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

Bis(4-chlorophenyl) sulfone (BCPS)

EC Number: 201-247-9

CAS Number: 80-07-9

July 2026

Contents

1. Proposal

Substance name: Bis(4-chlorophenyl) sulfone (BCPS)

EC Number: 201-247-9

CAS Number: 80-07-9

Bis(4-chlorophenyl) sulfone (BCPS) has been identified as a substance of very high concern (SVHC) in accordance with the requirements set out in Annex 15 of EU REACH (ECHA, 2023a). This is based on the substance fulfilling the very persistent and very bioaccumulative (vPvB) criteria under Annex 13 of EU REACH.

This technical report provides an independent scientific assessment by the Agency[1] on whether BCPS should be identified as an SVHC under UK REACH. It considers only studies presented in the equivalent document produced by the European Chemicals Agency (ECHA), the EU Member State Committee (MSC) support document (ECHA, 2023b), except where stated otherwise. Relevant observations on studies made in the EU MSC support document have been summarised and Agency comments have been added where appropriate. Unpublished study reports were not available and have not been examined, unless stated otherwise. A literature search was conducted by the Agency, the scope of which was restricted to capturing further information relating to bioaccumulation. Further literature searches were not performed because the existing information is considered to be sufficient for decision making.

It is proposed to identify BCPS as vPvB according to Article 57(e) of UK REACH.

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

A weight-of-evidence determination according to the provisions of Annex 13 of UK REACH has been used to identify BCPS as vPvB.

<u>Persistence</u>

The freshwater sediment DT_{50} values of BCPS were above 394 days at 20 °C in a study conducted according to OECD Test Guideline (TG) 308. These were extrapolated to > 836 days at 12 °C, which exceeds the very persistent (vP) criterion of Annex 13 of UK REACH (half-life > 180 days).

[1] The Health and Safety Executive (HSE) acting in its capacity as the Agency for UK REACH, and with support from the Environment Agency in accordance with Article 2B of UK REACH.

Bioaccumulation

Despite uncertainties and the absence of detailed partitioning or full mass-balance data, the estimated terminal half-life of 12 days in adipose tissue of rats substantially exceeds the 4- and 7-day total biotransformation half-life benchmarks linked to a biomagnification factor (BMF) of 1. Given the rapid distribution to adipose tissue, efficient systemic uptake, and indications of diffusion-limited redistribution, this prolonged adipose residence strongly implies an extended effective elimination half-life from plasma and perfused tissues in air-breathing organisms.

This finding is supported by:

- A measured log K_{OW} > 2 (3.9) and a predicted log K_{OA} value > 5 (9.2) indicating that BCPS screens as potentially bioaccumulative in air-breathing organisms;

- The presence of BCPS at concentrations ranging up to around 2,700 ng/g lw (~1,600 ng/g [~1.6 mg/kg] ww) in a range of wildlife species, across multiple trophic levels and sensitive life stages (e.g. birds' eggs). There is good evidence of higher concentrations in air-breathing organisms (birds and mammals) than gill-breathers (fish). Wildlife tissue concentrations in the region of 1 mg/kg ww have been reported for other substances that have been formally identified as very bioaccumulative under REACH and equivalent criteria under POPs.

Overall, BCPS can be concluded to have a very high bioaccumulation potential in air-breathing organisms, consistent with exceeding the vB criterion of Annex 13 of UK REACH.

Conclusions

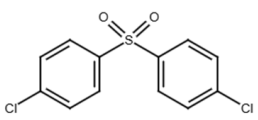
Based on the information available, the Agency concludes that BCPS fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

2. Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	201-247-9
EC name:	bis(4-chlorophenyl) sulphone
SMILES[a]:	O=S(=O)(c(ccc(c1)Cl)c1)c(ccc(c2)Cl)c2
CAS number:	80-07-9
IUPAC[b] name:	1,1'-sulfonylbis(4-chlorobenzene)
Index number in GB Mandatory Classification and Labelling (MCL) List[c]:	No mandatory classification
Molecular formula:	$C_{12}H_8Cl_2O_2S$
Molecular weight range:	287.1617 g/mol
Synonyms:	1,1'-Sulfonylbis(4-chlorobenzene) 4,4'-Dichlorodiphenyl sulfone 4,4'-Dichlorodiphenyl sulphone 4-Chlorophenyl sulfone Benzene, 1,1'-sulfonylbis(4-chloro-) Bis(4-chlorophenyl) sulfone Bis(4-chlorophenyl) sulphone Di-p-chlorophenyl sulfone *p,p'*-Dichlorodiphenyl sulfone *p*-Chlorophenyl sulfone Sulfone, bis(*p*-chlorophenyl) BCPS DCDPS
Structural formula:	

[a] SMILES: Simplified Molecular Input Line Entry System

[b] IUPAC: International Union of Pure and Applied Chemistry

[c] GB MCL list in accordance with the retained Regulation (EC) No 1272/2008 as amended for Great Britain

2.1.2 Composition of the substance

Description: solid, white

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
BCPS	≥ 80% w/w

2.1.3 Identity and composition of transformation products relevant for the SVHC assessment

No relevant degradation products or metabolites are identified in ECHA (2023b) and the vPvB assessment is based on the parent substance only.

The Agency has not considered any transformation products as part of this assessment.

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

No structurally related substances are used as part of a grouping or read-across approach for the vPvB assessment.

ECHA (2023b) notes several substances for which data are compared to BCPS in phototransformation or field monitoring studies. These include dichlorodiphenyltrichloroethane (DDT, CAS no. 50-29-3); DDT metabolites such as 4,4'-dichlorodiphenyldichloroethylene (4,4´-DDE, CAS no. 72-55-9); 4,4′-diaminodiphenylsulphone (dapsone, CAS no. 80-08-0); and certain polychlorinated biphenyls (PCBs). These substances typically differ from BCPS in terms of polarity and other key physicochemical properties, which can influence environmental behaviour. As a result, direct comparisons may not reliably reflect the behaviour or effects of BCPS. Such comparisons have been retained on a case-by-case basis e.g., phototransformation data for dapsone were considered relevant by the Agency and have been retained fully in this report (Section 2.3.1.1.3).

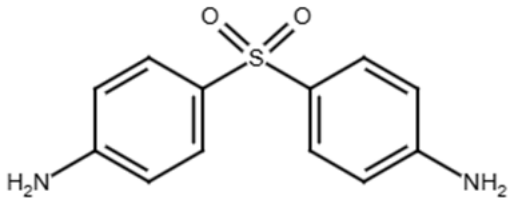


Figure 1: Structure of dapsone

ECHA (2023b) reports a benchmark approach as part of the weight-of-evidence for the conclusion of BCPS being very bioaccumulative (vB), whereby monitoring data for BCPS in biota are compared with concentrations of structurally unrelated substances that have been identified as persistent organic pollutants (POPs) and therefore concluded to fulfil the vB criteria of REACH Annex 13. The POPs used for the benchmark approach, hexachlorocyclohexane (HCH), pentachlorobenzene (PeCB), and 2,2',4,4',5-pentabromodiphenyl ether (BDE-99), are identified in ECHA (2023b) as having similar long-range transport potential (LRTP) to BCPS as identified by the OECD Tool (OECD, 2008). The Agency does not consider similar long-range transport potential from modelling to be a sufficient basis for comparison of the environmental fate and biological behaviour of these chemicals, given that the substances are structurally unrelated to BCPS. Similarities and/or differences in monitoring data could be related to reduced use of POPs due to risk management measures as well as differences in tonnage, exposure, and chemical fate and behaviour. The Agency considers that regulatory observations relating to substance concentrations in biota collected from field contexts are empirical and retrospective rather than mechanistic or predictive, and should therefore be interpreted with caution. While absolute tissue concentrations may provide useful supporting evidence, particularly where consistent with known bioaccumulative substances, their interpretation is highly uncertain and case-specific, and they cannot reliably distinguish between high exposure and strong accumulation potential (Sections 2.3.2.3, 2.3.2.4 and Appendix B).

2.1.5 Physicochemical properties

Physicochemical property information for BCPS from the EU registration dossier, as reported in ECHA (2023b), are summarised in Table 3. These data are considered to be reliable without restriction by the registrants (ECHA, 2025). The Agency has not independently assessed the physicochemical properties.

Table 3: Overview of physicochemical properties of BCPS from ECHA (2023b)

Property	Value
Physical state at 20 °C and 101.3 kPa	White solid
Melting/freezing point	147 to 150 °C at 101.3 kPa
Boiling point	397 °C at 101.3 kPa; decomposition close to boiling temperature
Vapour pressure	5.1×10^{-6} Pa at 20 °C
Density	1.504 g/cm^3 at 20 °C
Water solubility	0.86 mg/L at 20 °C
n-octanol/water partition coefficient (log K_{OW})	3.9 at 20 °C

ECHA (2023b) reports calculated Henry's Law Constants (HLC) of 1.37×10^{-7} atm m^3/mol (bond method) and 2.50×10^{-7} atm m^3/mol (group method), from HENRYWIN v3.20 (EPISuite™ v4.11; (US EPA, 2026)). The Agency notes that whilst there is no universally accepted applicability domain for these models, the molecular weight of BCPS is within the range covered by the training set, and aromatic carbon-hydrogen and carbon-chlorine bonds are represented by the training set compounds (US EPA, 2026). However, the sulfone group is not represented in the model training set, and coefficient values for S=O bonds are only estimated based on sulphate data. In addition, BCPS has more aromatic carbon-sulfur bonds than the maximum number of instances of these bonds occurring in any of the training set compounds. Therefore, estimates of the Henry's Law Constant obtained from HENRYWIN may be less accurate for BCPS.

2.2 Mandatory classification and labelling

BCPS is not listed on the GB mandatory classification and labelling (MCL) list nor on Annex 6 of Regulation (EC) No 1272/2008.

2.3 Environmental fate properties

2.3.1 Degradation

2.3.1.1 Abiotic degradation

The information on abiotic degradation presented in ECHA (2023b) is summarised in Table 4.

Table 4: Summary of abiotic degradation data for BCPS

Abiotic degradation process	Information presented	Results / conclusions
Hydrolysis	OECD TG 111, GLP, unpublished study report (2007). Reliable.	No hydrolysis (≤ 10%) of BCPS observed after 21 days at 50 °C (pH 4, 7, and 9).
Oxidation	No experimental data.	Modelled data presented for phototransformation in air.
Phototransformation in air	No experimental data. Calculated atmospheric half-life of BCPS (AOPWIN v.1.92) presented.	BCPS half-life in air calculated as 54.7 days (12-hour day). Predicted sorption of BCPS to atmospheric particulates: 2.7 to 8.3%.
Phototransformation in water	No data.	Data for a structurally similar substance (dapsone, CAS No. 80-08-0) indicated increased photoinduced toxicity to bacteria and therefore potential formation of toxic transformation products (Kawabata *et al.*, 2013).
Phototransformation in soil	No data.	-

2.3.1.1.1 Hydrolysis

Experimental data (considered reliable) presented in ECHA (2023b) indicate that BCPS is hydrolytically stable (Table 4).

2.3.1.1.2 Oxidation

There are no experimental data for oxidation of BCPS presented in ECHA (2023b). Transformation of BCPS in air was modelled using AOPWIN (v.1.92; EPISuite™) with atmospheric oxidation by hydroxyl radicals (Section 2.3.1.1.3).

2.3.1.1.3 Phototransformation/photolysis

Estimations of transformation of BCPS in air (AOPWIN v.1.92) are reported in ECHA (2023b) and presented in Table 4. The Agency notes that the complete training sets for the AOPWIN estimation methodology are not available (US EPA, 2026), and so it is not possible to determine whether BCPS lies within the applicability domain of the model. Calculations assumed an average atmospheric hydroxyl concentration of 5×10^5 OH/cm^3, corresponding to the Northern hemisphere. ECHA (2023b) reports that the calculated atmospheric half-lives for BCPS indicate a potential for long-range transport (half-life > 2 days) according to Annex D of the Stockholm Convention (UNEP, 2025). Half-lives are noted in ECHA (2023b) to be underestimations of actual atmospheric half-lives due to predicted sorption of BCPS to particulates in the air, which may prevent oxidation by

hydroxyl radicals. The presence of BCPS in vapour and particulates from monitoring data is presented as supporting evidence (Norström *et al.*, 2010).

No data on phototransformation in water or soil are presented in ECHA (2023b). The document notes that there is evidence of a similar substance (dapsone) undergoing phototransformation in water, with photoinduced toxicity to bacteria attributed to formation of toxic transformation products (Kawabata *et al.*, 2013). The original study (Kawabata *et al.*, 2013) reports rapid transformation, with complete photodegradation of dapsone within 6 hours in sunlight.

2.3.1.2 Biodegradation

2.3.1.2.1 Biodegradation in aqueous media

2.3.1.2.1.1 Screening tests

One ready biodegradability study (method equivalent to the OECD test guideline (TG) 301C) is summarised in ECHA (2023b) and considered reliable without restrictions (Klimisch 1). Results are summarised in Table 5 and indicate that BCPS is not readily biodegradable. ECHA (2023b) notes that no toxicity controls were included, and any potential adaptation of the sludge was not specified. The Agency notes that the exposure concentration (100 mg/L) was in exceedance of the water solubility (0.86 mg/L at 20 °C).

Table 5: Summary of biodegradation screening data for BCPS

Author / year	Study	Results / conclusions
NITE (1999)	Modified MITI Test (I) (1992) Equivalent to OECD TG 301C GLP, Klimisch 1	Mean of 1% degradation after 28 days (based on biological oxygen demand; BOD) at test substance concentration of 100 mg/L.

