157.25 g/mol) | Rabiet et al. (2009); cited by Rogowska et al. (2018) |
| WWTPs effluent South France | Gd: 0.0128 (mean) (0.0004 – 0.1663) Gd/Gd³: 0.0037 (mean) (0.0002 – 0.0481) | 23 | | |
| Ruhr River (Germany) | Gd: 0.0330 (mean) (0.0129 – 0.0483) ∑(Gd-DOTA + Gd-BT-DO3A + Gd-DTPA): 0.0291 (mean) (0.0138 – 0.0412) | 6 | filtered; reported as pmol/L ($M_{Gd}$ = 157.25 g/mol) | Birka et al. (2016); cited by Rogowska et al. (2018) |
| **Sediment [mg/kg d.w.]** | | | | |
| Queensland Rivers (Australia) | Gd: 6.66 (mean) (3.6 – 9.46) | 30 | alluvial sediments; wet-sieved to < 80 µm; reported as ppm | Kamber Balz et al. (2005); cited by Rogowska et al. (2018) |
| Europe (FOREGS-EuroGeoSurveys) | Gd: 4.88 (mean) or 5.06 (mean) (0.20 – 90.5) | 848 | stream sediment; size fraction < 0.15 mm; analytics: XRF | (Rogowska *et al.* 2018, Sandström *et al.* 2005) |
| | Gd: 3.92 (mean) (0.21 – 22.6) | 743 | floodplain sediment; size fraction < 2.0 mm; analytics: XRF | |
| China | Gd: 8.89 (mean) (1.64 – 16.81) | 59 | sieved to < 2 mm; reported as µg/g | Zhu et al. (1997); cited by |
| Mouth of Vistula River into Gulf of Gdańsk (Poland) | Gd: 0.833 (mathematic mean)⁴, 0.635 (geometric mean) (0.280 – 3.020) | 27 | not sieved | Wolska et al. (2022) |

[1] Gd anomaly interpolated by ratio of Post-Archaean Australian Shale (PAAS) normalized Gd and normalized Sm × Tb concentrations.
[2] Gd anomaly interpolated by ratio of Sm-Nd normalized Gd and 2 × $\log_{Sm}$ and $\log_{Nd}$ to the power of ten.
[3] Gd anomaly interpolated by ratio of North American Shale Composite (NASC) normalized Gd and normalized Sm + Tb concentrations.
[4] As stated in Wolska et al. (2022)

# 5 Quality standards for water

## 5.1 Effect data

The databases of ECHA[4], RIVM[5], UBA/ETOX[6], US UPA/ECOTOX[7], EMA and Swissmedic were searched for ecotoxicity data for the CAS numbers and chemical names as indicated in section 1.1. Additionally, a literature search was performed in Scopus using the search terms as above and "aquatic", "toxicity", "bioavailability" in different combinations.

**Due to the dependence of speciation and bioavailability on salinity and pH (see section 2.1), saltwater data were excluded from the dataset.** Precipitation of phosphate from test media can also occur when using chloride and nitrate lanthanide salts (e.g. (Aharchaou *et al.* 2020)), which is why phosphate deficiency rather than direct toxicity may be a reason for measured effects in primary producers. Carbonate hardness of the test medium can also influence the measured toxicity (reviewed by Herrmann *et al.* (2016)). The quantification of dissolved $Gd^{3+}$ as well as phosphate and carbonate is therefore considered essential to be able to attribute effects to dissolved, i.e. bioavailable ions. However, Herrmann *et al.* (2016) could not establish a reliable relationship between $CaCO_3$ in exposure media in toxicity tests and La toxicity across different organism groups for the development of EQS as a function of hardness. A similar study for Gd has not been performed, however, the same behavior can be expected. Thus, exclusion of studies or correction of effect values for hardness was not performed. In principle, the expected concentrations of dissolved lanthanoids are low, in the range of 1 µg/L, due to complexation and precipitation (Maas & Botterweg (1993), cited in RIVM (2000)). Thus, higher effect concentrations must be checked for plausibility. A recent publication concludes that precipitation in the presence of test organisms leads to high scattering of results of acute toxicity tests, which is why the authors advise against the use of acute effect concentrations for risk assessment if total concentrations are used (Blinova *et al.* 2018). **Since precipitation affects bioavailability in any test system with Gd, only studies reporting measured dissolved concentration and effects related to this are considered.** This is also in line with the Guidance on information requirements and chemical safety assessment Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds (section 4.2, (ECHA 2008)) and Technical Guideline for EQS (EC 2018). Unless measured dissolved concentrations dropped to or below the LOQ in the respective study, average exposure concentrations were accepted to derive effect concentrations. Further, according to the TGD for EQS (p. 60), data from tests with added dissolved organic carbon (DOC) concentrations > 2 mg/L should not be used. Studies were thus excluded in case DOC concentrations exceeded the recommended threshold.

Only reliable and relevant data should be used for EQS derivation (EC 2018). These data are often referred to as "valid". Different approaches to assessment and classification of (eco)toxicological data have been published. An established method introduced by Klimisch *et al.* (1997) uses four levels of validity: (1) reliable, (2) reliable with restrictions, (3) not reliable, (4) not assessable. The CRED approach published by (Moermond *et al.* 2016) is based on a similar classification scheme but additionally takes into account the relevance of test results in a separate indicator for the derivation of quality standards. Both methods are recommended in the EU TGD for EQS (EC 2018). Here, relevance ("C" in Table 6) and reliability ("R" in Table 6) of the studies were evaluated according to the CRED-criteria.

Information on ecotoxicity studies in the ECHA database are provided by the registrants and qualify as "secondary literature" according to Moermond *et al.* (2016) as verification and assessment by the competent authority are not publicly available. This information should thus be considered "R4" according to the CRED recommendations. In case the general reliability criteria (see above) were apparently not fulfilled, studies were rated "R3".

[4] https://echa.europa.eu/de/home
[5] https://rvszoeksysteem.rivm.nl/
[6] http://webetox.uba.de/webETOX/public/search/test/open.do
[7] https://cfpub.epa.gov/ecotox/

In total, 66 effect values were identified, with two of these values having been reported twice ((Lachaux *et al.* 2022, Lachaux *et al.* 2023); *Daphnia magna*). Of the 66 values, 21 were based on measured dissolved concentrations, and 16 were based on measured total concentrations. Five effect values were reported on measured concentrations without information on whether these referred to total or dissolved Gadolinium or concentrations were referred to as "partially dissolved". Of the 21 effects values based on measured dissolved concentrations, seven were categorized as reliable and relevant and comprised acute data for fish, crustaceans, algae, and nitrifying bacteria (Table 6). Studies on formulations are considered as irrelevant due to potential effects of (unknown) co-formulants but are listed in Table 6 for comparison with active substance data.

