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Report of the Persistent Organic Pollutants Review Committee on the work of its seventeenth meeting

Addendum

Risk profile for UV-328

At its seventeenth meeting, by its decision POPRC-17/3, the Persistent Organic Pollutants Review Committee adopted a risk profile for UV-328 on the basis of the draft contained in the note by the Secretariat (UNEP/POPS/POPRC.17/4), as revised during the meeting. The text of the risk profile as adopted is set out in the annex to the present addendum. It has not been formally edited.

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Annex*

UV-328

Risk profile

January 2022

* The studies and other information referred to in this risk profile do not necessarily reflect the views of the Secretariat, the United Nations Environment Programme (UNEP) or the United Nations. The designations employed and the presentation of the material within such studies and references do not imply the expression of any opinion whatsoever on the part of the Secretariat, UNEP or the United Nations concerning geopolitical situations or the legal status of any country, territory, area or city or their authorities.
The annex has not been formally edited.

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Executive summary

1. The POPs Review Committee at its sixteenth meeting concluded that UV-328 fulfilled the screening criteria set out in Annex D to the Convention (decision POPRC-16/3). Based on this decision, the present draft risk profile on UV-328 was prepared in accordance with Annex E to the Convention.

2. UV-328 (CAS No. 25973-55-1) is a phenolic benzotriazole that is used as a UV absorber to protect surfaces against discoloration and degradation under UV/sunlight. UV-328 has a wide range of applications, but its main uses are in paints and coatings, and as an additive in a wide variety of plastics, including in the non-food contact layer of food packaging. In the automobile sector, UV-328 is used in paints, coatings and sealants, as well as in liquid crystal panels and meters mounted on vehicles, and resin for interior and exterior parts of vehicles. In food packaging, it is used as an additive in plastics, printing ink and adhesives.

3. The earliest known production of UV-328 began in 1970, and as of 2021, UV-328 is designated as a high production volume chemical (>1000 tonnes per annum) according to the OECD Existing Chemicals Database.

4. The releases of UV-328 to the environment have not been quantified. Based on monitoring data, UV-328 is expected to be released to the environment during industrial production and use of the substance, during its use in products, and when products containing UV-328 are disposed or treated at end-of-life. Sources of UV-328 in the environment can include industrial facilities that produce or use the substance, wastewater treatment plants, stormwater, landfills and plastic litter/debris.

5. UV-328 has been detected in various environmental media, including ambient air (particulate phase), water (streams, rivers, seawater, marine plastic debris, wastewater, stormwater), soil, sediment, biota and humans (adipose tissue, breast milk) in many regions of the world.

6. UV-328 is considered to be persistent in sediment, soil and water as the half-lives of UV-328 in these matrices exceed the respective Annex D thresholds. Monitoring data of sediment cores taken near a historical UV-328 production facility in Narragansett Bay, USA, confirm that UV-328 is persistent in sediment, with high levels of UV-328 being detected even decades after the facility stopped producing UV-328.

7. UV-328 is considered to be bioaccumulative, and has bioconcentration factors experimentally determined in fish that are greater than 5000. This is supported by field evidence that UV-328 enriches in top predators. In addition, the slow kinetics and low metabolism of UV-328 in humans, and the ability of UV-328 to bind to blood proteins indicate a potential for UV-328 to bioaccumulate in humans.

8. UV-328 has been detected frequently in Arctic biota (common eider, European shag, kittiwake, glaucous gull, common gull, northern fulmar, mink) and in migratory seabirds on remote islands (great shearwater on Gough Island, blue petrel on Marion Island), which indicates the potential for UV-328 to be transported long distances from source to remote regions. UV-328 has also been detected in plastic particles present in the stomach of seabirds that exclusively forage in the open ocean (black-footed albatross, northern fulmar). Modelling results have shown that the long-range environmental transport potential of UV-328 in the atmosphere via aerosols is in the range of acknowledged POPs. UV-328 is therefore considered to have the potential to undergo long-range environmental transport via air (aerosols), water (marine plastic debris) and migratory species (seabirds).

9. UV-328 has been detected in human breast milk and adipose tissue in various parts of the world. Exposure of the general population to UV-328 can occur via consumption of contaminated foodstuffs (fish, seafood), as well as ingestion or inhalation of contaminated dust. Additionally, consumption of breast milk can be relevant for exposure in breast-feeding infants. Exposure to UV-328 via ingestion of dust is reported to be higher in toddlers compared to adults. Exposure levels in humans are currently below adverse effect levels.

10. Based on repeated-dose toxicity studies conducted in rats and dogs, UV-328 has been found to be associated with adverse health effects in mammals, with the primary health effect being liver toxicity. UV-328 is also associated with adverse effects on the kidney based on the study in rats. In addition, limited evidence of adverse effects on reproductive organs in rats and dogs have been identified (significant testicular weight changes in rats, reduced spermiogenesis in dogs). There are also indications of anti-androgenic effects of UV-328, based on an *in vitro* study. In fish, long-term exposure to UV-328 may result in adverse effects on the liver.

11. While UV-328 levels in the environment and humans are generally lower than adverse effect levels, some elevated levels that have been measured in source and remote regions indicate a potential for adverse effects. The elevated levels of UV-328 found in migratory seabirds on remote islands may have the potential for adverse effects in their mammalian predators, in addition to unknown consequences for the birds.

12. UV-328 is a substance that does not occur naturally in the environment, but has been detected in various environmental compartments, biota and humans all over the world. Based on evidence that UV-328 is persistent, bioaccumulative, toxic to mammals, and transported to locations far from where it is produced or used, it is concluded that UV-328 is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects, such that global action is warranted.

1. Introduction

13. In May 2020, Switzerland submitted a proposal to list UV-328 in Annex A to the Convention. The proposal was submitted in accordance with Article 8 of the Convention, and was reviewed by the Persistent Organic Pollutants Review Committee (POPRC) at its sixteenth meeting held in January 2021.

1.1 Chemical identity

14. UV-328 is a phenolic benzotriazole that is substituted with two *tert*-pentyl groups at the 4th and 6th position of its phenolic moiety. UV-328 absorbs the full spectrum of UV light in a fully reversible and non-destructive process (ECHA, 2014). It is therefore used as a UV absorber to protect various surfaces against discoloration and weathering under UV/sunlight. Table 1 shows the various chemical identifiers and registration numbers of UV-328. Table 2 shows the molecular characteristics of UV-328.

Table 1. Names and registration numbers of UV-328.

Common name	UV-328
IUPAC name	2-(2*H*-Benzotriazol-2-yl)-4,6-bis(2-methylbutan-2-yl)phenol
CAS name	Phenol, 2-(2*H*-benzotriazol-2-yl)-4,6-*bis*(1,1-dimethylpropyl)-
Synonym	2-(2*H*-Benzotriazol-2-yl)-4,6-di-*tert*-pentylphenol (BDTP), 2-(2′-Hydroxy-3′,5′-di-*t*-amylphenyl) benzotriazole
Commercial names	BLS 1328, Chiguard 328, Chisorb 328, Cyasorb UV 2337, Eversorb 74, GSTAB 328, Hostavin 3310 P, Kemisorb 74, Lowilite 28, Milestab 328, Seesorb 704, Songsorb 3280, Sumisorb 350, Thasorb UV328, Tin 328, Tinuvin 328, UV 2337, UV 74, Uvinul 3028, Viosorb 591
CAS number	25973-55-1
EC number	247-384-8

Table 2. Molecular characteristics of UV-328.

Molecular formula	$C_{22}H_{29}N_3O$
Molecular weight	351.5 g/mol
SMILES code (canonical)	CCC(C)(C)c1cc(c(c(c1)n2nc3ccccc3n2)O)C(C)(C)CC
Chemical group	Organic
Chemical sub-group	Benzotriazole, phenol
Substance type	Mono-constituent
Degree of purity	≥ 80–100% (w/w)

15. UV-328 can exist in two forms – open and closed (Figure 1). In the open form, there is no *intra*molecular hydrogen bond. Therefore, UV-328 is able to form *inter*molecular hydrogen bonds, for example, with water molecules. In its closed form, UV-328 contains an *intra*molecular hydrogen bond that is formed between a nitrogen atom in the benzotriazole moiety and the hydroxy (OH) group in the phenolic moiety. Hence, these functional groups are unable to form *inter*molecular hydrogen bonds. For this reason, the water solubility of UV-328 in the closed form is 3–4 orders of magnitude lower than in the open form.

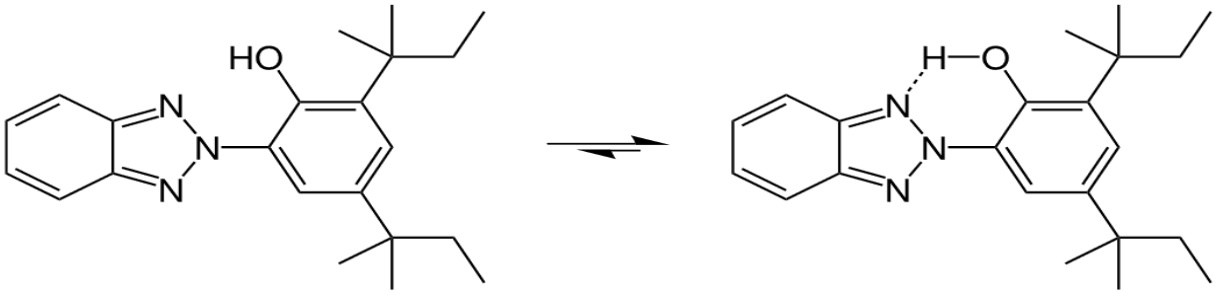

Figure 1. Chemical structure of UV-328 in its open form (left) and closed form (right). The open form of UV-328 does not contain an intramolecular hydrogen bond, whereas the closed form of UV-328 does.

16. Several studies have reported that UV stabilizers of the 2-(hydroxyphenyl)benzotriazole class, including UV-328, possess *intra*molecular hydrogen bonds that are shielded against being opened by polar solvents due to the substituents at the 4th and 6th position of the phenolic moiety (note: the cited studies reported substituents at the 3′ and 5′ positions; the different numbering of the positions arises from the use of different chemical nomenclatures for the same substance) (Chang et al., 2013; Fluegge et al., 2007; Rieker et al., 1992).

17. COSMOtherm also predicts that UV-328 exists only in the closed form, meaning it possesses an *intra*molecular hydrogen bond (COSMOtherm, 2020). However, EPI Suite predicts only the open form of UV-328 (using the SMILES code given in Table 2 as input) and consequently calculates the physico-chemical properties only for the open form of UV-328. Therefore, when available, the physico-chemical properties calculated by COSMOtherm will be considered here, as they are more consistent and accurate compared to EPI Suite values specifically for the case of UV-328 and its closed form. The physico-chemical properties of UV-328 are shown in Table 3. It should be noted that the assessment of the environmental fate properties of UV-328 (see section 2.2) is primarily based on experimental findings, which would have accounted for the appropriate form of UV-328 in the environment. Therefore, the fact that different forms of UV-328 can exist would not significantly influence the conclusion on its environmental fate properties.

Table 3. Physico-chemical properties of UV-328.

Property	Value	Reference(s)
Physical state	Yellow powder (20 °C, 101 kPa)	ECHA (2020a)
Melting point	81.2 °C	Thermal Analysis, ECHA (2020a)
	80–88 °C	Bolgar et al. (2016)
Boiling point	Decomposition	Experimental, Differential Scanning
	> 180 °C, before boiling	Calorimetry (DSC, 2013); ECHA (2020a)
	> 230 °C	Estimated, Thermogravimetric Analysis (2012), ECHA (2020a)
	461 °C	COSMOtherm
Vapour pressure	$5.0 \cdot 10^{-6}$ Pa (20 °C), 0.1 Pa (100 °C)	Experimental, DSC (1976), ECHA (2020a)
	$6.5 \cdot 10^{-6}$ Pa (20 °C)	COSMOtherm
	$1.4 \cdot 10^{-5}$ Pa (25 °C)	COSMOtherm
Henry's law constant	4.2 Pa m^3/mol	COSMOtherm
pK_a	8.9 ± 0.5 (acid), 0.7 ± 0.3 (base)	ACD/Labs, Classic Module Report
	10.3 ± 0.8 (acid), −1.0 ± 1.5 (base)	ACD/Labs, GALAS Module Report
Water solubility	< 0.001 mg/L (20 °C, pH 6.3–6.4)	Experimental, EU Method A.6, Column Elution Method (2001), ECHA (2020a)
	0.02 mg/L	Experimental, Dynamic Coupled Column (Lopez-Avila & Hites, 1980)
	$2.7 \cdot 10^{-4}$ mg/L (25 °C)	COSMOtherm
	$1.7 \pm 0.7 \cdot 10^{-4}$ mg/L (25 °C)	Ngoc Do et al. (2021)
Density	1.2 g/cm^3 (20 °C)	Experimental, IA 79/1 (Air Comparison Pycnometer, 1976), ECHA (2020a)
log K_{AW}	−2.8	COSMOtherm
log K_{OW}	> 6.5 (23 °C, pH 6.4)	Experimental, OECD TG 117, ECHA (2020a)
	8.5 (wet octanol)	COSMOtherm
	8.8 (dry octanol)	COSMOtherm
log K_{OA}	11.5	COSMOtherm
log K_{OC}	5.43	COSMOtherm

1.2 Conclusion of the POPs Review Committee regarding Annex D information

18. At its sixteenth meeting, the POPs Review Committee evaluated the proposal by Switzerland to list UV-328 in Annex A to the Convention. The Committee decided that, in accordance with paragraph 4 (a) of Article 8 of the Convention, it is satisfied that the screening criteria specified in Annex D to the Convention have been fulfilled for UV-328 (decision POPRC-16/3).

1.3 Data sources

19. The draft risk profile on UV-328 is based on the following data sources:

(a) Proposal to list UV-328 in Annex A to the Convention submitted by Switzerland;

(b) Information submitted in accordance with Annex E to the Convention by the following Parties and observers: Australia, Canada, Colombia, Costa Rica, Egypt, Hungary, Monaco, Norway, Peru, Republic of Korea, Russian Federation, Sweden, Alaska Community Action on Toxics (ACAT) & the International Pollutants Elimination Network (IPEN) and the European Chemical Industry Council (CEFIC);

(c) Support document for the identification of UV-328 as a Substance of Very High Concern in the European Union;

(d) Assessment of UV-328 by Environment and Climate Change Canada and Health Canada (ECCC and Health Canada), as well as other national evaluations on UV-328;

(e) Peer-reviewed scientific literature and grey literature;

(f) Registration dossier submitted for the authorization of UV-328 under the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation;

(g) Information presented at the sixteenth meeting of the POPs Review Committee (POPRC-16) and its premeeting.

1.4 Status of the chemical under national regulations and international forums

20. In the European Union, UV-328 was identified as a Substance of Very High Concern in 2014, and has been classified as persistent, bioaccumulative and toxic (PBT) as well as very persistent and very bioaccumulative (vPvB) (ECHA, 2014). Since 2020, UV-328 is regulated under Annex XIV (Authorisation) of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation of the European Union (ECHA, 2020b). In Norway, UV-328 was added to the national list of priority substances in 2017 (Annex E, 2021). UV-328 is restricted in the legislation of the Kingdom of Bahrain (Bahrain, 2021).

21. According to Australia's national assessment of UV-328, UV-328 is considered to be persistent and bioaccumulative, with uncertain toxicity (NICNAS, 2017). According to Canada's assessment of UV-328, it has been concluded that UV-328 does not meet the criteria under section 64 of the Canadian Environmental Protection Act (CEPA, 1999), as it is not entering the Canadian environment in a quantity or concentration having a harmful effect on the environment or constituting a danger to human life or health (ECCC and Health Canada, 2016).

22. Under the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention), UV-328 was listed as a substance of possible concern in 2006 (as cited by Germany, 2014).