2.3.1.2.1.2 Simulation tests

2.3.1.2.1.2.1 Biodegradation in water

No data on biodegradation in water (e.g. OECD TG 309) are presented in ECHA (2023b).

2.3.1.2.1.2.2 Biodegradation in sediment

One water/sediment simulation study is summarised in ECHA (2023b) and assigned reliable without restrictions (Klimisch 1). Results are summarised in Table 6. Degradation DT_{50} values at 20 °C in the dark were converted to 12 °C using Equation 1.

Table 6: Summary of biodegradation data in water/sediment for BCPS

Author / year	Study	Results / conclusions
Unpublished study report (2014)	OECD TG 308 GLP, Klimisch 1	Whole system degradation DT_{50} values of 1,287 and 394 days at 20 °C in a pond[a] and a river sediment system, respectively, equivalent to 2,732 and 836 days at 12 °C.

[a] The Agency notes that ECHA (2023b) identifies both systems as being river systems, but the information in the EU registration dossier (ECHA, 2025) notes a pond system and a river system.

ECHA (2023b) reports half-lives of 2,748 and 842 days at 12 °C. Using the reported 20 °C values converted to 12 °C with Equation 1, the Agency derives corresponding half-lives of 2,732 and 836 days. The Agency-derived values are presented in the table above and are not considered to differ appreciably from those reported in ECHA (2023b).

$$DT_{50(T1)} = DT_{50(T2)} \times exp\left(\frac{E_a}{R} \times \left(\frac{1}{T_1} - \frac{1}{T_2}\right)\right)$$ **Equation 1**

Where $DT_{50(T1)}$ = degradation half-life at 12 °C, $DT_{50(T2)}$ = degradation half-life at 20 °C, E_a = activation energy (65.4 kJ/mol), R = gas constant (0.008314 kJ/K/mol), T_1 = 285.15 K, and T_2 = 293.15 K.

ECHA (2023b) notes that in both systems, the redox potential and dissolved oxygen content of the water indicated aerobic conditions (97 to 196.9 mV and 7.94 to 8.73 mg/L, respectively), but the redox potential of the sediment indicated anaerobic conditions (-382.2 to -163 mV) and was generally below the typical range for the sediment anaerobic zone stated in the test guideline. The sediment redox potential was also measured at an unknown depth. ECHA (2023b) states that as BCPS dissipated gradually from the water to the sediment, there was sufficient time under aerobic conditions for degradation to occur.

Tests were carried out with nominal radiolabelled (^{14}C) BCPS concentrations of 0.37 and 0.30 mg/L in the two systems. Negligible degradation was observed in both systems over the course of the study (0 to 100 days), with 0.4 and 0.5% applied radioactivity (AR) as carbon dioxide at study end in the two systems and no degradation products ≥ 5% AR at two consecutive sampling intervals. ECHA (2023b) notes that the DT_{50} values are greater than the study duration of 100 days, but that the results suggest that ≥ 50% primary degradation is unlikely to occur over a subsequent 80-day period at 20 °C. The DT_{50} values for the total systems can be considered equivalent to DT_{50} in sediment, as BCPS adsorbs to sediment (sediment concentrations increased from 10.3 and 12.8% AR on day 0 to 82.4 and 81.1% AR on day 100; water dissipation half-lives of 7.1 and 6.2 days were reported).

The Agency notes that the number of replicates and controls, and details of analytical methods, are not described in ECHA (2023b) although duplicate experiments appear to

have been carried out. Overall, there is no information to indicate that the study is not reliable. Given that aerobic conditions were maintained in the water throughout the study, it is likely that aerobic conditions existed at the sediment surface and therefore the anaerobic conditions measured at an unknown depth should not affect the reliability of the study. The Agency notes that the DT_{50} values should however be treated with caution, as they were extrapolated well beyond the study period of 100 days.

2.3.1.2.2 Biodegradation in soil

No data on biodegradation in soil are presented in ECHA (2023b).

2.3.1.3 Field data

ECHA (2023b) provides a summary of BCPS concentrations in water, sediment, sewage sludge, and air. Data for BCPS in soil were noted as not available. These data are further summarised in Table 7 for aqueous samples, Table 9 for sediment and sludge, and Table 10 for air. For some studies, the Agency has examined the original datasets and obtained different values to those presented in ECHA (2023b); these data are noted in Table 7.

The reliability of these monitoring data was not assessed in ECHA (2023b). The Agency does not consider that these data add further weight to the persistence assessment of BCPS (Section 2.3.1.4) and has therefore not assessed the reliability of the studies.

Table 7: Summary of water monitoring data for BCPS

Matrix	BCPS concentration (µg/L)	Date	Location	References
Surface water	0.004 to 0.12	2012 to 2017	England, UK	Environment Agency (2025)[a]
Groundwater	0.007 to 0.08			
Lake water	Detected (not quantified)	1991, 1992	Italy	Guzzella and Sora (1998)
Raw water	0.01 to 0.11	2003	Sweden	Arnér *et al.* (2004)
Estuarine water	0.003 to 0.32	2012 to 2017	England, UK	Environment Agency (2025)
	6.8×10^{-4}	1990	Germany	Bester *et al.* (2001)
Seawater	8×10^{-5} to 2.2×10^{-3}	1990 to 2017	Various locations in Europe	Bester *et al.* (2001); Norström *et al.* (2010); Unpublished data (2017)
Landfill leachate	0.01[a]	2012 to 2017	England, UK	Environment Agency (2025)

Matrix	BCPS concentration (µg/L)	Date	Location	References
Wastewater influent	n.d. to 3.9[b]	2003 to 2020	Various locations in Europe	Arnér *et al.* (2004); Norström *et al.* (2010); Unpublished report (2017); Unpublished report (Unweltbundesamt, 2020)
Wastewater effluent	$< 5 \times 10^{-5}$ to 0.017[c]	2020	Austria	Norström *et al.* (2010); Unpublished report (Unweltbundesamt, 2020)

[a] ECHA (2023b) reports values from the Environment Agency's National Laboratory Service for surface water, groundwater, and landfill leachate of 0.004 to 0.4, 0.007 to 0.3, and 0.01 to 1 µg/L, respectively; the Agency has examined the original dataset and obtained different values, which are presented in this table.

[b] The Agency notes that ECHA (2023b) summarises the maximum wastewater influent concentration as 17 µg/L, which appears to be a transcription error from a value of 17 ng/L (0.017 µg/L) reported by Norström *et al.* (2010). The value of 3.9 µg/L reported by Arnér *et al.* (2004) is higher than 0.017 µg/L. In addition, the value of 0.017 µg/L reported by Norström *et al.* (2010) corresponds to wastewater effluent, not wastewater influent.

[c] A value of 17 ng/L (0.017 µg/L) is reported for wastewater influent in ECHA (2023b), however the original study reports this value for wastewater effluent (Norström *et al.*, 2010) and so it has been summarised as such here.

For completeness, the Agency has summarised Environment Agency monitoring data for 2018 to 2025 in Table 8. These values were sourced from semi-quantitative scan data so are only approximate (Environment Agency, 2025).

Table 8: Summary of monitoring data for BCPS in the UK from 2018 to 2025

Matrix	BCPS concentration (µg/L)	Date	Location	References
Surface water	0.003 to 3	2018 to 2025	England, UK	Environment Agency (2025)
Groundwater	0.005 to 0.008			
Estuarine water	0.002 to 2.3			
Seawater	0.002 to 0.026			

Table 9: Summary of sediment and sewage sludge monitoring data for BCPS

Matrix	BCPS concentration (µg/kg)[a,b]	Date	Location	References
Sediment	< 4 to 14	2003 to 2017	Various locations in Europe	Arnér *et al.* (2004); Norström *et al.* (2010); Unpublished data (2017)
Sludge	10 to 2,000	2003	Sweden	Arnér *et al.* (2004)

[a] The Agency notes that for all detections of BCPS in sediment (8.1 to 14 µg/kg), it is not specified whether data correspond to sediment wet or dry weight, and the Agency has been unable to verify this information from the unpublished study (Unpublished data, 2017). Remaining data for sediment, which are below LOQ values of 10 and 4 µg/kg (Arnér *et al.*, 2004; Norström *et al.*, 2010), correspond to sediment dry weight.

[b] Data for sludge correspond to sludge dry weight.

Table 10: Summary of air monitoring data for BCPS

Matrix	BCPS concentration (ng/m^3)	Date	Location	References
Air	0.05 to 0.3	2003	Sweden	Arnér *et al.* (2004)

2.3.1.4 Summary and discussion of degradation

BCPS screens as potentially P/vP based on the results of a ready biodegradability study. The Agency notes that toxicity control tests were not performed in the study. In addition, the test concentration of BCPS (100 mg/L) was approximately two orders of magnitude above its water solubility (0.86 mg/L), so bioavailability of BCPS in the test system may have been rate limiting. BCPS is not expected to undergo hydrolysis (based on experimental data), or oxidation (based on modelled data for air). It may have the potential for rapid photodegradation in water by analogy with the structurally similar substance dapsone (which has amine groups in place of the chlorine atoms in BCPS). However, the influence of photodegradation in the aquatic environment is limited by depth, shading and quenching effects.

A water/sediment simulation study provides direct evidence that BCPS fulfils the P/vP criteria. Estimated degradation DT_{50} values for pond and river sediment systems are derived as ≥ 836 days at 12 °C in the dark. The Agency notes that there is some uncertainty associated with the derived degradation DT_{50} values as they were extrapolated beyond the end of the study period of 100 days; however, negligible degradation and mineralisation were observed over the course of the study (≤ 0.5% AR as CO_2 at study end).

Field data demonstrate that BCPS is present in the environment; the reliability of these data were not assessed. The Agency notes that these data do not provide direct evidence

of persistence, as environmental concentrations also depend on the sources of BCPS, their spatial and temporal separation from the sampling sites, and overall emissions. The Agency therefore concludes that only the water-sediment simulation data are relevant in the weight-of-evidence.

2.3.2 Bioaccumulation

2.3.2.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

2.3.2.1.1 Screening data

ECHA (2023b) reports an experimental log K_{OW} of 3.9 at 20 °C for BCPS (OECD TG 107). Measured and estimated log K_{OW} values of 3.9 are also reported (KOWWIN v1.68, EPISuite™ v4.1). Therefore, the screening criterion for potential bioaccumulation in aquatic organisms (log K_{OW} > 4.5) is not fulfilled.

2.3.2.1.2 Aquatic bioaccumulation data

One experimental aquatic bioaccumulation study is reported in ECHA (2023b). This was conducted to GLP. ECHA (2025) provides reference to two test guidelines - a Japanese guideline "Bioaccumulation test of a chemical substance in fish or shellfish" provided in "the Notice on the Test Method Concerning New Chemical Substances" and the 1996 version of the OECD TG 305, where a deviation is noted '*no lipid normalized BCFs are reported, no depuration observed*'. The study investigated the bioconcentration of BCPS (test material: "K-1200") in *Cyprinus carpio* (Common carp) at a temperature of 25.1 ± 0.6 °C (ECHA, 2025). Fish were exposed under flow-through conditions for 35 days, with the exposure phase extended to ensure attainment of steady state. Steady-state bioconcentration was considered to be achieved, as the mean bioconcentration factor (BCF) values determined at 21, 28, and 35 days varied by less than 20%.

Exposure was performed at two nominal test concentrations, 5 and 50 µg/L, both of which were well below the reported water solubility of the substance (0.86 mg/L at 20 °C). A dispersant (hydrogenated castor oil; HCO-40) was used to aid test substance delivery. The fish had a lipid content of approximately 2%, measured at both the start and end of the exposure period.

Prior to exposure, fish were acclimated for 21 days at 25 °C under flow-through conditions, followed by a further 19-day acclimation period in the test tanks at 25 °C. The details are summarised in Table 11.

Table 11: Summary of experimental aquatic bioaccumulation data for BCPS

Author / year	Study	Results / comments
NITE (2001)	OECD TG 305 (1996 version) using *C. carpio*) GLP, Klimisch score 2	BCF_{SS} at 5 µg/L BCPS: 187.5 L/kg BCF_{SS} at 50 µg/L BCPS: 205 L/kg Values normalised to 5% lipid content.

ECHA (2023b) considers the study to be reliable with restrictions (Klimisch 2) based on the following limitations: no depuration phase was carried out (so a depuration rate constant and kinetic BCF could not be determined), the test item was not radiolabelled, and lipid normalised BCF values were not reported in the original study (but could be calculated from the reported fish lipid content). It is noted that the updated OECD TG 305 (OECD, 2012) states that a depuration phase is always necessary, except where uptake is insignificant during the uptake phase.

The Agency fully reviewed the original study report (NITE, 2001) and agrees with the reliability assessment of ECHA (2023b), but notes the following further limitations: total organic carbon measurements were not carried out; it is not stated whether tanks were cleaned shortly after feeding; limit of quantitation (LOQ) values were determined through extrapolation; and fish weights were not recorded. The Agency notes that *C. carpio* exhibit moderate to slow growth relative to other bioaccumulation test species, such as *Oncorhynchus mykiss* (Rainbow Trout), which are considered fast-growing. There are currently no established methods for growth-correction of a steady-state BCF (OECD, 2012). All other validity criteria according to the guideline were met.

