Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g) on

The evaluation of the availability and suitability of alternatives to Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) and (ratio 3:2), short: RP 1:1 and RP 3:2 for PT 2, 6, 11, 12 (only RP 3:2) and 13

ECHA/BPC/405/2023

Adopted

23 November 2023

Opinion of the Biocidal Products Committee

on the evaluation of the availability and suitability of alternatives to Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) and (ratio 3:2), short: RP 1:1 and RP 3:2 for PT 2,6, 11, 12 (only RP 3:2) and 13

In accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the evaluation of the availability and suitability of alternatives to RP 1:1 and RP 3:2 for PT 2, 6, 11, 12 (only RP 3:2) and 13

This document presents the opinion adopted by the BPC, having regard to the conclusions of the rapporteur.

Process for the adoption of opinions

A request by Commission was received by ECHA on 17 February 2023. The request was confirmed by ECHA to be passed to the BPC. The BPC appointed the rapporteur at its 46th meeting on 1 March 2023. The rapporteur presented the draft opinion to the BPC at its 48th and 49th meetings on 15 September and 23 November 2023, respectively. Following the adoption of the opinion at the BPC meeting of 23 November 2023, the opinion was amended accordingly and delivered by ECHA to the Commission.

Adoption of the opinion

Rapporteur: Austria

The BPC opinion was adopted on 23 November 2023.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.

1. Further details of the opinion and background

Request for the opinion and background

Opinion basis

This opinion is made per Commission's mandate of 16/02/2023 requesting an ECHA opinion under Article 75(1)(g) of the BPR on the evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)[1]. The BPC agreed at its 46th meeting that the member from Austria will act as the rapporteur for this request[2].

Background on the approval of RP1:1 and RP3:2

The Task Force Lubrizol Deutschland GmbH and Schülke & Mayr GmbH submitted an application for approval of the following active substances under Regulation (EU) No 528/2012 on biocidal products (the BPR):

- Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), hereinafter referred to as "RP 1:1". [also named "Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1.1)" in the BPR opinion of 8 June 2022; originally notified as α,α′,α″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol – "HPT"].
  The applications were submitted for product types (PT) 2, 6, 11 and 13.

- Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), furthermore addressed as "RP 3:2". [also named "Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)" in the BPR opinion of 8 June 2022; originally notified as 3,3'-methylene-bis(5-methyloxazolidine) – "MBO"].
  The applications were submitted for PT 2, 6, 11, 12 and 13.

The evaluating Competent Authority (eCA) of Austria submitted under the biocidal active substance approval process an assessment report and the conclusions of its evaluation to the European Chemicals Agency (ECHA) on 29 September 2016 for both substances and all associated PTs.

Both active substances are formaldehyde-releasers (FARs). Due to the formaldehyde they release, they meet the exclusion criterion set out under Article 5(1)(a) of Regulation (EU) No 528/2012, being classified as Carcinogenic, Category 1B.

Consultations on alternatives and on meeting the derogation to the exclusion criteria

Since both substances meet the exclusion criteria, ECHA launched a consultation on candidates for substitution (4 November 2016 - 3 January 2017) in accordance with Article 10(3) of BPR, aiming to gather information on available alternatives[3]. During this first

[1] See: https://echa.europa.eu/documents/10162/3443005/alternatives_rp_1_1_and_rp3_2_mandate_en.pdf/e25ab1aa-2909-a713-9b98-e6475221b5b3?t=1678170410228
[2] See BPC-46 minutes at https://echa.europa.eu/documents/10162/18349255/bpc-46_minutes_en.pdf/d8d42ff7-8da5-e28f-217a-9f9a3dc9a441?t=1688017298381
[3] See received comments on https://www.echa.europa.eu/web/guest/potential-candidates-for-substitution-previous-consultations/-/substance-rev/25004/term (RP1:1) and https://www.echa.europa.eu/web/guest/potential-candidates-for-substitution-previous-consultations/-/substance-rev/25005/term (RP 3:2)

consultation very limited information was received for both substances as only the applicants, one stakeholder and one Member State (FI CA) contributed to the consultation:

> Information provided by the Formaldehyde Biocide Interest Group (FABI) included mainly statements on the necessity of FARs in PT 6 and PT13 since only few alternatives are available. For PT 13 in total 17 bactericidal active substances were available at that time, including 11 FARs and three isothiazolinones. For fungicidal active substances, only 7 substances were listed. The applicant Lubrizol supported the general comments of FABI. The FI CA shared the information on RP 1:1 available in their Chemical Product Register – 12 products were found which were used in PT 2 and PT 13.

