



Initial assessments of substances added to the EU Candidate List in 2021

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1. Introduction

The [UK REACH work programme for 2021/22](#) states that we will assess all the substances that have been submitted for identification as Substances of Very High Concern (SVHCs) in EU REACH at the time the work programme was published (if they are not already on the UK REACH Candidate List) and consider if they are appropriate for SVHC identification in UK REACH.

The EU SVHCs pipeline includes 2 substances that were added to the EU Candidate List in January 2021, 1 substance that is awaiting a decision by the EU on its SVHC status and 8 substances that the EU proposed to identify as SVHCs in the consultation that took place during spring 2021. This document presents the initial assessments that were performed by HSE and the Environment Agency to consider if SVHC identification is an appropriate action for these substances under UK REACH or if a more detailed assessment is required to decide on the most appropriate regulatory approach.

UK REACH entered into force on 31st December 2020 at the end of the transition period. It regulates the access of chemicals to the GB market. Under the Northern Ireland Protocol, EU REACH continues to regulate the access of chemicals to the Northern Ireland market. It will take some time for the UK database (*Comply with UK REACH-IT*¹) to become fully populated with information on substances registered under UK REACH (in accordance with the transitional arrangements provided for in UK REACH). Where we have robust information on the volume and use of substances within Great Britain (GB) we will base our assessments on this information. Where this information is lacking, HSE will take ECHA data into account, acknowledging that this approach will introduce a source of uncertainty.

For this exercise we provisionally allocated substances to one of three groups:

- Group 1: Call for evidence and regulatory options management analysis (RMOA)
- Group 2: Possible RMOA but of lower priority
- Group 3: No action under UK REACH at this time

The assessments for each substance are outlined in section 2. Calls for evidence for the 4 substances identified as requiring an RMOA will be hosted on HSE's website at: <https://consultations.hse.gov.uk/>. HSE invites you to respond to this call with any GB specific information you may have about these substances to help it refine these assessments and decide what further action may be needed. Information can also be submitted via the UK REACH helpdesk at: ukreach.clp@hse.gov.uk.

¹ Comply with UK REACH is the service introduced to allow industry users in the UK to register and manage their chemicals handling in the UK.

2. Assessment outcomes by substance

2.1 Group 1: Call for evidence and RMOA

2.1.1 Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivatives, and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives wherein C12 is the predominant carbon number of the fatty acyloxy moiety

Substance Names: Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivatives, and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives wherein C12 is the predominant carbon number of the fatty acyloxy moiety.

EC Number: -

CAS Number: -

This is a group of substances that includes the monoconstituent substance dioctyltin dilaurate, the UVCB substance stannane, dioctyl-, bis(coco acyloxy) derivatives and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives wherein C12 is the predominant carbon number of the fatty acyloxy moiety. For convenience the group will be referred to by the acronym DOTL in this document.

SVHC-relevant intrinsic properties

Toxic for reproduction (Article 57c)

Tonnage and Use

One registration has been submitted to Comply with UK REACH for the monoconstituent substance dioctyltin dilaurate (CAS 3648-18-8), tonnage band 10 – 100 tonnes per year (tpy). For the same substance, one joint submission has been submitted under EU REACH supported by 9 companies. The total tonnage band in the EU is 100-1,000 tpy.

REACH registrations have not been submitted for stannane, dioctyl-, bis(coco acyloxy) derivatives (CAS 91648-39-4) in either Great Britain (GB) or the EU.

DOTL is used predominantly as a catalyst in the manufacture of a variety of polyurethane applications, including rigid foams, varnish and powder coatings and sealants. DOTL based products also catalyse processes for manufacturing polyester polyols and other polyester products such as the cross-linked low-density polyethylene cable insulation that is used for communications applications and high voltage power cables which may be used underground, overhead, across the oceans, in buildings, tunnels, vehicles, ships, trains etc.

