UV-328

Draft risk profile

Prepared by the intersessional working group of the
Persistent Organic Pollutants Review Committee

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Table of contents

Executive summary

[to be inserted]

1. Introduction

1. 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

2. 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)
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)

3. 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.

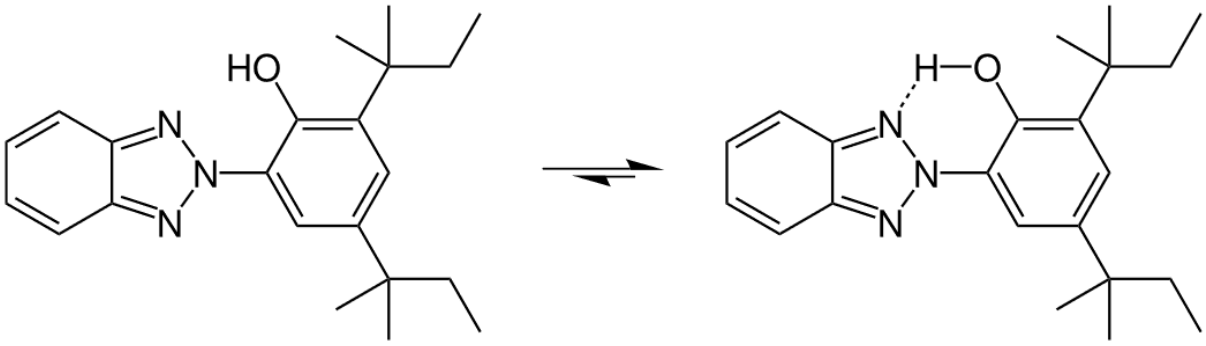

Figure 1. Chemical structure of UV-328 in its open form (left) and closed form (right). The open form of UV-328 does not contain an intramolecular hydrogen bond, whereas the closed form of UV-328 does.

4. COSMOtherm predicts that UV-328 exists only in the closed form, meaning it possesses an *intra*molecular hydrogen bond (COSMOtherm, 2020). Experiments conducted at the Swiss Federal Institute of Technology Zurich in 2021 confirm that UV-328 exists in its closed form in water and air, under environmentally relevant conditions (manuscript in preparation). However, EPI Suite predicts only the open form of UV-328 (using the SMILES code given in Table 2) and consequently calculates the physico-chemical properties only for the open form of UV-328. Therefore, the physico-chemical properties calculated by COSMOtherm will be used 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.

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)
	202 °C	EPI Suite, US EPA (2012)
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
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

5. 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

6. 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, as well as other national evaluations on UV-328;

(d) Peer-reviewed scientific literature;

(e) 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

7. 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).

8. In Norway, UV-328 was added to the national list of priority substances in 2017 (Annex E, 2021). 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, 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).

9. 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

10. According to the OECD Existing Chemicals Database, UV-328 is designated as a high production volume chemical (HPVC), with production > 1000 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 Denmark, Finland, Norway and Sweden, 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, there was a sharp increase to 244 t in the use of UV-328 in 2015, followed by a decline to 1 t in 2016 (SPIN, 2021). The import of UV-328 between 2016 and 2019 was 1.3 t/a (Annex E, 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).

11. 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).

12. 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).

13. 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).

14. 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

15. 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 (e.g. clear coat automotive finishes), as an additive in plastics (e.g. transparent plastics, food packaging) and in personal care products (e.g. sunscreen lotion). It is also used as a printing ink additive in food contact materials.

16. 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 resin, epoxy resin, fiber resin, polypropylene and polyvinyl chloride (PVC) (ECHA, 2020b). It is also effective in light stabilization of unsaturated polyesters, polyacrylate and polycarbonate (ECHA, 2020b). Additionally, it is used in construction materials, fillers, surface treatments, adhesives, paints/lacquers/varnishes, printing inks, consumer fragrances, fabric/textile/leather products and inert pesticides (ECHA, 2020b). Its recommended use as a UV absorber has been for polyolefins, polyurethanes, PVC, polyacrylate, epoxy and elastomers (ECHA, 2020b).

17. UV-328 can reach 3% of the total mass in coatings. In plastics, the loading of UV-328 as an additive during manufacturing is typically between 0.1–1% by mass (Hunan Chemical BV, 2016). However, recent studies have found lower concentrations of UV-328 in recently-produced plastics and packaging materials (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.

18. In Australia, UV-328 is used in industrial sealants in aftermarket automotive products. 50% of UV-328 is used for surface coatings, 40% as an additive in plastics and rubber, and 10% in personal care products (NICNAS, 2017). In Canada, 63% of UV-328 was used in the plastics sector and 37% in paints and coatings in 1986. UV-328 is used in automotive paints and coatings, 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 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).

2.1.3 Releases to the environment

19. No quantitative data on the releases of UV-328 to the environment are available. However, based on Annex E information submissions, various national assessments of UV-328 and findings from peer-reviewed scientific literature, UV-328 is expected to be released to the environment during industrial production and use of the substance, during its use in products (e.g. as sunscreen lotion at beaches) and when products containing UV-328 are disposed into waste streams and the environment (e.g. plastics and food packaging). This is because UV-328 is not chemically bonded to substrates, which implies that abrasion and volatilization facilitate its release into the environment.