2. Summary information relevant to the risk profile

2.1 Sources

2.1.1 Production and trade

23. The earliest known production of UV-328 began in 1970 (Lopez-Avila & Hites, 1980). No time trends are publicly available regarding the global production of UV-328 since production began. According to the OECD Existing Chemicals Database, UV-328 is designated as a high production volume chemical (HPVC), with production > 1000 tonnes per annum (t/a) (OECD, accessed 2021). In the EU, UV-328 is registered under the tonnage band of 100–1000 t/a (ECHA, 2020a). In the Nordic countries of Norway, Sweden, Denmark and Finland, the total use of UV-328 in 2018 was < 10 t, according to the Substances in Preparations in Nordic Countries (SPIN) database (SPIN, 2021). In Norway, there is no production of UV-328 and its use has declined from 1.9 t in 2009 to 0.17 t in 2019 (Annex E, 2021). In Sweden, usage of UV-328 declined from 9 t in 2005 to 0.7 t in 2019, except for a sharp increase to 244 t in 2015 that was followed by a decline to 1 t in 2016 (SPIN, 2021). The import of UV-328 between 2016 and 2019 in Sweden was 1.3 t/a (Annex E, 2021). In Denmark and Finland, 0.1 t and 4.5 t of UV-328 were used in 2019, respectively (SPIN, 2021). In Hungary, 21 companies produce UV-328 at < 1 t/a/company (Annex E, 2021). In Russia, UV-328 is imported from the People's Republic of China; however, no tonnage or company information has been reported (Annex E, 2021).

24. In Canada, 100–1000 t of UV-328 was imported in 2000, and 10–100 t was imported in 2010 and 2013 (ECCC and Health Canada, 2016). UV-328 is not produced in Canada. In the USA, the reported national aggregate production volume was approximately 1000 t in 2011, and 450–4500 t/a from 2012 to 2015 (US EPA, 2021). In Mexico, total imports of UV-328 in 2015 and 2017 were 90 t and 51 t, while total exports were 2 t and 0.9 t, respectively (Annex E, 2021).

25. In Japan, 1–1000 t/a of UV-328 was produced or used from 2012 to 2014, 1000–2000 t in 2015 and 1–1000 t from 2016 to 2018 (NITE, 2018). In the Republic of Korea, 0.25 t was produced, 58 t was imported, and 113 t was used in 2018 (Annex E, 2021).

26. Between 2016 and 2019, Oman imported many chemicals that contained UV-328 as one of the components but not as a raw material. Since 2020, Oman has not imported UV-328 (Oman, 2021).

27. UV-328 is not produced in Costa Rica and Monaco, and no production of UV-328 has been reported by Australia, Colombia, Egypt and Peru (Annex E, 2021). UV-328 is not imported or used in Bahrain (Bahrain, 2021).

28. In a presentation at POPRC-16, a large producer of UV-328 declared that it had intentionally begun a phase-out of UV-328 production.

2.1.2 Uses

29. UV-328 absorbs the full spectrum of UV light in a fully reversible and non-destructive process (ECHA, 2014). It is therefore used as a UV absorber to protect surfaces from discoloration and degradation under UV/sunlight. Most of its use is in surface coatings and paints (e.g. clear coat automotive finishes), and as an additive in plastics (e.g. transparent plastics, food packaging). It is also used in printing inks and adhesives used in food contact materials (EuPIA, 2013).

30. More specifically, UV-328 is used as a UV stabilizer in plastic shrink films, outdoor furniture and clear coat automotive finishes, as well as for light stabilization in coatings, acrylonitrile butadiene styrene (ABS) resin, epoxy resin, fiber resin, polypropylene (PP), rigid and flexible polyvinyl chloride (PVC) and polystyrene (PS) (Bolgar et al., 2016; ECHA, 2020b). It is also effective in light stabilization of unsaturated polyesters, polyacrylate and polycarbonate (PC) (ECHA, 2020b). Additionally, it is used in construction materials, fillers, surface treatments, adhesives, paints/lacquers/varnishes, thinners, paint removers, printing inks, consumer fragrances, fabric/textile/leather products and inert pesticides (Danish EPA, 2015; ECHA, 2020b). Its recommended use as a UV absorber has been for polyolefins, polyurethanes, PVC, polyacrylate, epoxy and elastomers (ECHA, 2020b). UV-328 was found in toys and hair accessories (Karlsson et al., 2022).

31. In Australia, UV-328 is used in industrial sealants in aftermarket automotive products (NICNAS, 2017). In Canada, 63% of UV-328 was used in the plastics sector and 37% in paints and coatings in 1986; and currently UV-328 is used in automotive paints and coatings, to a minor degree as a sealant in the manufacture of automobiles, and as an additive in plastic food packaging in the non-food contact layer (ECCC and Health Canada, 2016). In Norway, UV-328 is mainly used in paints and varnishes, but also in rubber and transparent plastics (Annex E, 2021). In Sweden, UV-328 is mainly used as an additive in plastics, paints and sealants (Annex E, 2021). In Russia, UV-328 is mainly used as a corrosion inhibitor (anti-corrosion agent), in polishes for metal surfaces, as well as for the gravimetric determination of metals such as copper, silver and zinc (Annex E, 2021).

32. In various jurisdictions, UV-328 is used as an additive in the non-food-contact layer of food contact articles. According to the FACET tool of the European Commission's Joint Research Centre (JRC), UV-328 is included as being used in food contact materials (JRC, 2017). UV-328 is also part of the 2013 inventory list of the European Printing Ink Association (EuPIA) for additives in printing ink used on the non-food contact surface of food contact articles (EuPIA, 2013). In Switzerland, UV-328 is included in the "List of permitted substances for the production of packaging inks, and related requirements" of the Ordinance on Materials and Articles in Contact with Food (Swiss FDHA, 2020). In the USA, UV-328 is listed in the US Food and Drug Administration's (FDA) Inventory of Indirect Additives used in Food Contact Substances (US FDA, 2021). In Japan, UV-328 is in the 2020 Positive List for food contact plastics additives (MHLW, 2020). In China, UV-328 is included in the list of additives for plastic food contact materials and articles (NHFPC, 2016).

33. UV-328 has been reported to have three main uses in the automobile sector: 1) in optical polarizing plate and polarizing film for liquid crystal panels (of the super twisted nematic type) and meters mounted on vehicles, 2) in paint and 3) in resin used for interior and exterior parts (e.g. door handles and levers) (JAPIA, 2021).

34. In coatings, the typically recommended concentration of UV-328 is between 1 and 3% (by weight, based on solids) (Hangzhou Sunny Chemical Corp Ltd., 2003). For the consumer use in automotive clearcoat finish and topcoat glaze for boats, concentrations of UV-328 ranging up to 10% were identified in material safety data sheets in the USA (as reported in ECCC and Health Canada, 2016).

35. In plastics, the recommended loading of UV-328 as an additive during manufacturing is typically 0.1–1% by mass (Hunan Chemical BV, 2016). Polymer-specific recommendations are 0.15–0.3% for PC, 0.2–0.4% for polyethylene (PE), 0.2–0.5% for PS and PVC and 0.3–0.5% for polyesters (Disheng Technology, 2017). However, recent studies have found lower concentrations of UV-328 in recently-produced plastics and packaging materials (Chang et al., 2013; Rani et al., 2017; Zhang et al., 2016). Zhang et al. (2016) found UV-328 in the range of 25–76 µg/g (0.0025–0.0076% by mass) in milk packaging and snack packaging together with other UV absorbers. Chang et al. (2013) reported a concentration of 2.01 µg/g of UV-328 in commercial polyethylene terephthalate (PET)

beverage packaging and 13.88 µg/g in low-density polyethylene (LDPE) packaging. Rani et al. (2017) reported even lower concentrations in the range of 0.0027–0.4 µg/g in newly-produced plastics. In addition, UV-328 has been detected in recycled post-consumer PET intended for subsequent production of food contact materials, although the concentration of UV-328 was not reported (Dutra et al., 2014).

36. For the use of UV-328 in textiles, it is not known what the typical loading of UV-328 is. Avagyan et al. (2015) measured UV-328 in various clothing articles. From 26 clothing articles made from different materials, UV-328 was detected at concentrations of 8.05 and 108 ng/g in two samples composed primarily from cotton.

2.1.3 Releases to the environment

37. UV-328 may be released to the environment during industrial production and use of the substance, during its use in products, and when products are disposed or treated at end-of-life. No empirical data are available that quantify the releases of UV-328 from different sources to the environment. However, the Canadian assessment of UV-328 provides estimates on the releases of UV-328 to surface waters due to the industrial uses of UV-328 in the plastics manufacturing sector and the paints and coatings sector in Canada, and predicted environmental concentrations (PEC) in surface waters, sediment, biosolids and soil under different release scenarios, which are summarized in Table 4 and Table 5. Additional details on how the PECs were calculated in the Canadian assessment are available in UNEP/POPS/POPRC.17/INF/17. After its release to surface waters, UV-328 likely partitions to particles and organic matter, and ends up in sediment (ECCC and Health Canada, 2016).

Table 4. Predicted environmental concentrations resulting from releases of UV-328 due to industrial uses in the plastics sector. A use of 25 tonnes per facility per year is assumed. Source: ECCC and Health Canada, 2016.

	Site specific	Generic
Surface waters near the discharge point (short-term concentration) (mg/L)	$2.52 \cdot 10^{-4}$	$1.28 \cdot 10^{-4} – 8.81 \cdot 10^{-3}$
Surface waters in receiving water bodies (long-term concentration) (mg/L)	$6.90 \cdot 10^{-6}$	$3.52 \cdot 10^{-6} – 2.41 \cdot 10^{-4}$
Sediment (mg/kg dw)	0.19	6.80
Biosolids (mg/kg dw)	18.62	2446.23
Soil (mg/kg dw)	0.64	84.60

Table 5. Predicted environmental concentrations resulting from releases of UV-328 due to industrial uses in the paints and coatings sector. A use of 12 tonnes per facility per year is assumed. Source: ECCC and Health Canada, 2016.

	Site specific	Generic (solvent-based coating)	Generic (aqueous-based coating)
Surface waters near the discharge point (short-term concentration) (mg/L)	$4.92 \cdot 10^{-5}$	$2.67 \cdot 10^{-6} – 7.78 \cdot 10^{-4}$	
Surface waters in receiving water bodies (long-term concentration) (mg/L)	$1.35 \cdot 10^{-6}$	$7.31 \cdot 10^{-8} – 2.13 \cdot 10^{-5}$	
Sediment (mg/kg dw)	0.038	0.14	0.60
Biosolids (mg/kg dw)	92.42	1016.62	84.72
Soil (mg/kg dw)	3.20	35.16	2.93

38. Findings from monitoring studies conducted in Narragansett Bay, Rhode Island, USA, also implicated industrial releases as a source of UV-328 in the environment, where sediment cores showed high levels of UV-328 corresponding to the years (1970–1985) during which UV-328 was being manufactured in a nearby production facility (Cantwell et al., 2015; Hartmann et al., 2005; Jungclaus et al., 1978; Lopez-Avila & Hites, 1980).

39. The discharge of products containing UV-328 into waste streams is relevant for the detection of UV-328 in different environmental compartments such as oceans, rivers, beaches, sediment and soil. This is because UV-328 is not chemically bound to materials, which implies that processes such as abrasion, leaching and volatilization may result in the release of UV-328 from products into the environment. Wastewater treatment plants, landfills and storm water are therefore considered to be sources of UV-328 to the environment (Brorström-Lundén et al., 2011; Montesdeoca-Esponda et al., 2021).

40. According to Norway, emission of UV-328 to both the indoor and outdoor environment has been observed. UV-328 has been detected in indoor air and dust, wastewater, wastewater sludge, river water and biota in source regions and in biota in remote regions (Annex E, 2021).

41. UV-328 is expected to enter soil from the application of wastewater biosolids (Lai et al., 2014b) and as a result of the degradation of disposed products that contain UV-328.

42. A major use of UV-328 is as an additive in plastics. Currently there are no data quantifying the release of UV-328 from consumer plastic products into the environment. It is known that significant amounts of plastics are released to the oceans (18.6–26.1 Mt) every year and these originate both from terrestrial and ocean-based sources (Borrelle et al., 2020; Ryan et al., 2009). Once in the open ocean, plastic debris is known to accumulate within each of the ocean gyres where a significant accumulation occurs (Eriksen et al., 2014). Plastic debris containing UV-328 in the accumulation zones of the gyres may therefore act as sources of release of UV-328 to receiving environments. UV-328 has been detected in a fraction of marine plastic debris at maximum concentrations of 0.2–1.6 µg/g (Rani et al., 2015, 2017; Tanaka et al., 2020a), as well as in plastics ingested by seabirds such as northern fulmar and black-footed albatross (Tanaka et al., 2019a) and in other seabirds that feed in the open ocean and are known to frequently ingest fragments of marine plastic debris (Tanaka et al., 2019b; Yamashita et al., 2021). UV-328 is also found in and/or on industrial plastic pellets on beaches all over the world, although it cannot be distinguished whether it is adsorbed or in the matrix (Karlsson et al., 2021) (see para 82). Data from Canada indicate that Arctic seabird species that show a higher frequency of occurrence of any ingested plastics may be more exposed to UV-328 as compared to species that have very low or negligible levels of ingested plastics. Plastic litter containing UV-328 may therefore be a relevant entry pathway of UV-328 in the marine environment and an exposure pathway for biota that ingest plastics (Yamashita et al., 2021; Provencher et al. submitted for publication, 2022).

43. The use of UV-328 in textiles can also be a source of releases of UV-328 to the environment and wastewater treatment plants when textiles are washed. It was shown that after 10 wash cycles, as much as 80% of UV-328 was removed from textiles made from polyesters (Luongo et al., 2016).

2.2 Environmental fate

2.2.1 Persistence

44. UV-328 has a very low degradation potential and long disappearance half-lives (DT_{50}) in soil and sediment, which has been demonstrated through experimental and monitoring data. For these reasons, UV-328 has been classified under a weight-of-evidence approach as persistent as well as very persistent in the EU (Brandt et al., 2016; ECHA, 2014).

45. UV-328 does not contain any hydrolysable moiety in its chemical structure and possesses inherent UV-absorber characteristics, and is therefore not expected to degrade significantly via hydrolysis, oxidation or direct photo-transformation (ECHA, 2014).

46. Moreover, UV-328 is not readily biodegradable. In a ready biodegradability test according to OECD 301 B, it was found that only 2–8% of UV-328 was degraded after 28 days in activated sludge (Ciba-Geigy, 1988).

47. A study monitored the disappearance of UV-328 from sludge-amended agricultural soils (Lai et al., 2014a). For these field trials, dewatered sludge was collected from a wastewater treatment plant in Beijing in May 2006 and then applied to fluvo-aquic test soils in Shandong, China. Two types of treatments were applied. The first treatment involved a one-time application of sludge amendment to the test soils in May 2007, whereas in the second treatment, sludge was applied every year on October 5 from 2007 to 2010. The sludge applied to test soils contained UV-328 at an initial concentration of 108 ± 2.6 ng/g. No UV-328 was detected in control soils (where sludge amendment was not applied). From October 2010 to October 2011, soil samples were taken every month and analyzed. Data from January and February 2011 were excluded from the analysis due to sampling difficulties during the frost period in Shandong. The authors therefore performed a dynamic curve fitting of data only from March to October 2011. From this, the DT_{50} of UV-328 in soil was found to be 179–218 days for the two treatments. A similar study was conducted in Shandong using the same type of test soil; the field trials ran from October 2006 to 2011 (Lai et al., 2014b). The authors found a DT_{50} of 99–223 days. These values indicate that UV-328 is persistent in soil. Actual degradation half-lives of UV-328 in soil are expected to be even longer, because the disappearance half-life includes other loss processes beside degradation, e.g. volatilization, leaching to deeper soil layers, surface runoff, etc.