Summary of Assessment

This group of substances was added to the EU Candidate List on 19th January 2021 in accordance with ECHA decision [D\(2020\)9139-DC](#). This activity follows the harmonisation of classifications for reproductive toxicity and repeated exposure for

dioctyltin dilaurate (CAS 3648-18-8) and stannane, dioctyl-, bis(coco acyloxy) derivatives (CAS 91648-39-4) which were adopted via the 15th ATP to EU CLP (Index No. 050-031-00-9) and transferred into the GB MCL at the end of the transition period.

Industry respondents to ECHA's [public consultation](#) claimed that no suitable alternatives are available for most uses of these substances. The selection of catalysts is usually optimised for each process therefore it may be challenging to find a drop-in replacement. It is recommended that a RMOA is carried out for this group of substances to obtain GB specific information about manufacture, import (including importation of mixtures and articles containing the substance), use of the substance and articles containing the substance, the potential for the substance to leach from articles and information about possible alternatives. This information will help us assess whether SVHC identification (and eventual inclusion in Annex 14) is an appropriate regulatory action in a GB only context.

2.1.2 1,4-dioxane

Substance Name: 1,4-Dioxane

EC Number: 204-661-8

CAS Number: 123-91-1

SVHC-relevant intrinsic properties

Carcinogenic (Article 57(a))
Persistent, mobile, and toxic (PMT) (Article 57(f)).

Tonnage and Use

There are no known UK production sites. However, the substance is imported. One registration has been submitted to Comply with UK REACH for 1,4-dioxane, tonnage band 10 – 100 tpy.

1,4-Dioxane is registered under EU REACH. There are 7 joint registrants supplying an aggregated tonnage of $\geq 1,000$ tpy. EU annual production was estimated at 2,000-2,500 tonnes in 1997 ([ESR RAR, 2002](#)).

1,4-Dioxane is used as a solvent in the production of lacquers, varnishes, cleaning and detergent preparations, adhesives, cosmetics, deodorant fumigants, emulsions and polishing compositions, pulping of wood, extraction medium for animal and vegetable oils, laboratory chemical (eluent in chromatography), cassettes, plastic and rubber, and insecticides. It is also used as a stabilizer for 1,1,1-trichloroethane. However, this use has declined considerably because of the restriction on the use of substances depleting the ozone layer. In addition, there can be unintended production during manufacture of some organic substances, including polymers (e.g., polyethylene terephthalate (PET)) and alcohol ethoxylates. As a result, it may be found as a contaminant in consumer products such as plastics, detergents and cosmetics.

Summary of Assessment

1,4-Dioxane was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#). In addition to this action, the EU is also considering possible restrictions. ECHA held a [call for evidence](#) between March and June 2021 to help Germany prepare an Annex 15 report which ECHA anticipates will be submitted during 2022. As of 12th November 2021, no intention has been submitted to the EU Registry of Intentions. Alongside this call for evidence the EU held a separate [call for evidence](#) to gather information to help ECHA recommend an occupational exposure limit.

Since 1,4-dioxane has been detected in UK groundwater it is a substance of interest to UK government. In addition to carcinogenicity, the EU has identified 1,4-dioxane as an SVHC on the grounds of its PMT properties. Discussions are ongoing on the most appropriate way to for GB to manage risks from substances that are persistent, toxic and mobile in the environment. Given this and that various regulatory actions are in progress at the EU level, it seems appropriate to carry out an RMOA to help identify the best regulatory approach for this substance in GB. The RMOA will help us obtain GB specific information about manufacture, import (including importation of mixtures and articles containing the substance), use of the substance and articles containing the substance, the potential for the substance to leach from articles and information about possible alternatives. This information will help us assess whether SVHC identification (and eventual inclusion in Annex 14) is an appropriate regulatory action in a GB only context.

2.1.3 Small brominated alkylated alcohols (SBAA)

This group includes three substances.

Substance Name:	2,2-Bis(bromomethyl)propane1,3-diol (BMP)
EC Number:	221-967-7
CAS Number	3296-90-0
Substance Name:	2,2-Dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA)
EC Number:	253-057-0
CAS Numbers:	36483-57-5 1522-92-5
Substance Name:	2,3-Dibromo-1-propanol (2,3-DBPA)
EC Number:	202-480-9
CAS Number:	96-13-9

SVHC-relevant intrinsic properties

Carcinogenicity (Article 57(a)) for all three.