20. According to Norway, emission of UV-328 to 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 and remote regions (Annex E, 2021). Due to its industrial uses, releases of UV-328 to surface waters are also expected, where UV-328 will likely partition to particles and organic matter, and end up in sediment (ECCC and Health Canada, 2016). The aquatic predicted environmental concentrations (PEC) resulting from releases to surface waters from plastics manufacturing (for a facility that uses 25 t of UV-328) are 2.52×10^{-4} mg/L (short-term concentration after release near the discharge point) and 6.90×10^{-6} mg/L (long-term exposure in the receiving water) (ECCC and Health Canada, 2016). From the paints and coatings sector (assuming a usage of 12 t of UV-328), the aquatic PECs are 4.92×10^{-5} mg/L (short-term concentration after release near the discharge point) and 1.35×10^{-6} mg/L (long-term exposure in the receiving water) (ECCC and Health Canada, 2016). UV-328 is expected to enter soil from wastewater biosolids and the degradation of disposed products that contain UV-328.

21. Some fraction of UV-328 is also released to the environment during the industrial production of UV-328. This aligns with findings from monitoring studies conducted in Narragansett Bay, Rhode Island, USA, where

sediment cores showed high levels of UV-328 corresponding to the years 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).

22. In some regions, UV-328 is used in sunscreen lotions. Thus, this use is a source of UV-328 in water bodies and beaches in areas with high tourism (Kameda et al., 2011; Montesdeoca-Esponda et al., 2021; Tashiro & Kameda, 2013).

23. A major use of UV-328 is as an additive in plastics. Plastics often end up in the oceans in significant amounts (4.8 to 12.7 Mt) every year in the form of plastic debris (Jambeck et al., 2015). Consequently, there are massive plastics gyres in the world's oceans (Eriksen et al., 2014) that may act as sources of UV-328. UV-328 has been detected in marine plastic debris at maximum concentrations of 0.2–1.6 µg/g (Rani et al., 2015, 2017; Tanaka et al., 2020a) and was found at high concentrations in seabirds that are known to frequently ingest fragments of marine plastic debris (Takada, 2020; Tanaka et al., 2019a). Plastic litter containing UV-328 is therefore likely to be a major source of UV-328 in the marine environment and for biota that ingest plastics.

24. Diffuse spreading through wastewater treatment plants (WWTPs), landfills and storm water may be important for the occurrence of UV-328 in the environment, indicating also that UV-328 is distributed to the environment via products containing UV-328 (Brorström-Lundén et al., 2011).

2.2 Environmental fate

2.2.1 Persistence

25. UV-328 has a very low degradation potential and long disappearance half-lives (DT_{50}) in soil and sediment, which have 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).

26. 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 photo-transformation (ECHA, 2014).

27. 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).

28. 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 etc.

29. 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 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 4th and 6th 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 lower 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.

30. 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). This demonstrates that UV-328 persists in (anaerobic) sediments even decades after its production and releases to the environment have ceased.

31. According to the 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). This translates to a half-life of 74 days for UV-328 in water and 136 days in soil, based on the following equations described by Strempel et al. (2012) and Rorije et al. (2011), respectively:

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

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

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

The 74-day half-life in water exceeds the trigger value of 60 days for persistence in water.

32. Under a weight-of-evidence approach, UV-328 fulfills the criteria for persistence.

2.2.2 Bioaccumulation

33. UV-328 has a log K_{OW} > 5, which indicates potential for bioaccumulation. Measured bioconcentration factors (BCFs) and modelled bioaccumulation factors (BAFs) were found to be above the bioaccumulation threshold, while metabolic transformation rates were low, thus confirming that UV-328 bioaccumulates.

34. 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 fish, crustaceans, marine mammals and algae. Under EU's REACH regulation, UV-328 has been classified as bioaccumulative as well as very bioaccumulative (ECHA, 2014).

35. 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, 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.

36. 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 < 1 µg/L (ECHA, 2020a). The higher exposure concentration, i.e. 0.78 µg/L, might therefore in fact be at or 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 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 BCF values between 5200 and 6600 L/kg ww. The average lipid normalized BCF was 5500 L/kg ww. 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.

37. 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 (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 4.

Table 4. 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

38. 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 bioaccumulate UV-328 in the Ariake Sea (Nakata et al., 2009).

39. Based on kinetic modelling, 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). This indicates that biomagnification is likely to occur when UV-328 undergoes trophic transfer (i.e. consumption of UV-328 by a higher trophic level organism through diet) due to low metabolism.

40. 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.

41. According to the AQUAWEB model, 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).

42. In conclusion, the BCF values for carp as well as the data presented for finless porpoises and their prey indicate that UV-328 fulfils the criteria for bioaccumulation.

2.2.3 Potential for long-range environmental transport

43. UV-328 has the potential to undergo long-range atmospheric transport via aerosols because of its high log K_{OC} and log K_{OW}, which imply that UV-328 strongly adsorbs to aerosol particles; see Bidleman et al. (1990), where extensive evidence for the long-range environmental transport of high-K_{OC} chemicals is provided. UV-328 also undergoes long-range marine transport via plastic debris (Rani et al., 2017; Takada, 2020; Tanaka et al., 2020a; Andrade et al., in review). Additionally, UV-328 may undergo long-range transport mediated by migratory species e.g. seabirds (Takada, 2020).