48. As there are no simulation tests on UV-328 in sediment and water, a read-across from a structurally similar substance, M1 (CAS No. 84268-36-0), was performed to estimate the disappearance half-lives (DT_{50}) of UV-328 in sediment (ECHA, 2014). The justification for performing the read-across in this study is in line with the European Chemical Agency's read-across assessment framework, which states that structurally similar substances (e.g. due to common functional groups) may be considered as a category of substances, and that a read-across may be carried out on a reference substance (e.g. M1) to interpolate information on a target substance (e.g. UV-328) within the same category of substances (ECHA, 2017). M1 is also a phenolic benzotriazole and only differs from UV-328 in that M1 contains an *n*-propionic acid group and a *tert*-butyl group, whereas UV-328 contains two *tert*-pentyl groups at the 4^{th} and 6^{th} position of the phenolic group. As propionic acid groups are more readily degradable than *tert*-pentyl groups, it is expected that the DT_{50} of M1 would be shorter than that of UV-328 (Brandt et al., 2016). The simulation test on

M1 found a DT_{50} of 238 and 248 days in the sediment phase of a pond system under anaerobic and aerobic conditions, respectively (ECHA, 2014). This suggests that the DT_{50} of UV-328 in sediment would be at least 238 days.

49. Monitoring data confirm that UV-328 is persistent in sediment cores. Several monitoring studies have been conducted in Narragansett Bay, Rhode Island, USA, where UV-328 was produced in a nearby chemical manufacturing facility between 1970 and 1985 (Cantwell et al., 2015; Hartmann et al., 2005; Jungclaus et al., 1978; Lopez-Avila & Hites, 1980). Cantwell et al. (2015) found that the highest concentration of UV-328 in sediment cores was 74 µg/g dw, corresponding to the year 1976, when it was still being produced at the nearby facility. Concentrations of UV-328 near the surface, which correspond to more recent (post-production) years, ranged between 3 and 6 µg/g dw. Similar concentration trends have been reported by Hartmann et al. (2005). The data support the environmental persistence of UV-328 in sediments.

50. According to the screening tool for persistence, BIOWIN 4.10 module of EPI Suite, UV-328 has a score of 2.054 in Biowin3, a sub-model for estimating ultimate biodegradation of substances in aerobic environments (calculated for the open form). This translates into a half-life of 74 days for UV-328 in water and 136 days in soil, based on the following equations described in Scheringer et al. (2012), Rorije et al. (2011) and Boethling et al. (1995):

$$\log t_{1/2\,water} = -0.80 \cdot score_{Biowin3} + 3.51 \text{ (with } t_{1/2 \text{ water}} \text{ in days)}$$

$$t_{1/2\,soil} = 1.85 \cdot t_{1/2\,water}$$

where $t_{1/2\,water}$ and $t_{1/2\,soil}$ are the half-lives in water and soil, respectively.

The first equation is based on half-life values and scores provided in the EPI Suite User Guide (Scheringer et al., 2012). The second equation was derived from biodegradation data from grab sample studies, focusing on relative rates of aerobic biodegradation in fresh water and surface soil (Boethling et al., 1995). The estimated half-life of 74 days in water exceeds the Annex D threshold of two months for persistence in water.

51. Based on evidence that UV-328 has a degradation half-life greater than the Annex D thresholds of six months in soil, six months in sediment and two months in water, UV-328 fulfills the criteria for persistence.

2.2.2 Bioaccumulation

52. UV-328 has a log K_{OW} > 5, which indicates potential for bioaccumulation. Measured bioconcentration factors (BCFs) and modelled bioaccumulation factors (BAFs) are above the Annex D threshold of 5000 and metabolic transformation rates are low, thus confirming that UV-328 bioaccumulates. Under EU's REACH regulation, UV-328 has been classified as bioaccumulative as well as very bioaccumulative (ECHA, 2014).

53. Bioaccumulation of UV-328 occurs primarily after uptake of UV-328 by organisms through their diet, and there is evidence of bioaccumulation of UV-328 in aquatic ecosystems.

54. Bioaccumulation of UV-328 in aquatic organisms was tested in two studies (test protocol OECD TG 305 C, 2000, 2007) on common carp, *Cyprinus carpio* (ECHA, 2014, 2020a). In the study from 2007, carp were exposed to UV-328 in water over 60 days at nominal concentrations of 0.1 and 0.01 µg/L. Average measured concentrations were 0.102 µg/L and 0.0095 µg/L, respectively. BCFs for UV-328 at 0.1 µg/L between day 40 and 60 ranged from 820 to 1000 L/kg ww. When normalized to a lipid content of 5%, the BCFs range from 980 to 1190 L/kg ww, respectively. BCFs for UV-328 at 0.01 µg/L between day 40 and 60 ranged from 980 to 1800 L/kg ww. The average lipid content in the fish was 4.9%, so normalizing lipid content to 5% would not change these values significantly. The depuration half-lives were 33 days at a concentration of 0.01 µg/L and 16 days at 0.1 µg/L. As no information on fish weight or growth rates was reported, it is not possible to back-calculate BCFs from the depuration rate with the BCF Estimation Tool (OECD, 2020). In addition to the concentrations in the whole body of the carp, BCF measurements from different tissues were reported in this study. Highest BCFs were observed in innards, followed by head, skin and edible parts.

55. In the study from 2000, carp were exposed to UV-328 in water over 56 days at (measured) concentrations of 0.78 and 0.07 µg/L. However, it should be noted here that UV-328 is a highly hydrophobic chemical with a measured solubility in water 0.17 ± 0.07 µg/L (Ngoc Do et al. (2021). The higher exposure concentration, i.e. 0.78 µg/L, was above the water solubility. Thus, a resulting overestimation of the concentration of UV-328 in water for the higher tested concentration could have led to underestimated BCF values. Therefore, we report here only the BCFs from the lower exposure concentration. The non-lipid normalized BCF steady-state values at the end of the exposure period (week 6 to 8) for the exposure concentration of 0.07 µg/L ranged from 4400 to 4800 L/kg ww (ECHA, 2014). Normalizing these values to a lipid content of 5% using the lipid content at the start of exposure (4.2%, no lipid content was reported for the end of the exposure period) gives steady-state BCF values between 5200 and 6600 L/kg ww. The average lipid normalized steady-state BCF was 5500 L/kg ww. According to OECD TG 305, the steady state was not reached (regardless, the calculation would have led to a kinetic BCF > 5000 L/kg). Depuration half-lives at 0.78 µg/L and 0.07 µg/L exposure levels of UV-328 were 26 days and 24 days, respectively. The BCF values that are less than one order of magnitude different in these two studies in common carp may be partially explained by the relatively high intra-species variation as well as considerations of the challenges associated with testing substances that have a low water solubility.

56. Based on kinetic modelling of the experimental BCF data, UV-328 has a low metabolic transformation rate with a calculated metabolic rate constant of 0.01/day for a 184-g fish (ECCC and Health Canada, 2016).

57. It is important to note that BCFs only account for respiratory exposure of a substance from water, and do not consider dietary uptake of the substance. As UV-328 has a low water solubility and is more likely to be taken up through an organism's diet than from water, an appropriate parameter for assessing bioaccumulation potential of UV-328 would be to consider the BAF of a substance after correcting for metabolic transformation.

58. According to the AQUAWEB model (v1.3), the BAF of UV-328 in mid-trophic level fish is estimated to be 87,000 L/kg ww, indicating a significant biomagnification factor in aquatic organisms when dietary uptake of UV-328 is considered (Arnot & Gobas, 2004; ECCC and Health Canada, 2016). EPI Suite estimations of BCFs and BAFs also predict bioaccumulation of UV-328 in the marine food web (US EPA, 2012).

59. UV-328 was monitored in finless porpoises (*Neophocaena phocaenoides*) in the Ariake Sea, Japan, from 1998 to 2009 (Nakata et al., 2010). On average, 29 ng/g ww of UV-328 was found in blubber samples of five finless porpoises. Based on the blubber content in finless porpoises and the weight fractions of the blubber (29% on average), the whole-body concentration of UV-328 was 8.4 ng/g ww. If the values are normalized using the blubber lipid content of finless porpoises to a 5% lipid content, a value of 1.9 ng/g ww of UV-328 is obtained. This allows for a comparison of the values of UV-328 in the finless porpoises and in small fish also sampled from the Ariake Sea during 2004 and 2007 (Nakata et al., 2009). The lipid normalized UV-328 content in finless porpoises was 4 times higher than in small fish, while the non-lipid normalized UV-328 content in finless porpoises was as much as 30 times higher than in small fish sampled from the same region (Nakata et al., 2009, 2010). The values are shown in Table 6.

Table 6. Concentrations of UV-328 found in finless porpoises and small fish sampled from the Ariake Sea, Japan. Concentrations are reported in ng/g ww.

	Blubber (mean lipid content 80%)	**Whole body**	**Lipid-normalized** (5% lipid)	**Reference(s)**
Finless porpoises	29 ± 19	8.4 ± 5.5	1.9 ± 1.3	Nakata et al., 2010
Small fish	–	0.25 ± 0.03	0.5 ± 0.2	Nakata et al., 2009

60. Based on the feeding behavior of finless porpoises and their prey, a plausible pathway for bioaccumulation of UV-328 in finless porpoises is through trophic transfer: starting from benthic organisms taking up UV-328 from sediment, prey of finless porpoises taking up UV-328 by feeding on benthic organisms, and eventually finless porpoises taking up UV-328 by feeding on prey (ECHA, 2014). Finless porpoises in the Ariake Sea are known to feed on small fish such as sea bass (*Lateolabrax japonicus*) and sandperch (*Parapercis sexfasciata*), as well as cephalopods (e.g. squid) and crustaceans (e.g. shrimp) (Shirakihara et al., 2008), which were found to accumulate UV-328 in the Ariake Sea (Nakata et al., 2009). Based on these field data, UV-328 has been reported to enrich in top predators (ECHA, 2014). It is noted that monitoring of UV-328 in finless porpoises was conducted over a long period of time and involved a small sample size, and that the finless porpoises and their prey were sampled at different times. However, it is also noted that finless porpoises can live up to 30 years and can accumulate chemicals during their entire lifetime.

61. In a study in the Pearl River Delta, China, nine species of wild freshwater fish were collected along with river water samples with the intent to assess the bioaccumulation of UV-328 and other UV filters (Peng et al., 2020). Due to low detection of UV-328, a BAF for UV-328 could not be reported in this study. However, the study reported a measured biota-sediment accumulation factor (BSAF) of 1.36 ± 1.96 and an estimated trophic magnification factor (TMF) of 1.2 ± 0.1. The BSAF > 1 and TMF > 1 indicate a potential for UV-328 to bioaccumulate due to exposure to contaminated sediment and to undergo trophic magnification, respectively. Given the indicated low detection of UV-328, these values should be treated with caution.

62. In terms of bioavailability in mammals, the Advanced Chemistry Development Inc. (ACD) model *Percepta* predicts that UV-328 will not be ionized in the small intestine and is likely to be absorbed to a certain extent in the gastrointestinal tract after oral dosing (ECCC and Health Canada, 2016). Based on UV-328's hydrophobic properties, the liver is expected to be the main metabolism site and metabolites would mostly be excreted via the kidneys. This is supported by observations from the repeated-dose toxicity studies on UV-328 discussed in section 2.4.1.1 as well as toxicokinetic studies conducted in humans, discussed below. According to the REACH registration dossier, dermal uptake of UV-328 by organisms is unlikely (ECHA, 2020a).

63. In a recent study on the metabolism and kinetics of UV-328 in humans, UV-328 was orally administered at a dose of 0.3 mg/kg bw in three adult human volunteers (Denghel et al., 2021). After 72 h, only about 0.1% of the administered dose was recovered in the form of UV-328 and its metabolites in urine. Of the metabolites that were identified, two contained hydroxy-substituents, two contained oxo-substituents and one contained both a hydroxy- and oxo-substituent (Denghel et al., 2021). The substitutions occurred on the *tert*-pentyl groups of the phenolic moiety, while the benzotriazole moiety remained unaltered (Denghel et al., 2021). The slow metabolism observed in this study indicates the resorption of UV-328 that may be stored in lipid depots, and an accumulation of UV-328 and of some of

its metabolites may be expected for repetitive exposure scenarios due to the minor relevance of renal elimination and the slow kinetics (Denghel et al., 2021). Additionally, a study on the structure-activity relationships of various benzotriazole UV filters with human serum albumin, the most abundant transport protein in human plasma, found that UV-328 can bind to human serum albumin and cause conformational changes (Zhuang et al., 2016). The ability to bind to proteins in blood, combined with a low metabolic clearance and slow excretion in urine are considered to be good predictors of the potential and extent of bioaccumulation of a chemical (Tonnelier et al., 2012). The findings from Denghel et al. (2021) and Zhuang et al. (2016) may therefore also be an indication of the potential for bioaccumulation of UV-328 in humans.

64. In conclusion, the experimentally derived BCF values for carp above 5000 and estimated BAF values above 5000 indicate that UV-328 fulfills the criteria for bioaccumulation. This is supported by the suggestion that UV-328 enriches in top predators based on the field data presented for finless porpoises and their prey, as well as measured BSAF > 1 and estimated TMF > 1.

2.2.3 Potential for long-range environmental transport

65. UV-328 has the potential to undergo long-range atmospheric transport via aerosols because of its high log K_{OC}, log K_{OW} and log K_{OA}; see Bidleman et al. (1990), where extensive evidence for the long-range environmental transport of high-K_{OC} chemicals is provided. UV-328 has also been reported to undergo long-range marine transport via plastic debris (Andrade et al., 2021; Rani et al., 2017; Tanaka et al., 2020a; Yamashita et al., 2021). Additionally, UV-328 may undergo long-range transport mediated by migratory species e.g. seabirds (Yamashita et al., 2021).

66. UV-328 is not expected to undergo long-range transport in air in the gas phase, nor in water in the aqueous phase. This is according to its physico-chemical properties i.e. low vapour pressure, low air-water partition coefficient (K_{AW}), short estimated half-life in air in the gas phase, low water solubility and high affinity to sedimentation.

67. While UV-328 has not been regularly included in monitoring campaigns, recent studies have found UV-328 at high detection frequencies in the biota of remote regions such as the Arctic as well as remote islands (e.g. Gough Island and Marion Island) with no known sources or usage of UV-328 (Lu et al., 2019a; Schlabach et al., 2018; Yamashita et al., 2021). The findings indicate that UV-328 underwent long-range environmental transport from source to remote regions. Three modes of long-range environmental transport of UV-328, i.e. via air, water and migratory species, are discussed below.

Long-range environmental transport via air

68. UV-328 has a high log K_{OW}, log K_{OC} and log K_{OA}. Its high log K_{OA} (> 10) indicates that UV-328 partitions to aerosols in air and the fraction remaining in gas phase is likely to be small. Under the generic settings of the OECD P_{OV} and LRTP Screening Tool, which has been used for POP evaluations in the past, the fraction of UV-328 bound to particles is 62%. Environmental monitoring data (see section 2.3.1.2) confirm that UV-328 associates with particles in air (Wu et al., 2020; Maceira et al., 2019).

69. No second-order rate constants for degradation of UV-328 in the gas phase with OH radicals have been measured experimentally. The second-order rate constants for degradation of UV-328 in the gas phase reaction with OH radicals calculated by AOPWIN v.1.92 and COSMOtherm 2020 are $1.58 \cdot 10^{-11}$ and $2.3 \cdot 10^{-11}$ cm^3 $molecule^{-1}$ s^{-1}, respectively (US EPA, 2012; COSMOtherm, 2020). With a 24-hour average OH-radical concentration in air of 7.5 10^5 OH radicals/cm^3 (as implemented in AOPWIN), the half-lives for the atmospheric gas-phase reaction of UV-328 with photochemically produced OH radicals estimated by AOPWIN v.1.92 and COSMOtherm 2020 are 16.3 hours and 11.2 hours, respectively. However, according to the uncertainties in the second-order rate constant (see UNEP/POPS/POPRC.17/INF/17), the degradation half-lives of UV-328 in the gas phase reaction with OH radicals could also be as high as 22 hours to 112 hours (11.2 hours multiplied by a factor of 1.94 and 16.3 hours multiplied by 6.88, respectively). These estimated factors are based on two highly chlorinated substances, and the applicability to UV-328, which contains no chlorine atoms, is unknown.

