UV-328

Draft risk profile

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

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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 4 and 6 positions 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.

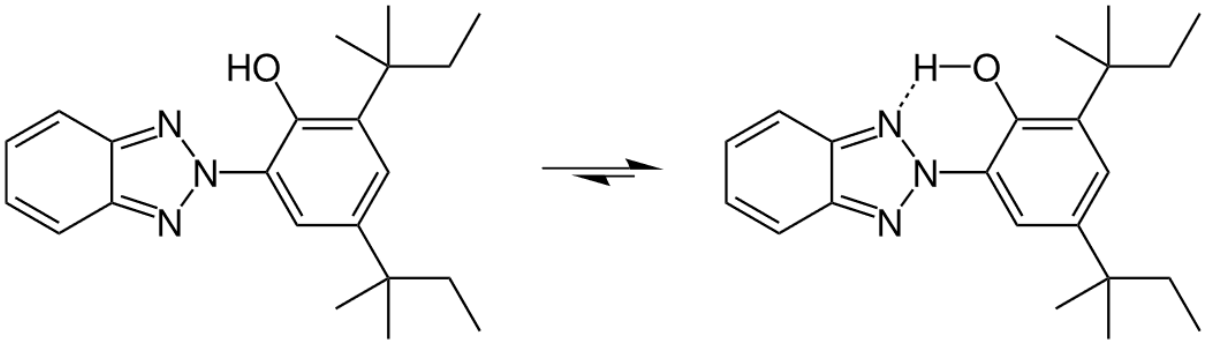

Figure 1. Chemical structure of UV-328 in its open form (left) and closed form (right). The open form of UV-328 does not contain an intramolecular hydrogen bond, whereas the closed form of UV-328 does.

4. COSMOtherm predicts that UV-328 exists only in the closed form, meaning it possesses an *intra*molecular hydrogen bond. Experiments conducted at the Swiss Federal Institute of Technology Zurich in 2021 confirm that UV-328 exists in its closed form in water. 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)
	137 °C	Estimated (104–202 °C), US EPA
Boiling point	Decomposition > 180 °C, before boiling	Experimental, Differential Scanning Calorimetry (DSC, 2013); ECHA (2020a)
	> 230 °C	Estimated, Thermogravimetric Analysis (2012), ECHA (2020)
	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)
	$1.3 \cdot 10^{-5}$ mg/L	Estimated ($4.2 \cdot 10^{-8}$–$3.1 \cdot 10^{-5}$ mg/L), US EPA
	0.02 mg/L	Experimental, Dynamic Coupled Column (Lopez-Avila & Hites, 1980)
	$2.7 \cdot 10^{-4}$ mg/L	COSMOtherm
Density	1.1 g/cm^3	Estimated (1.1–1.2 g/cm^3), US EPA
	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

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, Alaskan Community Action on Toxics & International POPs Elimination Network (ACAT/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 high enough amounts to pose a significant threat to human health and the environment in Canada (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 USA, the reported national aggregate production volume was approximately 1000 t in 2011, and 450–4500 t/a from 2012 to 2016. 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 treatment, adhesives, paint/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. Currently, 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 of the substance, during its use (e.g. as sunscreen lotion at beaches) and post-use disposal of products containing UV-328 into waste streams and the environment (e.g. plastics and food packaging).

20. According to Norway, emission of UV-328 to the indoor and outdoor environment has been observed. UV-328 has been detected in air, dust, wastewater, wastewater sludge, river water and biota in source and remote regions (Annex E, 2021). According to Canada, release to surface waters is expected according to industrial uses (ECCC and Health Canada, 2016).

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. As UV-328 is used in sunscreen lotions in some regions, the use of such personal care products is a source of UV-328 contamination 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, which are often mismanaged at the end-of-life stage and 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 act as continuous point sources of UV-328. UV-328 has been detected in marine plastic debris (Rani et al., 2015, 2017; Tanaka et al., 2020a) and was found at high concentrations in seabirds that are known to ingest fragments of marine plastic debris (Takada, 2020; Tanaka et al., 2019a). Plastic litter containing UV-328 is therefore a major source of UV-328 in the environment and in biota that ingest plastics. 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

24. 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, modelling, 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).