2.3.2.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

2.3.2.2.1 Screening data

The measured log K_{OW} is 3.9 at 20 °C (Section 2.1.5). An estimated log K_{OA} value of 9.2 at 20 °C is reported in ECHA (2023b) using EPISuite™ model KOAWIN v1.10. These data indicate a potential for bioaccumulation in air-breathing organisms based on screening criteria (log K_{OW} > 2 and log K_{OA} > 5) (ECHA, 2017a). ECHA (2023b) reports that the KOAWIN model is expected to be applicable to BCPS. The Agency notes that BCPS falls within the molecular weight, log K_{OW}, and Henry's Law Constant ranges of the experimental dataset (noting that KOAWIN does not have a training set domain), and there is some representation of aromatic carbon-chlorine and S=O groups. However, aromatic carbon-sulfur and sulfone functional groups are not covered by the dataset (US EPA, 2026). In addition, experimental data are preferred as inputs to the KOAWIN model, and a predicted Henry's Law Constant (1.37×10^{-7} atm m^3/mol, HENRYWIN) has been used; the Agency also notes that HENRYWIN may be less accurate for BCPS (Section 2.1.5).

KOAWIN is also less accurate for log K_{OA} values ≥ 8 (US EPA, 2026). Therefore, there are uncertainties associated with the estimated log K_{OA} for BCPS.

2.3.2.2.2 Toxicokinetic data

The results of two toxicokinetic studies are presented in ECHA (2023b) and summarised in Table 12.

Table 12: Results of rat toxicokinetic studies with BCPS presented in ECHA (2023b)

Author / year	Study	Results / comments
Mathews *et al.* (1996)	Similar to OECD TG 417 using Fischer 344 (F344) rats Non-GLP, Klimisch score 2	A terminal elimination half-life[a] in adipose of approximately 10 to 12 days was estimated for a single intravenous dose of BCPS at 10 mg/kg body weight (bw). BCPS distributed rapidly from blood to tissues (tissue:blood ratio of 90 by 24 hours), predominantly to adipose in both intravenous and oral dose studies (41 and 49%, respectively, for single doses of 10 mg/kg bw).
Poon *et al.* (1999)[b]	Non-guideline study using Sprague-Dawley rats Non-GLP, Klimisch score 2	BCPS predominantly distributed to adipose after repeated oral dosing for four weeks at 0, 0.8, 8.1, and 75.6 mg/kg bw/day, and the concentration remained unchanged between one and four weeks.

[a] The terminal half-life refers to the half-life after equilibration of BCPS distribution between tissues; the half-life was estimated for days 1 through 21 as the tissue to blood ratio in adipose remained constant after approximately 24 hours (Mathews *et al.*, 1996).

[b] The Agency notes that this study focussed primarily on distribution and metabolism aspects and therefore not all toxicokinetic endpoints were considered. However, the data confirm observations noted in Mathew (1996) and are therefore presented.

The Agency considers that Mathews *et al.* (1996) and Poon *et al.* (1999) are key papers for determining whether BCPS is bioaccumulative in air-breathing organisms.

- Mathews *et al.* (1996)

Mathews *et al.* (1996) report a non-GLP study that is similar to the current OECD TG 417 (OECD, 2010). The work was instigated because unpublished data indicated that BCPS is readily absorbed and distributed following exposure, with evidence of accumulation in adipose tissue and the occurrence of various sublethal effects.

The study was designed to characterise the absorption, distribution, metabolism, and excretion of BCPS in F344 rats following both intravenous and oral exposure. Intravenous administration was included to represent complete systemic availability (100 % absorption), allowing intrinsic distribution and elimination kinetics to be assessed

independently of gastrointestinal absorption. Oral exposure was investigated to characterise uptake following the most relevant exposure route for mammals. Only male F344 rats were used, in line with recommendations for mammalian bioaccumulation studies, to avoid variability related to sex-specific physiological differences.

For all exposure scenarios, the rats received a mixture of carbon-14 radiolabelled (^{14}C)-BCPS and an appropriate amount of unlabelled BCPS. Both single-dose (intravenous and oral) and repeated-dose (oral) experiments were conducted. For the single-dose experiments, BCPS doses of 10 mg/kg bw (intravenous) or 10, 100, and 1,000 mg/kg bw (oral) were applied, with three to five animals per treatment group. In the repeated-dose studies (four animals per treatment group), animals were either dosed daily for seven consecutive days at 1, 10, and 100 mg/kg bw, or in a longer-term experiment five times per week for periods of two, three, or five weeks at 10 mg/kg bw only.

A broad range of tissues was analysed, including adipose tissue, skin (analysed in triplicate for each animal), three different muscle types, blood, liver, kidney, and gastrointestinal tract. Sample preparation procedures were described separately for different tissue types. Recovery of radiolabelled material was generally greater than 80%, indicating a borderline acceptable mass balance. Urine collected from days 7 to 9 following repeated dosing at 100 mg/kg/day was used for metabolite characterisation, with approximately 95% radiochemical recovery. Additional groups of rats were dosed orally with 0 (vehicle control), 1, 10, or 100 mg/kg/day BCPS for seven days for the investigation of hepatic protein content, cytochrome P450 levels, and enzyme activities; these animals were sacrificed 72 hours after the final dose.

Following single dose exposure, BCPS was shown to distribute widely following both intravenous and oral administration, with quantifiable levels detected in adipose tissue, blood, kidney, liver, muscle, skin, small intestine, caecum, and large intestine 72 hours after dosing. In both exposure routes, adipose tissue contained the highest fraction of the administered dose, accounting for approximately 41% and 49% of total recovered radioactivity following intravenous and oral administration, respectively, at a dose of 10 mg/kg. Comparison of the 10 mg/kg intravenous and oral exposures demonstrated that the oral dose was almost completely absorbed and distributed in a manner closely resembling that of the intravenous dose. Tissue-to-blood ratios and overall excretion profiles were not meaningfully affected by the route of administration, further supporting efficient oral absorption.

At the highest oral dose (1,000 mg/kg), BCPS remained well absorbed, with approximately 50% of the administered dose recovered in tissues and around 10% recovered in urine. However, a higher fraction of the dose was recovered in faeces (approximately 20%, compared with 5 to 10% at lower doses), suggesting some reduction in absorption at very high dose levels. Increased urinary excretion with increasing dose was also observed, consistent with dose-dependent induction of metabolic pathways. Only trace amounts of parent BCPS were detected in urine. The presence of parent compound in faeces was

attributed largely to unabsorbed material, although BCPS was also detected in faeces following intravenous dosing, suggesting that passive partitioning and biliary secretion may also contribute. Cumulative excretion in urine and faeces over 72 hours accounted for approximately 13% of the dose following intravenous administration and 20% following oral administration.

Adipose tissue contained approximately 49%, 43%, and 37% of the administered dose 72 hours after oral dosing at 10, 100, and 1,000 mg/kg, respectively. Elimination was slow but approximately linear for 0 – 24 hours, 24 – 48 hours, and 48 – 72 hours post-dose. Total mean cumulative excretion was 20%, 27%, and 29% for the 10, 100, and 1,000 mg/kg dose groups, respectively. The authors noted that BCPS distributed rapidly from blood into tissues, with tissue-to-blood ratios for adipose reaching ~90 within 24 hours of administration and remaining at this level for at least 21 days.

Repeated oral-dose studies were conducted in response to indications of potential bioaccumulation from single-dose experiments. The proportion of the administered dose present in adipose tissue was approximately 41%, 28%, and 20% 72 hours after completion of a seven-day repeat oral dosing regimen at 1, 10, and 100 mg/kg/day, respectively; 31%, 49%, and 54% of the dose had been excreted in urine and faeces. Total recovery from tissues and excreta ranged from 85% to 94%, indicating acceptable mass balance. The results demonstrate a dose-dependent increase in excretion accompanied by a decrease in the fraction retained in adipose tissue, muscle, and skin compared with single-dose exposure.

Longer-term studies employing repeated oral dosing at 10 mg/kg/day (five days per week) for two, three, or five weeks showed that BCPS equivalents in adipose tissue accounted for approximately 20%, 15%, and 7% of the administered dose at the respective time points. Total radioactivity in all analysed tissues declined over time (28%, 23%, and 10% at two, three, and five weeks, respectively). Radiochemical concentrations in adipose tissue and blood peaked at approximately three weeks, with a slight decline observed by five weeks, while levels in kidney, liver, and skin approached maximal values by approximately two weeks and then remained relatively constant. In the three- and five-week studies, the amount of BCPS excreted during the final week was 99 and 106% of the administered dose during that period, respectively, indicating that steady state had been reached after approximately two to three weeks of repeated exposure.

Additional tissues, including adrenal gland, brain, lung, prostate, seminal vesicle, spleen, testes, and thymus were analysed, although quantitative data for these organs were not reported.

Based on graphical presentation of tissue and excretion data following a single intravenous dose of 10 mg/kg, the terminal half-life of BCPS in adipose tissue was estimated at approximately 12 days over the period from day 1 to day 21 post-dose. This is

the time required for the concentration of the substance to decrease by exactly 50% during its final elimination phase, after it has distributed throughout the body.

Three primary metabolites were identified in urine and faeces, including a glucuronide conjugate, an aglycone, and a composite metabolite referred to as “metabolite A”, which comprised several components. Parent BCPS was detected almost exclusively in faeces and was predominant only at the highest dose level (1,000 mg/kg). Bile collected following a 10 mg/kg dose contained almost exclusively conjugated metabolite, indicating that biliary excretion was the major source of metabolites detected in faeces. Compared with single-dose exposure, the proportion of parent compound in faeces decreased by approximately 50% following repeated administration, with corresponding increases in conjugated and aglycone metabolites.

Radiochemical analysis showed that parent BCPS accounted for at least 90% of the total BCPS equivalents present in skin, muscle, adipose tissue, and liver 72 hours after oral dosing at 10, 100, and 1,000 mg/kg, with the exception of liver tissue at 1,000 mg/kg, where parent compound represented approximately 80%. At all doses, radioactivity in adipose tissue consisted almost entirely of unchanged parent compound.

The Agency considers that the study of Mathews *et al.* (1996) is of general high quality, with detailed descriptions of experimental methods, extensive investigation of tissue distribution and excretion pathways, and inclusion of multiple doses, exposure routes, and repeated-dose regimens. Use of only male rats, radiolabelled compound of high purity (~98%), and detailed metabolite characterisation further support reliability.

However, several limitations introduce uncertainty. The overall recovery of the radiolabel was approximately 80%, whereas OECD TG 417 states that recoveries of administered test substance in the order of > 90% are generally adequate. Control groups were clearly described only for the repeated-dose studies. Statistical analyses were not presented. The derivation of the reported adipose tissue half-life was not described in detail, and no explicit elimination rate constants were reported. Body weight data and growth correction were not provided, and lipid content of adipose tissue was not quantified. The Agency therefore considers the study to be reliable with restrictions (Klimisch 2).

- Poon *et al.* (1999)

Poon *et al.* (1999) conducted a non-GLP sub-chronic oral toxicity study to investigate the short-term (28-day) effects of BCPS in male Sprague–Dawley rats. The primary aim of the study was to identify target organs, characterise systemic, biochemical, and metabolic effects following repeated dietary exposure, and determine the tissue distribution of BCPS. In particular, the study focused on assessing hepatic, renal, and haematological responses, as well as evaluating the absorption and accumulation of BCPS in different tissues after repeated exposure.

Animals (n = 6 per group) were exposed via the diet to 0, 10, 100, or 1,000 ppm (0 to 76 mg/kg bw/day) BCPS for up to four weeks, with additional control and high-dose groups sampled at weeks 1, 2 and 3 to evaluate time-course effects.

In brief, BCPS exposure produced clear, dose-dependent toxicological responses, with the liver identified as the primary target organ. Effects included increased liver weight, marked induction of hepatic microsomal enzymes (predominantly CYP2B-associated activities), increased phase II metabolism (UDPGT and GST), elevated urinary ascorbic acid, hypercholesterolaemia, and increased hepatic lipid peroxidation at the highest dose.

Toxicokinetic data demonstrated pronounced, dose-related accumulation of BCPS in tissues, with distribution following the order adipose ≫ liver > kidney ≫ brain, spleen, and lung (Table 13). Adipose tissue contained the highest concentrations, confirming the strongly lipophilic nature of BCPS.

Table 13: Mean (± standard deviation) tissue BCPS residues (µg/g wet weight) in rats following 4-week dietary exposure at different dose levels, taken from Poon *et al*. (1999)

BCPS in diet (ppm)	Lung	Spleen	Brain	Kidney	Liver	Adipose (abdominal fat)
0	0	0	0	0	0	0
10	2.0 ± 0.4	1.1 ± 0.2	1.0 ± 0.2	2.3 ± 0.8	5.1 ± 1.0	69 ± 9
100	7.3 ± 3.9	5.8 ± 1.8	5.2 ± 0.9	7.6 ± 1.6	29 ± 7.9	450 ± 120
1000	16 ± 4.2	18 ± 3.4	19 ± 2.5	33 ± 9.3	77 ± 8.2	1600 ± 110

BCPS levels in liver and adipose reached steady state by week 1, whereas kidney concentrations increased with time, suggesting potential for progressive renal burden with longer exposure. Hepatic and biochemical effects were apparent from the lowest dose tested (10 ppm in diet, approximately 0.8 mg/kg bw/day). A no-observed adverse effect level (NOAEL) was not established but was concluded in the paper to be below 0.8 mg/kg bw/day.

The Agency review highlighted that:

- At the highest dietary concentration (1,000 ppm), BCPS exposure resulted in a statistically significant reduction in food consumption and a consequent depression in growth rate (approximately 7%) compared with controls.
- Reduced growth observed at this dose was considered, by the authors, likely secondary to decreased food intake (considered partly secondary to palatability) rather than a direct manifestation of systemic toxicity.

- Marked haematuria (blood in the urine) was observed in one high-dose animal in each of the 1-, 3- and 4- week exposure groups, indicating potential renal involvement at this dose level. No overt clinical signs of toxicity were reported at lower concentrations.