44. 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 Henry's law constant, short estimated half-life in air in the gas phase, low water solubility and high affinity to sedimentation.

45. While UV-328 has not been regularly included in monitoring campaigns, studies that did include UV-328 have found it in the environment and biota of remote regions such as the Arctic, the Pacific Ocean as well as remote islands (e.g. Gough Island and Marion Island) with no known sources or usage of UV-328. The findings indicate that UV-328 underwent long-range environmental transport from source to remote regions. The three modes of long-range environmental transport of UV-328, i.e. via aerosol, plastic debris and migratory species, are discussed below.

Long-range atmospheric transport via aerosols

46. UV-328 has a high log K_{OW} and log K_{OC}, implying that it strongly adsorbs to particles in air. Its high log K_{OA} (> 10) also indicates that UV-328 partitions to aerosols in air and the fraction remaining in gas phase is likely to be small.

47. 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 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). Using a 24-hour average OH-radical concentration in air of $7.5 \cdot 10^5$ OH radicals/cm^3 (as implemented in the OECD LRTP Tool), the half-lives for the atmospheric gas-phase reaction

of UV-328 with photochemically produced hydroxy (OH) radicals predicted by AOPWin v.1.92 and COSMOtherm 2020 are 16.3 hours and 11.2 hours, respectively.

48. The OECD P_{OV} (overall persistence) and LRTP Screening Tool was used to estimate the long-range transport potential of UV-328 via air. Using the photodegradation half-lives for the gas phase from COSMOtherm, P_{OV}, the characteristic travel distance (CTD) and transfer efficiency (TE) of UV-328 are 196 days, 535 km, and 0.32%, respectively. However, it has been shown that for large molecules, the estimated second-order rate constants for degradation in air from AOPWin are too high compared to the experimentally determined values (Anderson & Hites, 1996; Brubaker & Hites, 1998; Liu et al., 2005). Liu et al. (2005) report a factor of 6.88 between estimated and measured rate constants for DDT. COSMOtherm calculates lower values for large molecules; however, the second-order rate constants for DDT and γ-HCH are still higher than the experimentally determined values by factors of 1.74 and 1.94, respectively (Table 5: Available experimental and calculated second-order rate constants (kOH) for larger molecules. The SMILES codes used to perform the modelling are shown as table footnotes.

Compound	**Experimental** *kOH* [cm3/s]	**COSMOtherm** *kOH* [cm3/s]	**EPI Suite** *kOH* [cm3/s]	**Reference**
DDT1	5 10^{-13}	8.72 10^{-13}	3.44 10^{-12}	Liu et al. 2005
γ-HCH2	1.9 10^{-13}	3.69 10^{-13}	5.73 10^{-13}	Brubaker & Hites 1998
UV-3283		2.30 10^{-11}	1.58 10^{-11}	

1 C1=CC(=CC=C1C(C2=CC=C(C=C2)Cl)C(Cl)(Cl)Cl)Cl 2 Cl[C@H]1[C@@H](Cl)[C@H](Cl)[C@@H](Cl)[C@@H](Cl)[C@@H]1Cl

3 CCC(C)(C)c1cc(c(c(c1)n2nc3ccccc3n2)O)C(C)(C)CC (as stated in Table 2)

49.).

Table 5: Available experimental and calculated second-order rate constants (k_{OH}) for larger molecules. The SMILES codes used to perform the modelling are shown as table footnotes.

Compound	**Experimental** k_{OH} [cm^3/s]	**COSMOtherm** k_{OH} [cm^3/s]	**EPI Suite** k_{OH} [cm^3/s]	**Reference**
DDT[1]	5 10^{-13}	8.72 10^{-13}	3.44 10^{-12}	Liu et al. 2005
γ-HCH[2]	1.9 10^{-13}	3.69 10^{-13}	5.73 10^{-13}	Brubaker & Hites 1998
UV-328[3]		2.30 10^{-11}	1.58 10^{-11}	

1 C1=CC(=CC=C1C(C2=CC=C(C=C2)Cl)C(Cl)(Cl)Cl)Cl 2 Cl[C@H]1[C@@H](Cl)[C@H](Cl)[C@@H](Cl)[C@@H](Cl)[C@@H]1Cl

3 CCC(C)(C)c1cc(c(c(c1)n2nc3ccccc3n2)O)C(C)(C)CC (as stated in Table 2)

50. According to this uncertainty in the second-order rate constant, the photodegradation half-lives of UV-328 in the gas phase 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). In the OECD P_{OV} and LRTP Screening Tool, a 22-hour photodegradation half-life 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 of UV-328 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 other acknowledged POPs.