70. The OECD P_{OV} and LRTP Screening Tool was used to estimate the long-range transport potential of UV-328 via air. The input parameters are given in UNEP/POPS/POPRC.17/INF/17. Using the degradation half-lives for the gas phase reaction with OH radicals from COSMOtherm, the overall persistence (P_{OV}), characteristic travel distance (CTD) and transfer efficiency (TE) of UV-328 are 196 days, 535 km and 0.32%, respectively.

71. In the OECD P_{OV} and LRTP Screening Tool, a 22-hour degradation half-life in the gas phase leads to a P_{OV} of 196 days, a CTD of 920 km and a TE of 0.95%, and places UV-328 in a very similar position as HBCDD or PCB-28. A 112-hour photodegradation half-life in the gas phase leads to a P_{OV} of 196 d, CTD of 2422 km and a TE of 6.6%, placing UV-328 in the range of acknowledged POPs.

72. It is noted that UV-328 has not been regularly monitored in air in remote regions. According to the only available study that measured UV-328 in Arctic air, UV-328 was not detected in aerosol particles sampled from Mount Zeppelin, Ny Ålesund, Svalbard (Schlabach et al., 2018).

73. Atmospheric transport has recently been described as an important pathway for road microplastics to travel to remote regions (Evangeliou et al., 2020). The travel efficiencies of microplastics via this route to the Arctic can range between 0.46% and 10%, depending on whether the microplastics are associated with $PM_{2.5}$ or PM_{10} (Evangeliou et al., 2020). UV-328 was detected in road dust samples from a road with significant traffic in Kumamoto Prefecture, Japan, with concentrations ranging between 2 and 40 ng/g dw, depending on traffic density (Nakata et al., 2013), which indicates a potential for UV-328 to be released to the environment via road dust particles. It is therefore plausible that when products containing UV-328 break down into microplastics, e.g. in the form of tire wear particles, UV-328 may undergo long-range atmospheric transport along with the microplastics to remote regions, provided that UV-328 does not degrade or dissociate from microplastic particles.

Long-range environmental transport via water

74. The long-range transport of plastic debris and microplastics (plastics <5 mm) in the marine environment has been extensively documented (Eriksen et al., 2014; Howell et al., 2012; Maximenko et al., 2012; Obbard, 2018; Van Sebille et al., 2020). It is estimated that 18.6 to 26.1 Mt of plastics enter the oceans every year (Borrelle et al., 2020) and that 330 to 485 Mt of plastics may have entered the oceans by now (Andrade et al., 2021). Plastic debris cannot feasibly be removed by human intervention. In the marine environment, plastics undergo weathering and break down into smaller fragments and microplastics, which are considered to be persistent due to their non-biodegradability (ECHA, 2020c). Plastic debris and microplastics are widely present in the oceans and floating plastic debris is capable of long-range transport via ocean currents (Lebreton et al., 2012; van Sebille et al., 2012). Different plastics lead to different transport, fractionation and leaching behavior under environmental conditions (Andrady & Rakapakse, 2016). For additives that do not leach out of plastic (debris) into water over a long period of time, plastic debris can act as an environmental medium or "vector" for the long-range marine transport of plastic additives to remote regions (Andrade et al., 2021). As UV-328 is a plastic additive with a typically recommended loading of 0.1–1% by weight but does not significantly leach out of plastics into water (Pouech et al., 2014), marine plastic debris that contains UV-328 can be a relevant source of UV-328 in remote regions. The fraction of UV-328 that is not degraded in plastic debris and does not leach out of the plastic matrix quickly is subject to long-range environmental transport. Importantly, this fraction is not static as leaching and transport in the marine environment can occur in parallel, i.e. there may be some continuous leaching of UV-328 during environmental transport via plastic debris because the concentration of UV-328 in plastic debris is not in equilibrium with the surrounding ocean water and conditions in the marine environment may enhance the leaching of UV-328 into water.

Leaching of UV-328 from plastics into water

75. Pouech et al. (2014) studied the leaching of UV-328 into water from three types of commercial polymers, i.e. polypropylene, polycycloolefin and copolyester. Leaching experiments were conducted at different temperatures and pH values. One type of leaching experiment was conducted in an autoclave in which 25 g of the test polymer granules containing UV-328 were immersed in 100 mL water, and the following temperature regime implemented in the autoclave: from 0 to 20 mins, linear gradient from 25 °C to 121 °C; 121 °C for 20 mins; decrease to 40 °C and maintain at 40 °C for a one month. Two pH conditions were tested: pH 2 and neutral. The other type of experiment was conducted at room temperature and in three pH conditions: pH 2, neutral and pH 9. In this type of experiment, 10 g of test polymer granules containing UV-328 were immersed in 40 mL water, and two extraction periods were studied: 16 hours and 7 days. In all experiments, UV-328 was not detected in water after the extraction periods, indicating that virtually no UV-328 leached out of the polymers.

76. It should be noted that no leaching experiments have been conducted for UV-328 under oceanic conditions (e.g. turbulent water). However, oceanic conditions may have influences on the leaching of UV-328 from plastic debris. For example, it has been reported that turbulence in water increases the leaching of additives (Suhrhoff & Scholz-Böttcher, 2016). The leaching of additives from plastics into water also depends on many other factors, such as the plastic's porosity, the additive's molecular size, concentration and physico-chemical properties, the extent of weathering, pH, temperature, surface-area-to-volume ratio of plastic particles (shape and size) and duration of exposure to water (Andrade et al., 2021; Luo et al., 2019; Teuten et al., 2009; Xu et al., 2020). In addition, the rate of diffusion of additives within and out of polymers differs based on the polymer's glass transition temperature (T_g), and is higher when the temperature is above the T_g of the specific polymer (Andrade et al., 2021). Ambient temperatures exceed the T_g of PE (150 K) and PP (260 K), indicating that the leaching of UV-328 into water would be faster from these polymers than from PET (345 K), PVC (360 K) and PS (373 K) (Andrade et al., 2021).

77. Leaching of UV-328 out of weathered plastic particles has also not been investigated experimentally. It has been stated that for semicrystalline polymers such as PE, an increase in crystallinity (and brittleness) occurs as a result of chain scissions in amorphous regions (Arp et al., 2021). However, it is not clear what this means for the leaching of UV-328. It is, however, expected that weathering increases fragmentation, which leads to an increase in leaching due to the higher surface-area-to-volume ratio of smaller fragments.

78. Taking all these factors into account, leaching of UV-328 in ocean water is expected to be fastest from very small PE fragments in highly turbulent water. To simulate these conditions, the model of Endo et al. (2013) can be

used (information on the applicability of the model to UV-328 is described in UNEP/POPS/POPRC.17/INF/17). Endo et al. (2013) investigated the long-term desorption behavior of PCBs from marine PE pellets (unspecified if low- or high-density PE). The results indicated that for PCBs with a logarithm of PE-water partition coefficient (log $K_{PE/w}$) > 6, diffusion from the PE pellets was dominated by aqueous boundary layer diffusion (diffusion between particle and water) and not by internal diffusion within the plastic matrix (Endo et al., 2013). These results are in line with findings by Lee et al. (2018). However, as the content of the substance inside the matrix is not known, no definitive conclusion on the rate limiting process can be drawn from the model of Endo et al. (2013). Endo et al. (2013) showed furthermore that the desorption kinetics from PE are highly dependent on the $K_{PE/w}$. The $K_{PE/w}$ values in Endo et al. (2013) were calculated with an empirical correlation between log $K_{PE/w}$ and log K_{OW} derived by Lohmann (2012):

$$\log K_{\mathrm{PE/w}} = 1.14 \cdot \log K_{\mathrm{OW}} - 1.14$$

79. Applying the same empirical correlation from Lohmann (2012) to the log K_{OW} of UV-328 (8.5) results in a $K_{PE/w}$ of 8.55. For a PE pellet of 1 mm radius, assuming an aqueous boundary layer of 10 µm (which corresponds to high turbulences), UV-328 has a leaching half-life of 70 years from weathered PE (unspecified if low- or high-density PE) in water. Taking into consideration the information given here and in paragraphs 76 and 77, it can be stated that there remain uncertainties with these estimates concerning environmentally relevant conditions. Nevertheless, the estimate presented here reflects a conservative estimate.

Detection of UV-328 in marine plastic debris

80. The presence of UV-328 in marine plastic debris has been demonstrated in various studies (Rani et al., 2015, 2017; Tanaka et al., 2020a). Rani et al. (2017) sampled plastic debris along the coast of Geoje, South Korea, and found UV-328 in 97% of the samples (n = 29). The concentrations of UV-328 found in these samples ranged from not detected to 1.6 µg/g, with a median concentration of 0.01 µg/g.

81. Tanaka et al. (2020a) sampled marine plastic debris (n = 141) from a beach on the island of Kauai, Hawaii, USA. UV-filters were detected in 13% of small plastic fragments (4–7 mm length) and 33% of the larger plastic fragments (1.5–8 cm). The detection frequency of UV-328 in larger fragments was 1% with a concentration of 0.2 µg/g. Upon further examination of the sample containing UV-328, it was observed that the concentration of UV-328 was lowest in the outer layers of the plastic fragment, which indicates that the UV-328 found in the plastic fragment originated from its use as an additive as opposed to adsorption of UV-328 in surrounding waters to the plastic fragment.

82. UV-328 was detected in 101 of 110 samples of weathered industrial plastic pellets collected along beaches of 22 countries around the world, although it cannot be distinguished whether it is adsorbed or in the matrix. The concentrations ranged from 2 to 800 ng/g (Karlsson et al., 2021; 2022).

Transfer of UV-328 from plastics to seabirds

83. Ingestion of marine plastic debris is widespread in seabirds, especially those of the order Procellariiformes (i.e. albatrosses, petrels, shearwaters, storm petrels and diving petrels) as they typically feed in the open ocean and can mistake floating plastic debris for food items (Nishizawa et al., 2021; Roman et al., 2019; Ryan, 1987; van Franeker & Law, 2015). Some seabird species in this order have a high prevalence of plastic ingestion (i.e. percentage of individuals within a species that have been found to have ingested plastic debris), which can vary between species, maturity of individuals within the species, geographical distribution etc. The prevalence of plastic ingestion in seabirds is following an increasing trend, and it is estimated that by 2050, 99% of all seabird species will have ingested marine plastic debris (Wilcox et al., 2015). It is important to note that seabirds ingest multiple pieces of plastic. For example, an investigation of regurgitated boluses of albatrosses on Mukojima Island showed that black-footed albatrosses ingested 4 pieces/individual, Laysan albatrosses ingested 15 pieces/individual (Tanaka et al., 2019a), and northern fulmars ingested approx. 30 to 50 pieces/individual (van Franeker et al., 2011). In the case of great shearwaters from Inaccessible Island (near Gough Island), up to 194 pieces of plastic fragments and pellets per individual were reported to have been ingested (Yamashita et al., 2021). Flesh-footed shearwaters in Australia have been reported to have ingested up to 276 plastic items per individual (Lavers et al., 2014). The ingestion of multiple (up to 276) pieces of plastics would lead to a high probability of exposure to UV-328 in individual seabirds, even if the detection frequency of UV-328 in plastic debris is ~1%. Based on the number of plastics ingested by individual seabirds across several species (ranging from 4 to >100 items per bird), probability of exposure to UV-328 via plastic ingestion, based on a UV-328 detection frequency in plastic debris of 1%, is estimated to be 86% in great shearwaters (1 − (1 − 0.01)^194) and 94% in flesh-footed shearwaters.

84. When seabirds ingest plastics containing UV-328, the hydrophobic biological fluids (e.g. stomach oil) in their bodies can substantially enhance the leaching of UV-328 out of the plastics and lead to accumulation of UV-328 in their organs' tissues (Takada et al., 2019; Tanaka et al., 2015; Tanaka et al., 2019b). The higher body temperature inside the birds' stomachs compared to ocean temperatures may also contribute to leaching of UV-328 out of ingested plastics (Nakashima et al., 2016; Sun et al., 2019).

85. To demonstrate the transfer of UV-328 from ingested plastics into seabirds' tissues, a study by Tanaka et al. (2020b) conducted an *in vivo* plastic feeding experiment, in which polyethylene pellets (LDPE) industrially

compounded with UV-328 were fed to streaked shearwater (*Calonectris leucomelas*) chicks under field conditions for 32 days. PE pellets were prepared by mixing and molding UV-328 and PE powders in a co-rotating twin-screw kneading extruder, after which pellets were melted and re-extruded twice to obtain a uniform distribution of UV-328 in the pellets. The concentration of UV-328 in the pellets was 0.4% by weight. 5 PE pellets (total weight ~ 0.4 g) were administered in the exposed group (n = 11) in addition to a natural diet (fed by parent birds), while the control group (n = 10) was only fed a natural diet. Examinations revealed that UV-328 had accumulated in the liver, abdominal adipose tissue and preen gland oil of the streaked shearwater chicks in the exposed group. Analysis of the ingested plastic pellets showed that 42% of UV-328 had leached out of the plastic after 15–16 days and 60% after 32 days, compared to UV-328 concentrations in the originally administered plastic pellets. Moreover, the exposure to UV-328 from ingested plastics was as much as 1900 times higher than from environmental sources. This indicates that ingestion of plastics containing UV-328 may lead to leaching of UV-328 out of plastics and subsequent accumulation of UV-328 in seabirds. Note: The plastic debris ingested by seabirds under environmental conditions would be expected to have undergone weathering in the environment.

Detection of UV-328 in seabirds in remote regions

86. UV-328 was detected in an ingested polypropylene plastic fragment from the stomach of a northern fulmar sampled (n = 100) from the Faroe Islands, Denmark at a concentration of 1.1 µg/g-plastic (Tanaka et al., 2019a). It has been reported that northern fulmars feed only at sea and never on land (van Franeker et al., 2011); therefore, the detection of UV-328 is likely to be as a result of ingestion of marine plastic debris containing UV-328.

87. Black-footed albatross sampled (n = 5) from the remote, uninhabited island of Mukojima, Japan, contained ingested polypropylene plastic fragments, with UV-328 detected at a single concentration of 1.4 µg/g-plastic (Tanaka et al., 2019a). Black-footed albatrosses in this region (western North Pacific) have been reported to change their trajectory of flight towards floating plastic debris and interact with plastic debris, based on GPS- and video-logging data (Nishizawa et al., 2021). Moreover, the species has a high prevalence of plastic ingestion, reported at 96.4% in chicks and 58.8% in adults (Rapp et al., 2017). Therefore, the detection of UV-328 in this species is also likely a result of ingestion of marine plastic debris containing UV-328.

88. In black-footed albatross sampled opportunistically from Tern Island, Hawaii, USA, UV-328 was detected in the preen gland oil of the birds at concentrations ranging from 2.8 to 4.8 ng/g lw (n = 3, DF = 100%) (Tanaka et al., 2020b). Sampling of preen gland oil is a non-invasive approach for monitoring hydrophobic contaminants in seabirds as it involves live birds and has been used previously to detect PCB contamination in seabirds (Yamashita et al., 2007).

89. In a global monitoring study of UV-328 in the preen gland oil of seabirds (details in paragraph 124) the highest concentrations of UV-328 were in the range of 1–7 µg/g lw, measured in great shearwaters (n = 3, DF = 100%) and blue petrels (n = 3, DF = 100%) sampled on two remote islands, Gough Island and Marion Island, respectively (Yamashita et al., 2021). These seabird species have some of the highest prevalence of plastic ingestion in the African sector of the Southern Ocean (> 90%) (Ryan, 1987). Great shearwaters are trans-equatorial migrants that move from their breeding grounds in the South Atlantic to feed in the North Atlantic during the boreal summer (Marchant & Higgins, 1990), and thus could have ingested plastic e.g. in the North Atlantic Ocean, where a plastic ingestion prevalence of 71% in great shearwaters has been reported (Provencher et al., 2014). Blue petrels, on the other hand, typically remain in the Southern Oceans, south of the Antarctic Polar Front (Quillfeldt et al., 2020). Based on the geographical distribution of blue petrels (Quillfeldt et al., 2020), it is unlikely that they travel to regions that may be considered sources of UV-328. It is therefore likely that the frequent detection of UV-328 in blue petrels was a result of ingestion of marine plastic debris containing UV-328 that had undergone long-range transport to the Antarctic Polar Front, which is a very remote region.