- Significant, dose-related changes in organ weights were observed. An increased liver-to-body weight ratio was detected at 100 ppm, while an increased kidney-to-body weight ratio occurred at the highest dose (1,000 ppm). These findings are consistent with the identification of the liver as the primary target organ and suggest possible renal involvement at high exposure levels.

- BCPS induced hepatic enzymes, including cytochrome P450, UDP-glucuronosyltransferase (UDPGT) and glutathione S-transferase (GST).

The Agency considers that overall, BCPS induced clear hepatic effects at the lowest dose tested (10 ppm in the diet, corresponding to approximately 0.8 mg/kg bw/day). The liver was identified as the most sensitive and prominent target organ, characterised by hepatomegaly and marked induction of microsomal enzyme activities.

The Agency concludes that this study provides robust evidence that BCPS is readily absorbed, widely distributed, and accumulates predominantly in adipose tissue, with sustained internal exposure and target-organ effects at low doses. While acute toxicity was limited, the demonstrated bioaccumulation and early onset of systemic effects support concern for potential adverse outcomes following long-term exposure. The Agency agrees with a reliability score of Klimisch 2.

2.3.2.3 Field data

2.3.2.3.1 Biomonitoring data

ECHA (2023b) reports extensive monitoring data indicating the presence of BCPS in several wildlife species across trophic levels. However, the reliability of this information is not assessed in ECHA (2023b). The Agency has therefore reviewed the original studies where possible (unless otherwise stated) and assessed their reliability in terms of general considerations surrounding analytical methods and study design, as well as based on recommendations given in relevant guidance (ECHA, 2023c; OECD, 2024). Reliability scores were then confirmed by the Agency using Criteria for Reporting and Evaluating Exposure Datasets (CREED) at the Silver level (Merrington *et al.*, 2024). The data are summarised in Table 14.

ECHA (2023b) disputes a claim from the EU REACH registrant(s) of BCPS that high levels of BCPS in biota are due to historical usage of DDT (with BCPS used intentionally as an insecticide, or being present as an impurity in insecticides containing DDT), noting that 4,4’-DDE (a DDT metabolite) concentrations decreased between 1971 and 2001 (with

DDT banned in 1983), whereas BCPS concentrations increased from 1996 to 2003 (Jörundsdóttir *et al.*, 2008; Jörundsdóttir *et al.*, 2006). It is also noted that DDT and its metabolites were not detected in fish in 2019, whereas BCPS was detected in all samples (Hornek-Gausterer *et al.*, 2021). BCPS is also expected to be less persistent than DDT and 4,4'-DDE.

The Agency notes that concentrations of 4,4'-DDE of 950 µg/g lw (1971) to 10 µg/g lw (2001) reported in ECHA (2023b) are reported as 950 to 10 ng/g lw in the original study (Jörundsdóttir *et al.*, 2006). In addition, when comparing BCPS concentrations over the same time period as data for 4,4'-DDE (1971 to 2001), BCPS concentrations also decrease, with a slope of -1.6% for BCPS compared with -16% for 4,4'-DDE (Jörundsdóttir *et al.*, 2006). Similarly, there are no statistically confirmed trends for either BCPS or DDT for 1996 to 2003 (Jörundsdóttir *et al.*, 2009; Jörundsdóttir *et al.*, 2006). The increase in BCPS concentrations in bird eggs for this time period reported in ECHA (2023b), 890, 1,000, and 1,100 ng/g lw for 1996, 2001, and 2003 respectively, can be called into question when using the average concentration of 1,000 ng/g lw in 2003 reported by Jörundsdóttir *et al.* (2009), rather than that of Jörundsdóttir *et al.* (2008). However, the Agency agrees overall that the presence of BCPS in biota cannot be attributed only to historic BCPS usage in agriculture, based on the data of Hornek-Gausterer *et al.* (2021) combined with the expected faster degradation of BCPS compared to DDT and the slower reduction in BCPS concentrations between 1971 and 2001 (Jörundsdóttir *et al.*, 2006).

Table 14: Summary of monitoring data for BCPS in wildlife, with Agency reliability scores and comments on reliability

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
Olsson and Bergman (1995)	Latvian coast	1994	Perch (30)	Unknown	Muscle (30)	Not reported (N.R.)	N.R.	(40 to 100)	--	Reliability 4. Not accessible to the Agency.
	Sweden	1987	White-tailed Sea Eagle (1)	Unhatched	Egg (1)			(500)		
		1993	Grey Seal (3)	Unknown	Blubber (3)			(53 to 88)		
Olsson *et al.* (1999)	Latvian coast	1994 to 1995	Perch (62)	Live caught	Muscle (62)	N.R.	N.R.	Arithmetic mean 55 to 82 (38 to 100)	--	Reliability 4. Unclear whether LOD/LOQ values were determined. Method of BCPS quantitation and validation details not reported.
Valters *et al.* (1999)	Latvia	1997	Perch (23)	Unknown	Muscle	N.R.	100%	Geometric mean 32 to 160 (28 to 190)	--	Reliability 4. Not accessible to the Agency.
Arnér *et al.* (2004)	Sweden	2003 to 2004	Perch (49)	Live caught	Muscle (28)	LOD: 1,900 ng/g lw (10 ng/g ww) LOQ: N.R.	0%	Not detected (n.d.)	n.d.	Reliability 4. No information on methods for identification, calibration, or quantitation. No mention of blanks or recovery. GC-MS parameters and Selected Ion Monitoring (SIM) not described in detail.
Norström *et al.* (2004)	Sweden	1971 to 1999	Fish spp. (83, pooled	Live caught	Muscle (13)	LOD: 0.2 ng	77%	(n.d. to 37)	(n.d. to 2.79)[b]	Reliability 2.

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
			into 13 samples)			LOQ: 0.6 ng				Age not reported for some individuals. Sex of individuals not reported.
		1989	Guillemot (10, pooled into 2 samples)	Unknown	Muscle (2)		100%	(1,600 to 1,900)	(54.4 to 60.8)[b]	
		1995 to 1997	Grey Seal (9)	Killed by accidental drowning in fishing nets	Blubber (5)		100%	(49 to 480)	(43.6 to 153.6)[b]	
Norström *et al.* (2010)	Baltic Sea	2008 or not reported	Perch, herring (110)	Unknown	Muscle (11)	N.R. BCPS reported to be > LOD in all samples	100%	(17 to 69)	(0.2 to 1.7)[b]	Reliability 2. Age and sex of individuals not reported. Sampling year not reported for some samples. LOD not reported (but BCPS concentration > LOD in all samples).
Hornek-Gausterer *et al.* (2021)	Austria	2019	Fish spp. (8)	Live caught, except one fish found in stomach of cormorant	Whole body (8)	LOD: 0.33 to 3.7 ng/g lw LOQ: 0.66 to 7.3 ng/g lw	100%	(1.3 to 9.3)	(0.09 to 0.4)[b]	Reliability 2. Sex was reported for only some individuals. Specific detail of quantitation and calibration method not described.
		2001 to 2005, and 2019	Cormorant (11)	Killed by shooting	Muscle (11) and liver (6)	Muscle LOD: 1.2 to 7.4 ng/g lw Muscle LOQ: 2.3 to 17 ng/g lw Liver LOD: 1 to 2.7 ng/g lw	100%	Muscle: (2.8 to 40) Liver: (28 to 86)	Muscle: (0.06 to 1.5) Liver: (1.1 to 3.5)	

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
						Liver LOQ: 2 to 5.5 ng/g lw				
Letcher *et al.* (1995)[c]	Canada	1989	Gull (1)	Unknown	Egg (1)	--	100%	Detected	Detected	Reliability 4. Not accessible to the Agency.
Helander *et al.* (2002)	Baltic Sea	1970 to 1976, and 1987 to 1991	White-tailed Sea Eagle (20)	Dead eggs which failed to hatch	Egg (21)	LOD: 1 ng/g lw LOQ: N.R.	71%	(n.d. to 610)	(n.d. to 149)[b]	Reliability 4. CREED Reliability 2 based on: details of calibration, identification and quantitation, and method of determining LOD are not reported; recovery of surrogate standard for BCPS not reported. The Agency considers Reliability 4 to be more appropriate as no blank analysis was described. The clean-up method was not optimised for BCPS and the authors noted this may explain the large variation in the data.
Verreault *et al.* (2005)	Norway (Arctic)	2002 and 2004	Gull (87)	Live caught	Blood plasma (87)	LOD: 0.001 to 0.35 ng/g ww LOQ: N.R.	100%	Arithmetic mean 19.5 to 26.5 (5.24 to 143)	--	Reliability 1.
Jörundsdóttir *et al.* (2006)	Baltic Sea	1971 to 2001	Guillemot (35)	Replacement eggs	Egg (35)	N.R.	100%	Geometric mean 890	--	Reliability 2.

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
				(following lost eggs)		BCPS reported to be > LOQ in all samples		to 1,500 (760 to 2,600)		Blanks and recovery determined, however unclear whether samples were corrected. Method of determining LOQ and some details of quantitation (such as calibration) not reported.
Jörundsdóttir *et al.* (2009)[d]	Iceland, Faroe Islands, Sweden, Norway	2002 to 2005	Guillemot (60)	Collected live	Egg (60)	LOD: 3.2 ng/g lw LOQ: N.R.	98%	Geometric mean 6.2 to 1,000 (n.d. to 1,300)	--	Reliability 2. Method of identification and quantitation not described in detail. Samples only corrected for surrogate standard recovery (87.4%), whereas BCPS recovery was lower (69 – 80%).
Millow *et al.* (2015)[e]	San Diego Bay	2011	Black Skimmer (4)	Collected live	Egg (4)	N.R.	75%	Detected, not quantified	Detected, not quantified	Reliability 1. CREED was not used to assess the reliability of this study, as CREED does not cover non-target screening studies.
Larsson *et al.* (2004)	Baltic Sea	2000 to 2001	Grey Seal (10)	Killed by accidental drowning in fishing nets	Liver (20), lung (20), and blubber (20)	LOD: N.R. LOQ: 3.5 ng	100%	Liver: median 200 (55 to 700) Lung: median 29 (21 to 98)	--	Reliability 2. Not reported whether samples were recovery-corrected (recovery of surrogate standard = 84 ± 16%). Method of quantitation

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
								Blubber: median 60 (41 to 240)		and calibration not described in detail.
Plaßmann *et al.* (2016)	Germany	2013	Human (16)	Living subjects	Blood (16)	Instrument LOD: 20.5 ng/mL extract. Method LOD: 2 ng/mL blood. LOQ: N.R.	0%	n.d.	n.d.	Reliability 2. Details of calibration and LOD determination not reported.
Ellerichmann *et al.* (1998)[c]	Germany	--	Human (6)	Killed by accidents or heart failure	Liver (6) and lung (6)	--	Liver: 100% Lung: 0%	Liver: Detected Lung: n.d.	Liver: Detected Lung: n.d.	Reliability 4. Not accessible to the Agency.
Schlabach *et al.* (2017)[f]	Norway (Arctic)	2017	Bird spp. (30)	Collected live	Egg (30)	LOD: 0.5 ng/g ww LOQ: N.R.	3%	--	(n.d. to 0.20) ng/g ww	Reliability 4. Details of extraction procedure, GC-MS analysis, and standard mixture not described in full. Frequency of use or preparation procedure for lab blanks not described. Method of identification and quantification not described. Unclear LOD for BCPS with same LOD values across species, tissue types, units, and environmental compartments. One
		2013 to 2014	Mink (5)	Unknown	Liver (5)		20%		(n.d. to 0.53) ng/g ww	
		2017	Polar Bear (10)	Unknown	Blood (10)		0%		n.d.	

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
										reported BCPS detection is below apparent LOD. Recovery experiment not performed.
LIFE APEX project[c]	Germany and the Netherlands	2015 and 2019	Bream and eelpout (--)	Unknown	Muscle (3)	LOD: N.R. LOQ: 50.9 to 74 ng/g lw (0.9 ng/g ww) or unknown.	33%	(n.d. to 95.3)	(n.d. to 2.8)	Reliability 4. Not accessible to the Agency.
	Germany	2015 to 2018	Buzzard (--)	Unknown	Liver (1)	LOD: N.R. LOQ: 26.6 ng/g lw (0.9 ng/g ww)	0%	n.d.	n.d.	
	UK, the Netherlands, Sweden, Germany	2015 to 2018	Otter (--)	Unknown	Liver (6)	LOD: N.R. LOQ: 29.9 to 54 ng/g lw (0.9 ng/g ww) or unknown.	67%	(n.d. to 236)	(n.d. to 7.2)	

[a] Reliability classes are defined as: Reliability 1 = reliable without restriction; Reliability 2 = reliable with restrictions; Reliability 3 = not reliable; Reliability 4 = not assignable.

[b] Wet weight concentrations calculated by the Agency from reported lipid weight concentrations and lipid content.

[c] Not known whether analyses were targeted or non-targeted.

[d] An earlier report (Jörundsdóttir *et al.*, 2008) is referenced in ECHA (2023b)for these data. All of the methods described by Jörundsdóttir *et al.* (2008) are the same as in the above study (Jörundsdóttir *et al.*, 2009), and the ranges of BCPS values are identical (however calculated average concentrations are slightly different). The study of Jörundsdóttir *et al.* (2009) has therefore been reviewed and evaluated by the Agency, as the data have been peer-reviewed and more detail is given on the methods and analyses.

[e] Non-target screening study.

[f] Referenced as Screening Programme 2017 in ECHA (2023b).