**Table 6** Aquatic effect data collection for Gd salts (including respective hydrates), complexes and formulations in mg/L. Data were evaluated for relevance and reliability according to the CRED criteria (Moermond *et al.* 2016). Data assessed as not relevant and not reliable is in grey font. Data used for QS derivation is underlined. Abbreviations/acronyms: n. a. = not applicable; n. r. = not reported. as: active substance; form.: formulation. D: dissolved. T: total. Please note that the species *Raphidocelis subcapitata* was previously known as *Selenastrum capricornutum* and *Pseudokirchneriella subcapitata. Danio rerio* was previously known as *Brachydanio rerio.*

| Substance name | Test item | Purity | Standard test | Taxonomic group | Species | Effect | Exposure regime | Duration | Endpoint | Effect conc. based on Gd compound | Effect concentration based on Gd | Analytics | D/T | Reliability and relevance | Reference |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | **acute** | | | | | | | | |
| Gd2(SO3)3*3H2O | as | n.r. | Y | bacteria | n.r. | respiration | n.r. | 3 h | EC50 | > 1000 mg/L | | nom | unclear | R4/C4 | Anonymous (2003) cited in ECHA (2025b) |
| Gd2(SO3)3*3H2O | as | n.r. | Y | algae | *Desmodesmus subspicatus* | growth | S | 72 h | EbC50 | 2.08 mg/L | | m-gm | n.r. | R4/C4 | Anonymous (2003) cited in ECHA (2025b) |
| Gd2(SO3)3*3H2O | as | n.r. | Y | algae | *Desmodesmus subspicatus* | growth | S | 72 h | ErC50 | 2.58 mg/L | | m-gm | n.r. | R4/C4 | Anonymous (2003) cited in ECHA (2025b) |
| Gd(NO3)3 6H2O | as | 99.9 | Y | algae | *Phaeodactylum tricornutum* | growth | S | 72 h | EC50 | 0.98 mg/L | | m | total | R3/C1 | (Siciliano *et al.* 2022) |
| GdCl3 6H2O | as | > 99.99 | Y | green algae | *Pseudokirchnerella subcapitata* | physiology | S | 72 h | EC50 | | 3.111 mg/L | nom | dissolved | R3/C3 | (González *et al.* 2015) |
| GdCl3 6H2O | as | > 99.99 | Y | green algae | *Pseudokirchnerella subcapitata* | physiology | S | 72 h | EC50 | | 2.219 mg/L | nom-m | dissolved | R1/C3 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | Y | green algae | *Pseudokirchnerella subcapitata* | physiology | S | 72 h | EC50 | | 1.257 mg/L | nom-m | free ion (modeled) | R3/C3 | González, 2015 #15} |
| GdCl3*6H2O | as | > 99 | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC50 | | <u>0.084 mg/L</u> | nom-i & m-e | dissolved | R1/C1 | (Lachaux *et al.* 2022) |
| GdCl3*6H2O | as | > 99 | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC50 | | 1.445 mg/L[1] | nom-i & m-e | dissolved | R1/C3 | (Lachaux *et al.* 2022) |
| GdCl3 | as | n.r. | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC50 | 0.267 mg/L | | m | total | R3/C1 | (Siciliano *et al.* 2021) |
| GdCl3 | as | n.r. | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC50 | n.r. | | m | total | R3/C1 | (Siciliano *et al.* 2021) |
| GdCl3*6H2O | as | > 99 | N | annelid | *Tubifex tubifex* | behavior | S | 3 min | LC50 | 27400 mg/L | | nom | total | R3/C3 | (Rucki *et al.* 2021) |
| GdCl3 6H2O | as | > 99.99 | N | cnidaria | *Hydra attenuata* | score | S | 48 h | EC50 | | 2.549 mg/L | nom | dissolved | R3/C3 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | N | cnidaria | *Hydra attenuata* | score | S | 48 h | EC50 | | 2.07 mg/L | nom-m | dissolved | R1/C1 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | N | cnidaria | *Hydra attenuata* | score | S | 48 h | EC10 | | 0.803 mg/L | nom-m | dissolved | R1/C3 | González, 2015 #15} |

| Substance name | Test item | Purity | Standard test | Taxonomic group | Species | Effect | Exposure regime | Duration | Endpoint | Effect conc. based on Gd compound | Effect concentration based on Gd | Analytics | D/T | Reliability and relevance | Reference |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GdCl3 6H2O | as | > 99.99 | Y | rotifer | *Brachionus calyciflorus* | population | S | 48 h | EC50 | | 0.775 mg/L | nom | total | R3/C3 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | Y | rotifer | *Brachionus calyciflorus* | population | S | 48 h | EC50 | | 0.914 mg/L | nom-m | dissolved | R2/C1 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | Y | rotifer | *Brachionus calyciflorus* | population | S | 48 h | EC50 | | 0.0639 mg/L | nom-m | free ion (modeled) | R3/C3 | González, 2015 #15} |
| n.r. | n.r. | n.r. | n.r. | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | 6.8 mg/L | | n.r. | n.r. | R4/C4 | Den Ouden (1995) cited in (RIVM 2000) |
| Gd(NO3)3 | as | n.r. | Y | crustaceans | *Daphnia magna* | immobilization | R | 48 h | EC50 | | 1.3 mg/L | m-gm | dissolved | R4/C4 | Anonymous (2017) cited in (ECHA 2025a) |
| Gd2(SO3)3*3H2O | as | n.r. | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | | > 1.91 mg/L | m-gm | dissolved | R4/C4 | Anonymous (2003) cited in (ECHA 2025b) |
| Tris[oxalato(2-)]digadolinium | as | n.r. | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | > 0.745 mg/L | | mm | partly dissolved | R3/C4 | Anonymous (2016/2017) cited in ECHA (2025c) |
| Gd(NO3)3 6H2O, | as | n.r. | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | 62.92 mg/L | | m | total | R3/C1 | (Pinto *et al.* 2025) |
| Gd(NO3)3·6H2O | as | 99.9 | N | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | 18.5 mg/L | | nom-m | total | R3/C4 | (Blinova *et al.* 2018) |
| Gd(NO3)3·6H2O | as | 99.9 | N | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | > 50 mg/L | | nom-m | total | R3/C4 | (Blinova *et al.* 2018) |
| GdCl3 6H2O | as | > 99.99 | Y | crustacean | *Daphnia magna* | immobilization | S | 48 h | EC50 | | > 6.4 mg/L | nom | total | R3/C3 | González, 2015 #15} |
| GdCl3*6H2O | as | > 99 | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | | 3.011 mg/L | nom-i & m-e | dissolved | R1/C1 | (Lachaux *et al.* 2022) |
| GdCl3*6H2O | as | > 99 | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | | 5.791 mg/L[1] | nom-i & m-e | dissolved | R1/C3 | (Lachaux *et al.* 2022) |
| n.r. | as | n.r. | Y | crustaceans | *Daphnia magna* | immobilization | S | 48 h | EC50 | | n.r. | nom-m | dissolved | R4/C4 | (Revel *et al.* 2025) |
| GdCl3*6H2O | as | > 99.9 | N | crustaceans | *Thamnocephalus platyurus* | immobilization | S | 24 h | LC50 | 11.8 mg/L | | nom | total | R3/C2 | (Manusadžianas *et al.* 2020) |
| Gd(NO3)3 | n.r. | n.r. | Y | fish | *Danio rerio* | mortality | R | 96 h | LC50 | 19 mg/L | | m | n.r. | R4/C4 | Den Ouden (1995) cited in (RIVM 2000) |
| Gd2(SO3)3*3H2O | as | n.r. | Y | fish | *Danio rerio* | mortality | R | 96 h | LC50 | | > 1.03 mg /L | m-am | dissolved | R4/C4 | Anonymous (2003) cited in (ECHA 2025b) |