Long-range marine transport via plastic debris

51. The long-range transport of plastic debris and microplastics 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). Plastics enter the oceans in massive amounts every year (4.8 to 12.7 Mt) (Jambeck et al., 2015) and accumulate in the oceans as plastic gyres (Eriksen et al., 2014) that cannot feasibly be removed from the oceans by human intervention. In the marine environment, plastics weather into plastic debris and microplastics, which are persistent, widespread, present in large amounts and capable of long-range transport via ocean currents. Plastic debris therefore acts as an environmental medium or “vector” for the long-range transport of contaminants in the oceans. This pathway is particularly relevant for chemicals such as UV-328 that are intentionally added to plastics as additives during manufacturing (Andrade et al., in review). It is less relevant for organic chemicals already in the oceans that adsorb to floating plastic debris (Koelmans et al., 2013), because the amounts of these substances adsorbed to plastic particles are much smaller than the amounts of additives initially added to plastics.

52. The fraction of chemical additives that are not degraded in the plastic and do not leach out of the plastic matrix quickly can undergo long-range transport in the marine environment along with the plastic (debris) in which they were originally added during manufacturing (Andrade et al., in review). Importantly, this fraction is not static,

and leaching and transport in the environment occur in parallel, so there is some continuous leaching of plastic additives during environmental transport via plastic debris.

53. The leaching of additives from plastics depends on many factors, such as the plastic's porosity, the additive's molecular size and concentration, chemical properties, the extent of weathering, pH value, temperature, surface-area-to-volume ratio of plastic particles (shape and size), and duration of exposure to water (Luo et al., 2019; Teuten et al., 2009; Xu et al., 2020). Higher temperatures can also increase leaching within the body of organisms following ingestion (Nakashima et al., 2016; Sun et al., 2019). It has also been found that turbulence in the water increases the leaching of additives (Suhrhoff & Scholz-Böttcher, 2016). In addition, as additives can only occupy amorphous regions of the polymer, diffusion through polymers with a higher percentage of amorphous regions will be faster. Polyethylene (PE), polypropylene (PP), and plasticized polyvinyl chloride (PVC) have low crystallinity, which means that they have many amorphous regions, while unplasticized PVC and polystyrene (PS) have higher crystallinity (Bergmann et al., 2015). This has also been shown in an experimental study where leaching of additives was fastest for PE and plasticized PVC, followed by PS and PET (Suhrhoff & Scholz-Böttcher, 2016).

54. Taking all these factors into account, leaching of UV-328 in ocean water would 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. Endo et al. (2013) investigated the long-term desorption behavior of PCBs from marine PE pellets. 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 in the plastic particle. These results are in line with findings by Lee et al. (2018). Endo et al. (2013) showed furthermore that the desorption kinetics from PE are highly dependent on the PE-water partition coefficient ($K_{PE/w}$). 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):

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

55. 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 unweathered PE in water.

56. As described above, leaching depends also on an additive's molecular size and its chemical properties. The substances used to develop the model of Endo et al (2013) covered a molecular weight range of 223 to 499 g/mol and a $\log K_{OW}$ of 5.1 to 7.4 (Lohmann, 2012). UV-328 has a molecular weight of 351 g/mol and a predicted $\log K_{OW}$ of 8.5, and is thus very similar to the substances that were used to develop the model.

57. As approximately 40% of the use of UV-328 is as an additive in plastics and rubber, and UV-328 leaches out of plastic over a long period of time (decades), it can undergo long-range transport in the marine environment along with the plastic (debris) in which it was originally added during manufacturing (Andrade et al., in review). Even though weathering may enhance leaching, large fractions of UV-328 are still transported over long distances; see above regarding leaching and transport in the environment occurring in parallel.

58. 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. The concentrations of UV-328 found in these samples ranged from not detected to 1.6 µg/g.

59. Tanaka et al. (2020a) sampled marine plastic debris 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 concentration of UV-328 in plastic debris found in this study was 0.20 µg/g. Upon further examination of a 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.

60. The findings discussed so far indicate that when plastics containing UV-328 enter the open oceans, become plastic debris and undergo long-range transport, UV-328 also undergoes long-range transport along with them.

61. It should be noted that when plastics containing UV-328 are ingested by seabirds, 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., 2019a; Tanaka et al., 2019b). The higher body temperature inside the birds' stomachs compared to ocean temperatures can also contribute to leaching of UV-328 out of ingested plastics.

62. To demonstrate this, a study by Tanaka et al. (2020b) conducted an *in vivo* plastic feeding experiment, in which polyethylene pellets containing UV-328 were fed to streaked shearwater (*Calonectris leucomelas*) chicks. Examinations revealed that UV-328 had accumulated in the liver, abdominal adipose tissue and preen gland oil of the streaked shearwaters 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 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 leads to leaching of UV-328 out of plastics and subsequent accumulation of UV-328 in seabirds.

63. In a global monitoring campaign of UV-328 in seabirds, UV-328 was found in very high amounts in the preen gland oil of seabirds sampled in remote islands (n = 145, DF = 21%) (Takada, 2020). Sampling of preen gland oil is a non-invasive approach for monitoring hydrophobic contaminants in seabirds and has been used previously to detect PCB contamination in seabirds (Yamashita et al., 2007). The highest concentrations of UV-328 in this study were in the range of 1–7 µg/g lw and were found in the preen gland oil of two seabird species, great shearwater and blue petrel, sampled from two remote islands, Gough Island and Marion Island, respectively (Takada, 2020). These seabird species have some of the highest incidences of plastics ingestion in the African sector of the Southern Ocean (> 90%) (Ryan, 1987). Great shearwaters are trans-equatorial migrants that feed in the North Atlantic during the boreal summer and thus could have ingested plastic in the North Atlantic. Blue petrels, on the other hand, hardly move outside of the Southern Ocean and remain typically in cold water (<10 ºC), south of the Antarctic Polar Front (H. Takada, personal communication, 2021). It is therefore very likely that the plastic ingested by the blue petrels originated from the Antarctic Polar Front, which is a very remote region.