An additional literature search was conducted to capture additional research on field biomonitoring and mammalian toxicokinetics not covered in ECHA (2023b). Search terms, databases, and numbers of results are presented in Appendix A. Papers were screened first by title and then by abstract to identify studies relevant to BCPS monitoring in wildlife or toxicokinetics. Only three relevant papers were identified. An opinion piece (Sonne *et al.*, 2021) referenced detection of BCPS in Polar Bear fat reported by Liu *et al.* (2018); however the original study, which measured halogenated contaminants in polar bear blood (Liu *et al.*, 2018), does not mention BCPS. These studies were excluded from the evaluation. The two remaining relevant papers relating to field biomonitoring of BCPS in birds and marine mammals are summarised in Table 15.

For the majority of studies assigned Klimisch 4, BCPS concentrations were consistent with those reported in studies classed as reliable or reliable with restrictions (i.e. Klimisch 1 and 2; Table 14 and Table 15). Reliable or reliable with restriction data are presented in Table 15.

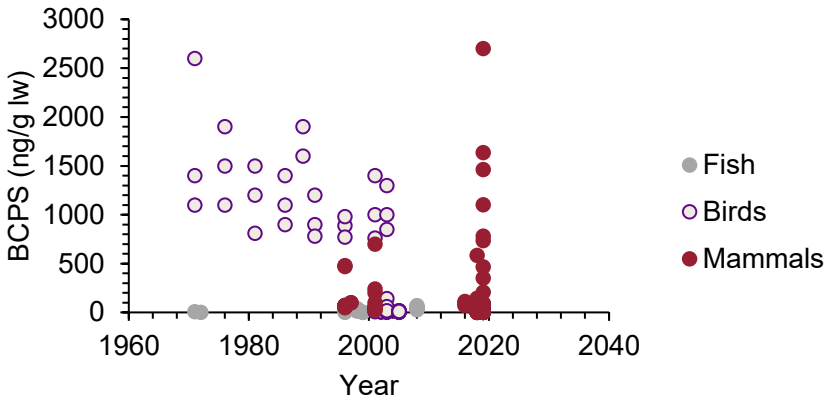


Figure 2 Concentrations of BCPS measured in various tissues from fish, birds, and marine mammals between 1971 and 2019 (from studies classed as Klimisch 1 or 2 by The Agency); non-detects are presented as 0 ng/g lw

Most studies indicate that fish contain lower concentrations of BCPS compared to mammals and birds. However, detailed comparisons between species groups are generally limited by:

- sampling of different tissue types and few data for whole body concentrations;
- sampling across different areas and timeframes which may represent differing levels of exposure; and
- the sampled species potentially representing different trophic levels and habitats.

Table 15: Additional studies with BCPS biomonitoring data reviewed by the Agency

Reference	Sampling location	Sampling year	Species (no. of individuals)	Organism status	Tissues analysed (no. of samples)	LOD and LOQ	Detection frequency	Average BCPS conc. (range) in ng/g lw	Average BCPS conc. (range) in ng/g ww	Agency comments on reliability[a]
Jörundsdóttir *et al.* (2010)	Iceland	2002 to 2004	Arctic Tern (6), Common Eider (10), Common Guillemot (10), Arctic Fulmar (10), Great Black-backed Gull (9), Lesser Black-backed Gull (8), Great Skua (10)	Collected live	Egg (63)	LOD: 3 ng/g lw LOQ: N.R.	N.R.	Close to LOD in all samples	--	Reliability 2. Method of quantitation and calibration for BCPS not described in detail. Unclear use of volumetric standard for BCPS. Actual BCPS concentrations and detection frequency not reported.
Reiter *et al.* (2023)	North Sea and Baltic Sea	2016 to 2019	Harbour Porpoise (7), Harbour Seal (3), Ringed Seal (1), Orca (1)	Killed by stranding, bycatch, or pneumonia and sepsis	Blubber (12), liver (12), kidney (8), and brain (8)	LOD: 3.5 ng / mL extract. LOQ: N.R.	Blubber: 75% Liver: 33% Kidney: 50% Brain: 25%	Blubber: (n.d. to 1,637) Liver: (n.d. to 353) Kidney: (n.d. to 2,702) Brain: (n.d. to 207)	Blubber: (n.d. to 1,560)[b] Liver: (n.d. to 14)[b] Kidney: (n.d. to 63)[b] Brain: (n.d. to 16)[b]	Reliability 2. CREED Reliability 1. The Agency considers Reliability 2 to be more appropriate as the absolute accuracy of quantitative BCPS concentrations is unclear due to the use of an average lipid-polydimethylsiloxane partition coefficient for BCPS quantitation.

[a] Reliability classes are defined as: Reliability 1 = reliable without restriction; Reliability 2 = reliable with restrictions; Reliability 3 = not reliable; Reliability 4 = not assignable.

[b] Wet weight concentrations calculated by the Agency from reported lipid weight concentrations and lipid content.

Caution should be applied in inferring bioaccumulation from organ and tissue concentrations, as chemical concentrations in individual tissues cannot be assumed to represent whole body concentrations (Environment Agency, 2022). Data from some studies suggest higher BCPS levels in the liver rather than fat, lung or muscle in mammals and birds (Hornek-Gausterer *et al.*, 2021; Larsson *et al.*, 2004). Larsson *et al.* (2004) reported that two other sulfone-containing compounds along with BCPS were specifically retained in Grey Seal livers ($p < 0.001$) and suggested this may involve protein binding facilitated by the sulfone groups. This may limit the relevance of concentrations reported on a lipid weight basis. For birds, where both lipid and wet weight concentrations are available, lipid weight concentrations are two orders of magnitude higher (2.8 to 1,900 ng/g lw compared to 0.06 to 60.8 ng/g ww) (Hornek-Gausterer *et al.*, 2021; Norström *et al.*, 2004). However, Reiter *et al.* (2023) found preferential accumulation of BCPS in the blubber of marine mammals compared to their livers, in line with rat toxicokinetic data (see Section 2.3.2.2.1). Lipid weight concentrations of BCPS are more comparable to wet weight concentrations, where available, for marine mammals (n.d. to 2,702 ng/g lw compared to n.d. to 1,560 ng/g ww) (Norström *et al.*, 2004; Reiter *et al.*, 2023).

Data from some studies indicate potentially lower concentrations of BCPS in bird eggs from remote regions compared with those from populated areas, up to a difference of three orders of magnitude (Jörundsdóttir *et al.*, 2009; Jörundsdóttir *et al.*, 2010; Jörundsdóttir *et al.*, 2006); concentrations of BCPS in the surrounding environment were not measured in these studies.

Hornek-Gausterer *et al.* (2021) suggested a potential increase in BCPS concentrations in cormorant muscle over time (2001 to 2019) and with organism age, but the results were for a small sample size ($n = 11$) and were not statistically significant.

Jörundsdóttir *et al.* (2006) reported a statistically significant annual decrease of 1.6% in BCPS concentrations in birds from 1971 to 2001. In contrast, higher concentrations of BCPS were reported in some samples of marine mammals sampled from 2016 to 2019 (Reiter *et al.* (2023), 153 samples across 12 individuals) compared to data for Grey Seals sampled from a similar region between 1996 and 2001 (Larsson *et al.* (2004) and Norström *et al.* (2004); collectively 25 samples across 19 individuals). These three studies analysed BCPS by GC-MS after solvent and/or solid phase extraction, although Reiter *et al.* (2023) employed an additional extraction step (partitioning to polydimethylsiloxane).

Larsson *et al.* (2004) reported that age, size and sex of Grey Seals had no effect on BCPS concentrations. Norström *et al.* (2004) noted an unusually high mean BCPS concentration of 475 ng/g lw (152 ng/g ww) in the blubber of an individual Grey Seal (compared to a range of 49 to 98 ng/g lw (44 to 87 ng/g ww) in other individuals) which had a low blubber fat content, indicating that it was unhealthy. The Agency notes that lipid weight concentrations should be treated with caution in this case, and for other data which were obtained from dead organisms (Table and Table), as unhealthy or dead animals may have

unusually high lipid weight concentrations of BCPS (due to low body fat) which are not representative of concentrations in healthy organisms.

Further analyses of other factors which may have influenced BCPS concentrations, including seasonal or climate effects, organism diets, nutritional condition, and reproduction have not been discussed in the literature. The Agency also notes that sampling was heavily biased towards the Baltic region.

In summary, BCPS levels up to around 2,700 ng/g lw (~1,600 ng/g ww) have been detected in various species of air-breathing organisms, across several decades (1970s to 2019).

2.3.2.3.2 Field biomagnification factors

Biomagnification factors (BMFs) calculated using biomonitoring data (Section 2) are reported in ECHA (2023b). Some of these values were also calculated and reported in the original biomonitoring studies (Hornek-Gausterer *et al.*, 2021; Norström *et al.*, 2004). Values are summarised in Table 10.

Table 10: Summary of calculated BMF values for BCPS

References	Trophic relationship	Mean BCPS concentrations used in calculations (range), in ng/g lw	BMF (range)
Norström *et al.* (2004); Norström *et al.* (2010)	Bird / fish	Guillemot muscle: (1,600 to 1,900) Herring muscle: 30	(53 to 63)
Jörundsdóttir *et al.* (2008); Jörundsdóttir *et al.* (2006); Norström *et al.* (2004); Norström *et al.* (2010)	Bird / fish	Guillemot egg: 1,118 (760 to 2,600) Herring muscle: 30	37 (25 to 86)
Hornek-Gausterer *et al.* (2021)	Bird / fish	Cormorant muscle: 16.3 Whole fish: 4.9	3.2
		Cormorant muscle (individual): 23 Whole ingested fish (individual): 5.5	4.2
		Cormorant liver: 53.5 Whole fish: 4.9	10.9
Larsson *et al.* (2004); Norström *et al.* (2004); Norström *et al.* (2010)	Mammal / fish	Seal liver: 200 Herring muscle: 30	6.7
		Seal blubber: 60 Herring muscle: 30	2

References	Trophic relationship	Mean BCPS concentrations used in calculations (range), in ng/g lw	BMF (range)
		Seal blubber: (49 to 98) Herring muscle: 30	(1.6 to 3.2)

ECHA (2023b) notes that for the bird / fish BMF values of 53 to 63, herring samples were from the years 1998 (Norström *et al.*, 2004) and 2008 (Norström *et al.*, 2010), whereas guillemot samples were from 1989 (Norström *et al.*, 2004). BCPS concentrations in herring were generally constant from 1998 to 2008 in herring from multiple regions, at around 30 ng/g lw, with no obvious trend between country and sampling location (Norström *et al.* (2004); Norström *et al.* (2010); n = 20). ECHA (2023b) considers that it is therefore reasonable to take the value of 30 ng/g lw for herring muscle and compare it to guillemot muscle concentrations.

In addition, the bird / fish BMF values were calculated using egg / muscle BCPS concentrations, rather than whole body concentrations. ECHA (2023b) states that guillemot eggs are likely to be a good surrogate for muscle, with egg-to-maternal tissue concentration often being < 1 (referencing Drouillard and Norstrom (2001)), meaning BCPS concentrations in guillemot muscle were likely similar to, or higher than, egg concentrations. The uncertainty associated with comparing different tissue types for the remaining bird / fish and mammal / fish BMFs is acknowledged in ECHA (2023b), including that BMFs determined from liver concentrations may not be a good measure for whole body BMF. Uncertainty associated with cormorant migration patterns is also recognised, as cormorant food sources could be from anywhere along their migration route. The Agency notes that the same is true for guillemots.

The Agency has classed the associated BCPS concentration data used to calculate BMF values as either reliable or reliable with restrictions (Section 2). However, the BMF values are classed as not reliable (Klimisch 3) for the following reasons:

- For the bird / fish BMF values of 53 to 63, the guillemots (1989) were sampled nine years before the earliest herring samples (1998). Temporal changes in BCPS concentrations cannot be ruled out.

- It is not recommended to compare substance concentrations between different tissues across trophic levels when calculating a BMF, as tissue-specific concentrations are not representative of whole body concentrations (Environment Agency, 2022).

- The study of relative concentrations in bird eggs versus maternal tissues (Drouillard and Norstrom, 2001) cited in ECHA (2023b) relates to a specific polychlorobiphenyl (PCB) and is not specific to BCPS or universal across other chemical compounds. Drouillard and Norstrom (2001) also reference Russell *et al.* (1998), who reported similar findings for a large number of organochlorine compounds and PCBs. However,

neither study examined muscle tissue in adult birds, with only egg-to-whole-body ratios being characterised by Russell *et al.* (1998), and so comparison of BCPS levels in bird eggs with concentrations in fish muscle is still significantly limited. These data suggest that comparison of BCPS concentrations in guillemot eggs with whole body herring concentrations would be more relevant, but only herring muscle concentrations are available from the literature.

The derived BMFs are based on datasets compiled from disparate sampling campaigns spanning multiple years and sources. As a result, the underlying food web is not well constrained, with limited trophic coherence and potential inconsistencies in predator–prey relationships. This introduces uncertainty and weakens confidence in the resulting estimates. The Agency therefore does not consider the calculated BMF values to be relevant as part of the weight-of-evidence. However, it is noted that the data do indicate exposure of sensitive life stages (birds' eggs) to BCPS.

2.3.2.4 Summary and discussion of bioaccumulation

Based on its log K_{OW} and log K_{OA} values, BCPS does not screen as bioaccumulative in aquatic organisms, but has the potential for bioaccumulation in air-breathing animals. The Agency notes that there are uncertainties associated with the estimated log K_{OA} for BCPS.

Reported lipid normalised steady state BCF values from a fish bioaccumulation study (NITE, 2001) according to OECD TG 305 (1996 version) were significantly below 2,000 L/kg. This indicates that bioaccumulation in gill-breathing species is not the primary concern for this substance.