| Substance name | Test item | Purity | Standard test | Taxonomic group | Species | Effect | Exposure regime | Duration | Endpoint | Effect conc. based on Gd compound | Effect concentration based on Gd | Analytics | D/T | Reliability and relevance | Reference |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Tris[oxalato(2-)]digadolinium | n.r. | n.r. | Y | fish | *Danio rerio* | mortality | S | 96 h | LC50 | > 100 mg/L | | nom | unclear | R3/C4 | Anonymous (2000) cited in ECHA (2025c) |
| GdCl3*6H2O | as | > 99 | N | fish | *Danio rerio* | mortality | R | 96 h | EC50 | | > 0.256 mg/L | nom-i & m-e | dissolved | R1/C1 | (Lachaux *et al.* 2022) |
| GdCl3*6H2O | as | > 99 | N | fish | *Danio rerio* | mortality | R | 96 h | EC50 | | > 0.562 mg/L[1] | nom-i & m-e | dissolved | R1/C3 | (Lachaux *et al.* 2022) |
| GdCl3*6H2O | as | n.r. | Y | fish | *Danio rerio* | mortality | S | 96 h | LC50 | 25.17 mg/L | | nom | total | R3/C1 | (Lin *et al.* 2022) |
| GdCl3*6H2O | as | > 99.9 | Y | fish | *Danio rerio* | mortality | S | 96 h | EC50 | | > 0.300 mg/L | nom-m | dissolved | R4/C4 | (Piarulli *et al.* 2024) |
| GdCl3 | as | Analytical Reagent grade | N | fish | *Danio rerio* | sperm motlity | S | <0.0002-<0.0019 d | NOEC | 10.54436 mg/L | | nom | total | R3/C3 | (Wilson-Leedy *et al.* 2009) |
| GdCl3 | as | Analytical Reagent grade | N | fish | *Lepomis macrochirus* | sperm motility | S | 0.0069 d | LOEC | 5.27218 mg/L | | nom | total | R3/C3 | (Zuccarelli & Ingermann 2007) |
| | | | | | | | **Chronic** | | | | | | | | |
| GdCl3 | as | Analytical Reagent grade | N | algae | *Chlorella vulgaris* | population dynamics | n.r. | 91.32-121.76 d | LOEC | 2.3 mg/L | | nom | total | R3/C3 | De Jong,L.E.D. (1965) cited in ECOTOX |
| GdCl3 | as | Analytical Reagent grade | N | algae | *Chlorella vulgaris* | population dynamics | n.r. | 91.32-121.76 d | NOEC | 1.1 mg/L | | nom | total | R3/C3 | De Jong,L.E.D. (1965) cited in ECOTOX |
| Gd2(SO3)3*3H2O | as | n.r. | Y | algae | *Desmodesmus subspicatus* | growth | S | 72 h | NOEC | 0.31 mg/L | | m-gm | n.r. | R4/C4 | Anonymous (2003) cited in ECHA (2025b) |
| GdCl3*6H2O | as | > 99.9 | N | algae | *Nitellopsis obtusa* | cell death | n.r. | 24 d | LC50 | 0.39 mg/L | | m | total | R3/C2 | (Manusadžianas *et al.* 2020) |
| Gd(NO3)3*6H2O | as | 99.9 | Y | algae | *Phaeodactylum tricornutum* | growth | S | 72 h | EC50 | 0.21 mg/L | | m | total | R3/C1 | (Siciliano *et al.* 2022) |
| GdCl3 6H2O | as | > 99.99 | Y | green algae | *Pseudokirchnerella subcapitata* | physiology | S | 72 h | EC10 | | 1.38 mg/L | nom-m | dissolved | R1/C3 | González, 2015 #15} |
| GdCl3 | as | n.r. | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC10 | 0.0008 mg/L | | m | total | R3/C1 | (Siciliano *et al.* 2021) |
| GdCl3 | as | n.r. | Y | algae | *Pseudokirchnerella subcapitata* | growth | S | 72 h | EC10 | 1.136 mg/L | | m | total | R3/C1 | (Siciliano *et al.* 2021) |
| n.r. | as | n.r. | N | macrophytes | *Wolffia globosa* | growth | S | 7 d | IC50 | 122.4 mg/L | | nom | total | R3/C1 | (Kurnia *et al.* 2023) |
| GdCl3 6H2O | as | > 99.99 | Y | rotifer | *Brachionus calyciflorus* | reproduction | S | n.r. | EC10 | | 0.175 mg/L | m | dissolved | R3/C4 | González, 2015 #15} |

| Substance name | Test item | Purity | Standard test | Taxonomic group | Species | Effect | Exposure regime | Duration | Endpoint | Effect conc. based on Gd compound | Effect concentration based on Gd | Analytics | D/T | Reliability and relevance | Reference |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Gd(NO3)3 | as | n.r. | Y | crustaceans | *Daphnia magna* | mortality and reproduction | R | 21 d | NOEC | | 0.09 mg/L[2] | m | dissolved | R4/C4 | Neubert (2008) cited in (ECHA 2025a) |
| Gd(NO3)3·6H2O | as | 99.9 | N | crustaceans | *Daphnia magna* | reproduction | S | 21 d | NOEC | > 0.1 mg/L | | nom-m | total | R3/C2 | (Blinova *et al.* 2022) |
| GdCl3 6H2O | as | > 99.99 | Y | crustacean | *Heterocypris incongruens* | n.r. | S | 6 d | EC10 | | 0.028 mg/L | nom | dissolved | R3/C3 | González, 2015 #15} |
| GdCl3 6H2O | as | > 99.99 | Y | crustacean | *Heterocypris incongruens* | n.r. | S | 6 d | EC50 | | > 6.4 mg/L | nom-m | dissolved | R3/C3 | González, 2015 #15} |
| Nitric acid, Gadolinium (3+) salt | as | Analytical Reagent grade | N | fish | *Cyprinus carpio* | mortality | R | 45 d | NR-ZERO[3] | 0.5 mg/L | | nom | total | R3/C3 | Tu (1994) cited in ECOTOX |
| GdCl3 | as | n.r. | N | microcosm | *microcosm* | growth | S | 130 d | NOEC | 50 uM[5] | | nom | total | R3/C3 | (Fuma *et al.* 2001) |
| **Sub-chronic** | | | | | | | | | | | | | | | |
| Gd3+[4] | as | n.r. | Y | crustaceans | *Daphnia magna* | mortality | R | 7 d | EC50 | | 0.67 mg/L | m | dissolved | R3/C3 | (Revel *et al.* 2024) |

**Legend**

**Notes**
* Value recalculated to mg/L (a more detailed table with the originally reported data is available on request)
[#] former names: *Raphidocelis subcapitata/Selenastrum capricornutum*
[1] in the presence of 8 mg/L DOC
[2] value differs from original publication; this value was calculated based on measured total Gd concentrations; test item was GdCL3
[3] endpoint used in the original publication
[4] not further specified in the original publication
[5] medium contained peptone

**Chemical analytics**
nom based on nominal concentrations
nom-m based on nominal concentrations confirmed by analytical verification
m based on measured concentrations (not further defined)
mm based on mean measured concentrations (not further defined)
mm-gm based on mean measured concentrations (geometric mean)
m-i based on measured start concentration
nom-i & m-e based on the mean of nominal start concentrations and measured concentrations at the end of the experiment

**Exposure**
S static

| | |
|---|---|
| R | semi-static |
| T | flow-through |

## 5.2 Quality standards for aqueous toxicity

### 5.2.1 Chronic toxicity

#### 5.2.1.1 Derivation of CQC (AA-EQS) using the Assessment Factor (AF) method

The derivation of a $CQC_{AF}$ ($AA\text{-}EQS_{AF}$) is based on applying an assessment factor (AF) to the lowest credible datum from long-term toxicity tests.