25. 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).

26. 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).

27. 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 like volatilization.

28. 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 and water (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 4 and 6 positions 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 means that the DT_{50} of UV-328 in sediment would be at least 238 days.

29. 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, 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. 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.

30. 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:

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

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

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

31. Taking all the available information into account, UV-328 fulfills the persistence criteria.

2.2.2 Bioaccumulation

32. 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.

33. 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).

34. 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, carps 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.

35. In the study from 2000, carps were exposed to UV-328 in water over 56 days at (measured) concentrations of 0.78 and 0.07 µg/L. However, 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 only 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 UV-328 were 26 days and 24 days, respectively.

36. Several monitoring studies also provide evidence of bioaccumulation of UV-328 in aquatic organisms, where measured concentrations have been in the order of several hundred ng/g lipid weight (Kim et al., 2011; Nakata et al., 2009, 2012).

37. UV-328 was also 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 the 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 Long-range transport potential

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). 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, 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.

2.2.3.1 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 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 photodegradation half-lives of UV-328 in the gas phase 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).

Table 5: Available experimental and calculated second-order rate constants (k_{OH}) for larger molecules.

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

49. 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.

2.2.3.2 Long-range marine transport via plastic debris

50. The long-range transport of plastic debris in the marine environment has been well-documented (Eriksen et al., 2014; Howell et al., 2012; Maximenko et al., 2012; Obbard, 2018; Van Sebille et al., 2020). Mismanaged 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, which is 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. It is less relevant for organic chemicals already in the oceans that adsorb to floating plastic debris (Koelmans et al., 2013).

51. The fraction of chemical additives that are not degraded in the plastic and do not leach out of the plastic matrix can undergo long-range transport in the marine environment along with the plastic (debris) in which they were originally added during manufacturing. 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.

52. 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, and duration of exposure to water (Luo et al., 2019; Teuten et al., 2009; Xu et al., 2020). Higher temperatures or higher surface-to-area ratios 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).

53. 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):

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

54. 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.

55. As approximately 40% of the use of UV-328 is as an additive in plastics and rubber, and UV-328 does not leach out of plastic for a long period of time, it can undergo long-range transport in the marine environment along with the plastic (debris) in which it was originally added during manufacturing. Even though weathering enhances leaching, large fractions of UV-328 are still transported over long distances; see above regarding leaching and transport in the environment occurring in parallel.

56. 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.

57. 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.

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

59. It should be noted that when plastics containing UV-328 are ingested by organisms, particularly 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 in the oceans can also contribute to leaching of UV-328 out of ingested plastics.

60. 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 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 not only leads to leaching of UV-328 out of plastics and subsequent accumulation of UV-328 in seabirds, but also that it is a more dominant pathway for UV-328 contamination in seabirds than other environmental sources such as diet.

61. 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 (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 1–10 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). 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.

62. 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).

63. As certain seabirds have high plastic ingestion rates (Rapp et al., 2017) and plastic ingestion is a dominant source of UV-328 contamination in seabirds, it is expected that the source of UV-328 exposure in the seabirds sampled at the remote islands was ingestion of plastic debris containing UV-328.

2.2.3.3 Long-range transport via migratory birds

64. Migratory birds may accumulate contaminants from source regions and transport those contaminants to remote regions depending on their migration behavior. It has been shown in the past that POPs such as PCBs and DDT have been transported by migratory seabirds to the remote ecosystem of Lake Ellasjøen, Norway, >500 km from any known emission source of POPs (Evenset et al., 2004). While the primary source of POPs contamination in Lake Ellasjøen was identified to be due to long-range atmospheric transport, the study indicated that the input of guano (i.e. excrement) from migratory seabirds was a significant additional source of POPs in the lake, which is used by migratory seabirds as a resting area.