64. In addition, preen gland oil samples from thick-billed murre from Pribilof Islands, Hawaiian petrel from Hawaii and red-billed tropicbird from the Galapagos Islands showed concentrations of UV-328 as high as in the plastic feeding experiment discussed above. High amounts of UV-328 were also detected in the preen gland oil of crested auklet sampled from St. Lawrence Island, red-footed booby from the Galapagos Islands, flesh-footed shearwater from Western Australia, short-tailed shearwater from Eastern Australia and fairy prion from New Zealand. In birds sampled in Hawaii, concentrations of UV-328 in the order of 10–100 ng/g lw were present in the preen gland oil of Bulwer's petrels, and UV-328 was also detected in black-footed albatrosses (1–10 ng/g lw).

65. As certain seabirds have high plastic ingestion rates (Rapp et al., 2017; Ryan, 1987) and plastic ingestion is an important source of UV-328 contamination in seabirds, it is likely that the source of UV-328 exposure in the seabirds sampled at the remote islands was ingestion of plastic debris containing UV-328.

Long-range transport via migratory birds

66. UV-328 has been found to accumulate in migratory bird species and has also been detected in migratory birds sampled at remote, uninhabited islands (Takada, 2020). UV-328 was measured in the preen gland oil of birds sampled from 19 locations around the world (Takada, 2020). UV-328 was detected in 31 of 145 samples (DF = 21%), including those collected from remote islands. Extremely high concentrations of UV-328 in the range of 1–7 µg/g lw were found in the preen gland oil of two migratory bird species, great shearwater and blue petrel, sampled from two remote islands, Gough Island and Marion Island, respectively. As discussed earlier, great shearwaters are trans-equatorial migrants that feed in the North Atlantic during the boreal summer. UV-328 might therefore have undergone long-range transport mediated by these migratory birds travelling from source regions to remote regions. The other explanation is that the birds ingested fragments of plastic debris containing UV-328 that had undergone long-range marine transport to the remote islands. There are currently insufficient data to conclude which of these two pathways dominates.

67. No quantitative data are available that demonstrate the extent of contamination in remote environments due to transport of UV-328 by migratory birds.

Conclusion on potential for long-range environmental transport

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

2.3 Exposure levels

69. 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 in both source and remote regions, as well as in humans and biota in many parts of the world.

70. The concentrations of UV-328 found recently in the preen gland oil of some seabirds (in the range of 1–7 µg/g lw) (Takada, 2020) may be especially of concern as they correspond to values close to the predicted no-effect concentration (PNEC) for secondary poisoning in predators (13.2 µg/g food) (ECHA, 2020a). This is discussed further in section 2.3.1.1.

71. Additionally, concentrations of UV-328 found in various matrices in Narragansett Bay, USA, which represents a historical hotspot of UV-328 contamination, have come close to or exceeded the respective PNEC values

for aquatic organisms (ECHA, 2020a; Jungclaus et al., 1978; Lopez-Avila & Hites, 1980). PNEC values of UV-328 in various matrices are shown in Table 6.

Table 6. Predicted no-effect concentrations (PNEC) of UV-328 for aquatic organisms in freshwater, marine water, sewage treatment plant, freshwater sediment, marine sediment, soil (for terrestrial organisms), and secondary poisoning (in predators). Source: ECHA, 2020a

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	13.2 µg/g food

2.3.1 Environmental monitoring data

2.3.1.1. Remote regions

72. UV-328 has been detected in the environment and biota of regions far from known point sources of UV-328, such as the Arctic (Annex E, 2021; Lu et al., 2019a; Schlabach et al., 2018) and remote islands such as Gough Island and Marion Island (Takada, 2020).

73. 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 may have been more appropriate matrices for monitoring UV-328 to overcome this methodological issue, as it is a highly hydrophobic chemical. On Prince Leopold Island in the Canadian Arctic, UV-328 was detected in 11% of the liver samples (n = 9) of northern fulmars at a concentration of 3.8 ng/g ww (Lu et al., 2019a). The concentrations and detection frequencies of UV-328 found in Artic 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%)

74. A global monitoring campaign of preen gland oil in seabirds also demonstrated the presence of UV-328 in remote regions (Takada, 2020). UV-328 was detected in the preen gland oil of 31 of the 145 individuals sampled (DF = 21%). High concentrations of UV-328 in the order of 1–7 µg/g lw were detected in the preen gland oil of great shearwater and blue petrel sampled from two remote islands, Gough Island and Marion Island, respectively. Similar concentrations of UV-328 were found in the preen gland oil of red-billed tropicbird sampled from the Galapagos Island in the Pacific Ocean. At Pribilof Island, an island in the Bering Sea >500 km west of Alaska, the concentration of UV-328 found in the preen gland oil of thick-billed murre was as much as 0.7 µg/g lw. These concentrations come close to the PNEC value of 13.2 µg/g food for secondary poisoning in predators shown in Table 6 (ECHA, 2020a). 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 birds (Spear & Ainley, 1998), concentrations of UV-328 in the birds would still only be one (to two) orders of magnitude lower than the PNEC for secondary poisoning in predators (0.05 to 1.1 µg/g in the birds compared to 13.2 µg/g food for secondary poisoning).