Although a large dataset of aquatic toxicity studies is available, most of the reported effect concentrations cannot be regarded as reliable and relevant due to missing analytical verification of exposure concentrations, substantial decline of exposure concentrations over time or non-relevant exposure conditions.

No relevant and reliable long-term data were available. Thus, the $CQC_{AF}$ needs to be based on the lowest short-term result (see section 5.2.2; 84 µg/L, *Raphidocelis subcapitata*) with an AF of 1000. This factor can be lowered to >100 in case of evidence being available that the uncertainty is lower than depicted by a factor of 1000. In the absence of a specific mode of action, we would suggest using an AF of 1000.

$$\mathrm{CQC}_{AF}\ (\mathrm{AA}-\mathrm{EQS}_{AF}) = \frac{lowest\ EC_{10}\ or\ NOEC}{AF}$$

$$\mathrm{CQC}_{AF}\ (\mathrm{AA}-\mathrm{EQS}_{AF}) = \frac{84\left(\frac{\mu g}{L}\right)}{1000} = 0.084\ \left(\frac{\mu g}{L}\right)$$

The application of an AF of 1000 to the lowest credible acute datum results in a **$CQC_{AF}$ ($AA\text{-}EQS_{AF}$) = 0.084 µg/L**.

#### 5.2.1.2 Derivation of CQC (AA-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 NOEC/$EC_{10}$, from different species covering at least eight taxonomic groups (EC (2018), p. 43).

In this case, not enough data are available for applying the SSD approach.

#### 5.2.1.3 Determination of CQC (AA-EQS) according to mesocosm/field data

No AQC (MAC-EQS) based on field data or mesocosm data has been derived in the absence of publicly available data.

One microcosm study was identified (Fuma *et al.* 2001) combining *Euglena gracilis*, *Tetrahymena thermohila*, and *Escherichia coli*. The microcosms were spiked with $GdCl_3$ at four different nominal concentrations after around 2 months of the start of the experiment and then observed for another 2.5 months. Analytics were not performed. Thus, the exposure concentrations at the start and during the experiment are unknown.

## 5.2.2 Acute toxicity

### 5.2.2.1 Derivation of AQC (MAC-EQS) using the Assessment Factor (AF) method

The derivation of an $AQC_{AF}$ ($MAC\text{-}EQS_{AF}$) is based on applying an assessment factor (AF) to the lowest credible datum from short-term toxicity tests.

Although a large dataset of aquatic toxicity studies is available, most of the reported effect concentrations cannot be regarded as reliable and relevant due to missing analytical verification of exposure concentrations, substantial decline of exposure concentrations over time or non-relevant exposure conditions. We have compiled a basic acute dataset based on the criteria listed in 5.2 (Table 8).

The lowest short-term effect datum available for $Gd^{3+}$ is the $LC_{50}$ of 84 µg/L (Table 8) for the algae *Raphidocelis subcapitata* which was tested following the ISO 8692:2012 guideline for algal growth inhibition. Cultures were exposed to gadolinium for 72 hours in OECD standard algal medium. The test was run at 23 °C, under continuous light, with pH maintained at 8.1 ± 0.2. Phosphate was present in the medium at 1.6 mg/L as $KH_2PO_4$. Dissolved organic matter (DOM) was evaluated in two conditions: absent (0 mg C/L) and present (8 mg C/L as fulvic acid). Gadolinium concentrations were measured at the start and end of exposure by ICP-MS, and mean dissolved concentrations were used to represent actual exposure, since precipitation occurred in the absence of DOM. Test validity was confirmed, as control algal growth met ISO criteria. For MAC-EQS derivation, data obtained from the exposure without DOM was selected.

Brief study summaries of the other studies in the basic data are available in Annex 2.

**Table 8** Most sensitive relevant and reliable acute data summarized from Table 6

| Group | Species | Duration | Effect concentration | Value [µg/L] | Reference |
|---|---|---|---|---|---|
| **Basic data** | | | | | |
| Algae | *Pseudokirchnerella subcapitata* | 72 h | EC50 | 84 | (Lachaux *et al.* 2022) |
| Crustaceans | *Daphnia magna* | 48 h | EC50 | 3011 | (Lachaux *et al.* 2022) |
| Fish | *Danio rerio* | 96 h | LC50 | >256 | (Lachaux *et al.* 2022) |
| **Additional data** | | | | | |
| Cnidaria | *Hydra attenuata* | 48 h | EC50 | 2007 | (González *et al.* 2015) |
| Rotifer | *Brachionus calyciflorus* | 48 h | EC50 | 914 | (González *et al.* 2015) |

In case of short term tests being available for at least three species representing different living and feeding conditions, the EU TGD for EQS recommends the application of an assessment factor of 100 on the lowest credible datum (Table 11 in EC (2018)). It can be reduced to 10 in case acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions (i.e., if the standard deviation of the log10 transformed L(E)C50 values is < 0.5) or known mode of toxic action and representative species for the most sensitive taxonomic group included in the data set.

In this case, the standard deviation of the log10 transformed L(E)C50 values is 1.14. A specific mode of action is not known; thus, a most sensitive group of organisms cannot be identified. A comprehensive study on marine organisms reported among others mollusks and echinoderms as most sensitive species (Markich *et al.* 2024). While there is no comparative study of gadolinium toxicity in freshwater and saltwater species, this study provides some evidence that algae may not be the most sensitive group of organisms. Whether the specific speciation of Gd in saltwater influences species sensitivity is unknown. Thus, we suggest an AF of 100 in accordance with EU TGD for EQS:

$$\mathrm{AQC}_{AF}\ (\mathrm{MAC} - \mathrm{EQS}_{AF}) = \frac{lowest\ EC_{50}}{AF}$$

$$\mathrm{AQC}_{AF}\ (\mathrm{MAC} - \mathrm{EQS}_{AF}) = \frac{84\left(\frac{\mu g}{L}\right)}{100} = 0.84\ \left(\frac{\mu g}{L}\right)$$

The application of an AF of 100 to the lowest credible acute datum results in a **AQC (MAC-$EQS_{AF}$) = 0.84 µg/L**.

#### 5.2.2.2 Derivation of AQC (MAC-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 $EC_{50}$, from different species covering at least eight taxonomic groups (EC (2018), p. 43).

In this case, not enough data are available for applying the SSD approach.