Tonnage and Use

One registration for BMP has been submitted to Comply with UK REACH in the tonnage range 100 – 1,000 tpy. BMP is also registered by two companies under EU REACH. The aggregated tonnage for these EU registrations is 100 – 1,000 tpy. It is used as a reactive flame retardant in polymer resins. Information submitted by the registrants in 2014 during a stakeholder consultation under the Restriction of Hazardous Substances (RoHS) Directive (this Directive aims to prevent risks to human health and the environment arising from the use of certain substances in electronic and electrical equipment) suggests that over 90% of the BMP supplied to the EU market is used as a flame retardant in unsaturated polyester roofing sheets. The suppliers state that this substance is not used in electric and electronic equipment (EEE).

TBNPA is not registered in GB but is registered in the EU by two companies. One is a full registration covering the tonnage band 100 – 1,000 tpy. The other registration covers use as an intermediate only. TBNPA is used as a reactive intermediate for high molecular weight flame retardants, particularly in the production of phosphorus- and bromine-containing flame retardants. It is also used as a reactive flame retardant for polyurethanes. According to the [EU Annex 15 SVHC report](#), TBNPA may be present in polymer preparations supplied to consumers.

2,3-DBPA is not registered in GB but is registered in the EU as an intermediate by one company, PALCHEM, based in France. No information has been published about the tonnage covered by the registration. Although ECHA's disseminated information does not provide details of the types of chemicals that are manufactured using this substance, information published in a report from the [US National Toxicology Programme](#) suggests that this substance can be used as an intermediate in the preparation of flame retardants, insecticides, and pharmaceuticals. The NTP report states that the chemical has also been used as a flame retardant as such, but it is not known if it is still used as a flame retardant.

Although the [EU Annex 15 SVHC report](#) identifies alternative flame retardants, it is not clear if these are technically suitable for the various uses for these small brominated alcohols. Further assessment of alternatives will be needed if substitution is a desirable regulatory goal.

Summary of Assessment

SBAAs were added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#).

The extent to which this group of substances is used in GB, or in articles supplied to the GB market, is not known. It will therefore be useful to carry out a RMOA to obtain information about the uses for these substances and articles containing these substances in GB and whether suitable alternatives are available.

2.1.4 Phenol, alkylation products (mainly in *para* position) with C12-rich branched or linear alkyl chains from oligomerisation, covering any individual isomers and/or combinations thereof (PDDP)

Substance Name: Phenol, alkylation products (mainly in *para* position) with C12-rich branched or linear alkyl chains from oligomerisation, covering any individual isomers and/or combinations thereof.

EC Number: -

CAS Number: -

SVHC-relevant intrinsic properties

Toxic for reproduction (Article 57(c))

Endocrine disrupting properties (Article 57(f) – human health and environment)

Tonnage and Use

According to the [EU Annex 15 report](#), the PDDP acronym covers a group of substances. The registered substance phenol, dodecyl-, branched, (PDB) is manufactured and/or imported into GB at > 1,000 tpy (so far 4 full registrations have been submitted under UK REACH) and into the European Economic Area at 10,000 – 100,000 tpy (currently 13 full registrations have been submitted under EU REACH and an additional individual submission covering intermediate use only). The main use is as a chemical intermediate in the production of lubricant additives, hydraulic oils and fuel system cleaners, synthetic rubbers, tyres and floor coatings, paints, printing inks, varnishes, epoxy and phenolic resins. Products may unintentionally contain residual PDDP.

No information on alternatives is provided in the EU Annex 15 SVHC dossier.

Summary of Assessment

PDDP was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#).

Given that these substances are mainly used as chemical intermediates, and that REACH Article 2(8)(b) excludes use as an on-site isolated intermediate or transported isolated intermediate from the scope of authorisation, it may be useful to carry out a RMOA to determine the best regulatory approach for this group of substances. The RMOA will need to take into account the findings in the [environmental risk evaluation assessment](#) performed for *para*-C12-alkylphenols by the Environment Agency for England and Wales in 2007.