Long-range transport via migratory species

90. UV-328 has been detected in the preen gland oil of several migratory seabird species (see section 2.3.1.8), including those sampled on remote islands (Yamashita et al., 2021). The highest concentrations of UV-328 were found in the preen gland oil of great shearwaters from Gough Island (4–7 µg/g lw) (Yamashita et al., 2021). Great shearwaters are migratory seabirds that breed mainly in the Tristan da Cuhna Archipelago and Gough Island (Brooke, 2004). Gough Island supports a population of approximately 1 million breeding pairs of great shearwater (Schoombie et al., 2018). During the breeding period (September to May), great shearwaters remain within the South Atlantic Ocean, and can be distributed between the South American coast and South African coast (3500 west and 2800 km east of Gough Island, respectively), as well as frontal zones in the ocean (Marchant & Higgins, 1990). During the boreal summer (June to September), great shearwaters perform a trans-equatorial migration to the North Atlantic, reaching Nova Scotia, Newfoundland and Greenland (Marchant & Higgins, 1990). During the incubation period and chick-rearing period, great shearwaters on Gough Island travel upwards of 6000 km on average, with longer-trips during the chick-rearing period being >9000 km on average (Schoombie et al., 2018). The detection of UV-328 in great shearwaters on Gough Island indicates that UV-328 may have undergone long-range transport via these migratory birds from source regions (e.g. in the North Atlantic) to remote regions during migration. The other

explanation is that when the birds were foraging in the open ocean, they ingested fragments of plastic debris containing UV-328 that had undergone long-range marine transport. There are currently insufficient data to conclude which of these two pathways dominates.

91. No quantitative data are available that demonstrate the extent of UV-328 occurrence in remote environments that can confidently be attributed to the long-range transport of UV-328 by migratory birds.

Conclusion on potential for long-range environmental transport

92. UV-328 has the potential to undergo long-range environmental transport (1) in the atmosphere via aerosols and microplastics, (2) in the marine environment via plastic debris and (3) via migratory birds. Consequently, UV-328 has been detected in remote regions, including in Arctic biota and in seabirds on remote islands with no known sources of UV-328. Therefore, UV-328 fulfills the criteria for the potential for long-range environmental transport.

2.3 Exposure levels

93. While UV-328 has not been regularly included in monitoring campaigns, recent monitoring campaigns that did seek to measure UV-328 have found it in various environmental matrices and biota in source regions and in biota in remote regions, as well as in humans in many parts of the world.

2.3.1 Environmental monitoring data

2.3.1.1. Remote regions

94. UV-328 has been detected in the biota of regions far from known point sources of UV-328, such as the Arctic (Provencher et al. submitted for publication, 2022; Annex E, 2021; Lu et al., 2019a; Schlabach et al., 2018) and remote islands such as Gough Island and Marion Island (Yamashita et al., 2021).

95. UV-328 was frequently detected in Artic biota on the island of Svalbard, Norway (Schlabach et al., 2018). The detection frequency (DF) of UV-328 in biota depended on the species, and concentrations were in the low ng/g range. UV-328 was detected in all the eggs of common eider and kittiwake and in the livers of mink that were sampled in the monitoring campaign. UV-328 had a DF of 60% in the eggs of European shag and glaucous gull. UV-328 was not detected in the blood plasma of polar bears nor in air. The limit of detection in the plasma samples was, however, high compared to other matrices, and adipose tissue or liver samples might have been more appropriate matrices for monitoring UV-328 to overcome this methodological issue, as UV-328 is a highly hydrophobic chemical. On Prince Leopold Island in the Canadian Arctic, UV-328 was detected in one out of nine liver samples of northern fulmars at a concentration of 3.8 ng/g ww (Lu et al., 2019a). A recent monitoring study investigated the occurrence and temporal variations of UV-328 in the eggs of black-legged kittiwakes, northern fulmars and thick-billed murres from the Prince Leopold Island, Nunavut, Canada, between 1975 and 2019 (Provencher et al. submitted for publication, 2022). UV-328 levels were comparable in black-legged kittiwake (mean 0.29 ± 0.07 ng/g) and northern fulmar (0.22 ± 0.04 ng/g) eggs, with the same median concentration of 0.11 ng/g ww. The detection frequency of UV-328 was 35%, 30%, and 2% across all the examined eggs of the black-legged kittiwakes (n = 43), northern fulmars (n = 44) and thick-billed murres (n = 52), respectively. Black-legged kittiwakes and northern fulmars are surface feeders that were found to ingest plastics, whereas thick-billed murres are divers and are known to have very low or negligible levels of ingested plastics. The concentrations and detection frequencies of UV-328 found in Arctic biota are summarized in Table 7.

Table 7. Concentrations and detection frequencies of UV-328 in Arctic biota.

Species (common name)	Matrix	Sampling location	Mean concentration (ng/g ww)	Detection frequency
Common eider	Eggs	Svalbard, Norway	0.16	10/10 (100%)
European shag	Eggs	Røst, Norway	0.17	3/5 (60%)
Kittiwake	Eggs	Svalbard, Norway	0.19	5/5 (100%)
Glaucous gull	Eggs	Svalbard, Norway	0.12	3/5 (60%)
Mink	Livers	Sommarøy, Norway	0.18	10/10 (100%)
Polar bear	Blood plasma	Svalbard, Norway	<0.3	0/10 (0%)
Common gull	Eggs	Tromsø, Norway	0.17	3/5 (60%)
Northern fulmar	Livers	Prince Leopold Island, Canada	3.8	1/9 (11%)
Black-legged kittiwake	Eggs	Prince Leopold Island, Canada	0.29	15/43 (35%)
Northern fulmar	Eggs	Prince Leopold Island, Canada	0.22	13/44 (30%)

Thick-billed murre	Eggs	Prince Leopold Island, Canada	n/a	1/52 (2%)

96. UV-328 was frequently detected in the preen gland oil of great shearwaters and blue petrels sampled on two remote islands, Gough Island and Marion Island, respectively (Yamashita et al., 2021). Concentrations of UV-328 in the preen gland oil of these birds were in the range of 1 to 7 µg/g lw, which are the highest concentrations of UV-328 reported in biota so far (further discussion presented in paragraphs 153 and 154).

97. The highest concentration of UV-328 found in biota in remote regions, i.e. (7055 ng/g lw), is higher than the maximum concentrations of acknowledged POPs as reported in their respective risk profiles, with the exception of HBCD. Every other POP had lower maximum concentrations in biota in remote regions compared to UV-328, i.e. SCCPs (5200 ng/g lw), PeCB (1510 ng/g lw), β-HCH (810 ng/g lw), α-HCH (593 ng/g lw), pentaBDE (366 ng/g lw), decaBDE (250 ng/g lw), PCNs (162 ng/g lw), endosulfan (130 ng/g lw), HBB (44 ng/g lw) and HCBD (9 ng/g lw). As laid out in "POPRC-9/7: Approach to the evaluation of chemicals in accordance with Annex E to the Stockholm Convention", comparison of concentrations of a candidate chemical in biota from remote areas to those in acknowledged POPs may be made. Note that the concentrations selected for this comparison are those that were reported on a lipid basis for comparability.

2.3.1.2 Ambient air

98. In Chicago, USA, UV-328 was detected in aerosol particles in urban air (n = 20) at a median concentration of 1.60 pg/m^3, with a detection frequency of 95% (Wu et al., 2020). In Spain, UV-328 was detected in particulate matter (PM_{10}) in ambient air near two industrial parks that include plastic manufacturers, Constantí (n = 10, DF = 70%) and Tarragona harbour (n = 10, DF = 100%), at mean concentrations of 20 and 14 pg/m^3, respectively (Maceira et al., 2019).

2.3.1.3 Water

99. In a monitoring campaign conducted in Sweden, UV-328 was detected in surface waters (n = 6, DF = 100%) in both urban and background locations at concentrations of 0.001–0.01 µg/L (Brorström-Lundén et al., 2011). Up to 0.001 µg/L of UV-328 was also found in stormwater (n = 4, DF= 75%) in this study.

100. In Okinawa, Japan, UV-328 was detected in seawater and freshwater from beaches, reefs and a river (Tashiro & Kameda, 2013). UV-328 was the predominant UV absorber in seawater, in which the concentrations of UV-328 detected were in the range of 0.003 to 0.29 µg/L. In Saitama Prefecture, Japan, UV-328 was detected in surface waters of rivers and a stream (Kameda et al., 2011). In rivers (n = 18, DF = 67%), the concentration range was 0.03–4.8 µg/L. In one of two streams that were analysed, the concentration of UV-328 was 0.07 µg/L.

101. In Toronto, Canada, UV-328 was detected in two urban streams, Mimico Creek and Little Rouge Creek, at mean concentrations of 0.02 and 0.24 µg/g (suspended sediment), respectively (Parajulee et al., 2018). The study suggested that the relatively high and consistent emissions that led to homogenous UV absorber profiles in urban and rural sites were likely a result of plastic litter/debris or industrial releases. In surface water collected near the city of Montreal, Canada, UV-328 was measured at a maximum concentration of 0.003 µg/L (Giraudo et al., 2020).

102. In the past, UV-328 was found in a concentration range of 7–85 µg/L in river water collected near Narragansett Bay, USA, where UV-328 was produced in a nearby facility between 1970 and 1985 (Jungclaus et al., 1978).

103. It is noted that the maximum concentrations of UV-328 detected in water by Jungclaus et al. (1978) (i.e. 85 µg/L) and Kameda et al. (2011) (i.e. 4.8 µg/L) were above the water solubility limit of UV-328. Jungclaus et al. (1978) did not filter the water samples using a mesh, and therefore, suspended particulate matter to which UV-328 was adsorbed may have been present in the analyte. Kameda et al. (2011) filtered the water samples using a mesh with pore size of 1 µm; however, it has been shown that even when using standard filters of pore size 0.45 µm, some particulate matter remains in the filtered water (Nebbioso & Piccolo, 2013).

2.3.1.4 Wastewater and landfill leachate

104. UV-328 has been found frequently in the influent, effluent and sludge from wastewater treatment plants (WWTPs) in many parts of the world. It has also been detected in landfill leachate.

105. In a study in Japan, UV-328 was found in all samples (n = 5) of WWTP influent, effluent and sludge at concentrations of 0.02–0.05 µg/L, 0.002–0.003 µg/L and 0.5 µg/g dw, respectively (Nakata & Shinohara, 2010). A 90% removal rate of UV-328 in WWTPs was reported. In a study in Saitama Prefecture, Japan, UV-328 was detected in WWTP effluents (n = 4, DF = 75%) at a mean concentration of 0.06 µg/L (Kameda et al., 2011).

106. A study that measured 60 sewage sludge samples collected from WWTPs in 33 cities across China reported a median concentration of 0.06 µg/g dw of UV-328 (DF = 97%) (Ruan et al., 2012). Sewage sludge collected from

Hubei Province had exceptionally high concentrations of UV-328, at 24.7 µg/g dw (Ruan et al., 2012). In another study that measured various UV filters in sediment from Songhua River (China), Saginaw and Detroit Rivers (Michigan, USA), and sewage sludge from five WWTPs in northeastern China, the concentration of UV-328 in sludge was found to be the highest among the target compounds, with a mean concentration of 1.3 µg/g dw (Zhang et al., 2011).

107. On the Gran Canaria Island in Spain, UV-328 was detected in the influent and effluent of WWTPs at concentrations of 0.02–0.24 µg/L and 0.03 µg/L, respectively (Montesdeoca-Esponda et al., 2019). In another study in the Northwest of Spain, UV-328 was detected in untreated wastewater of a WWTP at average concentrations of 0.053 and 0.065 µg/L (triplicate samples collected one month apart) (Carpinteiro et al., 2012). In the same study in Lisbon, Portugal, UV-328 was detected in untreated wastewater of a WWTP at an average concentration of 0.076 µg/L and in treated wastewater at 0.02 µg/L (Carpinteiro et al., 2012).

108. In a monitoring study conducted in Sweden, UV-328 was found in 100% of WWTP effluent samples at concentrations in the range of 0.007–0.015 µg/L and in 50% of WWTP sludge samples at concentrations up to 37 µg/g dw (Brorström-Lundén et al., 2011). In the same study, UV-328 was also detected in landfill leachate at concentrations in the range of 0.007–0.091 µg/L. In Norway, UV-328 was found at notable concentrations in sewage treatment plant samples, especially in sludge (Ruus et al., 2019, 2020). Also, in an earlier screening study in Norway, UV-328 was detected in sewage water in the concentration range of 0.02–0.07 µg/L (Schlabach et al., 2019).

109. In Canada, UV-328 was frequently detected in WWTP influent (n = 34, DF = 97%), effluent (n = 34, DF = 79%) and biosolids (n = 39, DF = 92%) at maximum concentrations of 0.13 µg/L, 0.06 µg/L and 0.82 µg/g dw, respectively (Lu et al., 2017a). In another study near and in Lake Ontario, Canada, UV-328 was detected in WWTP influents, effluents, biosolids, surface water and sediments at ng/L and ng/g levels (De Silva et al., 2014). Additionally, UV-328 was found in all layers of sediment cores collected from Lake Ontario for the time period 1975–2013.

110. Extensive monitoring campaigns conducted in Narragansett Bay, USA, in the past have revealed high levels of UV-328 in WWTP sludge and effluent near a chemical plant that produced UV-328 (Hites et al., 1979; Jungclaus et al., 1978; Oviatt et al., 1987). Concentrations of UV-328 in WWTP effluent were in the range of 550–4700 µg/L (Jungclaus et al., 1978).

2.3.1.5 Sediment

111. In a study in Japan, two marine sediment cores were collected representative for the period 1930–1999 based on core depths (Nakata, 2011). The data showed an increasing temporal trend of UV-328, with concentrations rising since 1970. Maximum concentrations of UV-328 were 0.004 and 0.01 µg/g dw for the two sediment cores. In another study in Saitama Prefecture, Japan, UV-328 was detected in freshwater sediments at a concentration range of 0.01–1.7 µg/g dw (DF = 20/24); in background sites the concentration range was 0.03–0.09 µg/g dw (DF = 3/5) (Kameda et al., 2011).

112. UV-328 was also found in sediment cores in Narragansett Bay, USA, nearby a facility that produced UV-328 between 1970 and 1985 (Cantwell et al., 2015; Hartmann et al., 2005; Jungclaus et al., 1978; Lopez-Avila & Hites, 1980). The concentration of UV-328 in sediment cores was highest for the year 1976 (at 74 µg/g dw), but was still high (3–6 µg/g dw) decades after the facility ceased production of UV-328. Moreover, a UV-328 concentration of 300 µg/g dw was found in river sediment near the facility (Lopez-Avila & Hites, 1980).

113. In a study in the Pearl River Delta in China, UV-328 was found at a concentration < LOQ to 0.02 µg/g dw in bed sediments (n = 27) downstream of a sewage treatment plant (Peng et al., 2017a). Another study in China measured UV-328 in surface sediments of Laizhou Bay, as well as in coastal and marine sediments from the Bohai Sea and Yellow Sea (Apel et al., 2018a). Average concentrations of UV-328 were $4 \cdot 10^{-5}$ µg/g dw (n = 12, DF = 58%) in Laizhou Bay, $4 \cdot 10^{-5}$ µg/g dw (n = 22, DF = 91%) in the Bohai Sea and $6 \cdot 10^{-5}$ µg/g dw (n = 40, DF = 50%) in the Yellow Sea.