#### 5.2.2.3 Derivation of MAC-EQS according to mesocosm/field data

No field or mesocosm studies that provide effect concentrations are available, thus, no AQC (MAC-EQS) based on field data or mesocosm data has been derived.

### 5.3 Biota standard to protect wildlife from secondary poisoning ($QS_{biota,\ sec\ pois,\ fw}$)

According to section 2.3.4 of EU TGD for EQS, derivation of a QS for secondary poisoning is warranted when measured BMF > 1 or BCF (BAF) ≥ 100 (w.w.) or log Kow ≥ 3 or there is other evidence of bioaccumulation potential (e.g., biota monitoring data, structural alerts). With the reported BCF in mussels, derivation of a QS for secondary poisoning would be warranted. For metals, the decision should not be based on reported BCF according to the EU TGD for EQS, but on information on mode of action, homeostasis, essentiality, and biomagnification. Currently, there is no evidence of biomagnification of Gd. However, as the mode of action of Gd is replacement of essential metals while it is not essential itself and there is no evidence of homeostasis mechanisms, we deem the assessment of secondar poisoning necessary.

The EU TGD for EQS states that the “food item that will determine the final value for the quality standard in biota” needs to be determined and “is not only dependent on the energy contents of the food items, but also on the bioaccumulation characteristics of the substance through the food chain.” Thus, the “critical food item” needs to be identified based on these properties. As discussed in section 4.4.3.1 of the TGD for EQS, if the trophic magnification factor (TMF) in freshwater is TMF(lipid)<0.8 or TMF(dry weight)<1.0, the $QS_{biota,\ sec\ pois,\ fw}$ should be derived for bivalves, otherwise for fish as critical food item. TMF specific for Gd have not been reported. As discussed in section 2, neither data on biomagnification nor on bioaccumulation is unequivocal, although several studies have concluded that Gd has little or no potential to biomagnify. We thus suggest invertebrates as critical food item.

Table 9 lists mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning. However, these studies had to be rated “R4” as only the applicant data submitted to the ECHA database was available. These data could not be verified as the original studies or study summaries or assessments by ECHA were not available. A $QS_{biota,\ sec\ pois,\ fw}$ was derived but is considered preliminary until further verification of the data. Effect data for wildlife species was not available, thus, the assessment is limited to laboratory test species. In the “Guidance on information requirements and chemical safety assessment Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds” (ECHA 2008) it is stated that “Often toxicity studies with mammals/birds used for the derivation of the oral PNECs are based on studies in which the animals are exposed to a highly soluble metal compound (e.g. metals salts). In such case, the oral PNECs are expected to overestimate the bioavailability of biologically incorporated metal in natural diets. […] Therefore, there is a need to derive a relative absorption factor [RAF] to refine the secondary poisoning analysis. RAFs can be determined for the ingestion of soil (soil RAF) and the ingestion of non-soil dietary items (dietary RAF). RAFs will be specific for the consumer organism in question and may vary depending upon the dietary items under consideration." No specific RAF for Gd compounds was found in the literature, thus, the effect concentrations (Table 9) need to be used as reported.

For the derivation of a $QS_{biota,\ sec\ pois,\ fw}$, two methods are described in the TGD for EQS: Method A that uses daily dose and body weight of mammalian toxicity studies as input parameters, and Method B which is based on diet concentrations and energy content of the diet. As both methods use similar results according to the TGD for EQS, Method B is applied by default for comparative reasons. The critical NOEL of 300 mg/kg bw/day gadoliniumsulfite trihydrate corresponding to 153.4 mg/kg bw/day Gd for systemic toxicity in rats is selected. The study was terminated after 4 weeks (groups 2 and 3) with additional 2 week recovery period for animals in the control and highest exposure groups (groups 1 and 4) and can thus be considered subacute according to the TGD for EQS (EC (2018); Table 9). An AF for 10 is thus applied to the NOEL yielding 15.34 mg/kg bw/day. The value is based on total nominal concentrations.

The diet concentration is assumed to be based on wet weight. For normalization of Gd concentration in food to energy content, a standard energy content of 15.1 kJ/$g_{dw}$ and moisture fraction of 8 % are assumed (see Table 8, EC (2018)).

$$c_{energy\ normalized}\left[\frac{mg}{kJ}\right] = \frac{c_{diet}\ [\frac{mg}{kgfw}]}{energy\ content_{\ diet,dw} x\ (1 - moisture\ fraction_{diet})}$$

This results in an energy content normalized concentration of Gd of 0.0117 mg/kJ.

To convert the derived endpoint to the Gd concentration in the critical food item, the following formula is used:

$$c_{food\ item}\left[\frac{mg}{kg_{ww}}\right] = c_{energy\ nomralized}\left[\frac{mg}{kJ}\right] x\ energy\ content_{food\ item,dw} x\ (1 - moisture\ fraction_{food\ item})$$

According to Table 7 of EU TGD for EQS, standard moisture content and energy content of bivalves are 92 % and 19 kJ/$g_{dw}$, respectively.

The resulting Gd concentration in bivalves is 60.7 mg/$kg_{ww}$.

To convert internal concentrations to water concentrations, a BAF needs to be selected assuming a steady state distribution of Gd between water and organism. According to the TGD for EQS derivation (EC 2018), BCF should not be used for metals as an apparent inverse relationship between BCF and external water concentration is observed.

No reliable BAF for bivalves was available from the public literature. We suggest using the reliable BCF of 249 ± 75 L/kg w.w. for exposure to Gd in the absence of DOM to extrapolate the $Gd^{3+}$ water concentration. The suggested assessment factor is 10 in accordance with EU TGD for EQS, as the assessment is based on an individual value and not a species sensitivity distribution in lack of sufficient data.

$$QS_{\text{biota,sec pois,fw}} = \frac{\text{Gd mg/kg}_{\text{ww}}}{10} \text{ or } QS_{\text{biota,sec pois,fw}} = \frac{\text{Gd µg/L}}{10}$$

The application of an AF of 10 to the lowest credible chronic datum (extrapolated from a subacute study) results in a preliminary **$QS_{Biota,\ sec\ pois,\ fw}$ = 6.07 mg/$kg_{ww}$** or **24.3 µg/L for bivalves** based on dissolved Gd.

