

**Risk Management Option Analysis Conclusion Document**

**Substance Name: Bis(4-chlorophenyl) sulphone (BCPS)**

**EC Number: 201-247-9**

**CAS Number: 80-07-9**

**Authority: Austria**

**Date: September, 2022**

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[[1]](#footnote-1).

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Bis(4-chlorophenyl)sulphone (BCPS) has been listed on the REACH CoRAP because of suspected PBT/vPvB properties, high aggregated tonnages and wide dispersive use. Substance evaluation (SEv) has been started in March 2019 by the evaluating MS Austria and finalized in March 2020; a SEv Conclusion Document is available[[2]](#footnote-2). An extended one generation reproductive toxicity study (EOGRTS) will be carried out following a testing proposal examination (TPE). BCPS is self-classified under the CLP Regulation (Regulation (EC) No 1272/2008) by the Registrant(s) and additional notifiers.

An overview of relevant processes for BCPS is given in Table 1 below.

**Table 1: Completed or ongoing processes**

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| --- | --- | --- |
| RMOA |  | [ ]  Risk Management Option Analysis (RMOA) other than this RMOA |
| REACH Processes | Registration | [x]  Registration of manufacture and/or import: Tonnage band: 1,000 - 10,000 t/yr. |
| Evaluation | [x]  Targeted Compliance check concluded, final decision 27.08.2014, Decision´s deadline 04.12.2014. The requested analytical data have been provided. |
| [x]  Testing proposal: Two testing proposals (TPEs)First TPE concluded, Decision date 31.05.2013. Decision deadline 31.05.2014[[3]](#footnote-3). The requested data (Pre-natal developmental toxicity study (OECD TG 314); Sediment simulation testing (OECD TG 308); Long-term toxicity to sediment organisms (OECD TG 218) have been provided.Second TPE (TPE-076/2018), information requested: Toxicity to reproduction, discussed at MSC-62, 2018; decision date: 30.01.2019, Registrant(s) are requested to carry out an EOGRTS (OECD TG 443) in rats, decision deadline for data submission: 06.08.2021[[4]](#footnote-4).  |
| [x]  CoRAP and Substance Evaluation: Started in March 2019 by Austria based on following initial concerns:* Suspected PBT/vPvB
* High aggregated tonnage
* Wide dispersive use

Concluded 2020[[5]](#footnote-5) (Conclusion: Need for follow-up regulatory action at EU level to be discussed in an RMOA) |
| Authorisation | [ ]  Candidate List |
| [ ]  Annex XIV  |
| Restri-ction | [ ]  Annex XVII |
| Harmonised C&L  |  | [ ]  Annex VI (CLP) (see section 3.1) |
| Processes under other EU legislation |  | [ ]  Plant Protection Products Regulation Regulation (EC) No 1107/2009  |
|  | [ ]  Biocidal Product RegulationRegulation (EU) 528/2012 and amendments  |
| Previous legislation |  | [ ]  Dangerous substances Directive Directive 67/548/EEC (NONS) |
|  | [ ]  Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS) |
| (UNEP) Stockholm convention (POPs Protocol) |  | [ ]  Assessment |
|  | [ ]  In relevant Annex  |
| Other processes/ EU legislation |  | [x]  Other (provide further details below)* Food Contact Material - Regulation (Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food): BCPS is listed in the Union list. The specific migration limit (SML) is 0.05 mg/kg. FCM substance No. 152, Ref. No. 15610.
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**National legislation or recommendations**

**Belgium:** Included in Belgian positive [[6]](#footnote-6) list for the acceptance of materials in contact with drinking water and water intended for the production of drinking Water. Maximum tolerable concentration in drinking water: 2,5 µg/l.

**Germany:** The substance is included in the recommendation by the German Bundesinstitut für Risikobewertung (BfR)[[7]](#footnote-7) “Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking equipment” as component for binding resin (Polysulfone), included is the specific migration limit (SML) according to (EU) No 10/2011 of 0.05 mg/kg. Furthermore, limit values for low molecular weight components in finished coatings are listed: for polyethersulfone the content in final coatings is 0.05 mg/dm2.

### CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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| --- | --- |
| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: |  |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* | x |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* |  |
| Need for action other than EU regulatory action | x |
| No action needed at this time |  |

### Need for follow-up regulatory action at EU level

### Identification as a substance of very high concern, SVHC (first step towards authorisation)

The substance BCPS is mainly used as monomer for the manufacture of polymers like high performance polymers (PESU, PSU, PPSU) and other chemicals in quantities of 1,000 – 10,000 tons per year. Professional and consumer uses have not been registered. Article service live is indicated. The manufactured articles are used by professionals and consumers. Typical sectors of use are e.g. the automotive industry, rubber production, food processing industry, the electrical and electronic industries. Further, BCPS is used for medicals equipment, water treatment applications and the aerospace sector.
A minor non-monomer use is as additive in fluoropolymers.

Main concerns for BCPS are the combination of the following properties: the substance is considered as very persistent (vP) and very bioaccumulative (vB) by the evaluating Member State. The substance is assumed to be mainly distributed via water and has the potential to contaminate drinking water. The main environmental transport will take place in water rather than in air. The ultimative sink of BCPS seems to be the sediment.