BCPS is rapidly distributed to adipose tissue in mammals. Comparative evaluation of intravenous and oral administration data demonstrates broadly similar elimination kinetics, indicating that systemic uptake via both gastrointestinal and circulatory routes is efficient and does not constitute a limiting step. Mathews *et al.* (1996) reported a terminal half-life in adipose of 12 days in rats following a single intravenous dose of 10 mg/kg, over the period from day 1 to day 21 post-dose. Oral exposure at the same dose was shown to result in almost complete absorption and very similar tissue distribution as intravenous dosing, so this exposure route is considered relevant in this case. The exact details of the derivation of this half-life are not available, and it should also be noted that fish bioaccumulation studies (e.g. according to OECD TG 305) require the use of test substance concentrations that are below chronic effect levels.

Although toxic effects were not reported for any of the exposure regimens used by Mathews *et al.* (1996), Poon *et al.* (1999) reported toxicological responses in another rat strain exposed orally over 28 days, with the NOAEL concluded to be below 0.8 mg/kg bw/day. It is therefore possible that the rats in the Mathews *et al.* (1996) study were exposed to higher concentrations than would normally be considered appropriate in

the case of aquatic bioaccumulation testing. Nevertheless, further testing would not be appropriate due to animal welfare considerations.

In the absence of detailed partitioning data describing transfer from the peripheral compartment (adipose) to the central compartment (plasma and well-perfused tissues), and without complete mass-balance elimination data, the estimated terminal half-life in rat adipose tissue of 12 days should be interpreted with appropriate caution. Nevertheless, this value substantially exceeds the 4- and 7-day half-life benchmarks associated with a BMF of 1 for rats (see Appendix B for further discussion of these). This reflects its rate-limiting step in whole-body elimination. Given the demonstrated rapid distribution of BCPS to adipose tissue, efficient systemic uptake, and evidence for redistribution processes that are likely constrained by diffusion rather than metabolism alone, the prolonged residence time in adipose strongly implies a correspondingly extended effective elimination half-life from plasma and perfused tissues.

In repeat-dose studies, decreasing concentrations in adipose tissue have been observed over time, accompanied by increasing concentrations in metabolically active organs (Mathews *et al.*, 1996). This pattern is consistent with enhanced metabolic capacity following repeated exposure, likely driven by the observed enzyme induction.

Poon *et al.* (1999) offers supportive qualitative evidence for rapid distribution to adipose tissue and dose-dependent induction of metabolism in a different rat strain. Nevertheless, the lack of toxicokinetic data for other species introduces some uncertainty in extrapolation of the findings to other mammalian species and birds.

Reliable biomonitoring data indicate that BCPS is present in many wildlife species, particularly air-breathing organisms, at concentrations up to approximately 2,700 ng/g lw (equivalent to ~1,600 ng/g, or 1.6 mg/kg ww). Wildlife tissue concentrations in the region of 1 mg/kg ww have also been reported for substances that have been formally identified as highly bioaccumulative under REACH (e.g., bis(hexachlorocyclopentadieno)cyclooctane (ECHA, 2017b), hexabromocyclododecane (ECHA, 2008) and decamethylcyclopentasiloxane (ECHA, 2018)). Biota concentrations of BCPS are also similar to, or higher than, those of some known POPs (ECHA, 2023b)

These observations, derived from field and regulatory contexts, are inherently empirical and retrospective rather than mechanistic or predictive of bioaccumulation behaviour, and should therefore be interpreted with caution. Nevertheless, absolute tissue concentrations can provide useful supporting evidence, particularly where they are consistent with patterns observed for known bioaccumulative substances. Their interpretation remains subject to considerable uncertainty arising from variation across chemical classes, trophic levels and species, and they cannot reliably distinguish between high exposure and strong accumulation potential. Consequently, standalone tissue concentrations are best regarded

as contextual, case-specific lines of evidence rather than as indicative thresholds for bioaccumulation.

Whilst BMF values have been reported from field studies, the Agency does not consider these to be reliable and so they are not considered further. BCPS has also been detected in sensitive life stages (birds' eggs). The preferential distribution to adipose tissue in rats is reflected in preferential accumulation in adipose tissue of marine mammals relative to liver in one study (Reiter *et al.*, 2023). However, other monitoring studies report higher concentrations in liver compared to adipose tissue in some species (Hornek-Gausterer *et al.*, 2021; Larsson *et al.*, 2004). These discrepancies may be explained by the potential for protein binding mediated by the sulfone functionality, which could favour hepatic retention in some species.

2.4 Conclusions on the SVHC properties

2.4.1 PBT and vPvB assessment

2.4.1.1 Persistence

The freshwater sediment DT_{50} values of BCPS were above 394 days at 20 °C in a study conducted according to OECD TG 308. These were extrapolated to > 836 days at 12 °C, which exceeds the vP criterion of Annex 13 of UK REACH (half-life > 180 days).

2.4.1.2 Bioaccumulation

Despite uncertainties and the absence of detailed partitioning or full mass-balance data, the estimated terminal half-life in adipose of 12 days in rats substantially exceeds the 4- and 7-day total biotransformation half-life benchmarks linked to a biomagnification factor (BMF) of 1. Given the rapid distribution to adipose tissue, efficient systemic uptake, and indications of diffusion-limited redistribution, this prolonged adipose residence strongly implies an extended effective elimination half-life from plasma and perfused tissues in air-breathing organisms.

This finding is supported by:

- A measured log K_{OW} > 2 (3.9) and a predicted log K_{OA} value > 5 (9.2) indicating that BCPS screens as potentially bioaccumulative in air-breathing organisms;
- The presence of BCPS at concentrations ranging up to around 2,700 ng/g lw (~1,600 ng/g [~1.6 mg/kg] ww) in a range of wildlife species, across multiple trophic levels and sensitive life stages (e.g. birds' eggs). There is good evidence of higher concentrations in air-breathing organisms (birds and mammals) than gill-breathers (fish). Wildlife tissue concentrations in the region of 1 mg/kg ww have been reported for other substances that have been formally identified as vB under REACH and equivalent criteria under POPs.

Overall, BCPS can be concluded to have a very high bioaccumulation potential in air-breathing organisms, consistent with exceeding the vB criterion of Annex 13 of UK REACH.

2.4.1.3 Overall conclusions on the PBT and vPvB properties

Based on the information available, the Agency concludes that BCPS fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

3. Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

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

In addition, 13 Downstream User Import Notifications (DUINs[2]) have been submitted.

Under EU REACH, the substance is registered with an aggregated tonnage of ≥ 1000 to < 10 000 tpa (12 active EU registrants)[3].

3.2 General description of uses and exposure

BCPS is primarily used as a monomer in the manufacture of high-temperature polymers. Such polymers are reportedly used in the production of articles for use across a variety of sectors. Reported applications (ECHA 2023) include in the automotive/aeronautic sectors, dental applications, electronic components, food service, hospital goods, medical devices, microwave cookware, piping, plumbing, water and oil pumps, membranes (food processing and water treatment), surgical instrument applications and visors for fire helmets. BCPS is less commonly used as an additive in fluoropolymers for rubber production.

Historically it has been used as an agricultural insecticide (either by itself or present as an impurity), but this use was banned a number of years ago (ECHA, 2023).

3.3 Alternatives

BCPS reacts with other monomers to form several high-temperature polymers. This includes 4,4'-sulphonyldiphenol (CAS 80-09-1, Bisphenol S) to form Polyethersulfone (PESU), 4,4'-isopropylidenediphenol (CAS 80-05-7, Bisphenol A) to form Polysulfone (PSU) or biphenyl 4,4'-diol (CAS 92-88-6) to form Polyphenylensulfone (PPSU). These polymers have a number of properties in addition to their performance at high

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

[3] ECHA Chemicals database; ECHA CHEM https://chem.echa.europa.eu/

temperatures that make them desirable. Whilst other types of high-temperature polymers exist, a case by case consideration would be necessary to determine whether they possess the properties necessary for the particular application (e.g. temperature resistance, resistance to oxidation and hydrolysis and good electrical insulation) (ECHA, 2023).

No information is currently available on suitable alternatives for the use of BCPS as an additive in fluoropolymers (ECHA, 2023).

References

Arnér, M., Forsberg, J., Taaler, M. & Forsgren, A. (2004). Screening av: Bisfenol A, 2,2',6,6'-tetra-butyl-4,4'-metendifenol, bis(4-klorfenyl)sulfon. *Screeninguppdrag inom nationell miljöövervakning*. [WSP 10033045]. WSP Environmental. Stockholm. Available at: http://naturvardsverket.diva-portal.org/smash/get/diva2:657620/FULLTEXT01.pdf

Arnot, J., Birk, B., Curtis-Jackson, P., Gobas, F. A. P. C., Goss, K.-U., Habekost, M., Hirmann, D., *et al.* (2022). Bioaccumulation assessment of air-breathing mammals: A discussion paper. European Chemicals Agency. Helsinki, Finland. Available at: https://echa.europa.eu/documents/10162/17228/bioaccumulation_assessment_of_air_breathing_mammals_en.pdf/56de6276-06e9-9eed-a7dd-a75336fda71b?t=1669388928484

Bester, K., Theobald, N. & Schroder, H. F. (2001). Nonylphenols, nonylphenol-ethoxylates, linear alkylbenzenesulfonates (LAS) and bis (4-chlorophenyl)-sulfone in the German Bight of the North Sea. *Chemosphere,* 45(6-7), 817–826. https://doi.org/10.1016/S0045-6535(01)00023-6

Drouillard, K. G. & Norstrom, R. J. (2001). Quantifying maternal and dietary sources of 2,2′,4,4′,5,5′-hexachlorobiphenyl deposited in eggs of the ring dove (*Streptopelia risoria*). *Environmental Toxicology and Chemistry,* 20(3), 561–567. https://doi.org/10.1002/etc.5620200315

ECCC (2017). Ecological screening assessment report on polybrominated diphenyl ethers: Chapter 2. Environment and Climate Change Canada. Ottawa, Ontario. Available at: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/ecological-screening-assessment-report-polybrominated/chapter-2.html

ECHA (2008). Member State Committee support document for identification of hexabromocyclododecane and all major diastereoisomers identified as a Substance of Very High Concern. European Chemicals Agency. Helsinki, Finland. Available at: https://chem.echa.europa.eu/100.239.157/obligations/candidateList/details?searchText=hexabromocyclododecane

ECHA (2017a). Chapter R.11: PBT/vPvB assessment (version 3.0). *Guidance on Information Requirements and Chemical Safety Assessment.* European Chemicals Agency. Helsinki, Finland. https://data.europa.eu/doi/10.2823/128621

ECHA (2017b). Member State Committee support document for identification of 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("dechlorane plus"^{tm}) [covering any of its individual anti- and syn-isomers or any combination thereof] as a Substance of Very High Concern because of its vPvB properties (Article 57(E)). European Chemicals Agency. Helsinki, Finland. Available at: https://chem.echa.europa.eu/100.253.516/obligations/candidateList/details

ECHA (2018). Member State Committee support document for identification of decamethylcyclopentasiloxane (D5) as a Substance of Very High Concern because of its PBT and vPvB properties (Article 57D&E). European Chemicals Agency. Helsinki, Finland. Available at: https://chem.echa.europa.eu/100.007.969/obligations/candidateList/details

ECHA (2023a). Registry of SVHC intentions until outcome (bis(4-chlorophenyl) sulphone). European Chemicals Agency. Available at: https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e18836e989

ECHA (2023b). Member State Committee support document for identification of bis(4-chlorophenyl) sulphone as a Substance of Very High Concern because of its vPvB (Article 57e) properties. European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/afb5a5c3-31d3-cc00-fc64-0048c380c601

ECHA (2023c). Chapter R.11: PBT/vPvB assessment. *Guidance on information requirements and chemical safety assessment.* [Version 4.0]. European Chemicals Agency. Helsinki, Finland. https://data.europa.eu/doi/10.2823/312974

ECHA (2025). ECHA Registration Dossier for Bis(4-chlorophenyl) sulphone (CAS No. 80-07-9). European Chemicals Agency. Available at: https://chem.echa.europa.eu/100.001.135/dossier-view/cbda3fcc-3f3d-4c00-8249-978a491f8b78/

Ellerichmann, T., Bergman, Å., Franke, S., Hühnerfuss, H., Jakobsson, E., Konig, W. A. & Larsson, C. (1998). Gas chromatographic enantiomer separations of chiral PCB methyl sulfons and identification of selectively retained enantiomers in human liver. *Fresenius Environmental Bulletin,* 7(5-6), 244–257. Available at: https://hero.epa.gov/reference/2160893/

Environment Agency (2022). Guidance on interpreting biota tissue concentrations for bioaccumulation assessment. Bristol, UK. Available at: https://assets.publishing.service.gov.uk/media/62d528f2d3bf7f2861b89394/Guidance_on_interpreting_biota_tissue_concentrations_for_bioaccumulation_assessment_-report.pdf

Environment Agency (2025). Water quality monitoring data GC-MS and LC-MS semi-quantitative screen (updated July 2025). Environment Agency. Available at: https://www.data.gov.uk/dataset/0c63b33e-0e34-45bb-a779-16a8c3a4b3f7/water-quality-monitoring-data-gc-ms-and-lc-ms-semi-quantitative-screen

Goss, K. U., Brown, T. N. & Endo, S. (2013). Elimination half-life as a metric for the bioaccumulation potential of chemicals in aquatic and terrestrial food chains. *Environmental Toxicology and Chemistry,* 32(7), 1663–1671. https://doi.org/10.1002/etc.2229