**Table 9** Mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning

| Species | Exposure | Duration | Endpoint | Effect concentration | Comment | Reference |
|---|---|---|---|---|---|---|
| Long-term toxicity to mammals | | | | | | |
| Not available | | | | | | |
| Short-term toxicity to mammals | | | | | | |
| *Rattus norvegicus,* Sprague-Dawley | Oral (gavage) Gadolinium trinitrate | Females: 1 treatment, 30 d observation period | LD50 | >5000 mg/kg bw/day (nominal) | Applicant: Klimisch 2<br>OECD Guideline 401 (Acute Oral Toxicity) (before 2002)<br>Age at study initiation: adult<br>Weight at study initiation: females: 190-250 g<br>20 females, 5000 mg/kg bw<br>Control: no data<br>No analytical verification of exposure concentrations<br><br>Mortality: No data<br>Clinical signs: Within 1 to 2 h after oral administration of RE nitrates most of the rats were depressed, and animals that received lethal doses showed little activity during the survival period. The animals were observed for 30 days although no deaths occurred later tha […]<br>Gross pathology: Throughout the observation period no gross pathological changes were noted.<br>Other findings: No data | Bruce DW, Hietbrink BE, DuBois KP (1963) cited in (ECHA 2025a) |
| *Rattus norvegicus,* Wistar | Oral (gavage) Gadoliniumsulfite trihydrate | Males/females: 1 treatment, 30 d observation period | LD50 | >2000 mg/kg bw/day (nominal) | Applicant: Klimisch 1<br>OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)<br>3 males and females, 2000 mg / kg bw<br>No control animals<br>No analytical verification of exposure concentrations<br><br>No signs of toxicity were detected in the rats (3 males and 3 females) after treatment with 2000 mg/kg. There were no deaths during the study. The gross pathological examination revealed no organ alterations. Based on the result of this study, it is considered that gadoliniumsulfite trihydrate has no toxic potential and that the LD50 value is higher than 2000 mg/kg after oral treatment in rats. | Anonymous 2002 cited in (ECHA 2025b) |
| *Rattus norvegicus,* Wistar | Oral (gavage) Gadoliniumsulfite trihydrate | Males/females: Daily treatment, 4 weeks | NOAEL | 300 mg/kg bw/day (actual dose received) | Applicant: Klimisch 1<br>OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents) | Anonymous 2003 cited in (ECHA 2025b) |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Control and highest dose groups allowed to cover for 2 weeks | | | Weight recorded but not publicly available<br>5 males and females, 200 and 300 mg/kg bw/day<br>10 males and females, 0 and 1000 mg/kg bw/day<br>Analytics: as no method was available during the course of the study, the test material suspensions were prepared daily, and an analysis was not performed.<br><br>Histopathological examinations revealed treatment-related changes in the stomach. They consisted of minimal to mild hyperplasia of mucous neck cells in the gastric fundus of 2 males and 1 female rat at 100 mg/kg. This finding was somewhat more pronounced in the 300 and 1000 mg/kg dose groups and almost all rats were affected. In addition, neutrophilic infiltrates in the submucosa, which were not observed at 100 mg/kg were noted at 300 and 1000 mg/kg. At the end of the 2-week recovery period 3 males and 4 females treated with 1000 mg/kg still showed a minimal to mild hyperplasia of mucous neck cells but without increased neutrophilic infiltrates in the submucosa. Therefore, the submucosal infiltration with granulocytes was completely reversible, whereas the hyperplasia of mucous neck cells was still present, but at a lower incidence and severity. Based on the findings observed at 1000 mg/kg at the end of the recovery, the findings observed in rats treated with 100 or even 300 mg/kg were considered to be completely reversible. | |
| *Rattus norvegicus*, Wistar | Oral (gavage)<br>Tris[oxalato(2-)]digadolinium | Females, 10 weeks old | LD50 | >2000 mg/kg bw | Applicant: Klimisch 1<br>OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)<br>6 females, 199 - 218 g<br>3 rats per group, 0 and 2000 mg/kg bw<br><br>All animals were symptom free during the study. | Anonymous 2016 cited in (ECHA 2025c) |
| *Rattus norvegicus*, Sprague-Dawley | Oral (gavage)<br><br>Substance not clear:<br>Tris[oxalato(2-)]digadolinium and | males approximately 10 weeks old, females approximately 9 weeks old | NOEL | 330 mg/kg/day (actual dose received) | Applicant: Klimisch 1<br>OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)<br>males: 470 g (range: 438 g to 495 g); females: 277 g (range: 259 g to 310 g)<br>10 animals/sex/dose; 4 groups: 0, 110, 330, 1200 mg/kg bw/day (actual dose received) | Anonymous 2016 cited in (ECHA 2025c) |

| | | | | | | |
|---|---|---|---|---|---|---|
| | gadolinium oxide are both mentioned in the study information | | | | Analytical verification of test concentrations: Measured concentration = nominal concentration ± 15% (85-115%)<br>- The NOAEL for parental systemic toxicity was considered to be higher than or equal to 1008 mg/kg/day based on the absence of adverse findings at this high dose level.<br>- The NOEL for reproductive performance and toxic effects on progeny was considered to be 330 mg/kg/day based on the lower numbers of delivered pups at the high dose level. | |
| Effects on reproduction in mammals | | | | | | |
| *Rattus norvegicus*, Sprague-Dawley | Oral (gavage)<br><br>Substance not clear: Tris[oxalato(2-)]digadolinium and gadolinium oxide are both mentioned in the study information | males approximately 10 weeks old, females approximately 9 weeks old | NOEL | 330 mg/kg/day (actual dose received) | Applicant: Klimisch 1<br>OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)<br>males: 470 g (range: 438 g to 495 g); females: 277 g (range: 259 g to 310 g)<br>10 animals/sex/dose; 4 groups: 0, 110, 330, 1200 mg/kg bw/day (actual dose received)<br>Analytical verification of test concentrations: Measured concentration = nominal concentration ± 15% (85-115%)<br>- The NOAEL for parental systemic toxicity was considered to be higher than or equal to 1008 mg/kg/day based on the absence of adverse findings at this high dose level.<br>- The NOEL for reproductive performance and toxic effects on progeny was considered to be 330 mg/kg/day based on the lower numbers of delivered pups at the high dose level. | Anonymous 2016 cited in (ECHA 2025c) |
| Effects on reproduction of birds | | | | | | |
| Not available | | | | | | |

# 6 Quality standards for sediment

The derivation of sediment standards in the EU TGD for EQS is based on the effect assessment under REACH (REACH 2008) but with additional consideration of field and mesocosm data. Different lines of evidence, including sediment toxicity tests, aquatic toxicity tests with equilibrium partitioning (EqP) and field/mesocosm studies, can be used to derive the final standard. Where sediment ecotoxicity data are available, this option is preferred because of the assumptions and uncertainties inherent in the equilibrium partitioning approach.

## 6.1 Effect data (spiked sediment toxicity tests)

No effect data from spiked sediment toxicity tests could be located for gadolinium.

## 6.2 Derivation of $QS_{sed,EqP}$ using the Equilibrium Partitioning (EqP) approach

If no reliable sediment toxicity data are available, the Equilibrium Partitioning (EqP) can be used to estimate a provisional $QS_{sed,EqP}$. This method uses the CQC (AA-EQS) for aquatic organisms and the partitioning coefficient as inputs as follows:

$$QS_{sed,EqP} = CQC \times K_p$$

### 6.2.1 Selection of quality criteria (CQC) for water

The EqP has been applied using the CQC (AA-EQS) of 0.084 µg/L.

### 6.2.2 Selection of partitioning coefficient

One of the main factors influencing the application of the EqP model is the choice of the partition coefficient. It is stipulated in the ECHA 2017 guideline (p. 143, ECHA (2017)) that "To increase the reliability of PNEC sediment screen derived using the EqP, it is imperative that a conservative but realistic partitioning coefficient (e.g. $K_d$, $K_{oc}$, $K_{ow}$) is chosen. A clear justification must be given for the chosen coefficient and any uncertainty should be described in a transparent way."