2.2 Group 2: Possible RMOA but of lower priority

2.2.1 Tetraglyme

Substance Name: Bis(2-(2-methoxyethoxy)ethyl) ether; (tetraglyme)

EC Number: 205-594-7

CAS Number: 143-24-8

SVHC-relevant intrinsic properties

Toxic for reproduction (Article 57(c))

Tonnage and Use

One registration has been submitted to Comply with UK REACH for tetraglyme, the tonnage band is 1-10 tpy. The substance is currently supplied to the EU market at ≥ 100 tpy. Six active registrants are listed on ECHA's website. A seventh registrant, BASF in Germany, ceased manufacture in 2019. The registrations cover industrial and professional uses. Information in the EU RMOA conclusion document indicates that tetraglyme is used as solvent for synthesis and extractions, gas absorption liquid, processing aid, solder flux, functional fluid and in inks. The EU registrants advise against consumer use. Its Repr. 1B classification will bring this substance into scope of REACH restriction 30 which restricts the supply of tetraglyme to consumers as the substance itself and in mixtures where it is present at ≥ 0.3 %.

The [EU Annex 15 SVHC report](#) suggests that it may be possible to substitute tetraglyme with a lower toxicity ethylene glycol ether or propylene glycol ether. Phenol ethers such as 2-phenoxyethanol and 2-(2-phenoxyethoxy)ethanol or cyclic ethers such as dimethyl isosorbide were also suggested as possible alternatives. Further information gathering will be needed to understand if tetraglyme is a genuine substitute for any glycol ethers already listed on the candidate list, also which substances may be viable alternatives for tetraglyme.

Summary of Assessment

Tetraglyme was added to the EU Candidate List on 19th January 2021 in accordance with ECHA decision [D\(2020\)9139-DC](#).

Based on use information provided in the EU Annex 15 dossier, it is workers that are potentially exposed to this substance. Since the substance is not supplied to consumers, no risks are anticipated for this group. Risks to workers from tetraglyme fall under the scope of the Control of Substances Hazardous to Health Regulations (COSHH) which requires employers to prevent exposure of their employees to hazardous substances. Where exposure cannot be prevented, exposure should be minimised using control measures that are proportionate to the risk. Schedule 2A of the [COSHH Regulations](#) sets out 8 principles of good occupational hygiene practice that must be applied to secure adequate control of exposure to hazardous substances. For a substance that can cause adverse reproductive effects, the principles of good occupational hygiene practice require a high level of control to be applied to prevent or, if this is not possible, minimise exposure. The measures already in place in GB (which

may not be present in the EU) mean that there may be little additional benefit to worker protection from identifying the substance as an SVHC and adding it to the Candidate List. Therefore, no action is proposed under UK REACH at this time.

This position will be reconsidered if any additional information emerges suggesting there could be concerns for tetraglyme.

2.2.2 2-(4-*tert*-butylbenzyl)propionaldehyde and its individual stereoisomers (Lysmeral)

Substance Name: 2-(4-*tert*-Butylbenzyl)propionaldehyde and its individual stereoisomers

EC Number: -

CAS Number: -

2-(4-*tert*-Butylbenzyl)propionaldehyde (EC 201-289-8, CAS 80-54-6) is manufactured as a racemic mixture (1:1) of the two enantiomers (2S)-3-(4-*tert*-butylphenyl)-2-methylpropanal (CAS 75166-30-2) and (2R)-3-(4-*tert*-butylphenyl)-2-methylpropanal (CAS 75166-31-3). For completeness, all three substance identities were included in the EU SVHC identification action.

SVHC-relevant intrinsic properties

Toxic for reproduction (Article 57(c))

Tonnage and Use

Currently no registrations for lysmeral have been submitted to Comply with UK REACH. In the EU, lysmeral is registered by two companies, BASF SE based in Germany and an only representative, Penman Consulting bvba, based in Belgium. The aggregated tonnage band for these registrations is 1,000 – 10,000 tpy.