Guzzella, L. & Sora, S. (1998). Mutagenic activity of lake water samples used as drinking water resources in Northern Italy. *Water Research,* 32(6), 1733–1742. https://doi.org/10.1016/S0043-1354(97)00418-1

Helander, B., Olsson, A., Bignert, A., Asplund, L. & Litzén, K. (2002). The role of DDE, PCB, coplanar PCB and eggshell parameters for reproduction in the white-tailed sea eagle

(*Haliaeetus albicilla*) in Sweden. *Ambio,* 31(5), 386–403. https://doi.org/10.1579/0044-7447-31.5.386

Hornek-Gausterer, R., Parz-Gollner, R., Moche, W., Sitka, A., Hölzl, C., Kinzl, M. & Scharf, S. (2021). Bis(4-chlorophenyl) sulfone (BCPS) concentrations found in Austrian freshwater fish and cormorants (*Phalacrocorax carbo sinensis*) indicating trophic transport and biomagnification - A screening pilot-study. *Chemosphere,* 263, 127902. https://doi.org/10.1016/j.chemosphere.2020.127902

Jackson, E., Shoemaker, R., Larian, N. & Cassis, L. (2017). Adipose tissue as a site of toxin accumulation. *Comprehensive Physiology,* 7(4), 1085–1135. https://doi.org/10.1002/cphy.c160038

Jörundsdóttir, H., Bignert, A., Svavarsson, J., Nygård, T., Weihe, P. & Bergman, Å. (2009). Assessment of emerging and traditional halogenated contaminants in guillemot (*Uria aalge*) egg from North-Western Europe and the Baltic Sea. *Science of the Total Environment,* 407(13), 4174–4183. https://doi.org/10.1016/j.scitotenv.2009.03.026

Jörundsdóttir, H., Löfstrand, K., Svavarsson, J., Bignert, A. & Bergman, Å. (2010). Organochlorine compounds and their metabolites in seven icelandic seabird species - a comparative study. *Environmental Science and Technology,* 44(9), 3252–3259. https://doi.org/10.1021/es902812x

Jörundsdóttir, H., Mattiasson, K., Svavarsson, J., Tomy, G., Weihe, P., Nygård, T., Bignert, A.*, et al.* (2008). Concentrations of organohalogen compounds in the West-Nordic compared to the Baltic region. [2008:550]. Nordic Council of Ministers. Copenhagen: TemaNord. Available at: https://www.diva-portal.org/smash/get/diva2:700863/FULLTEXT01.pdf

Jörundsdóttir, H., Norström, K., Olsson, M., Pham-Tuan, H., Hühnerfuss, H., Bignert, A. & Bergman, Å. (2006). Temporal trend of bis(4-chlorophenyl) sulfone, methylsulfonyl-DDE and -PCBs in Baltic guillemot (*Uria aalge*) egg 1971-2001--a comparison to 4,4'-DDE and PCB trends. *Environmental Pollution,* 141(2), 226–237. https://doi.org/10.1016/j.envpol.2005.08.054

Kawabata, K., Sugihara, K., Sanoh, S., Kitamura, S. & Ohta, S. (2013). Photodegradation of pharmaceuticals in the aquatic environment by sunlight and UV-A, -B and -C irradiation. *The Journal of Toxicological Sciences,* 38(2), 215–223. https://doi.org/10.2131/jts.38.215

La Merrill, M., Emond, C., Kim, M. J., Antignac, J. P., Le Bizec, B., Clément, K., Birnbaum, L. S.*, et al.* (2013). Toxicological function of adipose tissue: Focus on persistent organic pollutants. *Environmental Health Perspectives,* 121(2), 162–169. https://doi.org/10.1289/ehp.1205485

Larsson, C., Norström, K., Athanansiadis, I., Bignert, A., König, W. A. & Bergman, Å. (2004). Enantiomeric specificity of methylsulfonyl-PCBs and distribution of bis(4-chlorophenyl) sulfone, PCB, and DDE methyl sulfones in grey seal tissues. *Environmental Science and Technology,* 38(19), 4950–4955. https://doi.org/10.1021/es049361v

Letcher, R. J., Norstrom, R. J. & Bergman, Å. (1995). An integrated analytical method for determination of polychlorinated aryl methyl sulfone metabolites and polychlorinated hydrocarbon contaminants in biological matrices. *Analytical Chemistry,* 67(22), 4155–4163. https://doi.org/10.1021/ac00118a019

Levitt, D. G. (2010). Quantitative relationship between the octanol/water partition coefficient and the diffusion limitation of the exchange between adipose and blood. *BMC Clinical Pharmacology,* 10(1), 1. https://doi.org/10.1186/1472-6904-10-1

Liu, Y., Richardson, E. S., Derocher, A. E., Lunn, N. J., Lehmler, H. J., Li, X., Zhang, Y., *et al.* (2018). Hundreds of unrecognized halogenated contaminants discovered in polar bear serum. *Angewandte Chemie,* 130(50), 16639–16644. https://doi.org/10.1002/anie.201809906

Mathews, J. M., Black, S. L. & Matthews, H. B. (1996). P,p'-dichlorodiphenyl sulfone metabolism and disposition in rats. *Drug Metabolism and Disposition,* 24(5), 579–587. Available at: https://www.ncbi.nlm.nih.gov/pubmed/8723740

Merrington, G., Nowell, L. H. & Peck, C. (2024). An introduction to criteria for reporting and evaluating exposure datasets (CREED) for use in environmental assessments. *Integrated Environmental Assessment and Management,* 20(4), 975–980. https://doi.org/10.1002/ieam.4899

Millow, C. J., Mackintosh, S. A., Lewison, R. L., Dodder, N. G. & Hoh, E. (2015). Identifying bioaccumulative halogenated organic compounds using a nontargeted analytical approach: Seabirds as sentinels. *PLoS ONE,* 10(5), e0127205. https://doi.org/10.1371/journal.pone.0127205

NITE (1999). Microbial degradation test of mono(tetra)bromo(or chloro)diphenyl ether (or amine, sulfone); test conducted using 4,4'-dichlorodiphenyl sulfone (test substance number k-1200). Japan: National Institute of Technology and Evaluation. J-CHECK (Japan Chemicals Collaborative Knowledge database). Available at: https://www.nite.go.jp/chem/jcheck/direct.action?request_locale=ja&TYPE=DPAGE1&CAS=80-07-9&MITI=3-61

NITE (2001). Final report: Concentration test of 4,4'-dichlorodiphenyl sulfone (test substance number k-1200) in carp (test number: 51200). [original report title in Japanese]. Japan: National Institute of Technology and Evaluation. J-CHECK (Japan Chemicals Collaborative Knowledge database). Available at: https://www.nite.go.jp/chem/jcheck/direct.action?request_locale=ja&TYPE=DPAGE1&CAS=80-07-9&MITI=3-61

Norström, K., Olsson, A., Olsson, M. & Bergman, Å. (2004). Bis(4-chlorophenyl) sulfone (BCPS) in Swedish marine and fresh water wildlife-a screening study. *Environment International,* 30(5), 667–674. https://doi.org/10.1016/j.envint.2003.12.005

Norström, K., Remberger, M., Kaj, L., Wilklund, P. & Brorström-Lundén, E. (2010). Subreport 1: Bis(4-chlorophenyl) sulfone (BCPS). *Results from the Swedish National Screening Programme 2009*. Swedish Environmental Research Institute. Stockholm. Available at: https://www.diva-portal.org/smash/get/diva2:1552157/FULLTEXT01.pdf

OECD (2008). OECD screening tool for overall persistence (Pov) and long-range transport potential (LRTP). Available at: https://www.oecd.org/en/data/tools/screening-tool-for-overall-persistence-and-long-range-transport-potential.html

OECD (2010). Test No. 417: Toxicokinetics. *OECD Guidelines for the Testing of Chemicals.* OECD Publishing. Paris. https://doi.org/10.1787/9789264070882-en

OECD (2012). Test No. 305: Bioaccumulation in fish: Aqueous and dietary exposure. *OECD Guidelines for the Testing of Chemicals.* OECD Publishing. Paris. https://doi.org/10.1787/9789264185296-en

OECD (2024). Case study on the use of integrated approaches for testing and assessment (IATA) for bioaccumulation - ninth review cycle (2023). *OECD Series on Testing and Assessment.* [No. 404]. OECD Publishing. Paris. https://doi.org/10.1787/8bc8ad6f-en

Olsson, A. & Bergman, Å. (1995). A new persistent contaminant detected in Baltic wildlife: Bis (4-chlorophenyl) sulfone. *Ambio,* 24(2), 119–123. Available at: http://www.jstor.org/stable/4314307

Olsson, A., Vitinsh, M., Plikshs, M. & Bergman, A. (1999). Halogenated environmental contaminants in perch (*Perca fluviatilis*) from Latvian coastal areas. *Science of the Total Environment,* 239(1-3), 19–30. https://doi.org/10.1016/s0048-9697(99)00287-9

Plaßmann, M., Brack, W. & Krauss, M. (2016). Sub-project 2 – screening of target and non target contaminants in human blood and urine. *Human Biomonitoring of „new" contaminants*. [(UBA-FB) 002003/E]. Umweltbundesamt. Dessau-Roßlau, Germany. Available at: https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/u_g_01_2016_human-biomonitoring_of_new_contaminants.pdf

Pontolillo, J. & Eganhouse, R. P. (2001). The search for reliable aqueous solubility (sw) and octanol-water partition coefficient (Kow) data for hydrophobic organic compounds: Ddt and DDE as a case study. *Water-Resources Investigations Report 01-4201*. U.S. Geological Survey. Reston, Virginia, USA. Available at: https://pubs.usgs.gov/wri/wri014201/pdf/wri01-4201.pdf

Poon, R., Lecavalier, P., Chu, I., Yagaminas, A., Nadeau, B., Bergman, A. & Larsson, C. (1999). Effects of bis(4-chlorophenyl) sulfone on rats following 28-day dietary exposure. *Journal of Toxicology and Environmental Health, Part A,* 57(3), 185–198. https://doi.org/10.1080/009841099157755

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

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

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

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

Reiter, E. B., Escher, B. I., Rojo-Nieto, E., Nolte, H., Siebert, U. & Jahnke, A. (2023). Characterizing the marine mammal exposome by iceberg modeling, linking chemical analysis and *in vitro* bioassays. *Environmental Science: Processes and Impacts,* 25(11), 1802–1816. https://doi.org/10.1039/D3EM00033H

Russell, R. W., Gobas, F. A. P. C. & Haffner, G. D. (1998). Maternal transfer and in ovo exposure of organochlorines in oviparous organisms: A model and field verification. *Environmental Science and Technology,* 33(3), 416–420. https://doi.org/10.1021/es9800737

Schlabach, M., van Bavel, B., Lomba, J. A. B., Borgen, A. R., Gabrielsen, G. W., Gotsch, A., Halse, A.-K.*, et al.* (2017). Screening Programme 2017. *AMAP Assessment Compounds*. [M-1080, 2018]. Norwegian Institute for Air Research, Norwegian Environment Agency. Available at: https://www.miljodirektoratet.no/globalassets/publikasjoner/m1080/m1080.pdf

Sonne, C., Dietz, R., Jenssen, B. M., Lam, S. S. & Letcher, R. J. (2021). Emerging contaminants and biological effects in Arctic wildlife. *Trends in Ecology and Evolution,* 36(5), 421–429. https://doi.org/10.1016/j.tree.2021.01.007

UNEP (2025). Text and annexes. *Stockholm Convention on Persistent Organic Pollutants (POPS).* [2025 revision]. United Nations Environment Programme. Available at: https://www.pops.int/Portals/0/download.aspx?e=UNEP-POPS-COP-CONVTEXT-2025.English.pdf

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

Valters, K., Olsson, A., Vitinsh, M. & Bergman, Å. (1999). Contamination sources in Latvia: Levels of organochlorines in perch (*Perca fluviatilis*) from rivers daugava and lielupe. *Ambio,* 28(4), 335–340. Available at: https://www.jstor.org/stable/4314905

Verreault, J., Letcher, R. J., Muir, D. C., Chu, S., Gebbink, W. A. & Gabrielsen, G. W. (2005). New organochlorine contaminants and metabolites in plasma and eggs of glaucous gulls (*Larus hyperboreus*) from the Norwegian Arctic. *Environmental Toxicology and Chemistry,* 24(10), 2486–2499. https://doi.org/10.1897/05-067r.1

Glossary

4,4´-DDE	4,4'-dichlorodiphenyldichloroethylene
Agency, the	HSE
AR	Applied radioactivity
B	Bioaccumulative
BCF	Bioconcentration factor
BCF_{ss}	Steady-state BCF
BCPS	Bis(4-chlorophenyl) sulfone
BDE-99	2,2',4,4',5-pentabromodiphenyl ether
BMF	Biomagnification factor
BOD	Biochemical oxygen demand
bw	Body weight
CAS	Chemical Abstracts Service
DDT	dichlorodiphenyltrichloroethane
DT_{50}	Time taken for 50% decline in mass or concentration. If the decline is described by first order kinetics, then this is also called the half-life
DU	Downstream User
DUIN	Downstream User Import Notification
EC	European Community
ECHA	European Chemicals Agency
EPI Suite	Estimation Programs Interface Suite
EU	European Union
GB	Great Britain
GC-MS	Gas chromatography-mass spectrometry
GLP	Good Laboratory Practices