The EU TGD prefers measured $K_p$ values for sediment/suspended matter for freshwater, estuarine and marine water bodies respectively (EC 2018). Preference is given to field measurements and not laboratory sorption or toxicity experiments.

The $K_p$ selected for deriving a $QS_{sed,EqP}$ is 191279 L/kg which is the geometric mean from literature values retrieved for sediments (see Annex 1 and Table 1). Minimum and maximum values were used for comparison.

### 6.2.3 Derivation of $QS_{sed,EqP}$

The calculated $QS_{sed,EqP}$ using the different partitioning coefficient are listed in Table 10. According to the EU TGD "When the $QS_{sediment}$ has been calculated using the EqP and log $K_{ow}$ >5 for the compound of interest, $QS_{sediment}$ is divided by 10. This correction factor is applied because EqP only considers uptake via the water phase. Extra uncertainty due to uptake by ingestion of food should be covered by the applied assessment factor of 10." No specific guidance is provided for metals in the EU TGD, however the ECHA (2008) states "If the adsorption is relevant, an additional assessment factor of 10 should be added (…) to take exposure via ingestion into account.". However, no specific $K_d$ thresholds are available for metals to trigger the use of this extra AF of 10 according to ECHA.

For metals, log $K_{ow}$ cannot be determined. However, as discussed in section 2.2, it is suggested that uptake via ingestion of sediment particles may be driving Gd bioaccumulation in fish and filter feeders (i.e., bivalves). Thus, the additional AF of 10 has been applied to account for uptake via food in benthic organisms.

The derived preliminary $QS_{sed,EqP}$ is 1.607 mg/kg d.w. (geomean $K_p$) and 0.024-13.623 mg/kg d.w. (minimum and maximum $K_p$ values). The $QS_{sed,EqP}$ is to be considered preliminary because the $CQC_{AF}$ the value was derived from is based on acute effect data (see section 5.2.1).

**Table 10** Derived $QS_{sed,EqP}$ according to estimated geomean, maximum and minimum $K_p$ for freshwater sediments from Table 1 and Annex 1. The additional AF of 10 is applied to account for uptake via food in benthic organisms.

| $K_p$ [L/kg] | | CQC [µg/L] | Additional AF | $QS_{sed,EqP}$ [mg/kg d.w.] |
|---|---|---|---|---|
| Min | 2818 | 0.084 | 10 | 0.024 |
| Geomean | 191279 | 0.084 | 10 | 1.607 |
| Max | 1621810 | 0.084 | 10 | 13.623 |

### 6.3 Determination of $QS_{sed}$ according to mesocosm/field data

No mesocosm or field study have been located that can be used to support the derivation of sediment quality standards for Gd.

# 7 Proposed CQC (AA-EQS) and AQC (MAC-EQS) to protect aquatic species

The different QS values for each derivation method included in the EU TGD for EQS are summarized in Table 11. According to the EU TGD for EQS, the most reliable extrapolation method for each substance should be used (EC 2018).

**Table 11** QS derived according to the three methodologies stipulated in the EU TGD for EQS and their corresponding AF. Water concentrations are expressed as µg/L, sediment concentrations as mg/kg sediment d.w.

| | Value | AF |
|---|---|---|
| $CQC_{AF}$ ($AA\text{-}EQS_{AF}$) | 0.084 | 1000 |
| $AQC_{AF}$ ($MAC\text{-}EQS_{AF}$) | 0.84 | 100 |
| SQC ($EQS_{sed}$), preliminary | 1.607 | 10 |

A **CQC (AA-EQS) of 0.084 µg/L** and an **AQC (MAC-EQS) of 0.84 µg/L for Gd** including the application of an AF of 1000 and 100, respectively, are thus suggested. For sediments, a preliminary SQC ($EQS_{sed}$) of 0.95 mg/kg d.w. is proposed from the conversion of the CQC into the corresponding sediment concentration, and an additional AF of 10 to account for uptake via food. For the derivation of a preliminary $QS_{Biota, sec pois, fw,}$ an AF of 10 resulted in **6.07 mg/$kg_{ww}$** or **24.3 µg/L for bivalves**. These values are substantially higher than the suggested CQC, thus, secondary poisoning does not appear to be more relevant than direct toxicity based on the data available.

# 8 Protection of aquatic organisms and uncertainty analysis

As discussed in section 5.1, only studies reporting measured dissolved concentration and effects related to this are considered in line with the Guidance on information requirements and chemical safety assessment Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds (section 4.2, (ECHA 2008) and Technical Guidance for EQS (EC 2018). Further, due to the varying water solubility and bioavailability of Gd under various physico-chemical conditions, only the studies that were conducted under relevant environmental conditions (e.g. pH, salinity) were considered. The applied selection criteria narrowed down the reliable and relevant data almost exclusively to one study (Lachaux *et al.* 2022). While a full base acute dataset was available, no chronic data were available. Thus, the resulting AF for derivation of the CQC is high (1000). Chronic effect data for algae, the most sensitive group of organisms, and data for an additional group of organisms would make the assessment more robust allowing for lowering the AF to 100.

Data on bioaccumulation indicate that mussels can be considered as critical food item for secondary poisoning. Data for toxicity in mammals was only available from the ECHA registration information which cannot be verified. To derive water concentrations corresponding to calculated tissue concentrations, a BCF in bivalves was used as no reliable BAF was available. For both reasons, the $QS_{biota, sec pois,fw}$ is to be considered as preliminary value. The preliminary value is substantially higher than the suggested $CQC_{AF}$.

For the sediment compartment, the Equilibrium Partitioning (EqP) approach has been used to derive the proposed SQC in the absence of sediment toxicity data. The following assumptions apply for the application of the EqP: 1) sediment-dwelling organisms and water column organisms are equally sensitive to the chemical; 2) concentration of the substance in sediment, interstitial water and benthic organisms are at thermodynamic equilibrium: the concentration in any of these phases can be predicted using the appropriate partition coefficients; 3) sediment/water partition coefficients can either be measured or derived on the basis of a generic partition method from separately measurable characteristics of the sediment and the properties of the chemical. There is no information on the sensitivity of sediment-dwelling organisms compared to pelagic counterparts in the data set. The $K_p$ data is highly variable. The use of the minimum and maximum $K_p$ values from the database available returns SQC that span over five orders of magnitude. The proposed SQC should only be used as rough screening for assessing the level of risk to sediment-dwelling organisms. If with this method the risk ratio is > 1, then data improvement is necessary either by refining the exposure assessment with site-specific partitioning information ($K_p$ values) or by performing tests with benthic organisms, preferably using spiked sediment, to support a refined risk assessment for the sediment compartment.

The suggested quality criteria are sufficiently larger than reported limits of quantification (section 3), thus, implementation of the quality criteria is not limited by available analytical methods.