75. UV-328 was also detected in ingested polypropylene plastic fragments from the stomach of northern fulmars sampled from Faroe Islands, Denmark at a concentration of 1.1 µg/g-plastic and black-footed albatrosses sampled from the remote island of Mukojima, Japan, at a concentration of 1.4 µg/g-plastic (Tanaka et al., 2019a).

2.3.1.2 Air

76. 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 at two industrial parks, 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). In Oslo, Norway, UV-328 was detected in indoor air (*n* = 24, DF = 100%) in a concentration range of 20–5300 pg/m^3 (Pfaffhuber et al., 2019).

2.3.1.3 Water

77. 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.

78. In Okinawa, Japan, sun-blocking agents such as UV-328 were 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. The maximum concentration of 4.8 µg/L reported for rivers is in the same order of magnitude as the 10 µg/L PNEC value for freshwater.

79. 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.

80. 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). These concentrations exceeded the PNEC values of 10 µg/L for freshwater.

2.3.1.4 Wastewater and landfill leachate

81. 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.

82. 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).

83. In China, UV-328 was found in concentrations of <LOQ–0.02 µg/g dw in bed sediments (*n* = 27) downstream of a WWTP in the Pearl River Delta (Peng et al., 2017a). 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.

84. 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).

85. 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 (Pfaffhuber et al., 2019).

86. 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.

87. 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). These concentrations exceeded the PNEC values of 1000 µg/L for WWTPs.

2.3.1.5 Sediment

88. 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).

89. 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). This value is close to the 451 µg/g dw PNEC value for freshwater sediment.

90. More recently, in a study conducted in the Pearl River Delta in China, UV-328 was found at a concentration up to 0.02 µg/g dw in bed sediments (n = 27) (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 4×10^{-5} µg/g dw (n = 12, DF = 58%) in Laizhou Bay, 4×10^{-5} µg/g dw (n = 22, DF = 91%) in the Bohai Sea and 6×10^{-5} µg/g dw (n = 40, DF = 50%) in the Yellow Sea.

91. 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 ng/g (n = 5, DF = 100%) (Thomas et al., 2014). Since then, UV-328 has been detected frequently in sediments in Norway (Pfaffhuber et al., 2019; Ruus et al., 2020). 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 9×10^{-5} µg/g dw.

2.3.1.6 Soil

92. 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 soil sample at a concentration of 9×10^{-4} µg/g dw (Heimstad et al., 2020).

2.3.1.7 Indoor environments

93. 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 (Pfaffhuber 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). 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).

2.3.2 Exposure in humans and biota

2.3.2.1 Humans

94. 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. 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). The derived no effect levels (DNEL) for systemic effects due to long-term exposure to UV-328 via the oral, inhalation and dermal routes in workers and in the general population have also been reported (ECHA, 2020a), and are summarized in Table 8.

Table 8. DNELs for systemic effects due to long-term exposure to UV-328 in workers and in the general population.

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

95. 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 dust ingestion.

96. In the Republic of Korea, UV-328 was detected in human breast milk (*n* = 208), with a DF of 97.6% 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).

97. UV-328 has also been detected in human adipose tissues sampled in Japan (*n* = 18, DF = 81%), Republic of Korea (*n* = 16, DF = 88%), India (*n* = 5, DF = 60%), Spain (*n* = 12, DF = 16%) and USA (*n* = 24, DF = 13%) (Yanagimoto et al., 2011). The highest concentration of UV-328 was reported in Japan, at 35 ng/g lw.

2.3.2.2 Biota

98. 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).

99. 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).

100. 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).

101. Additionally, 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 concentration of 120 ng/g lw (*n* = 2, DF = 100%), in China at 96 ng/g lw (*n* = 5, DF = 60%), in Hong Kong 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 South 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).

102. 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.

103. 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).

104. 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 in the concentration range of 0.6–21 ng/g ww (Lu et al., 2017b). 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).

105. UV-328 has also been detected in seabirds around the world. UV-328 was measured in the preen gland oil of seabirds sampled from 19 locations around the world (n = 145, DF = 21%) (Takada, 2020). UV-328 was detected in crested auklet sampled from St. Lawrence Island; thick-billed murre from Pribilof Island; Bulwer's petrel, black-footed albatross and Hawaiian petrel from Hawaii; red-footed booby and red-billed tropicbird from the Galapagos Islands; flesh-footed shearwater from Western Australia; short-tailed shearwater from Eastern Australia; fairy prion from New Zealand; great shearwater from Gough Island; and blue petrel from Marion Island. Very high concentrations of UV-328 in the order of 1–7 µg/g lw were found in Hawaiian petrel, red-billed tropicbird, great shearwater and blue petrel.

2.4 Hazard assessment for endpoints of concern

106. 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 Risk Assessment Committee 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).

107. No evidence regarding the carcinogenicity, genotoxicity, mutagenicity, reproductive or developmental toxicity of UV-328 has been reported.