114. UV-328 was also detected in sediments in urban and background sites in Sweden at a concentration range of 0.65–1.3 µg/g dw (n = 6, DF = 67%) (Brorström-Lundén et al., 2011). In a screening study conducted in Oslofjord, Norway, UV-328 was detected in sediments at a concentration range of 0.003–0.025 µg/g dw (n = 5, DF = 100%) (Langford et al., 2015; Thomas et al., 2014). Since then, UV-328 has been detected frequently in sediments in Norway (Ruus et al., 2020; Schlabach et al., 2019). UV-328 was also detected in sediments of the North and Baltic Seas, specifically in surface sediments of the German Bight (n = 13, DF = 31%), the Skagerrak and Kattegat areas (n =11, DF = 82%) and the German Baltic Sea (n = 24, DF = 50%) (Apel et al., 2018b). Concentrations ranged from not detected to $9 \cdot 10^{-5}$ µg/g dw. In another study, UV-328 was detected at a median concentration of 0.0046 µg/g dw in sediments from the rivers Rhine and Elbe, and at similar levels in suspended particulate matter (Wick et al., 2016).

2.3.1.6 Soil

115. UV-328 was detected in one of four soil samples taken from an urban site in Sweden at a concentration of 0.74 µg/g dw (Brorström-Lundén et al., 2011). In a recent monitoring study conducted in Oslo, Norway, UV-328 was detected in a pooled soil sample at a concentration of $9 \cdot 10^{-4}$ µg/g dw (Heimstad et al., 2020).

2.3.1.7 Indoor environments

116. In Oslo, Norway, UV-328 was detected in indoor air (*n* = 24, DF = 100%) and settled floor dust (*n* = 26, DF = 96%) at concentration ranges of 0.02–5.3 ng/m^3 and 1–18,000 ng/g, respectively (Schlabach et al., 2019). UV-328 was also detected frequently in indoor dust samples in Spain (*n* = 27, DF = 100%), at a mean concentration of 91 ng/g (Carpinteiro et al., 2010). Among these dust samples, three were collected from vehicle cabins, with UV-328 concentrations ranging from 52 to 124 ng/g. In the Philippines, UV-328 was detected in 30 out of 37 samples of house dust collected from residential as well as municipal dumping areas, with a median concentration of 27 ng/g and a maximum concentration of 304 ng/g (Kim et al., 2012a; Kim et al., 2012b). UV-328 was also detected frequently in residential dust samples (*n* = 32) in the USA and Canada, at concentrations of 10–208 ng/g (DF = 100%) and <LOD–90 ng/g (DF = 95%), respectively (Wu et al., 2020). Additionally, UV-328 was detected in e-waste dust in Canada (*n* = 21, DF = 100%), with concentrations ranging from 5.6–161,000 ng/g (Wu et al., 2020). The concentrations of UV-328 in dust in these examples, with the exception of the e-waste dust example, are similar to each other and are orders of magnitude below the guideline values established by the Philippines, as described in section 2.3.2.

2.3.1.8 Biota

117. UV-328 has been detected in the biota of many regions of the world. Recent monitoring studies in Norway that included UV-328 in their measurements have detected UV-328 in various organisms. In one study, UV-328 was frequently detected in polychaetes, plankton, mussels, cod liver and in the blood and eggs of herring gulls (Ruus et al., 2020). UV-328 was detected in all cod livers (*n* = 15), at concentrations ranging from 3.7 to 70 ng/g ww. UV-328 was also found in the blood and eggs of all herring gull samples (*n* = 15), at concentrations in the range of 0.35–1.2 ng/g ww in blood and 0.23–11 ng/g ww in eggs. In another study, UV-328 was found in sparrowhawk, tawny owl and brown rat at mean concentrations of 0.43, 0.18 and 0.28 ng/g ww, respectively (Heimstad et al., 2020). In a similar study, UV-328 was found in earthworm, sparrowhawk, red fox, badger at mean concentrations of 0.24, 0.7, 0.17 and 0.12 ng/g ww, respectively (Heimstad et al., 2018).

118. Monitoring data from Denmark, Finland and Sweden also demonstrate the widespread occurrence of UV-328 in biota (Annex E, 2021). In Denmark, UV-328 was found at concentrations of up to 0.19 ng/g in the eggs of herring gull (*n* = 8, DF = 50%), 0.36–0.41 ng/g in cod liver (*n* = 2, DF = 100%) and in seal blubber at a concentration of 0.8 ng/g (*n* = 2, DF = 50%). In the Faroe Islands, UV-328 was detected at a concentration of 0.05 ng/g in the eggs of fulmar (*n* = 2, DF = 50%) and at 0.12 ng/g in cod liver (*n* = 2, DF = 50%). In Sweden, UV-328 was detected in the blubber of grey seal at a concentration of 0.56 ng/g (*n* = 1).

119. In Spain, UV-328 has been detected in various aquatic organisms, including fish that are commonly consumed by humans. On the Gran Canaria Island, UV-328 was detected in three fish species (*Boops boops*, *Sphyraena viridensis* and *Sphoeroides marmoratus*) collected close to marine outfalls of treated wastewater (Montesdeoca-Esponda et al., 2020). The maximum concentrations of UV-328 in muscle and viscera samples were 29.8 ng/g and 45.6 ng/g, respectively. In the Canary Islands and Catalonia, UV-328 was detected in muscle samples of fish obtained from markets, at concentrations of 100 ng/g dw and 300 ng/g dw for the fish species *Gadus morhua* and *Solea solea*, respectively (Gimeno-Monforte et al., 2020).

120. In a study that measured various benzotriazole UV stabilizers in the German rivers of Rhine, Elbe, Saar, Saale and Moselle, UV-328 was detected in all liver samples of bream (*Abramis brama*). A minimum of 20 bream were sampled at each of the rivers and the livers were pooled for analysis. A maximum UV-328 concentration of around 30 ng/g dw was measured in the livers of bream samples from the Rhine river (Wick et al., 2016).

121. In marine fish samples (*n* = 58) of 20 species taken from Manila Bay, the Philippines, UV-328 had a DF of 88% (Kim et al., 2011). The mean concentration of UV-328 in this study was 34.2 ng/g lw. The maximum concentration of UV-328 was found in bumpnose trevally, at 563 ng/g lw. Other notable concentrations include those found in flathead grey mullet and common ponyfish, with maximum concentrations reaching 179 ng/g lw and 255 ng/g lw, respectively. In the Pearl River Estuary, China, UV-328 was detected in 18 out of 24 species of marine organisms sampled in a study (Peng et al., 2017b). The highest concentration of UV-328 was found in bluespot mullet at 259 ng/g lw.

122. In a study that measured UV-328 in mussels sampled across Asia-Pacific coastal waters, UV-328 was found in mussels sampled in Cambodia at a mean concentration of 120 ng/g lw (*n* = 2, DF = 100%), in China at 96 ng/g lw (*n* = 5, DF = 60%), in Hong Kong Special Administrative Region of the People's Republic of China at 200 ng/g lw (*n* = 8, DF = 75%), in Indonesia at 120 ng/g lw (*n* = 2, DF = 100%), in Japan at 120 ng/g lw (*n* = 7, DF = 100%), in

the Republic of Korea at 220 ng/g lw (*n* = 17, DF = 94%), in Malaysia at 24 ng/g lw (*n* = 4, DF = 25%), in the Philippines at 170 ng/g lw (*n* = 2, DF = 100%) and in the USA at 69 ng/g lw (*n* = 15, DF = 33%) (Nakata et al., 2012). UV-328 was not detected in mussels sampled from India (*n* = 2) and Vietnam (*n* = 3).

123. In the Ariake Sea, Japan, UV-328 was detected in all sampled marine organisms, including tidal flat organisms (lugworm, lamp shell, oyster, clam, gastropod), shallow water organisms (crab and shrimp), fish (mudskipper, flathead, solefish, right eye flounder, sandperch, sweetlips, mullet, sea bass, hairtail, eagle ray and hammerhead shark), coastal birds (spot-billed duck and mallard) and marine mammals (finless porpoises) (Nakata et al., 2009, 2010). UV-328 was found in the blubber of finless porpoises (*n* = 5; DF = 100%) at a mean concentration of 29 ng/g ww and in small fish at a mean concentration of 0.25 ng/g ww (Nakata et al., 2009, 2010).

124. In a study in an urban creek in Ontario, Canada, UV-328 was detected in 33–57% of the sampled biota, with concentrations in crayfish as high as 1300 ng/g lw (Lu et al., 2016a). Another study in the same region found accumulation of UV-328 in fish liver (compared to carcass homogenate, bile and plasma) in the concentration range of 0.6–21 ng/g ww in white sucker (*Catostomus commersonii*) (Lu et al., 2017b). In the livers of northern pike sampled near Montreal's WWTP, maximum concentrations of UV-328 were in same range (39.7–40 ng/g lw) both upstream and downstream of the WWTP, indicating that WWTP effluent may not be the primary source of UV-328 in the receiving water body (St. Lawrence River) (Giraudo et al., 2020). In samples from USA and Canada, UV-328 was detected in blood plasma from several organisms including fish, snapping turtles, double-crested cormorants and bottlenose dolphins in the order of several hundred pg/g ww (Lu et al., 2019b). The highest concentration of UV-328 in blood plasma was 3.8 ng/g ww in common carp. Similar concentrations of UV-328 were found in an earlier study of samples from USA and Canada, with concentrations of up to 3.9 ng/g ww in the blood plasma of white suckers (Lu et al., 2016b).

125. In a study from the Great Lakes, UV-328 was frequently detected in herring gull eggs (DF = 83–100% in different colonies) at a maximum concentration of 13 ng/g ww (Lu et al., 2018). UV-328 was also detected in lake trout at varying frequencies depending on location (DF = 20–100%), with a maximum concentration of 6.7 ng/g ww found in trout from Lake Ontario (Lu et al., 2018).

126. UV-328 was measured in the preen gland oil of seabirds sampled on islands around the world (*n* = 145, DF = 21%) (Yamashita et al., 2021). UV-328 was measured in the range of 2–54 ng/g lw in crested auklet sampled from St. Lawrence Island (DF = 3/3); 654 ng/g lw in thick-billed murre from Pribilof Island (DF = 1/3); 16 - 67 ng/g lw in Bulwer's petrel (DF = 3/7), 3–5 ng/g lw in black-footed albatross (DF = 3/3) and 31–2213 ng/g lw in Hawaiian petrel from Hawaii (DF = 3/7); 274 ng/g lw in red-footed booby (DF = 1/3) and 1302 ng/g lw in red-billed tropicbird from the Galapagos Islands (DF = 1/3); 5–24 ng/g lw in flesh-footed shearwater from Western Australia (DF = 3/6); 2–4 ng/g lw in short-tailed shearwater from Eastern Australia (DF = 3/5); 3–5 ng/g lw in fairy prion from New Zealand (DF = 4/5); 4430–7055 ng/g lw in great shearwater from Gough Island (DF = 3/3); and 1047–3003 ng/g lw in blue petrel from Marion Island (DF = 3/3).

2.3.2 Exposure in humans

127. UV-328 has been found in human breast milk and adipose tissue in different parts of the world (Kim et al., 2019; Lee et al., 2015; Yanagimoto & et al, 2011). Humans may be exposed to UV-328 through ingestion of contaminated dust as well as consumption of contaminated foodstuffs such as fish and other seafood. Guideline values of UV-328 exposure via dust have been calculated as 90,000 ng/day and 22,500 ng/day for adults and toddlers, respectively (Kim et al., 2012a).

128. In the Philippines, the estimated daily intake (EDI) of UV-328 from dust was 0.2–0.8 ng/day for adults and 0.5–4.6 ng/day for toddlers (Kim et al., 2012a). The EDI of UV-328 in toddlers was five times higher than in adults; however, the EDIs in both toddlers and adults were orders of magnitude lower than the guideline values for UV-328 exposure via dust ingestion.

129. In the Republic of Korea, UV-328 was detected in human breast milk (*n* = 208), with a DF of 98% and a maximum UV-328 concentration of 334 ng/g lw (Lee et al., 2015). The EDI via consumption of breast milk was estimated to be 0.36 µg/kg bw/day. In breast milk samples (*n* = 87) from Japan, the Philippines and Vietnam, UV-328 had a DF of 16% and an average concentration of 1.2 ng/g lw (Kim et al., 2019).

130. UV-328 has also been detected in human adipose tissues sampled in Japan (*n* = 22, DF = 81%), Republic of Korea (*n* = 18, DF = 88%), India (*n* = 5, DF = 60%), Spain (*n* = 12, DF = 16%) and USA (*n* = 24, DF = 13%) (Yanagimoto et al., 2011 as cited in Germany, 2014). The maximum reported concentrations of UV-328 in human adipose tissue were highest in Japan (35 ng/g lw), followed by the Republic of Korea (20 ng/g lw), India (6 ng/g lw), Spain (6 ng/g lw) and USA (2 ng/g lw).

2.4 Hazard assessment for endpoints of concern

131. UV-328 is toxic to mammals as it can cause adverse effects upon repeated exposure in specific target organs, primarily the liver and kidneys. Consequently, the Committee for Risk Assessment of the European Chemicals Agency concluded that UV-328 meets the criteria for specific target organ toxicity – repeated exposure in sub-category 2 (STOT RE 2) in accordance with the Classification, Labelling and Packaging (CLP) Regulation EC 1272/2008, based on repeated-dose toxicity studies conducted in rats (ECHA, 2013, 2014).

132. No evidence of carcinogenicity, genotoxicity, mutagenicity of UV-328 has been reported (ECCC and Health Canada, 2016; ECHA, 2020a).

133. In the EU registration dossier, the following hazard statements have been attributed to UV-328: H373 – specific target organ toxicity, repeated exposure in sub-category 2 (STOT RE 2) and H413 – may cause long-lasting harmful effects to aquatic life (Aquatic Chronic 4) (ECHA, 2020a). 93% and 88% of the notifications in ECHA's classification and labelling inventory contain H373 and H413, respectively. H411 (Aquatic Chronic 2) and H412 (Aquatic Chronic 3) have been reported in 4% and 2% of the notifications. Other hazard classifications with less than 2% of the notifications are H302 (Acute Tox. 4, Ingestion), H312 (Acute Tox. 4, Skin), H315 (Skin Irit. 2), H319 (Eye Irit. 2), H332 (Acute Tox. 4, Inhalation), H334 (Resp. Sens. 1), H335 (STOT SE 3) and H372 (STOT RE 1) (ECHA, 2021). A hazard classification with the following H phrases was submitted by a Party: H303 (Acute Tox. 5, Ingestion), H312, H330 (Acute Tox. 1, Inhalation), H372 and H412 (Annex E, 2021).

2.4.1 Mammalian toxicity

2.4.1.1 Repeated-dose toxicity

134. Repeated-dose toxicity studies conducted in rats and beagle dogs demonstrate mammalian toxicity of UV-328, with liver and kidneys being the primary target organs.

135. Male and female rats were fed a diet containing UV-328 for 90 days (sub-chronic) (Til et al., 1968). The test protocol was similar to OECD test guideline (TG) 408 (1968, non-GLP). The nominal test concentrations of UV-328 in the diet of the treatment groups were 100, 200, 400, 800 and 1600 ppm, which corresponded to actual UV-328 dose levels of approximately 10, 19, 40, 81 and 173 mg/kg bw/day, respectively, based on bodyweight and food consumption of the test subjects (ECHA, 2020a; Til et al., 1968). No UV-328 was added to the diet in the control groups. Hematological examinations at week 12 of the study showed a dose-dependent decrease in hemoglobin content in males from the dose level of 19 mg/kg bw/day and in females from the dose level of 81 mg/kg bw/day onward (ECHA, 2013). In males and females exposed to the highest dose level, a 12% and 6% reduction in hemoglobin content compared to controls was observed, respectively (ECHA, 2013). The extent of reduction in the percentage of packed cell volume was proportional to the reduction in hemoglobin content (ECHA, 2013). Glucose-phosphatase activity of pooled livers and kidneys in both males and females were increased at all dose levels compared to controls (ECHA, 2013). No other biochemical examinations were conducted. Average relative liver weights were distinctly increased at all feeding levels in both males and females (ECHA, 2013). Relative kidney weights increased at the three highest dose levels in both male and females (ECHA, 2013). Relative thyroid weights were higher than in the controls starting at the dose level of 19 mg/kg bw/day (ECHA, 2013). In male rats, relative spleen weights were increased at the two highest dose levels, and relative weights of testes were increased at the three highest dose levels (ECHA, 2013). The relative weights of all organs measured in the study are available in UNEP/POPS/POPRC.17/INF/17. Gross pathological examination of the liver after 13 weeks revealed distinct enlargement and greenish-drab discoloration of livers (ECHA, 2013). Microscopic examinations of livers revealed hepatic damage at all UV-328 dose levels in both male and female rats, and the severity decreased with decreasing dose levels (ECHA, 2013). At the two highest dose levels, focal necrosis was occasionally observed in males and to a lesser extent in females (ECHA, 2013). Greenish discoloration of kidneys was observed in both males and females exposed to the two highest dose levels (ECHA, 2013). Microscopic examinations of kidneys revealed tubular nephrosis at the two highest feeding levels in males (ECHA, 2013). Based on the histopathologic changes observed in the liver and kidneys of males exposed to the dose level of 81 mg/kg bw/day, the ECHA Committee for Risk Assessment noted that the criteria for severe, adverse health effects defined for classification as STOT RE were met (ECHA, 2013). Based on the changes in hematology, clinical biochemistry, organ weights and histopathology observed in this study, a lowest-observed-adverse-effect level (LOAEL) of 10 mg/kg bw/day has been reported in the REACH registration dossier (ECHA, 2020a).

