Justification for the inclusion of a substance in the Rolling Action Plan (RAP) for UK REACH

Substance Name: 2,2'-diallyl-4,4'-sulfonyldiphenol

EC: 411-570-9, CAS: 41481-66-7

March 2022

Contents

1. Purpose/Aim

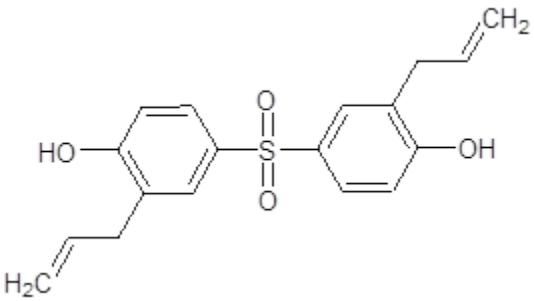
This document provides justification for including a substance in the rolling action plan (RAP) under Article 44 of UK REACH.

2. Identity of the substance

2.1 Identifiers of the substance

EC name:	2,2'-diallyl-4,4'-sulfonyldiphenol
IUPAC name:	4-[4-hydroxy-3-(prop-2-en-1-yl)benzenesulfonyl]-2-(prop-2-en-1-yl)phenol
CAS no.	41481-66-7
EC no.	411-570-9
Index number in GB Mandatory Classification and Labelling (MCL) List	016-075-00-8
Molecular formula:	$C_{18}H_{18}O_4S$
Molecular weight or molecular weight range:	330.4 g/mole
Synonyms/Trade names:	TG-SA, TG-SB, TG-SH, TG-SH(H)
Type of substance:	Mono-constituent substance

Structural formula:

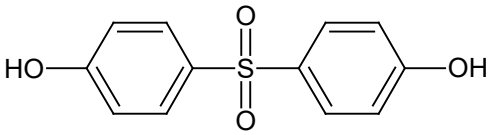


1.2 Similar substances/grouping possibilities

The substance 2,2'-Diallyl-4,4'-sulfonyldiphenol (referred to as TG-SA in this document) is a bisphenol. A close analogous substance is 4,4'-sulfonyldiphenol (bisphenol S, BPS) EC 201-250-5, CAS 80-09-1.

Structural formula:

BPS:



2. Hazard information (including classification)

2.1 Classification in the GB Mandatory Classification and Labelling List

The substance is listed in the GB Mandatory Classification and Labelling (MCL) list with the following classification:

- Skin Sens. 1 H317
- Aquatic Chronic 2 H411

2.2 Harmonised classification in Annex VI of EU CLP

The substance is listed in Annex VI of EU CLP with the following classification:

- Skin Sens. 1 H317
- Aquatic Chronic 2 H411

2.3 Self-classification

- Self-classification in the registration dossier:
  - Skin Sens. 1 H317
  - Aquatic Chronic 2 H411

- Self-classification in the ECHA Classification and Labelling (C&L) Inventory[1]

  - All notifications to the inventory use the mandatory/harmonised classification and labelling.

[1] European Chemicals Agency (ECHA) Classification and Labelling (C&L) Inventory, which includes information submitted by GB-based manufacturers and importers prior to 31st December 2021; https://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

3. Information on (aggregated) tonnage and uses

3.1 Aggregated tonnages

According to the ECHA dissemination site[2], the amount manufactured and/or imported into the European Union (EU) is in the range of 10 – 100 tonnes per year.

There is one UK registration of the substance, stated to be 10 – 100 tonnes per year

3.2 Uses

The following uses are identified in the registration dossier:

Use Type	Use identified
Industrial	Formulation or re-packing: Paper and board treatment products Uses at industrial sites: Manufacture of thermal paper
Professional	(Widespread) use of thermal paper by professionals
Consumer	(Widespread) use of thermal paper by consumers
Closed System	No

[2] Information on substances registered under EU REACH: https://echa.europa.eu/information-on-chemicals/registered-substances

4. Justification for the selection of the candidate substance

4.1 Legal basis for the proposal

In accordance with Article 44(1) of UK REACH, the substance meets the following criteria for inclusion in the RAP:

Selection Criteria Met:	
CMR[3]	Yes Potential reproductive toxicant
Sensitiser[4]	N/A
Endocrine disrupter (ED)[5]	Yes
PBT/vPvB[6]	N/A
substances that are suspected to be persistent, and for which environmental monitoring data or screening laboratory data (such as organic-water partitioning coefficient) indicate the likelihood of widespread distribution in the environment	N/A
High (aggregated) tonnage (>1000 tonnes per year)	N/A
Exposure information	Yes

[3] CMR: known or suspected (e.g., based on structural similarities) carcinogenic and/or mutagenic and/or reprotoxic properties.

[4] Known or suspected (e.g., based on structural similarities) skin and/or respiratory sensitisers.
[5] Known or suspected (e.g., based on reproductive effects and/or structural similarities) endocrine disruptors.
[6] PBT: Known or suspected Persistent, Bioaccumulative and Toxic. vPvB: known or suspected very Persistent and very Bioaccumulative.