108. 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

109. In terms of bioavailability, it is expected that UV-328 will not be ionized in the small intestine and is likely to be absorbed 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 below. Dermal uptake of UV-328 by organisms is unlikely (ECHA, 2020a). In a recent study, a method for detecting UV-328 and its metabolites in human urine was developed (Denghel & Göen, 2020). After oral dosing of UV-328 in an adult (human) volunteer, UV-328 was not detected in urine samples, but four metabolites of UV-328 were detected.

2.4.1.1 Repeated-dose toxicity

110. 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.

111. 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 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 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. Microscopic examinations of livers after 90 days revealed hepatic damage at all UV-328 dose levels in both male and female rats. The relative weight of liver, kidneys, thyroid and testes increased at the three highest dose levels. Enlargement of liver was observed at all dose levels in male rats. Enlargement of liver in female rats and of kidneys in rats of both sexes was observed at the two highest dose levels. The activity of the enzyme glucose-6-phosphatase in livers also increased at all doses. The lowest-observed-adverse-effect-level (LOAEL) was reported as 10 mg/kg bw/day (ECHA, 2020a; Til et al., 1968). According to Canada's assessment, the LOAEL for repeated dose oral exposure is 15 mg/kg bw/day, based on an analogue, 2-(2*H*-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol (CAS RN 70321-86-7) (ECCC and Health Canada, 2016).

112. In another study, 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). Dose levels of UV-328 in the study were 0 (controls), 15, 30, 60, 120 and 240 mg/kg bw/day. Liver and kidneys were again the main target organs, where histopathological effects were observed for dogs exposed to 60 mg/kg bw/day and higher doses of UV-328. The no-observed-adverse-effect-level (NOAEL) was 30 mg/kg bw/day. Some animals in the higher-dose groups had alterations in their reproductive organs. Moreover, changes in the activity of several enzymes in serum and change in protein pattern in serum were observed for dogs exposed to 30 mg/kg bw/day and higher dose levels of UV-328.

113. In a similar feeding study conducted in beagle dogs for 91 days, the no-observed-effect-level (NOEL) for male and female dogs were 32 and 35 mg/kg bw/day, respectively (Ciba-Geigy, 1981; OECD, 2017). No gross or histopathological changes related to the treatment were observed in this study.

2.4.1.2 Acute toxicity

114. 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).

115. In a study by Ciba-Geigy (1973) with test protocol similar to OECD TG 403, rats were exposed through the nose to UV-328 for 4 hours in aerosol form using ethanol as the vehicle. 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). The LC_{50} was higher than the test concentration of 0.13 mg/L air (ECHA, 2020a).

116. Measured dermal LD_{50} in rabbits was in the range of 1.1–3.0 g/kg bw after single exposure to UV-328 (Ciba-Geigy, 1969). No dermal irritation/sensitization or eye irritation was reported (ECHA, 2020a).

2.4.1.3 Effects on the endocrine system

117. An *in vitro* study by Zhuang et al. (2017) reported anti-androgenic activity towards the human androgen receptor at 0.25 mM UV-328, and the anti-androgenic activity became stronger after UV-328 had been metabolically activated through hydroxylation by the human CYP3A4 enzyme. No relevant estrogenic activity has been observed, however (Kawamura et al., 2003).

2.4.2 Ecotoxicity

118. Ecotoxicity of UV-328 has not been demonstrated conclusively in standard tests (details below). However, modelling data from ECOSAR predict that UV-328 is ecotoxic (US EPA, 2012).

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

120. Available ecotoxicity data obtained from standardized acute toxicity studies on aquatic organisms (fish, crustaceans and algae) 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.

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} > 100 mg/L after 96h	Ciba-Geigy, 1988a
Oryzias latipes	OECD TG 203, GLP, 2007	LC_{50} > 0.08 mg/L after 96h	ECHA, 2018

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

Crustacean species	Testing method	NOEC / LC_{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 EC_0 > 58 mg/L after 24h	Ciba-Geigy, 1988b
Daphnia pulex	OECD TG 202	LC_0/EC_0 > 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, semi-static, GLP, 2007	NOEC = 0.016 mg/L	ECHA, 2020a
Scenedesmus subspicatus		NOEC < 0.1 mg/L for growth inhibition after 72h	Hicks and Geldhill, 1993

121. 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).

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

123. The long-term effects of UV-328 exposure in aquatic organisms have recently been studied (Giraudo et al., 2017, 2020; Hemalatha et al., 2020). Hemalatha et al. (2020) studied the long-term effects of UV-328 exposure in adult zebrafish (*Danio rerio*). The test species were exposed to UV-328 at concentrations of 0.01, 0.1 and 1 mg/L in dimethyl sulfoxide (DMSO) for 14, 28 and 42 days. Examinations of the liver tissues indicated that superoxide dismutase, catalase and glutathione peroxidase activities were elevated at concentrations of 0.1 and 1 mg/L on the 14th and 28th day. Histopathological lesions such as hypertrophy, cellular and nuclear enlargement, cytoplasmic and nuclear degeneration, necrosis with pyknotic nuclei, lipid and cytoplasmic vacuolization, and nuclear displacement to the periphery were found to increase with dose and exposure duration (Hemalatha et al., 2020). No mortality of test subjects was observed during the exposure periods.