65. 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 160 birds of 35 species sampled from 19 locations around the world (Takada, 2020). Extremely high concentrations of UV-328 in the range of 1–10 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. One explanation of these findings is that UV-328 has undergone long-range transport mediated by 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 these two islands. There is currently insufficient data to conclude which of these two pathways dominates.

66. Depending on the specific migration behavior of different birds (e.g. regions located in their migration routes, duration of stay in the remote regions etc.), the amount of UV-328 transported by migratory birds to remote regions may vary. No quantitative data are available that demonstrate the extent of contamination in remote environments due to transport of UV-328 by migratory birds. However, given that UV-328 is persistent and bioaccumulative, the repeated transport of UV-328 via migratory birds may pose a risk to the local wildlife of remote regions.

2.2.3.4 Conclusion on long-range transport potential

67. UV-328 can undergo long-range 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. Therefore, UV-328 fulfills the criteria for long-range transport potential.

2.3 Exposure levels

68. 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.

69. The concentrations of UV-328 found recently in the preen gland oil of some seabirds (1–10 mg/kg lw) (Takada, 2020) may be especially of concern as they are close to the predicted no-effect concentration (PNEC) for secondary poisoning in predators (13.2 mg/kg food) (ECHA, 2020a).

70. Additionally, historical concentrations of UV-328 in various matrices in Narragansett Bay, USA, have come close to or exceeded the respective PNEC values for aquatic organisms (ECHA, 2020a; Jungclaus et al., 1978; Lopez-Avila & Hites, 1980). A comparison of PNEC values of UV-328 for aquatic organisms in various matrices and concentrations of UV-328 found in the corresponding matrices in Narragansett Bay is provided in Table 6.

Table 6. Comparison of predicted no-effect concentrations (PNEC) of UV-328 for aquatic organisms in freshwater, freshwater sediment and sewage treatment plant, and historical concentrations of UV-328 found in corresponding matrices in Narragansett Bay, USA.

Matrix	PNEC value	Environmental levels
Freshwater	10 µg/L	7–85 µg/L (river water)
Freshwater (intermittent releases)	100 µg/L	7–85 µg/L (river water)
Sewage treatment plant	1 mg/L	0.55–4.7 mg/L (effluent)
Sediment (freshwater)	451 mg/kg sediment dw	300 mg/kg (river sediment)

2.3.1 Environmental monitoring data

2.3.1.1. Remote regions

71. As a result of its long-range environmental transport, UV-328 has been detected in the environment and biota of regions far from known point sources of UV-328, such as the Artic (Annex E, 2021; Lu et al., 2019a; Schlabach et al., 2018) and remote islands such as Gough Island and Marion Island (Takada, 2020).

72. 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, comparatively high and adipose tissue samples would have been a more appropriate matrix for monitoring UV-328 as it is highly hydrophobic. On Prince Leopold Island in the Canadian Arctic, UV-328 was detected in 11% of the liver samples (n = 9) of northern fulmars at concentrations 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	100
European shag	Eggs	Røst, Norway	0.17	60
Kittiwake	Eggs	Svalbard, Norway	0.19	100
Glaucous gull	Eggs	Svalbard, Norway	0.12	60
Mink	Livers	Sommarøy, Norway	0.18	100
Polar bear	Blood plasma	Svalbard, Norway	<0.3	0
Common gull	Eggs	Tromsø, Norway	0.17	60
Northern fulmar	Livers	Prince Leopold Island, Canada	3.8	11

73. A global monitoring campaign of preen gland oil in seabirds also demonstrated the presence of UV-328 in remote regions (Takada, 2020). High concentrations of UV-328 in the order of 1–10 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 (ECHA, 2020a).

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

2.3.1.2 Water

75. In a monitoring campaign conducted in Sweden, UV-328 was detected in surface waters in both urban and background locations at concentrations of 1.3–10 ng/L (Brorström-Lundén et al., 2011). Up to 1.3 ng/L of UV-328 was also found in stormwater in this study.

76. 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 predominant in seawater, in which the concentrations of UV-328 detected were in the range of 2.8 to 287 ng/L.

