



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Comment

CHEM Trust's comments on the proposal for harmonised classification and labelling of bisphenol S

(submitted via ECHA online platform 7.2.2020)

General comments

- CHEM Trust would like to thank the dossier submitter for their important work on the CLH report to classify BPS as a substance toxic to reproduction.
- The similar substance Bisphenol A is already classified as Rep 1B and has been identified and included in the REACH Candidate List as a SVHC due to its endocrine disrupting properties.
- An identification as endocrine disruptor may also be warranted for BPS as many studies have shown estrogenic activity like BPA (see e.g. <https://academic.oup.com/toxsci/article/139/1/35/2338266>).
- Already in 2015 RAC highlighted that BPS has similar properties to BPA and still the substances was marketed without any information on its potential hazards despite indications for the damage on fertility (see insufficient self-classification by companies in the classification and labelling inventory, as summarized in the CHEM Trust report `From BPA to BPZ. <https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicoup-mar-18.pdf>)
- At the same time BPS was increasingly used as a replacement for BPA in thermal paper, as has been found in an ECHA survey (<https://echa.europa.eu/-/bpa-being-replaced-by-bps-in-thermal-paper-echa-survey-finds>).
- Use of BPS as a replacement for BPA may potentially lead to higher internal exposure to endocrine active substances as there may be a higher systemic bioavailability after oral ingestion of BPS compared to BPA as recently reported when studied in pigs (<https://doi.org/10.1289/EHP4599>).
- In order to avoid replacing a harmful substance with one with similar properties we urge taking a group approach to bisphenols in the necessary subsequent risk management measures.
- BPS has been included in ChemSec's SIN list in 2014 as an endocrine disrupter based on its estrogenic properties. It has shown to be estrogenic in in vitro studies. In vivo studies have shown impaired reproduction in zebrafish and uterine growth in rat. (<https://sinsearch.chemsec.org/chemical/80-09-1>).
- The need for classification due to other hazards e.g. acute toxicity should be scrutinised as a recent study in isolated mouse hearts may indicate a possibility for instant heart effects after exposure to BPS in amounts that mimicked typical human levels (<https://www.news-medical.net/news/20200109/Study-Bisphenol-S-can-hinder-heart-function-within-minutes-of-exposure.aspx>).
- It is very concerning that there is widespread exposure of the general population to BPS. The substance has also been included as a priority in the ongoing Human Biomonitoring Initiative <https://www.hbm4eu.eu/mdocs-posts/hbm4eu-ici-equas-report-bisphenols-in-urine-round-2/>
- BPS is meanwhile already ubiquitous in the environment, and has been shown to affect the development of Zebrafish larvae (Wu et al. 2018). Wu L-H et al, 2018 Occurrence of bisphenol S in

the environment and implications for human exposure: A short review. Sci Total Environ.615, 87-98; <https://doi.org/10.1016/j.scitotenv.2017.09.194>

Comments on the open hazard classes

- CHEM Trust supports the classification of BPS as a reprotoxic substance, category 1B (labelling GHS08 Dgr, H360FD) because:
- A new EORGTS study from 2019 (OECD 443) supported by a reproduction/developmental toxicity screening test and further one combined with a repeated dose toxicity study (OECD 421 and 422) clearly show adverse effects on sexual function and fertility which cannot be related to a general toxicity.
- A new EORGTS study from 2019 (OECD 443) supported by a prenatal developmental toxicity study (OECD 414) and a combined repeated dose toxicity study/reproduction/developmental toxicity screening test (OECD 422) clearly show adverse effects on development which cannot be related to a general toxicity.