124. In *Chlamydomonas reinhardtii*, reactive oxygen species production increased following exposure to UV-328 (Giraudo et al., 2017). In *Daphnia magna*, growth, reproduction and gene transcription remained unimpacted for 21 days following exposure to UV-328 at concentrations of 0.01 and 10 mg/L in DMSO (Giraudo et al., 2017). In *Oncorhynchus mykiss*, exposure to UV-328 induced ribosomal proteins transcription, downregulated genes involved in immune responses and affected genes involved in iron homeostasis (Giraudo et al., 2020).

125. Data on ecotoxicity of UV-328 in terrestrial wildlife are unavailable. Canada's screening assessment on UV-328 does, however, estimate chronic toxicity reference values of 2.34 and 3.86 mg/kg bw/day for river otters and mink, respectively (ECCC and Health Canada, 2016).

2.4.3 Toxicological interactions involving multiple chemicals

126. While there is a general lack of interaction studies with other members of the phenolic benzotriazole group, two recent studies 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). In *D. magna*, growth, reproduction and gene transcription were not impacted for 21 days following exposure to 0.01 and 10 mg/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

127. UV-328 has been found to be toxic for mammals, endangering human health and the environment, as it can cause damage to liver and kidney through prolonged or repeated oral exposure (STOT RE 2).

3. Synthesis of information

128. UV-328 is a phenolic benzotriazole that absorbs the full spectrum of UV light in a fully reversible and non-destructive process. UV-328 is produced in large amounts globally (>1000 tonnes per year) and is used as a UV absorber to protect various types of surfaces against UV light. Approximately 50% of its total use is in coatings, 40% as an additive in plastics and rubber, and 10% in personal care products such as sunscreen lotions.

129. UV-328 is released to the environment during industrial production of the substance, and as a result of the use and end-of-life management of products containing UV-328. Consequently, UV-328 has been detected in the influent and effluent of wastewater treatment plants as well as receiving water bodies and their sediments, in landfill leachate, at beaches and in water bodies near touristic areas, and in plastic debris circulating in the world's oceans. Quantitative data on the extent of release of UV-328 from point sources into the environment are unavailable.

130. Experimental and monitoring data have demonstrated that UV-328 is persistent in soil and sediment, with disappearance half-lives in soil and sediment greater than the trigger value of 180 days. Monitoring data from sediment cores collected near a facility that produced UV-328 in the past have demonstrated that UV-328 has persisted in sediment cores even decades after the facility stopped its production.

131. UV-328 is also bioaccumulative, with bioaccumulation factors exceeding 5000 L/kg ww. UV-328 has been detected in a wide-range of biota including marine mammals, fish, crustaceans and seabirds. UV-328 can be taken up by organisms through trophic transfer, from contaminated sediments and via ingestion of plastics containing UV-328. Uptake of UV-328 by organisms from water is expected to be low, given the low water solubility of UV-328.

132. UV-328 contamination in biota has been found to be highest when biota ingest plastic (debris) fragments containing UV-328 (as an additive), with contamination higher through the plastics ingestion pathway compared to other routes of environmental exposure such as trophic transfer. Subsequently, the highest concentrations of UV-328 detected in biota were in seabirds that are known to ingest fragments of marine plastic debris.

133. Monitoring data have shown the presence of UV-328 in the environment and biota of remote regions, including the Arctic as well as remote islands such as Gough Island and Marion Island, far away from any known emission sources of UV-328. The findings indicate that UV-328 underwent long-range environmental transport, travelling from source to remote regions. UV-328 has three modes of long-range environment transport: 1) via aerosols (e.g. adsorption to aerosol particles), 2) in the oceans via plastic debris and 3) via by migratory birds.

134. In addition to being persistent, bioaccumulative and capable of long-range environmental transport, UV-328 is toxic to mammals. The mammalian toxicity of UV-328 has been demonstrated through repeated dose toxicity studies conducted in rats and beagle dogs, for which it 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 effects of UV-328 are liver and kidney toxicity. There are also indications of anti-androgenic activity of UV-328.

135. UV-328 has been detected in adipose tissues and breast milk of humans in various parts of the world. Sources of UV-328 exposure in humans include ingestion of dust contaminated with UV-328 as well as consumption of foodstuffs (e.g. fish and other seafood) contaminated with UV-328.

4. Concluding statement

136. UV-328 does not occur naturally in the environment. Yet, it that has been found in various environmental matrices such as air, dust, soil, sediment and water, as a result of anthropogenic activities. UV-328 has been found to be associated with adverse health effects based on findings from mammalian toxicity studies and has been detected in humans and wildlife in many parts of the world. It has also been detected in the environment and biota of remote regions such as the Arctic as well as uninhabited islands far away from any known emission source of UV-328, which is a result of its long-range environmental transport.

137. Given that UV-328 is a chemical that is produced in high volumes globally; its use has led to the contamination of environments and wildlife far away from where it has been produced or used; its environmental release and transport cannot be influenced by national level regulations; and considering the inherent hazards posed by UV-328 due to its persistent, bioaccumulative and toxic nature, 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 environmental effects, such that global action is warranted.

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