77. In Canada, UV-328 was detected in urban streams at a concentration of 240 ng/g-sediment (Parajulee et al., 2018). The study also suggested that the relatively high and consistent emissions that led to homogenous UV absorber profiles in urban and rural sites were likely as a result of plastic litter/debris rather than industrial releases.

78. 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).

2.3.1.3 Wastewater

79. UV-328 has frequently been found in the influent, effluent and sludge from wastewater treatment plants (WWTPs) in many parts of the world.

80. In a study in Japan, UV-328 was found at a concentration of 34 ng/L in WWTP influents and < 5 ng/L in effluents (Nakata & Shinohara, 2010). The removal rate of UV-328 in WWTPs was above 90%. Subsequently, UV-328 was found at a concentration of 510 ng/g dw in wastewater sludge. In another study in the Pearl River Delta in China, UV-328 was found at a concentration up to 18 ng/g dw in bed sediments downstream of a WWTP (Peng et al., 2017a).

81. On the Gran Canary Island in Spain, UV-328 was detected in the influent and effluent of WWTPs at concentrations of 22–238 ng/L and 29 ng/L, respectively (Montesdeoca-Esponda et al., 2019). In another study in Spain, UV-328 was detected in untreated wastewater at concentrations of 53–65 ng/L (Carpinteiro et al., 2012). In the same study in Portugal, UV-328 was detected in untreated wastewater at a concentration of 76 ng/L and in treated wastewater at 21 ng/L (Carpinteiro et al., 2012).

82. In a monitoring study conducted in Sweden, UV-328 was found in 100% of WWTP effluent samples at concentrations in the range of 6.8–15 ng/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 detected in landfill leachate at concentrations in the range of 7–91 ng/L. In Norway as well, UV-328 has been 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 22–68 ng/L (Pfaffhuber et al., 2019).

83. In Canada, UV-328 was frequently detected in WWTP influent, effluent and biosolids at maximum concentrations of 126 ng/L, 63 ng/L and 824 ng/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.

84. 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 0.55–4.7 mg/L (Jungclaus et al., 1978).

2.3.1.4 Sediment

85. In a study in Japan, sediment cores were collected for the period 1930–1999 (Nakata, 2011). The data showed an increasing temporal trend of UV-328, with concentrations rising since 1970. Concentrations of UV-328 were in the range of 4–10 ng/g dw.

86. 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), but was still high (3–6 µg/g) decades after the facility ceased production of UV-328. Moreover, a UV-328 concentration of 300 µg/g was found in river sediment near the facility (Lopez-Avila & Hites, 1980).

87. More recently, in a study conducted in the Pearl River Delta in China, UV-328 was found at a concentration up to 18 ng/g dw in bed sediments (Peng et al., 2017a). 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 (Brorström-Lundén et al., 2011). In a screening study conducted in Oslofjord, Norway, UV-328 was detected in sediments at a concentration range of 3.2–25 ng/g (Thomas et al., 2014). Since then, UV-328 has been detected frequently in sediments in Norway (Pfaffhuber et al., 2019; Ruus et al., 2020).

2.3.1.5 Soil

88. UV-328 was detected in soil 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 Norway, UV-328 was detected in soil at a concentration of 0.89 ng/g dw (Heimstad et al., 2020).

2.3.1.6 Indoor environments

89. In Oslo, Norway, UV-328 has been detected in indoor air and settled floor dust at concentration ranges of 0.02–5.3 ng/m^3 and 1–18000 ng/g, respectively (Pfaffhuber et al., 2019). UV-328 has also been detected frequently in

indoor dust samples in Spain, at a mean concentration of 91 ng/g (Carpinteiro et al., 2010). In the Philippines, UV-328 was detected in house dust from residential as well as municipal dumping areas up to a concentration of 304 ng/g (Kim et al., 2012a; Kim et al., 2012b).

2.3.2 Exposure in humans and biota

2.3.2.1 Humans

90. UV-328 has been found in human breast milk and adipose tissue in different parts of the world. Humans may be exposed to UV-328 through ingestion of contaminated dust as well as consumption of contaminated foodstuffs. 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 are summarized in Tables 8 and 9, respectively (ECHA, 2020a). If UV-328 is taken up by humans via the oral route, it is expected that UV-328 will not be ionized in the small intestine and is likely to be absorbed in the gastrointestinal tract (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.