Lysmeral is used as a fragrance in a wide range of products including cleaning agents, biocidal products, air care products and scented articles, including products that are supplied for consumer use. Its scent is described as floral, fresh with hints of magnolia, lilac and honey-suckle. The [EU Annex 15 report](#) also indicates it is used as a chemical intermediate.

The EU Annex 15 SVHC dossier identified the substance 3-(4-isobutyl-2-methylphenyl)propanal as a possible alternative to 2-(4-*tert*-butylbenzyl)propionaldehyde.

Summary of Assessment

Lysmeral was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#).

This is a possible candidate for substitution, but it is not clear if this goal will be

achieved by identifying the substance as an SVHC because the substance may be able to fulfil its function as a fragrance in mixtures at concentrations below the thresholds triggering duties under the authorisation regime (the generic concentration limit of 0.3% triggering a requirement to seek authorisation for substances classified as Repr 1B would be applicable).

The concentration threshold may also render REACH restriction 30 ineffective (this restricts the use of substances classified with Repr 1B in products supplied to consumers where they are present at $\geq 0.3\%$ or other specific concentration limit if applicable). However, if the substance is used at low concentrations, this will also limit the risk that its use presents to consumers. For these reasons, it is proposed that no action needs to be taken now.

If information emerges to suggest that this substance may be posing a risk, it is recommended that a RMOA is performed to understand the range of products containing this substance in GB and the concentrations at which it is present. This will help inform decisions about the most appropriate regulatory approach for this substance.



Group 3: No action needed under REACH at this time

2.2.3 Resorcinol

Substance Name: Resorcinol

EC Number: 203-585-2

CAS Number: 108-46-3

SVHC-relevant intrinsic properties

Endocrine disrupting properties (Article 57(f) – human health)

Tonnage and Use

Information [provided by the Resorcinol Task Force to ECHA](#) during its public consultation in the SVHC identification process indicates that there is no production of resorcinol in EU28 and this has been the case since the early 1990s. The main production is now in Asia. All resorcinol used in manufacturing processes in EU28 is imported, amounting to a total of approximately 15,000 tpa.

Four registrations have been submitted to Comply with UK REACH. Twelve joint registrants are listed on ECHA's website. The registrations cover industrial, professional and consumer uses (professional and consumer uses are limited to use in cosmetics and hair dyes). The EU registrants advise against use in skin peels. A separate joint registration has been submitted covering use as an intermediate, but only one of these registrations is currently active.

Quantitatively, the major use of resorcinol in the EU (around 50% of the total volume) is in tyres and other rubber products with most of it being now supplied in the form of resorcinol formaldehyde (RF) or phenol resorcinol formaldehyde (PRF) resins. Resorcinol is also used in wood products (especially wood adhesives for structural laminated beams). Resorcinol based resins are used in structural applications because of their high bond strength and in laminated boards (e.g., plywood) because of their speed of cure. As with all phenolic resins, they have intrinsic high temperature resistance.

Resorcinol is used to produce diphosphate ester flame retardants and smaller amounts of resorcinol are used as a chemical intermediate in the production of UV stabilizers, functional and textile dyes, pharmaceuticals, explosives, and herbicides. Other specific uses include use as a component of hair dye formulations and as a minor component of some topical ointments. The latter use arises from resorcinol's antiseptic and disinfectant properties. Since the 1950s, the levels have been tightly regulated at <5% and typically in the order of 2%. These limits are stipulated within the pharmacopeia for topical ointments while resorcinol's use in hair dyes is evaluated and controlled under cosmetics legislation.

Resorcinol is approved as a food additive in the EU. It is used as an antioxidant in fresh, frozen and deep-frozen crustaceans.