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# 10 Annex 1

## Partitioning coefficients

As discussed in section 2.2, only field studies at freshwater sites are relevant in the context of EQS derivation. Studies not considered are in grey font. Where available, experimental data is identified as (exp.) and estimated data as (est.). Where available, salinity and OC content are indicated.

| Suspended matter | | log $Kp_{susp}$ | $Kp_{susp}$ (L/kg) | Reference/Source |
|---|---|---|---|---|
| Field study, Rhine-Meuse estuary, using median values in calculation (N = 6 sample sites, OC = 5.9 % (4.0 % - 24.2 %)) | exp. | 5.63 | 426,579.5 | Moermond et al. (2001) cited in (ECHA 2025c) |
| Field study, Forsmark area (Baltic Sea) | exp. | 5.11[1] | 128,825 | Kumblad and Bradshaw (2008) cited in (ECHA 2025c) |
| Field study, Gulf of Thailand, using paired sample values in calculation (pH 6.0 ± 0.1) | exp. | 6.61 (4.75 – 7.78) | 4,073,802.8 | Censi et al. (2005) cited in (ECHA 2025c) |
| | | 5.78 | 670202.3 | Geometric mean |

| Sediment | | log $Kp_{sed}$ | $Kp_{sed}$ (L/kg) | Reference/Source |
|---|---|---|---|---|
| Field study, Rhine-Meuse estuary, sediment-surface water, using median values in calculation (N = 6 sampling sites, OC = 5.9 % (4.0 % - 24.2 %)), filtered < 0.45 µm | exp. | 5.47 | 295,120.9 | Moermond et al. (2001) cited in (ECHA 2025c) |
| Field study, Rhine-Meuse estuary, pore water, using median values in calculation (N = 6 sampling sites, OC = 5.9 % (4.0 % - 24.2 %)) | exp. | 5.43 | 269,153.5 | Moermond et al. (2001) cited in (ECHA 2025c) |
| Lab study, Rhine-Meuse estuary, sediment-surface water, using median values in calculation (N = 1 sampling site, OC = 2.13 % (0.88 % - 2.81 %), pH 7.1 – 8.5, salinity 10, 20 and 30 g/L), filtered < 0.45 µm | exp. | 5.5 | 316,227.8 | Moermond et al. (2001) cited in (ECHA 2025c) |
| Lab study, Rhine-Meuse estuary, pore water, using median values in calculation (N = 1 sampling site, OC = 2.13 % (0.88 % - 2.81 %), pH 7.1 – 8.5, salinity 10, 20 and 30 g/L) | exp. | 4.75 | 56,234.1 | Moermond et al. (2001) cited in (ECHA 2025c) |
| Field study, Nieuwe Maas (Rhine estuary, The Netherlands), sediment-surface water (OC = 0.88 %, 2.17 % and 2.77 %, pH 8 – 8.5), filtered < 0.45 µm | exp. | 5.71 | 512,861.4 | Stronkhorst and Yland (1998) reported by Sneller et al. (2000) cited in (ECHA 2025c) |
| Field study, Nieuwe Maas (Rhine estuary, The Netherlands), pore water (OC = 0.88 %, 2.17 % and 2.77 %, pH 8 – 8.5), filtered < 0.45 µm | exp. | 5.42 | 263,026.8 | Stronkhorst and Yland (1998) reported by Sneller et al. (2000) cited in (ECHA 2025c) |
| Lab study, Nieuwe Maas (Rhine estuary, The Netherlands), sediment-surface water, filtered < 0.45 µm | exp. | 5.58 | 380,189.4 | Stronkhorst and Yland (1998) reported by Sneller et al. (2000) cited in (ECHA 2025c) |
| Lab study, Nieuwe Maas (Rhine estuary, The Netherlands), pore water, filtered < 0.45 µm | exp. | 4.74 | 54,954.1 | Stronkhorst and Yland (1998) reported by Sneller et al. (2000) cited in (ECHA 2025c) |
| Field study, To Lich River and Kim Nguu River (Hanoi, Vietnam), pore water, using paired sample values in calculation (N = 6 sampling sites, OC = 1.2 – 5.3 % in To Lich River and | exp. | ≥ 5.15 - ≤ 6.32 | ≥ 141,253.8 - ≤ 2,089,296.1 | Marcussen et al. (2008) cited in (ECHA 2025c) |

| | | | | |
|---|---|---|---|---|
| 1.8 – 10.6 % in Kim Nguu River, pH 7.4 – 8.1), filtered < 0.45 µm | | | | |
| Field study, Forsmark area (Baltic Sea), pore water | exp. | 3.45 | 2,818.4 | Kumblad and Bradshaw (2008) cited in (ECHA 2025c) |
| Field study, Mabechi River, Mogami River, Kuma River and Yura River (Honshu and Kyushu estuary, Japan), sediment- surface water, using paired sample values in calculation (N = 15 sampling sites, SPM[2] = 0.1 – 4.1 mg/L, pH 8.1 – 8.4, salinity 31.9 – 34.2 g/L, temperature 17.4 – 27 °C), filtered < 0.2 µm | exp. | 6.21 (≥ 5.6 - ≤ 6.48) | 1,621,810.1 | Takata et al. (2010) cited in (ECHA 2025c) |
| Lab study, deep-sea sediment Penrhyn Basin and artificial water (pH 7.5, temperature 25 °C) | exp. | 5.69 | 489,778.8 | Chen et al. (1996) cited in (ECHA 2025c) |
| Lab study, near-shore sediment Penrhyn Basin and artificial water (pH 7.5, temperature 25 °C) | exp. | 5.23 | 169,824.4 | Chen et al. (1996) cited in (ECHA 2025c) |
| Microcosm study, water and sediment from Xuanwu Lake (Nanjing, China) (pH 6.5 – 6.8, temperature 22 ± 1 °C), filtered < 0.45 µm | exp. | 2.6 | 398,1 | Yang et al. (1999) cited in (ECHA 2025c) |
| | | 5.28 | 191278.9 | Geometric mean |

[1] detection limit was used as aquatic gadolinium concentration because measured concentrations in filtered water were below detection limit, [2] suspended particulate matter

# 11 Annex 2

### *Daphnia magna* (Lachaux *et al.* 2022)

The mobility inhibition test with *D. magna* was conducted under ISO 6341:2012, exposing neonates (<24 h old) to gadolinium for 48 hours. Tests were carried out in ISO medium with pH adjusted to 6.5 ± 0.2 to increase gadolinium solubility, which still lies within the acceptable range for the species. DOM was tested in two conditions: 0 mg C/L and 8 mg C/L fulvic acid. Measured dissolved gadolinium concentrations (via ICP-MS) were used to account for significant precipitation and adsorption. Each concentration was replicated, and at least 20 daphnids per treatment were tested. Test validity was met, as immobilization in controls was below the acceptable threshold.

### *Danio rerio* (Lachaux *et al.* 2022)

Juvenile zebrafish (*D. rerio*, ~1 month old) were tested according to the OECD 203 fish acute toxicity test, using a threshold approach derived from the most sensitive of the algal and daphnid tests in the same study. Fish were exposed to gadolinium for 96 hours in crystallizing dishes at 25 °C (±2) and pH 7.7 (±0.2). The medium was renewed daily to prevent concentration losses, and gadolinium levels were verified by ICP-MS. DOM was again tested at 0 mg C/L and 8 mg C/L fulvic acid. Fish were monitored not only for mortality but also for abnormal behavior. The study followed animal welfare regulations, minimizing fish numbers in line with the 3Rs principles. Test validity was satisfied, since mortality in controls remained within OECD limits.