Table 8. Derived no effect levels (DNEL) for systemic effects due to long-term exposure to UV-328 in workers.

Exposure route	DNEL
Oral / inhalation	0.7 mg/m^3
Dermal	0.3 mg/kg bw/day

Table 9. Derived no effect levels (DNEL) for systemic effects due to long-term exposure to UV-328 in the general population.

Exposure route	DNEL
Inhalation	0.17 mg/m^3
Dermal	0.14 mg/kg bw/day
Oral	0.14 mg/kg bw/day

91. In the Philippines, the estimated daily intake 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.

92. In the Republic of Korea, UV-328 was detected in human breast milk, with a detection frequency (DF) of 97.6% and maximum UV-328 concentrations reaching 334 ng/g lw (Lee et al., 2015). In breast milk samples from Japan, Philippines and Vietnam, UV-328 had a detection frequency of 16% and an average concentration of 1.2 ng/g lw (Kim et al., 2019).

93. UV-328 has also been detected in human adipose tissues sampled in Japan, Republic of Korea, China, Spain and USA (Yanagimoto et al., 2011). The highest concentration of UV-328 was 35 ng/g lw and the DF was 45%.

2.3.2.2 Biota

94. 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, 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, 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 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 concentrations of 0.24, 0.7, 0.17 and 0.12 ng/g ww, respectively (Heimstad et al., 2018).

95. 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 up to 0.19 ng/g in the eggs of herring gull and 0.36–0.41 ng/g in cod liver. UV-328 was also detected in seal blubber at a concentration of 0.8 ng/g. In the Faroe Islands, UV-328 was detected at a concentration of 0.05 ng/g in the eggs of fulmar and at 0.12 ng/g in cod liver. In Sweden, UV-328 was detected in the blubber of grey seal at a concentration of 0.56 ng/g.

96. Additionally, in a study that measured UV-328 in mussels sampled from Asia-Pacific coastal waters, UV-328 was found in mussels sampled in Cambodia at a concentration of 120 ng/g lw (DF = 100%), in China at 96 ng/g lw (DF = 60%), in Hong Kong at 200 ng/g lw (DF = 75%), in Indonesia at 120 ng/g lw (DF = 100%), in Japan at 120 ng/g lw (DF = 100%), in South Korea at 220 ng/g lw (DF = 94%), in Malaysia at 24 ng/g lw (DF = 25%), in the Philippines at 170 ng/g lw (DF = 100%), in USA at 69 ng/g lw (DF = 33%) (Nakata et al., 2012). UV-328 was not detected in mussels sampled from India and Vietnam.

97. In the Ariake Sea, Japan, UV-328 was detected in the blubber of finless porpoises 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). UV-328 was also detected in the liver of mullets and hammerhead sharks (Nakata et al., 2010). In the Pearl River Estuary, China, UV-328 was detected in various marine organisms (Peng et al., 2017b). The highest concentration of UV-328 was found in bluespot mullet at 259 ng/g lw.

98. In a study in an urban creek in Canada, UV-328 was detected in 33–57% of the sampled biota, with concentrations in crayfish as high as 1.3 µg/g lw (Lu et al., 2016a). Another study in an urban creek in Canada 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 frequently in blood plasma from several species of fish and a bird, with concentrations of up to 3.8 ng/g ww in common carp (Lu et al., 2019b). 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 white sucker (Lu et al., 2016b).

99. UV-328 has also been detected in seabirds around the world. UV-328 was measured in the preen gland oil of 160 birds of 35 species sampled from 19 locations around the world (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 1–10 mg/kg lw were found in Hawaiian petrel, red-billed tropicbird, great shearwater and blue petrel. These concentrations of UV-328 come close to the predicted no-effect concentration (PNEC) for secondary poisoning in predators (13.2 mg/kg food).

2.4 Hazard assessment for endpoints of concern

100. 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).