136. In another study, male and female beagle dogs were fed a diet containing UV-328 for 90 days (sub-chronic) (Ciba-Geigy, 1970; ECHA, 2013). The test protocol was similar to OECD TG 409 (non-GLP), except 3 animals were tested per sex per treatment group instead of 5. Dose levels of UV-328 in the study were 0 (controls), 15, 30, 60, 120 and 240 mg/kg bw/day. One male dog in the treatment group of the highest dose level died during week 8 of the study, and animals exposed to the higher dose levels showed reductions in food consumption and body weight, as well as sleepy and weak behaviour (ECHA, 2013). Hematological examinations revealed a decrease in number of erythrocytes, diminution of packed cell volume, decreases in hemoglobin content of blood, increase of mean

corpuscular volume, and decrease of mean corpuscular hemoglobin concentration in dogs exposed to dose levels of 120 and 240 mg/kg bw/day (ECHA, 2013). The hemoglobin contents of male dogs exposed to 120 mg/kg bw/day and female dogs exposed to 240 mg/kg bw/day were more than 20% lower compared to those in controls (ECHA, 2013). Biochemical examinations revealed that the activity of several enzymes in serum were increased (ECHA, 2013). These included glutamate pyruvate transaminase (GPT) (or alanine transaminase (ALT)), glutamic-oxaloacetic transaminase (GOT) (or aspartate transaminase (AST)) and alkaline phosphatase (ALP) (ECHA, 2013). The increase in activity of the three enzymes was observed in males starting at the dose level of 15 mg/kg bw/day (ECHA, 2013). In females, high activities of serum ALP were observed at the 15 mg/kg bw/day dose level (ECHA, 2013). Total protein in serum was diminished in exposed male and female dogs; the values in male and female dogs exposed to the highest dose level were 86% and 81.5% of the control group values, respectively (ECHA, 2013). Changes in protein pattern in serum were observed starting from the 30 mg/kg bw/day dose level (ECHA, 2013). At necropsy, absolute liver weights of both males and females at all dose levels were increased significantly compared to controls (ECHA, 2013). Pathologic examinations of the liver revealed fatty changes in Kupffer cells, protein globules in cytoplasm, yellow pigmentation in Kupffer cells and Kupffer cell hyperplasia starting from the 15 mg/kg bw/day dose level (ECHA, 2013). Fatty degeneration of hepatocyptes was seen in dogs exposed to 60 mg/kg bw/day and higher dose levels (ECHA, 2013). Based on the histopathological effects observed in dogs exposed to dose levels of 60 mg/kg bw/day, changes in the activity of several enzymes in serum and changes observed in protein pattern in serum, the ECHA Committee for Risk Assessment stated that the criteria for classification of UV-328 in the STOT RE hazard class were met. Based on the findings from this study, a no-observed-adverse-effect level (NOAEL) of 30 mg/kg bw/day and a LOAEL of 60 mg/kg bw/day have been reported in the REACH registration dossier (ECHA, 2020a).

137. The Canadian assessment on UV-328 also considered the repeated-dose toxicity studies presented above and performed a read-across with two structurally-similar analogues, 2-(2*H*-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol (CAS No. 70321-86-7) and 2-(2*H*-benzotriazol-2-yl)-4-methylphenol (CAS No. 2440-22-4), to fill in data gaps on chronic toxicity (ECCC and Health Canada, 2016). In its conclusion, the Canadian assessment states that the low effect levels in the studies ranged upward from 5 mg/kg bw/day and determines the LOAEL to be 15 mg/kg bw/day (ECCC and Health Canada, 2016).

138. Based on the NOAEL from the repeated dose toxicity study conducted in dogs, derived no-effect levels (DNEL) were extrapolated for humans and reported in the REACH registration dossier by industry (ECHA, 2020a). The DNELs were not reviewed by an authority and are shown in Table 8. For more information on how these DNELs were calculated, see UNEP/POPS/POPRC.17/INF/17. However, if the DNELs were calculated based on the LOAEL from the repeated dose toxicity study conducted in rats, the values would be one-third of the values shown in Table 8. In addition, the DNEL represents an external reference value and is normally based on the lowest reliable NOAEL, not LOAEL. Therefore, the reported values in Table 8 have considerable uncertainties and should not be used for comparison with measured concentrations in human.

Table 8. DNELs for systemic effects due to long-term exposure to UV-328 in workers and the general population as reported in the REACH registration dossier (ECHA, 2020a).

Exposure route	DNEL workers	DNEL general population
Inhalation	0.7 mg/m^3	0.17 mg/m^3
Dermal	0.3 mg/kg bw/day	0.14 mg/kg bw/day
Oral		0.14 mg/kg bw/day

2.4.1.2 Acute toxicity

139. Several studies have tested the acute toxicity of UV-328 resulting from single-dose exposure (ECHA, 2020a). In an oral gavage study in rats and mice, no gross organ changes were reported after single-dose exposure to UV-328 (Ciba-Geigy, 1978). The oral LD_{50} (lethal dose) was approximately 2300 mg/kg bw. In another similar study in rats, the LD_{50} was higher than the maximum study dose of 7750 mg/kg bw (Ciba-Geigy, 1978). In albino rats (study similar to OECD TG 401, non-GLP, 1987), the LD_{50} was higher than the study dose of 2000 mg/kg bw (ECHA, 2020a).

140. In a study (1973) with test protocol similar to OECD TG 403 (non-GLP), rats were exposed through the nose to UV-328 for 4 hours in aerosol form using ethanol as the vehicle (ECHA, 2020a). The LC_{50} was higher than the study concentration of 0.4 mg/L air. Particle size distribution in the aerosol was approximately 7.5 % > 7 µm, 5 % 3–7 µm, 55 % 1–3 µm, 32.5 % < 1 µm. In another study (1977), rats were exposed to UV-328 for 1 hour through dust inhalation (whole body exposure) (ECHA, 2020a). The LC_{50} was higher than the test concentration of 0.13 mg/L air (ECHA, 2020a).

141. Measured dermal LD_{50} in rabbits was in the range of 1.1–3.0 g/kg bw after single exposure to UV-328 (ECHA, 2020a). No dermal irritation/sensitization or eye irritation was reported (ECHA, 2020a).

2.4.1.3 Toxicity to reproduction and development

142. No reproductive or developmental toxicity studies are available for UV-328. However, findings from the repeated-dose toxicity studies conducted in rats and dogs (described in 2.4.1.1) indicate a potential for adverse effects on reproduction/development in mammals. In male rats exposed to UV-328 dose levels of 40 mg/kg bw/day and higher, the relative weight of testis increased significantly (ECHA, 2013). No histopathological examinations of reproductive organs of rats were performed in the study. In male and female rats, relative thyroid weights were higher than in the controls starting from the dose level of 19 mg/kg bw/day. For data on the relative weights of testis and thyroid in the test subjects, see UNEP/POPS/POPRC.17/INF/17.

143. The study on dogs showed that some dogs exposed to dose levels of 60 mg/kg bw/day and higher had alterations in their reproductive organs that were attributable to the administration of UV-328 (ECHA, 2013, 2020a). In some male dogs, atrophy of tubules and presence of multi-nucleated giant cells in the testes as well as defects in spermiogenesis were reported (ECHA, 2013, 2020a). In the prostates of some male dogs exposed to dose levels of 120 mg/kg bw/day and 240 mg/kg bw/day, strong atrophy and sclerosis of the stroma were observed (ECHA, 2013, 2020a). In some female dogs exposed to dose levels of 60 mg/kg bw/day and higher, slight atrophy of all of layers of the uterus was reported (ECHA, 2013, 2020a). Based on these data, UV-328 may have the potential to adversely affect reproduction.

144. Zhuang et al. (2017) conducted *in vitro* experiments using a two-hybrid recombinant yeast bioassay to evaluate the disrupting activities of UV-328 towards the human androgen receptor (AR) before and after metabolic activation by human liver microsomes (HLM) and the CYP3A4 enzyme. Yeast cells were exposed to UV-328 in a concentration range of $5 \cdot 10^{-4}$ – 50 µM. No toxicity to the yeast cells was observed in this concentration range. Before metabolic activation by HLM and CYP3A4, no significant anti-androgenic activity was reported in the concentration range of $5 \cdot 10^{-4}$ – 5 µM. However, weak antagonistic toxicity was observed at a UV-328 concentration of 50 µM. Three concentrations, 0.0025, 0.025 and 0.25 µM, were further explored to compare the anti-androgenic effects before and after metabolism. After metabolic activation mediated by CYP3A4, exposure to UV-328 resulted in a significant increase in anti-androgenic activity compared to before metabolism at the test concentration of 0.25 µM; the inhibitory rate of UV-328 metabolites increased from 17.1 ± 3.0% to 40.7 ± 4.9%. After metabolic activation mediated by HLM, a marked increase in inhibitory rate (28.0 ± 6.3% to 43.3 ± 1.5%) was also observed. These data indicate that UV-328 may have anti-androgenic effects. In another *in vitro* study using a yeast two-hybrid assay, no relevant estrogenic activity of UV-328 was observed in the test range of 10^{-3} – 10^{-7} M (final concentration of UV-328 dissolved in DMSO) (Kawamura et al., 2003).

2.4.2 Ecotoxicity

145. Acute ecotoxicity of UV-328 has not been demonstrated conclusively in standard tests (details below). However, recent studies on long-term exposure of UV-328 in aquatic organisms indicate a potential for adverse effects based on findings in adult zebrafish (Hemalatha et al., 2020). Modelling data from ECOSAR also predict that UV-328 is ecotoxic (US EPA, 2012).

146. Given the low water solubility of UV-328, long-term ecotoxicity studies are more suitable for assessing the aquatic ecotoxicity of UV-328. Hemalatha et al. (2020) studied the effects of UV-328 exposure in adult zebrafish (*Danio rerio*). The test organisms (n = 750) were acclimatized to laboratory conditions according to OECD TG 305. After acclimatization, the fish were divided into five experimental groups – water control group, solvent control group and three treatment groups. Triplicates were maintained for each group, and each replicate contained 50 fish in 25 L test solution. The test species in the treatment groups were exposed to UV-328 at concentrations of 0.01, 0.1 and 1 mg/L prepared in dimethyl sulfoxide (DMSO) for 14, 28 and 42 days. The test solutions in the tanks were renewed every 24 h to maintain the appropriate test concentration, but the authors did not report whether the concentrations were verified by analytical measurements. Biochemical examinations of the liver tissues on days 14 and 28 indicated that superoxide dismutase (SOD), catalase (CAT) and glutathione peroxidase activities (GPx) were significantly increased at exposure levels of 0.1 and 1 mg/L. Histopathological examinations of liver samples were also conducted. In fish exposed to UV-328 at 0.01 and 0.1 mg/L for 14 days, few histological lesions such as liver sinusoids, with a low degree of hepatocyte vacuolation and nuclear enlargement, were observed throughout the liver tissue. In fish exposed to UV-328 at 1 mg/L, eosinophilic granules, pyknotic nuclei, cytoplasmic vacuolation and degeneration, dilated sinusoids, nuclear degeneration and hypertrophy were observed. On day 28, lesions became more prevalent and were accompanied by lipid vacuolization in all treatment groups. In addition, in fish exposed to 0.1 and 1 mg/L, cloudy swelling of hepatocytes and severe liver necrosis were observed in many places. On day 42, histological changes became more severe with increasing concentration, and the most severe of these included hemorrhage in the veins, pyknosis on the nuclei, necrosis with sinusoidal lesions and complete degeneration of hepatocytes. Additionally in the 1 mg/L exposure group, blood sinusoid and melanomacrophage aggregates were noticed in fish on the day 42. No mortality of fish occurred during the acclimatization or exposure periods. Effects on fish length or growth were not reported.

147. Giraudo et al. (2020) studied the effects of food-borne exposure to UV-328 in juvenile rainbow trout (*Oncorhynchus mykiss*) for 28 days according to OECD TG 305. Concentrated solutions of UV-328 were prepared in acetonitrile, which were then used to prepare working solutions in distilled water. Feed pellets for trout were prepared such that a nominal concentration of 50 ng/g of UV-328 in feed was obtained. Fish were placed in four 60-L assay tanks, with 13 fish per tank. Three of the tanks served as treatment tanks in which fish were fed a diet containing UV-328. The remaining tank served as a control (containing the same final concentration of acetonitrile as in the treatment tanks). Fish were fed daily with a fixed ration of diet that was 4% of mean fish body wet weight. The mean fish weight was 3.25 ± 0.14 g. After 28 days, fish were randomly sampled and euthanized for further analysis. Analyses showed that exposure to UV-328 at the feeding level did not result in any effects on fish length, weight and Fulton body condition. However, exposure to UV-328 resulted in transcriptional changes, inducing ribosomal proteins transcription, downregulating genes involved in immune responses and affecting genes involved in iron homeostasis (Giraudo et al., 2020). Fish in the treatment group that were not euthanized were fed a control diet for five days following the 28-day period to allow for depuration. During this depuration period, concentrations of UV-328 in fish liver decreased by 20.9% daily, and the estimated depuration half-life was reported to be 3 days.

148. Giraudo et al. (2017) studied the effects of UV-328 exposure in freshwater green algae *Chlamydomonas reinhardtii* and freshwater crustacean *Daphnia magna*. For experiments on algae, exponentially growing cells were diluted in fresh medium to achieve a cell density of $1 \cdot 10^6$ cell/mL. The algae were then exposed to UV-328 at concentrations of 0.01 and 10 µg/L (diluted in 0.05% DMSO) for 96 hours. Experiments were carried out in triplicates, and a control containing corresponding DMSO levels was maintained. Reactive oxygen species production was reported to increase following exposure to UV-328 (Giraudo et al., 2017). Viability of exposed cells was not significantly different from controls. For experiments on crustaceans (according to OECD TG 211), five replicate groups of 12 *Daphnia magna* neonates (< 24 h) were exposed to UV-328 at concentrations of 0.01 and 10 µg/L (diluted in 0.05% DMSO) for 21 days. No mortality occurred, and no effects on growth, reproduction and gene transcription were observed following the 21-day exposure period.

149. ECOSAR predicts a chronic value (ChV) and LC_{50}/EC_{50} < 0.1 mg/L for UV-328 in freshwater fish, daphnid and green algae (US EPA, 2012). The ChV is calculated as the geometric mean of NOEC and LOEC.

150. Available ecotoxicity data obtained from acute toxicity studies on freshwater organisms (fish, crustaceans and algae) according to OECD test guidelines report no adverse effect of UV-328 within the water solubility range. However, given the low solubility of UV-328 in water, it is expected that such a route of exposure (i.e., UV-328 freely dissolved in water, as opposed to in diet) within a short exposure period would not adequately lead to internal effect concentrations of UV-328 in the test organisms. Nonetheless, ecotoxicological values for UV-328 in fish, crustaceans and algae are reported here, as shown in Tables 9 to 11. Note: For ecotoxicological studies where the REACH registration dossier (ECHA, 2020a) is cited as a reference, only a summary is available.