In addition to commercial sources of exposure, resorcinol is a naturally occurring substance. Information from the [Finnish substance evaluation](#) report indicates that the resorcinol moiety has been found in a wide variety of natural products. Plant phenolic substances, of which resorcinol ring-containing constituents are a part, are ubiquitous in nature. Resorcinol itself has been found in the broad bean (*Vicia faba*), detected as a flavour-forming compound in the honey mushroom (*Armillaria mellea*) and found in exudates of seedlings of the yellow pond lily (*Nuphar lutea*). Resorcinol has also been found in extracts of tobacco leaves and is a component of tobacco smoke.

In terms of resorcinol derivatives, resorcinol ethers are components of fragrance agents, and there is considerable literature on long chain alk(en)yl resorcinols in plants and bacteria. Resorcinol is one of the main natural polyphenols in argan oil, extracted from fruit kernels of argan trees for culinary oil and cosmetic purposes. Resorcinol is also a monomeric by-product of the reduction, oxidation, and microbial degradation of humic substances. Humic substances are also present in coals, shales, and possibly other carbonaceous sedimentary rocks. This occurrence may explain the detection of resorcinol in wastewater effluents of coal conversion processes due to thermal breakdown. Resorcinol has also been found in some samples as a decomposition product of corn residues in soil.

Industry respondents to ECHA's public consultation stated that there are no suitable less hazardous alternatives.

Summary of Assessment

The [EU RMOA concluded](#) that use of this substance is not creating an unacceptable risk. HSE and the Environment Agency for England examined the scientific evidence on the endocrine disrupting properties for resorcinol and disagree that the SVHC criteria are met for this substance. This position was stated in the public consultation held by ECHA in Spring 2020. No new information has emerged that warrants a change to this conclusion. Therefore, no action is required under UK REACH at this time. It is noted that [France has requested](#) that a larval amphibian growth and development assay is conducted and submitted by 19 September 2022. We will reconsider our position on resorcinol if the results from this study demonstrate that action is required.

2.2.4 Bisphenol B

Substance Name: 4,4'-(1-Methylpropylidene)bisphenol (bisphenol B; BPB)

EC Number: 201-025-1

CAS Number: 77-40-7

SVHC-relevant intrinsic properties

Endocrine disrupting properties (Article 57(f) – human health and environment)

Tonnage and Use

BPB is not REACH registered in GB or the EU. Information from the [EU Annex XV](#)

[SVHC report](#) indicates that BPB may be used in the manufacture of phenolic and polycarbonate resins. It is registered by the US FDA as an “indirect” additive used in resinous and polymeric coatings applied to food cans as corrosion inhibitors.

Summary of Assessment

BPB was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#). One aim for this action is to limit potential use of BPB as a substitute for BPA. There is no supporting evidence to suggest that this substitution is viable, so it is not clear what regulatory benefits will be gained if this non-registered substance is added to the Candidate List. For this reason, no action is required under UK REACH at this time. Any future work to assess GB regulatory management options for bisphenols will include BPB.

2.2.5 Glutaraldehyde

Substance Name: Glutaryl (Glutaraldehyde)

EC Number: 203-856-5

CAS Number: 111-30-8

SVHC-relevant intrinsic properties

Respiratory sensitising properties (Article 57(f) – human health)

Tonnage and Use

Currently there are no registrations for glutaraldehyde in Comply with UK REACH. In EU REACH, the substance has one full registration (covering 7 registrants) and one registration for intermediate use only (covering 2 registrants). The tonnage band for the full registration is 10,000 – 100,000 tpy.

A major use for glutaraldehyde is as a biocide. Under the GB Biocidal Products Regulation, approvals have been granted for the use of glutaraldehyde in the following:

- PT02 – Disinfectants and algicides not intended for direct application to humans or animals
- PT03 – Veterinary hygiene
- PT04 – Food and feed area
- PT06 – Preservatives for products during storage
- PT11 – Preservatives for liquid-cooling and processing systems
- PT12 – Slimeicides

The expiry date for these approvals is 30 September 2026.

In the EU, glutaraldehyde may also be used in the health care sector, but it has been withdrawn from this use in GB.