101. Other potential toxicological endpoints of concern include alterations in reproductive organs, changes in activity of enzymes in serum, changes in protein pattern in serum and anti-androgenic activity.

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

103. 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

104. 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.

105. Male and female rats were fed a diet containing UV-328 for 49 days (short-term) and 90 days (sub-chronic) (Til et al., 1968). The test protocol was similar to OECD TG 408 (1968, non-GLP). The test range of UV-328 in the study was 100 to 1600 mg/kg. Microscopic examinations revealed adverse effects mainly in the liver and kidneys. These included focal necrosis of the liver and tubular nephrosis in the kidneys at the feeding level of 53–99 mg/kg bw/day. The NOAEL was 100 ppm of a UV-328 dose (equivalent to approximately 22 mg/kg bw/day for rats). The calculated NOAEL and LOAEL were <10 mg/kg bw and 10 mg/kg bw, respectively (ECHA, 2013; Til et al., 1968).

106. 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). Doses of UV-328 in the study were in the range of 15–240 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. Some animals in the higher-dose groups also 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 for 90 days to >15 mg/kg UV-328. The NOEL and NOAEL for this study were <15 mg/kg bw/day and 30 mg/kg/day, respectively.

107. In a similar feeding study conducted in beagle dogs for 91 days, the 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.

108. 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 uptake (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. Dermal uptake of UV-328 by organisms is unlikely (ECHA, 2020a).

109. Several studies have also 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 2.3 g/kg bw. In another study, the LD_{50} in rats was >7.75 g/kg bw (Ciba-Geigy, 1978). A study on albino rats (similar to OECD TG 401, non-GLP, 1987) reported an oral LD_{50} > 2.0 g/kg bw (ECHA, 2020a).

110. The measured acute inhalation lethal concentration (LC_{50}) in rats was in the range of 0.4–4.1 g/L (Ciba-Geigy, 1978). Ciba-Geigy (1973) showed LC_{50} > 0.4 mg/L after single exposure for 4 hours. Another study (1977) conducted in rats reported an LC_{50} > 0.13 mg/L air after 1 hour of exposure (ECHA, 2020a).

111. Measured dermal LD_{50} in rabbits was from 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).

112. In humans, UV-328 exposure may lead to anti-androgenic activity. A study by Zhuang et al. (2017) observed anti-androgenic activity towards the human androgen receptor at 0.25 mM of 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

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

114. 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. The predicted no-effect concentration (PNEC) for UV-328 is 1 µg/L in marine water and 45.1 mg/kg sediment dw in marine sediment (ECHA, 2020a).

115. Available ecotoxicity data obtained from 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 10 to 12.

Table 10. 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 11. 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 12. 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

116. 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).

117. 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).

118. 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.

119. 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).

120. 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

121. 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 *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 *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 two to six times upregulation of glutathione peroxidase, suggesting a potential impact on the antioxidant defense system of *C. reinhardtii* (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

122. 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

123. 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.

124. 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 gyres of 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.

125. Once in the environment, UV-328 can persist there for a long period of time. Experimental, modelling 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.

126. Various studies and modelling data have also shown that UV-328 is 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, with UV-328 concentrations in organisms increasing with trophic level. 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.

127. 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 orders of magnitude times 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.

128. Monitoring data have shown the presence of UV-328 in the environment and biota of remote regions, including the Artic as well as remote islands such as Gough Island and Marion Island, far away from any known emission source 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.

129. In addition to being persistent, bioaccumulative and capable of long-range environmental transport, UV-328 is inherently 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 international forums as STOT RE 2 (specific target organ toxicity, repeated exposure in sub-category 2). The primary endpoints of concern for UV-328 are liver and kidney toxicity.

130. UV-328 has been detected in adipose tissues and breast milk of humans in various part of the world. Sources of UV-328 contamination 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

131. 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 possesses an inherent toxicity to mammals 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 Artic 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.

132. Given that UV-328 is a chemical that is produced in high volumes globally; and that its use has led to the contamination of environments and wildlife far away from where it has been produced or used; and that 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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