4.2 Initial grounds for concern to be clarified under substance evaluation

Hazard based concern:

- **Potential endocrine disruptor**
- **Potential CMR**

The substance is indicated to have ED activity in *in vitro* assays detailed in the US EPA Toxcast database[7]. There are no environmental endocrine data included in the grandfathered UK REACH registration dossier. A long-term fish toxicity test performed according to OECD Test Guideline (TG) 215 (Fish, juvenile growth test) is summarised in the registration dossier, but this does not include relevant endpoints to assess endocrine disruption.

The substance has structural similarities to BPS – the difference being an allyl chain on each of the phenyl groups of TG-SA compared to BPS. ECHA's Risk Assessment Committee recently agreed to classify BPS as Repro. 1B due to effects observed in rats[8]. This was supported in the GB CLP Agency Technical Report for BPS (HSE 2021)[9]. A Medaka or Zebrafish Extended One Generation Reproduction test (OECD TG 240 and draft TG) has been requested under the EU REACH Substance Evaluation process for BPS to investigate endocrine disruption in fish. These data are not currently available in the EU registration of the substance[10]. The justification for the study included two *in vivo* fish studies[11] where effects on the sexual development and reproduction of Zebrafish (*Danio rerio*) were observed due to BPS exposure. The effect of the allyl substituents for the *in vivo* endocrine disrupting potential of TG-SA is not known.

Given the structural similarities with BPS, it will also be important to clarify if TG-SA shows similar mammalian reproductive hazards to those which have been observed for BPS, potentially leading to a recommendation to classify TG-SA as Repr 1B.

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[7] https://comptox.epa.gov/dashboard/chemical/details/DTXSID9047598 accessed 9th December 2021

[8] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e182ed4414 accessed 8th December 2021

[9] GB CLP - Article 37 - Technical Report - Bisphenol S - CAS 80-09-1 (hse.gov.uk); https://www.hse.gov.uk/chemical-classification/classification/harmonised-classification-self-classification/mcl-aacz-0151.pdf

[10] https://echa.europa.eu/registration-dossier/-/registered-dossier/14986/1/1 accessed 8th December 2021

[11] Ji K, Hong S, Kho Y, and Choi K. 2013. Effects of bisphenol S exposure on endocrine functions and reproduction of Zebrafish. Environmental Science and Technology, 47, 8793-8800 and Naderi M, Wong MYL and Ghoami F. 2014. Developmental exposure of zebrafish (*Danio rerio*) to bisphenol-S impairs subsequent reproduction potential and hormonal balance in adults. Aquatic Toxicology, 148, 195-203.

Exposure/risk based concerns

- **Wide dispersive use**
- **Exposure of environment**

The substance is formulated and used by professional and consumer users in the UK. The registration indicates a widespread use leading to inclusion into/onto articles (indoor) for the professional and consumer uses, and a service life with widespread use of articles with low release (indoor). The substance is used in thermal paper. Emissions to the environment can also occur both during the manufacture and recycling of paper.

According to the registration dossier, the substance is not readily biodegradable in a test performed according to OECD TG 301D, with 4% mineralisation occurring after 28 days. However, primary degradation of the substance may include degradation of the two allyl chains which could lead to a structure very similar to BPS. This requires further investigation in case TG-SA is a source of a potential endocrine disrupting substance.

A chemical safety assessment has not been provided in the UK dossier with the following explanation: *A CSR is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which do not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation.* Therefore, a current environmental exposure assessment is not available. An up-to-date exposure assessment would help to clarify whether there are any conventional PEC/PNEC risks and would provide context for future risk management if any of the hazard concerns are confirmed. If reproductive hazards are confirmed for TG-SA and given the existing classification as Skin Sens 1, it will also be important to understand potential human exposures both for workers and consumers to decide if the identified uses are creating an unacceptable risk.

The German regulatory authorities are understood to be considering an EU REACH restriction of bisphenols and this evaluation will help the UK to assess the need for risk management in a UK context.

There is a possibility that the use pattern of the substance could change (and level of supply increase) in the future as a result of the ECHA proposed Repro. 1B classification for BPS.

4.3 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

Regulatory Process	Action
Dossier Evaluation	No action
Annex 15 – SVHC identification	No action
Annex 14 - Authorisation	No action
Annex 17 - Restriction	No action
Plant Protection Products Regulation	No action
Biocidal Products Regulation	No action
Other	No action

4.4 Preliminary indication of information that may need to be requested to clarify the concern

Testing to assess the environmental endocrine disruption potential of the substance.

Testing to assess the likelihood of environmentally relevant degradants being formed that have endocrine disrupting potential.

Environmental risk assessment including details of current uses and information on releases to the environment from the life cycle (which may also include a request for monitoring data).

Further information

This publication is available on the HSE website.

Published by the Health and Safety Executive