HCH	Hexachlorocyclohexane
IUPAC	International Union of Pure and Applied Chemistry
K_{OA}	n-Octanol–air partition coefficient
K_{ow}	n-Octanol–water partition coefficient
LOD	Limit of detection
LOQ	Limit of quantitation
LRTP	Long-range transport potential
lw	Lipid weight
MCL	Mandatory classification and labelling
MITI	Ministry of International Trade and Industry (Japan)
MSC	Member State Committee
NER	Non-extractable residues
NITE	National Institute of Technology and Evaluation (Japan)
OECD	Organisation for Economic Cooperation and Development
P	Persistent
PBT	Persistent, bioaccumulative and toxic
PCB	Polychlorinated biphenyl
PDMS	Polydimethylsiloxane
PeCB	Pentachlorobenzene
POP	Persistent organic pollutant
REACH	Registration, evaluation, authorisation and restriction of chemicals
SIM	Selected ion monitoring
SMILES	Simplified Molecular Input Line Entry System
SVHC	Substance of very high concern
TG	Test guideline
UK	United Kingdom

UN	United Nations
UNEP	United Nations Environment Programme
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative

Appendix A: Literature search parameters

Table A 1: Literature search terms for location of additional biomonitoring studies for BCPS

Search engine	Search terms	Filters	Notes
Scopus	“dichlorodiphenyl sulphone” OR “bis 4 chlorophenyl sulphone” OR “BCPS”	Environmental Science	128 results
PubMed	“BCPS” AND (“environment” OR “detection” OR “biomonitoring”)	2020 to 2025	80 results
Google Scholar	“bis (4-chlorophenyl) sulphone biomonitoring”	2019 to 2025	50 results
	“bis (4-chlorophenyl) sulphone environment”	2019 to 2025	> 1,000 results (evaluated first 10 results only)
	“BCPS environment”	2019 to 2025	> 1,000 results (evaluated first 10 results only)

Table A 2: Literature search terms for location of additional toxicokinetic studies for BCPS

Search engine	Search terms	Filters	Notes
Scopus	(“dichlorodiphenyl sulphone” OR “bis 4 chlorophenyl sulphone” OR “BCPS”) AND “toxicokinetics”	--	4 results
PubMed	“BCPS” AND “toxicokinetics”	--	54 results
Google Scholar	“bis (4-chlorophenyl) sulphone toxicokinetics”	2019 to 2025	35 results
	“dichlorodiphenyl sulphone toxicokinetics”	2019 to 2025	86 results
	“BCPS toxicokinetics”	2019 to 2025	31 results

Appendix B: Mammalian toxicokinetic data in bioaccumulation assessment

Mammalian toxicokinetic data are accepted lines of evidence for bioaccumulation assessment. Guidance on the derivation of total elimination (terminal) half-life (HL_T; days) and total biotransformation half-life (HL_B; days) is set out in Arnot *et al.* (2022) and ECHA (2023c), where an HL_B of 4 or 7 days in rats can been used to approximate to a biomagnification factor (BMF) of 1 for neutral organic substances. Detailed derivations are presented in the original publication of Arnot *et al.* (2022) and summarised briefly below.

Goss *et al.* (2013) proposed using a model based on poly-parameter linear free energy relationships (ppLFERs) to predict how chemicals behave in the body, combined with information about human body composition (e.g. fat, water, proteins). Because different species have different body sizes and compositions, this information can be adjusted using allometric scaling to estimate how the chemical would behave in test animals with known body compositions.

This approach allows estimation of $K_{organism/water}$ and $K_{organism/air}$ partition coefficients, which are expressed by the authors of the paper as log "K_{OW}" and log "K_{OA}", respectively (not to be confused with the n-octanol–water and n-octanol–air partition coefficients used in the main report). Under the simplifying assumption that respiration and urination are the only elimination mechanisms, and that equilibrium is established between an organism's body, exhaled air, and excreted urine, these relationships can be used to derive threshold values consistent with a biomagnification factor (BMF) of 1 (with appropriate temperature corrections) relating to the K_{OW} and K_{OA} values to organism (represented by octanol) to loss via air and water only. Additional elimination processes such as metabolism and faecal elimination via the biliary system are accounted for in the HL_B. The corresponding thresholds in rats are:

BMF = 1 HL_B = 7 days log K_{OW} = 0.74 log K_{OA} at 25°C = 5.37

This relationship is based on empirically derived links between BMF and key parameters, including dietary intake rate, uptake efficiency, elimination rate, and chemical fugacity. For example, the threshold half-life of 7 days was derived assuming a feeding rate of 0.05 kg food per kg body weight per day for a 300 g rat, a lipid content of approximately 5% (about half that of the diet), and 100% uptake efficiency from food.

Arnot *et al.* (2022) presents parameter thresholds for mammalian top predators assuming that they consume mammalian or avian prey. In the derivation of these thresholds, it should be noted that the dietary energy content used is based on typical values for these prey species, in contrast to the daily energy expenditure parameter which is not specific to

terrestrial top predators. The relationship between daily energy expenditure and body weight applies broadly to all non-marine, non-desert placental mammals. Consequently, commonly used laboratory species can serve as metabolic surrogates for terrestrial mammalian top predators. Assuming a rat body weight of 300 g, the following values are derived:

BMF = 1 HL_B = 4 days log K_{OW} = 0.50 log K_{OA} at 25°C = 5.13

Although these indicative thresholds were originally developed for neutral organic compounds, the Agency considers that they are generally applicable to BCPS, which is a neutral polar organic compound. The thresholds are therefore considered relevant for this assessment, as they are derived from variables and parameters applicable to laboratory-bred rats, for which data are available.

Conversely, the above thresholds and guidance should be applied with caution to data presented by Mathews *et al.* (1996) and Poon *et al.* (1999) (see Section 2.3.2.2.2). In both studies, the information required to determine a whole-body terminal elimination or biotransformation half-life cannot be generated or reproduced without significant assumptions being made. Specifically, the datasets do not provide the correct lines of data required to parameterise even a basic one-compartment mass-balance toxicokinetic model.

In a one-compartment toxicokinetic framework, the organism is assumed to behave as a kinetically homogeneous compartment, with chemical input balanced against loss processes such as metabolism and excretion (i.e. a mass balance model). Estimation of any terminal elimination half-life under this approach requires derivation of an overall first-order elimination rate constant, typically obtained as the sum of individual rate constants describing elimination from plasma and well-perfused tissues (e.g. liver, kidney and lungs), together with excretory pathways (Equation 2). Key supporting data are absent from Mathews *et al.* (1996) and Poon *et al.* (1999), including organism body weights, food composition, and food and water intake rates. As a result, the overall elimination rate constant cannot be derived, and a reliable whole-body elimination or biotransformation half-life cannot be calculated using a one-compartment model.

In principle, summation of the relevant individual rate constants yields a total elimination rate constant, from which an elimination half-life could be calculated. The relevant equations are provided below (Equations 2 to 4):

$$\boldsymbol{k_{elimination} = k_{urine} + k_{faeces} + k_{respiration} + k_{metabolism}}$$ **Equation 2**

$$\boldsymbol{HL_T = \frac{\ln(2)}{k_{elimination}}}$$ **Equation 3**

$$HL_B = \frac{\ln(2)}{k_{metabolism}}$$ **Equation 4**

Where $k_{elimination}$ = total elimination rate constant, k_{urine}, k_{faeces}, $k_{respiration}$ and $k_{metabolism}$ are elimination rate constants via each respective route, HL_T = total elimination (terminal) half-life, and HL_B = total biotransformation half-life.

The paper of Mathews *et al*. (1996) only provides the terminal elimination half-life for a single compartment (adipose) from a single dose study. In terms of toxicokinetic compartments, the adipose tissue is considered a peripheral reservoir for lipophilic substances (Figure B.1), often making the terminal half-life from this tissue the rate-limiting step in elimination of the entire body burden (Jackson *et al.*, 2017; La Merrill *et al.*, 2013).

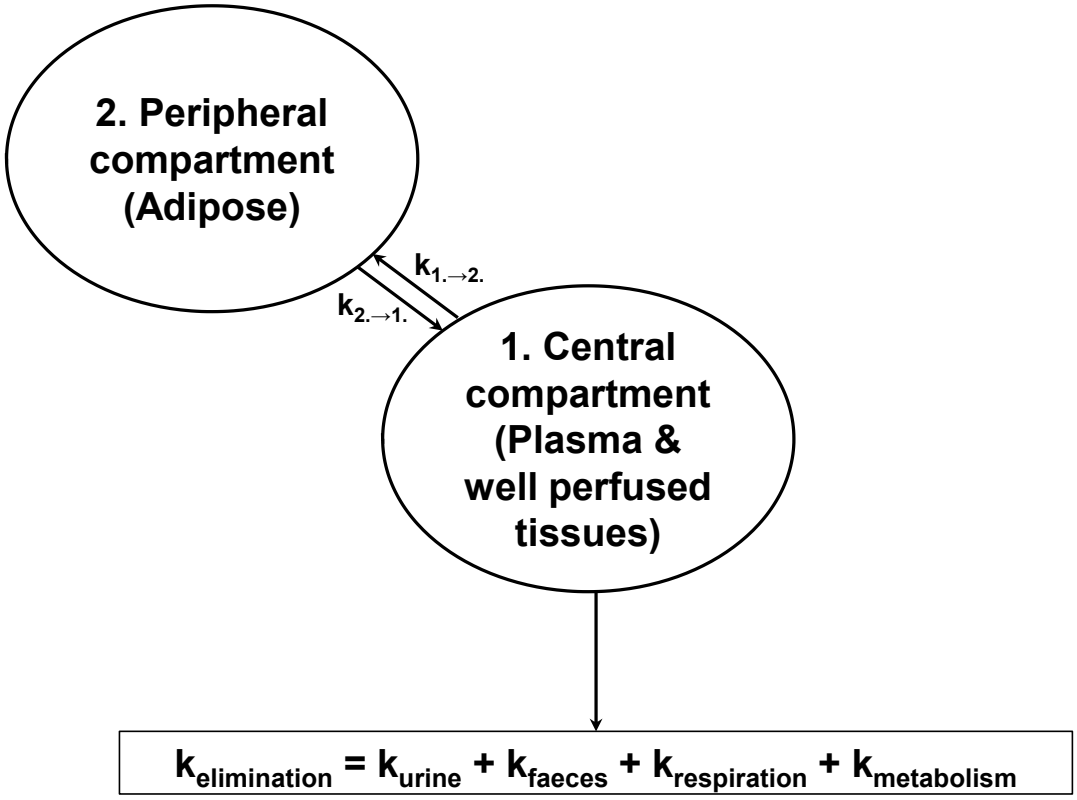


Figure B 1 Conceptual representation of the central compartment (plasma and well-perfused tissues), considered as the compartment from which true elimination occurs, and adipose as a peripheral compartment, considered as a storage compartment for lipophilic substances. The rate constants $k_{1.\rightarrow 2.}$ and $k_{2.\rightarrow 1.}$ represent exchange from the central to the peripheral compartment, and vice versa, respectively.

In the case of BCPS, exchange from the central compartment to adipose ($k_{1.\rightarrow 2.}$, Figure B 1) is rapid (Mathews *et al.*, 1996; Poon *et al.*, 1999). When $k_{2.\rightarrow 1.}$ is a slow return from adipose to the central compartment, this becomes the rate limiting step and thus will control the terminal elimination rate and result in slow whole-body elimination.

The observed slow exchange of BCPS from adipose tissue to plasma and other well-perfused tissues can be rationalised by considering the mechanistic constraints on tissue–blood exchange. Specifically, the rate-limiting step is not membrane permeation or lipid partitioning, but rather diffusion across the aqueous boundary layer at the capillary interface. This interface can be considered a distinct intermediate compartment between adipose lipid and the circulating blood. Transport across this region is governed by the diffusion of the free (aqueous) fraction of the compound. Even for compounds with moderate lipophilicity, this process may impose a kinetic limitation if the effective diffusion across this aqueous layer is reduced.

Levitt (2010) provides a quantitative framework linking octanol-water partitioning (log K_{OW}) to diffusion limitation in adipose-blood exchange. In this model, the extent of diffusion limitation is determined by the permeability-surface area product of the capillary interface and the blood-water partition coefficient ($K_{blood\text{-}water}$), which itself is related to K_{OW}. As $K_{blood\text{-}water}$ increases, the freely diffusible fraction decreases, and exchange becomes increasingly diffusion-limited.

BCPS is a polar, neutral sulfone with a measured log K_{OW} of 3.9 and a water solubility of 0.86 mg/L (both at 20 °C). Relative to typical neutral POPs, BCPS exhibits a comparatively low log K_{OW} and high water solubility (see Table B.1), indicating potentially greater bioavailability through reduced lipophilicity and a greater proportion in the aqueous phase. On this basis, the physicochemical properties of BCPS may suggest a relatively high free fraction in blood and tissues, and therefore a higher apparent bioavailability compared with classically bioaccumulative, highly lipophilic substances.

Table B 1 Comparison of log K_{OW} and water solubility between BCPS, DDT and PentaBDE

Substance	log K_{OW}	Water solubility	Reference
BCPS	3.9	0.86 mg/L	See main text.
DDT	~6.0–7.1	~0.005–0.01 mg/L (≈5–10 µg/L)	Pontolillo and Eganhouse (2001)
PentaBDE	6.57	2.4 µg/L at 25 °C	ECCC (2017)

Although BCPS has a lower log K_{OW} than classical POPs, the Levitt framework proposed that the presence of a finite aqueous diffusion barrier can potentially constrain exchange kinetics independently of membrane permeability or lipid affinity. Accordingly, the slower redistribution of BCPS from adipose tissue is potentially consistent with limitation by aqueous diffusion across the capillary interface, rather than by partitioning behaviour alone.

Further information

This publication is available on the HSE website here.

Published by the Health and Safety Executive 07/26.