Historically, glutaraldehyde was a major cause of occupational asthma in GB due mainly to cases in health care workers. [Work related asthma statistics for Great Britain](#) published on 4th Nov 2020 indicate a substantial decline in the cases of occupational asthma due to glutaraldehyde. This decline is thought to be due to its withdrawal from use in the health care sector. To illustrate this decline in cases, of the occupational asthma cases assessed for [Industrial Injuries Disablement Benefit](#), there have been no cases since 2011 where glutaraldehyde was the suspected causal agent. From 2005 (around the time glutaraldehyde was withdrawn from use in health care), the 3-year annual average number of cases of occupational asthma ascribed to glutaraldehyde and reported to the [THOR](#) scheme² was 0 or 1.

Non-biocidal uses include use in leather tanning as an alternative to chromium-based tanning solutions. Comments [submitted to ECHA during its public consultation](#) report that glutaraldehyde is used as an alternative to chromium based tanning solutions and that there are no other alternatives that provide the same quality of product.

Glutaraldehyde is also reportedly used for black and white x-ray film processing. It is not known if this technology is still used in GB. Digital x-ray technologies are a likely alternative for this use.

Summary of Assessment

Glutaraldehyde was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#). With respect to use in GB workplaces and the risk of respiratory sensitisation, the substance is already subject to [stringent requirements under COSHH](#) which includes requirements to reduce exposure to as low as is reasonably practicable. The measures already in place in GB (which are not present in the EU) mean that there may be little additional benefit to worker protection from identifying the substance as an SVHC and adding it to the Candidate List. For this reason, no action is proposed at this time.

2.2.6 MCCPs

Substance Name: Alkanes, C14-17, chloro; medium-chain chlorinated paraffins (MCCPs)

EC Number: 287-477-0

CAS Number: 85535-85-9

SVHC-relevant intrinsic properties

Persistent, bioaccumulative and toxic properties (Article 57(d))

Very persistent, very bioaccumulative properties (Article 57(e))

² The Health and Occupation Research (THOR) network is a surveillance scheme with the primary aim of monitoring incidence and trends in incidence of work-related ill-health in the UK. Reporting to THOR involves the systematic collection of incident cases on either a regular (every month) or sample (one randomly allocated month per year) basis by participating physicians (chest physicians, dermatologists, occupational physicians, and general practitioners).

Tonnage and Use

MCCPs is described by a single CAS number but contains thousands of constituents. The registered substance, identified by the CAS number 85535-85-9, is registered in GB at > 1,000 tpy by one registrant. Eleven active joint registrants are listed on ECHA's website, tonnage range 10,000 – 100,000 tpy.

MCCPs have a wide range of applications including use as flame retardants and secondary plasticising additives in plastics, sealants, rubber and textiles. MCCPs are also used as additives in coolants and lubricants used in machinery and for the manufacture of metal products. More detail on uses for MCCPs is available in the [EU SVHC Annex 15 report](#).

According to the [UK RMOA conclusion document](#), releases to the environment are estimated at approximately 300 tonnes per year, and arise from product formulation, use and service life.

Summary of Assessment

MCCPs were added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#).

In April 2021, the UK submitted a proposal that C14-17 chloroalkanes with chlorine contents $\geq 45\%$ w/w be listed on the Stockholm Convention for Persistent Organic Pollutants (POPs). Substances with lower chlorine contents are not considered to pose the same level of concern, although the EU SVHC proposal does not make this distinction (so diverges from the UK view). The UK proposal will be discussed at the POPs Review Committee (POPRC) in January 2022. If it is agreed to meet the screening criteria of the Convention, it will formally enter the POPRC assessment process. This includes an evaluation of the risk management (whether any uses require exemption) and the scope of any listing.

The identification of MCCPs as SVHCs under UK REACH would formally highlight PBT and vPvB properties at an earlier stage but would differ from the EU proposal because we would seek to cover a different range of compositions to those covered in the EU SVHC proposal and no further risk management under UK REACH is anticipated. It is also not clear that SVHC listing will generate more stringent risk management advice than that currently given by the precautionary statements listed in safety data sheets for MCCPs.

A typical MCCP SDS includes these statements:

H362: May cause harm to breast-fed children.