Table 9. Ecotoxicological values for UV-328 in fish.

Fish species	Testing method	NOEC / LC_{50}	Reference(s)
Danio rerio	OECD TG 203, non-GLP, 1988	$NOEC/LC_{50} \geq 100$ mg/L after 96h	ECHA, 2020a
Oryzias latipes	OECD TG 203, GLP, 2007	$LC_{50} > 0.08$ mg/L after 96h	ECHA, 2020a

Table 10. Ecotoxicological values for UV-328 in crustaceans.

Crustacean species	Testing method	NOEC / EC_{50}	Reference(s)
Daphnia magna	OECD TG 202, GLP, 2007	$EC_{50} > 83$ µg/L after 48h	ECHA, 2020a
	OECD TG 202, non-GLP, 1988	$EC_{50} > 10$ mg/L after 48h	ECHA, 2020a
		$EC_{50} > 100$ mg/L and NOEC = 5.8 mg/L after 24h	ECHA, 2020a
Daphnia pulex	OECD TG 202	NOEC ≥ 10 mg/L after 24h and 48h	Kim et al., 2011

Table 11. Ecotoxicological values for UV-328 in algae.

Algae species	Testing method	NOEC / LC_{50}	Reference(s)
Pseudokirchneriella subcapitata	OECD TG 201, static, GLP, 2007	NOEC = 0.016 mg/L (test limit)	ECHA, 2020a
Scenedesmus subspicatus		NOEC < 0.1 mg/L for growth inhibition after 72h	Hicks and Geldhill, 1993

151. It should be noted that for the algae, *Scenedesmus subspicatus*, some growth inhibition effect was observed 72 hours after UV-328 exposure at all tested concentrations (including the lowest concentration of 0.1 mg/L)

(Hicks & Gledhill, 1993). However, no effects were observed in a modern, GLP algae study performed according to OECD TG 201.

152. In microorganisms from sewage sludge, the EC_{50} and IC_{50} after 3 hours were greater than the test concentration of 100 mg/L (OECD TG 209, static conditions, non-GLP, 1988) (ECHA, 2020a).

153. Based on the unbounded effect concentrations from acute ecotoxicological studies in freshwater organisms, predicted no-effect concentrations of UV-328 for aquatic organisms were reported by industry in the REACH registration dossier (ECHA 2020a). Information on how the PNECs were calculated are provided in UNEP/POPS/POPRC.17/INF/17. The PNECs for various environmental matrices and the PNEC for secondary poisoning that were not reviewed by an authority are shown in Table 12. Note: If the PNEC for secondary poisoning is calculated based on the LOAEL from the repeated-dose toxicity study conducted in rats, the PNEC for secondary poisoning would be a factor of 6 lower than the value shown in Table 12.

Table 12. PNECs of UV-328 for aquatic organisms in freshwater, marine water, sewage treatment plant, freshwater sediment and marine sediment, for terrestrial organisms in soil and secondary poisoning in predators as reported in the REACH registration dossier. Source: ECHA, 2020a; UNEP/POPS/POPRC.17/INF/17.

Matrix	PNEC value
Freshwater	10 µg/L
Freshwater (intermittent releases)	100 µg/L
Marine water	1 µg/L
Sewage treatment plant	1000 µg/L
Sediment (freshwater)	451 µg/g sediment dw
Sediment (marine)	45.1 µg/g sediment dw
Soil	90 µg/g dw
Secondary poisoning in predators (dog)	13.2 µg/g food
Secondary poisoning in predators (rat)	2.2 µg/g food

154. Comparing environmental monitoring data (section 2.3.1) to these PNECs indicates that in most cases environmental concentrations are lower than the respective PNECs. However, there are instances where the environmental concentrations come close to or have exceeded the PNECs. These include the detection of UV-328 at concentrations of up to 4.8 µg/L in polluted Japanese rivers, which is in the same order of magnitude as the PNEC of 10 µg/L for freshwater systems. Monitoring data from Narragansett Bay, USA, which represents a historical UV-328 contamination site, indicate that the PNEC values for freshwater (10 µg/L) and wastewater treatment plants (1000 µg/L) were exceeded in the past, as maximum concentrations of 85 µg/L and 4700 µg/L were reported in these matrices, respectively; the concentrations of UV-328 measured in sediment (300 µg/g dw) also came close to the PNEC value for freshwater sediments (451 µg/g dw).

155. In addition, the high concentrations of UV-328 detected in the preen gland oil of seabirds in remote regions (i.e. 1–7 µg/g lw in great shearwater from Gough Island and blue petrel from Marion Island) may be relevant for secondary poisoning in predators. Mammalian predators of seabirds on islands can include rats, feral cats, house mice, pigs, mongooses, foxes and musk shrew (Towns et al., 2011). While the concentrations in preen gland oil may not be directly comparable to the PNEC for secondary poisoning, the feeding study by Tanaka et al. (2020b) showed that concentrations of UV-328 in preen gland oil, 32 days after exposure, were very similar to the concentrations in the abdominal adipose. Therefore, assuming a fat content between 5% and 15% of the total bodyweight in seabirds (Spear & Ainley, 1998), whole-body concentrations of UV-328 in the seabirds (0.05 to 1.1 µg/g) would be one to two orders of magnitude lower than the PNEC for secondary poisoning in predators (13.2 µg/g food, as calculated based on the NOAEL in dogs).

156. The PNEC for secondary poisoning calculated based on the LOAEL in rats ($PNEC_{oral}$ = 2.2 µg/g food; see UNEP/POPS/POPRC.17/INF/17) and the whole-body concentration of UV-328 in seabirds are in the same order of magnitude. This indicates that there may be a potential for adverse effects in the mammalian predators of seabirds in remote regions. Note: As there are no avian toxicity studies available for UV-328, the effects of the elevated concentrations of UV-328 on the seabirds are unknown.

157. There are no data on the ecotoxicity of UV-328 in terrestrial wildlife other than the repeated dose toxicity studies discussed in section 2.4.1. Canada's screening assessment on UV-328 does, however, estimate chronic toxicity reference values (TRV) of 2.34 and 3.86 mg/kg bw/day for river otters and mink, respectively, based on findings from the repeated-dose toxicity study conducted in rats (ECCC and Health Canada, 2016; Til et al., 1968). The chronic TRVs were calculated for river otters and mink as they represent terrestrial mammals that consume fish in the Canadian environment. Based on the estimated concentrations of UV-328 in surface waters resulting from industrial releases from the plastics sector and paints and coatings sector (Table 4 and Table 5, respectively), as well as considerations of bioaccumulation of UV-328 in mid-trophic level fish, tissue residues concentrations of UV-328 in fish were estimated (ECCC and Health Canada, 2016). Applying a bio-energetic wildlife model, the total daily intake

(TDI) of UV-328 for river otters and mink were calculated as 1.58 mg/kg bw/day and 1.50 mg/kg bw/day (ECCC and Health Canada, 2016). Risk quotients (RQ) were calculated for different industrial release scenarios previously mentioned in section 2.1.3. RQs were calculated by dividing the TDI by the chronic TRV. In most scenarios, the RQ was found to be less than 1 (ECCC and Health Canada, 2016). However, an RQ of 1.68 for river otters was reported for the scenario in which UV-328 is released to a small river from an industrial site in the plastics sector when a use of 25 t of UV-328 per year at the site is assumed (ECCC and Health Canada, 2016). Additional information on the different industrial release scenarios is provided in UNEP/POPS/POPRC.17/INF/17.

2.4.3 Toxicological interactions involving multiple chemicals

158. There is a general lack of interaction studies with other substances of the phenolic benzotriazole class. However, two recent studies (described in section 2.4.2) measured the effects of simultaneous exposure to UV-328 and UV-234 in *Chlamydomonas reinhardtii*, *Daphnia magna* and *Oncorhynchus mykiss* (Giraudo et al., 2017, 2020). In *C. reinhardtii*, reactive oxygen species production increased following exposure to UV-328 and lipid peroxidation increased following exposure to UV-234. Synergistic effects at the transcriptional level were observed following exposure to a mixture of UV-328 and UV-234, with upregulation of glutathione peroxidase by factors of two to six, suggesting a potential impact on the antioxidant defense system of *C. reinhardtii* (Giraudo et al., 2017). However, no adverse effect was observed. In *D. magna*, no effects on growth, reproduction and gene transcription were observed following 21 days of exposure to 0.01 and 10 µg/L of UV-328, UV-234 and a mixture of the two substances (Giraudo et al., 2017). In *O. mykiss*, no clear evidence of significant synergistic effects upon exposure to a mixture of UV-328 and UV-234 was observed (Giraudo et al., 2020).

2.4.4 Conclusion on toxicity

159. UV-328 has been found to be associated with adverse health effects based on the findings of mammalian toxicity studies, and may have the potential to endanger human health and the environment, as it can cause damage to the liver and kidney through prolonged or repeated oral exposure (STOT RE 2). Limited evidence for adverse effects on male reproductive tract is available from two old non-standard studies, conducted in rats and dogs. There are no modern standard reproductive studies available, conducted with UV-328, to corroborate the findings from these non-standard studies. Acute ecotoxicity of UV-328 has not been shown in standard tests. No long-term effects were observed in available data for algae or Daphnia. However, long-term effects of UV-328 observed in adult zebrafish indicate a potential for adverse effects on liver in fish. The elevated levels of UV-328 found in migratory seabirds in remote regions are similar to the predicted effect levels for secondary poisoning in their mammalian predators, which indicates a potential for adverse effects for mammals in remote regions, with unknown consequences to the birds themselves.

3. Synthesis of information

160. UV-328 is a phenolic benzotriazole that is used as a UV absorber in a wide range of industrial applications and consumer products, which include paints, coatings, sealants, adhesives, printing inks, consumer fragrances, inert pesticides, textiles, rubber and plastics. The main uses of UV-328 are in automotive paints and coatings, and as an additive in plastics, including in polymers, printing inks and adhesives used in food packaging. In the automobile sector, UV-328 is used in paints, coatings and sealants, as well as in liquid crystal panels and meters mounted on vehicles, and resin for interior and exterior parts of vehicles.

161. UV-328 is produced in high volumes globally (> 1000 tonnes per annum), but there are no publicly available data as to how much has been produced and for which uses. In recent years, UV-328 has been identified as a substance of very high concern in the EU and has been included in the national list of priority substances in Norway. UV-328 is restricted in the legislation of the Kingdom of Bahrain.

162. UV-328 is released to the environment during industrial production and use of the substance during its use in products and as a result of the end-of-life management of products containing UV-328. Consequently, it has been detected in various environmental compartments, including in air, water, soil, sediment, biota and humans in different parts of the world.

163. UV-328 is not readily biodegradable, and experimental and monitoring data have demonstrated that UV-328 is persistent in soil and sediment. Field studies have shown that UV-328 is persistent in soil, with a disappearance half-life great than the Annex D threshold of six months. A read-across with a structurally similar compound of the phenolic benzotriazole class indicates that the degradation half-life of UV-328 in sediment exceeds the Annex D threshold of six months. This is confirmed by monitoring data from sediment cores collected near a facility that produced UV-328 in the past, where UV-328 has persisted in sediment cores even decades after the facility stopped producing the substance. Modelling results indicate that UV-328 is persistent in water, with a half-life greater than the Annex D threshold of two months.

164. UV-328 is also bioaccumulative, with a log K_{OW} > 5, and experimentally-measured bioconcentration factors and estimated bioaccumulation factors exceeding the Annex D threshold of 5000 L/kg ww. Measured BSAF and estimated TMF values > 1 have also been reported. Based on field data on UV-328 levels in finless porpoises and their prey, it has been reported that UV-328 enriches in top predators.

165. The accumulation of UV-328 in biota most likely occurs via trophic transfer, exposure to contaminated sediment or ingestion of plastics containing UV-328. Field experiments in seabirds have shown that ingestion of plastics containing UV-328 can lead to higher levels of UV-328 being detected in the abdominal adipose, liver and preen gland oil of seabirds compared to other sources of environmental exposure.

166. UV-328 has been detected frequently in the biota of remote regions, including Arctic biota and migratory seabirds on remote islands, which is a result of its long-range environmental transport potential. Among these seabirds are blue petrels on Marion Island, which typically remain in the Southern Ocean, south of the Antarctic Polar Front, but have some of the highest concentrations of UV-328 measured in biota so far. Blue petrels mainly feed in the open ocean and over 90% of individuals have been reported to have ingested marine plastic debris. The high concentrations of UV-328 measured in their preen gland oil are likely a result of the long-range environmental transport of UV-328 in the oceans via plastic debris. The highest concentrations of UV-328 measured in biota so far were in great shearwaters on Gough Island, which may also be a result of the long-range transport of UV-328 in the oceans via plastic debris. However, given that great shearwaters are trans-equatorial migrants, it is possible that the long-range transport of UV-328 from source regions to the remote island mainly occurred due to their migration.

167. Based on its physico-chemical properties, UV-328 is expected to undergo particle-bound long-range atmospheric transport. Modelling results estimate that the potential for UV-328 to undergo long-range transport via this pathway is in the same range as acknowledged POPs.

168. In humans, exposure to UV-328 can occur via ingestion/inhalation of contaminated dust as well as consumption of contaminated fish and other seafood. Based on the slow metabolism of UV-328 in the human body, low excretion via urine and UV-328's ability to bind to blood proteins, UV-328 has the potential to bioaccumulate in humans. UV-328 has been detected in human adipose tissue and breast milk in various parts of the world.

169. The mammalian toxicity of UV-328 has been demonstrated in repeated-dose toxicity studies conducted in rats and dogs. Based on the significant adverse effects found in the studies, UV-328 has been classified under the UN GHS criteria as STOT RE 2 (specific target organ toxicity, repeated exposure in sub-category 2) in the EU. The primary health effect of UV-328 is liver toxicity. UV-328 is also associated with adverse effects on the kidneys based on the repeated-dose toxicity observed in rats. In addition, there are indications of potential adverse effects of UV-328 on reproduction in mammals based on the significant changes in testicular weight observed in rats, as well as reduced spermiogenesis and reproductive organ weight changes observed in dogs. UV-328 may also lead to anti-androgenic activity, based on findings from an *in vitro* study.

170. UV-328 has been found to be associated with adverse effects in fish, based on histopathology of liver being observed in a long-term UV-328 exposure study conducted in adult zebrafish. Modelling predictions indicate that UV-328 is ecotoxic to aquatic organisms, but acute ecotoxicological studies in aquatic organisms conducted according to OECD test guidelines were not able to report any effect levels.

171. The levels of UV-328 found in the environment so far are generally below adverse effect levels, but there are instances where current levels may reach adverse effect levels. In source regions, under certain industrial release scenarios, a potential for risk to terrestrial mammals due to consumption of contaminated fish has been reported. In some polluted rivers in Japan, the levels of UV-328 are close to the PNEC for freshwater systems. In remote regions, the elevated levels of UV-328 found in great shearwaters on Gough Island and in blue petrels on Marion Island are close to PNECs relevant for secondary poisoning in their mammalian predators, with unknown consequences to the birds, as there are no avian toxicity studies available.

4. Concluding statement

172. UV-328 does not occur naturally in the environment. Yet, it has been found in various environmental matrices such as air, soil, sediment, water and biota as a result of anthropogenic activities. UV-328 has been found to be associated with adverse health effects based on findings from toxicity studies conducted in mammals and fish, and has been detected in humans in different regions of the world. It has been detected frequently in Arctic biota and in migratory seabirds on remote islands at levels that come close to adverse effect levels for their mammalian predators. Its frequent detection in remote regions is a result of its potential to undergo long-range environmental transport via air, water and migratory species.

173. Based on evidence of its persistence, bioaccumulation and toxicity in mammals, widespread occurrence in environmental compartments and frequent detection in biota in remote regions, it is concluded that UV-328 is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects, such that global action is warranted.

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