Measured levels of BCPS show widespread environmental occurrence in the aquatic environment and biota. The need for minimizing emissions is also substantiated by the potential for long-range transport and wide dispersive use in polymers. Therefore, it is necessary to consider Europe-wide measures for risk reduction. Human and environmental exposure to BCPS may be the result of the use of polymers (unreacted monomer after polymerization; physical or UV–induced degradation of the polymer and release/leaching of monomer out of the polymer matrix, release of additive from fluoropolymers) as well as their manufacture.

Emissions can occur not only during the manufacture of the polymers, but also at subsequent stages during article production, service life and disposal. Emissions may also occur from the use of imported articles into Europe. Unreacted monomers are according to registrant(s) present in polymers in the range of <100 ppm. No data are available for other batches of polymer granules or for (imported) articles. Based on the high tonnage of a vP substance, even low fractions of release are of concern.

Minor uses as additive in polymer matrices in concentrations higher than monomer residuals may lead to higher emission losses than the monomer use.

It has been suggested that BCPS levels found in the environment may be explained by historical use of agricultural products such as DDT containing BCPS. However, this assumption seems very unlikely as DDT has been phased out many years ago, and current levels of DDT have sharply decreased, while measurements of BCPS manifestly demonstrate the occurrence of BCPS in biota and wastewater treatment plants. It is thus more likely that either current risk management measures during the use phase of BCPS containing polymers are ineffective or that there are unknown sources of BCPS, which are not identified in the current registrations.

The continuous release of a very persistent chemical may lead to a long lasting, widespread and ever increasing contamination. Steadily growing concentrations may finally lead to known and unknown effects. Once such adverse effects are identified, it will be technically challenging, energy intensive, and thus costly to reverse the contamination. It is, therefore, of importance to minimize emissions and to prevent further contamination by adequate precaution-based measures.

In a first step, the substance BCPS should be identified as an SVHC and included in the REACH Candidate list, thereby formally recognising its vPvB properties. For its major use as a monomer, subsequent inclusion of BCPS in Annex XIV of REACH is not an adequate option. However, registrants and future registrants will have to acknowledge the vPvB status of BCPS and thus make efforts to minimize emissions of the substance to the environment by applying specific operational conditions and risk management measures.

For the minor use as additive, authorization may ensure substitution where possible and minimization of emissions until substitution will be finally achieved. For this use, inclusion in Annex XIV would be an option, provided prioritization based on (potentially low) scores. Since the share of emissions from this use is low as compared to the major use as monomer, the risk reduction effect is probably low as well. It is noted that currently a comprehensive restriction for poly- and perfluorinated alkyl substances (PFAS) is under discussion. Such a restriction could potentially lead to an indirect halt of the use of BCPS as an additive in fluoropolymers.

Another risk management option would be a restriction. However, the currently available information about the sources and pathways of BCPS into the environment does not allow the formulation of a targeted, effective restriction measure following the SVHC identification. In order to improve the existing information basis, the Austrian CA proposes to consider jointly a European wide emission source tracing and environment monitoring involving voluntary programmes by Industry and/or Member States, respectively. Strategically targeted emission monitoring could support the identification of relevant emission sources, and monitoring in aquatic environments could constitute a clearer picture of the relevance of BCPS pollution and potential pollution trends in Europe.

Such measures should obtain a clearer picture of sources for the environmental contaminations and more information on residual monomers and the release potential of BCPS, which would allow to establish targeted restriction measures.

If voluntary monitoring measures turn out to be inefficient for identifying the relevant sources of the detected BCPS contamination, a restriction establishing a mandatory effluent monitoring programme may be considered as a further option.

Based on the outcome of currently performed additional toxicity testing, the substance may also need to be considered as a new POP candidate.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up**  | **Actor** |
| Annex XV dossier for SVHC identification | 02 / 2023  | Austria |

1. For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation> [↑](#footnote-ref-1)
2. [c63c93be-c901-864f-1d5a-9e21a35c81f8 (europa.eu)](https://echa.europa.eu/documents/10162/c63c93be-c901-864f-1d5a-9e21a35c81f8) [↑](#footnote-ref-2)
3. <https://echa.europa.eu/documents/10162/02798d91-5265-8620-b42a-59e8701ab288> [↑](#footnote-ref-3)
4. <https://echa.europa.eu/documents/10162/e12106b0-ca86-dbcc-2373-b3c2329738a9> [↑](#footnote-ref-4)
5. SEv Conclusion, 2020: [c63c93be-c901-864f-1d5a-9e21a35c81f8 (europa.eu)](https://echa.europa.eu/documents/10162/c63c93be-c901-864f-1d5a-9e21a35c81f8) [↑](#footnote-ref-5)
6. <http://www.belgaqua.be/document/Positive%20List.pdf> [↑](#footnote-ref-6)
7. Datenbank BfR-Empfehlungen zu Materialien für den Lebensmittelkontakt: LI. Temperaturbeständige Beschichtungssysteme aus Polymeren für Brat-, Koch- und Backgeräte als Komponente für Bindeharz (Polysulfon) <https://bfr.ble.de/kse/faces/resources/pdf/510.pdf;jsessionid=9C5033CAAFB132C331C25A32D29FC98D> (01.04.2022) [↑](#footnote-ref-7)