H410: Very toxic to aquatic life with long lasting effect

Precautionary statement(s)

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/container to: An approved hazardous waste facility.

P260: Do not breathe mist/vapours/spray.

P263: Avoid contact during pregnancy/while nursing.

P280: Wear protective gloves/protective clothing/eye protection/face protection

SVHC nomination does not therefore seem to be the best use of regulatory resource and therefore, no action is required under UK REACH at this time. This will be reviewed if the POPRC rejects the proposal at any point, although this is considered unlikely.

2.2.7 Orthoboric acid

Substance Name: Orthoboric acid, sodium salt

EC Number: 237-560-2

CAS Number: 13840-56-7

SVHC-relevant intrinsic properties

Toxic for reproduction (Article 57(c))

Tonnage and Use

Orthoboric acid, sodium salt is not registered under GB or EU REACH.

Summary of Assessment

Orthoboric acid, sodium salt was added to the EU Candidate List on 8th July 2021 in accordance with ECHA decision [D\(2021\)4569-DC](#). The aim for this action is to limit the potential that this substance could be used as a substitute for a borate salt that has already been identified as an SVHC. There is no supporting evidence that suggests such substitutions are occurring. It is therefore not clear what regulatory benefits will be gained if this non-registered substance is added to the Candidate List. For this reason, no action is required under UK REACH at this time.

3. Declarations

Within this document we have provided links to the following ECHA documents and information found on ECHA's website:

The following documents:

- Document [D\(2020\)9139-DC](#): Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency) dated 11 January 2021
- Document [D\(2021\)4569-DC](#): Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency) dated 23 June 2021
- [COMMENTS ON AN ANNEX XV DOSSIER](#): Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivatives and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives wherein C12 is the predominant carbon number of the fatty acyloxy moiety. 16 November 2020.
- [ESR RAR \(2002\)](#): European Union Risk Assessment Report: 1,4-dioxane.
- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. 2,2-Bis(bromomethyl)propane-1,3-diol (BMP), 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA), 2,3-dibromo-1-propanol (2,3-DBPA). March 2021.
- [COMMENTS ON AN ANNEX XV DOSSIER](#): 2,2-Bis(bromomethyl)propane-1,3-diol (BMP), 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA), 2,3-dibromo-1-propanol (2,3-DBPA)
- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. Phenol, alkylation products (mainly in *para* position) with C12-rich branched or linear alkyl chains from oligomerisation, covering any individual isomers and/or combinations thereof. March 2021
- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. Bis(2-(2-methoxyethoxy)ethyl) ether; (tetraglyme). August 2020.
- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. 2-(4-*tert*-butylbenzyl)propionaldehyde and its individual stereoisomers. March 2021.
- [COMMENTS ON AN ANNEX XV DOSSIER](#): Resorcinol. 28 May 2020.
- [SUBSTANCE EVALUATION CONCLUSION and EVALUATION REPORT](#), Resorcinol. Tukes, Finnish Safety and Chemicals Agency, 24 October 2017.
- [Risk Management Option Analysis Conclusion Document](#): Resorcinol. Tukes, Finnish Safety and Chemicals Agency, 7 May 2018.
- [DECISION ON SUBSTANCE EVALUATION](#): Resorcinol, 12 March 2021
- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. 4,4'-(1-ethylpropylidene)bisphenol (bisphenol B; BPB). March 2021
- [COMMENTS ON AN ANNEX XV DOSSIER](#): Glutaral. 21 May 2021.

- [Annex XV report](#): PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. Medium-chain chlorinated paraffins (MCCP). February 2021.
- [Risk Management Option Analysis Conclusion Document](#): Alkanes, C14-17, chloro. Environment Agency, November 2019.

The following web pages:

- Previous [calls for comments and evidence](#): 1,4-dioxane.
- Occupational exposure limits - Previous [calls for comments and evidence](#): 1,4-dioxane.

Any documents or information accessed via ECHA's website are subject to ECHA's Legal Notice (<https://echa.europa.eu/legal-notice>).

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