An active substance meeting the exclusion criteria should not be approved unless it is shown that at least one of the derogation conditions set out in Article 5(2) of the BPR is met. The availability of suitable and sufficient alternative substances or technologies is a key consideration in that process. The Commission launched a further consultation in cooperation with ECHA (5 September - 4 November 2017) in order to gather information on whether one or several of the conditions for derogation in Article 5(2) of the BPR are met[4]. Again, limited contributions were made during this second consultation:

> In total six industry representatives contributed for the active substances RP 1:1 and 10 for RP 3:2, respectively. A number of comments on potential alternatives were also submitted.
>
> When discussing potential chemical alternatives, mostly isothiazolinones were mentioned in the different contributions. All alternatives were dismissed as unsuitable due to various reasons such as limited efficacy in the respective PT, instability at high pH (which is essential in the respective uses), halogens contained or similar classification as RP1:1 and RP3:2 and general technical limitations.
>
> Other FARs were rarely discussed further since the same classifications and therefore restriction should apply for these active substances as for RP 1:1 and RP 3:2.
>
> No non-chemical alternative was identified by any of the contributors.

In the 56th meeting of the Standing Committee on Biocidal Products (SCBP) in January 2018, it was noted that an opinion of the BPC should be requested on the technical elements provided in the consultation, and to identify whether or not alternatives are available per PT, and per use within the PT[5]. However, as the scientific criteria for the determination of endocrine-disrupting (ED) properties were adopted during that time, it was also necessary to assess whether the substances would meet these criteria. Revised opinions of the BPC addressing the ED criteria were adopted on 8 June 2022[6].

The BPC opinions of June 2022 focused on assessing the ED properties of the substances, and did not revise the analysis of the availability of suitable and sufficient alternatives (AoA), in the absence of a specific mandate. As a result, the revised opinions contain no new information on the availability of suitable and sufficient alternatives and do not contain a clear conclusion on this aspect.

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[4] See consultation page here: https://echa.europa.eu/derogation-to-the-exclusion-criteria-previous-consultations and received comments on https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/1cba444c-5885-4886-9ef3-cc3a8add38cb

[5] See meeting minutes here: https://health.ec.europa.eu/system/files/2018-04/ev_20180119_mi_en_0.pdf

[6] See adopted opinions here: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

At the 77th meeting of the SCBP in October 2022, a revised preliminary analysis of alternatives made by the Commission services was presented for both substances and all associated PTs[7]. However, the Commission pointed out that this analysis should be considered indicative and not conclusive, since it was based on limited information (the past public consultations, the BPC opinions and the limited information provided by Member States).

It was therefore considered necessary to obtain an opinion on the availability of suitable and sufficient alternatives for the two substances for each PT. This information is necessary in order to decide whether at least one of the derogation conditions of the Article 5(2) of the BPR is met.

Consequently, a new consultation on alternatives to RP1:1 and RP3:2 was run by ECHA between 27 March and 26 May 2023[8]. Information submitted by stakeholders and Member State competent Authorities in this consultation is summarised and discussed in section 2 below (Please note that at the time of this assessment the applicant for RP 1:1 is Vink Chemicals GmbH & Co KG and for RP 3:2 the applicants are Lubrizol Deutschland GmbH and Vink Chemicals GmbH & Co KG).

2. Analysis of potential alternatives to RP 1:1 and RP 3:2

For the analysis of potential alternatives for RP 1:1 and RP 3:2, the following steps were performed: actives substances that are currently approved on the market according to R4BP3 were evaluated according to their intended use, hazard profile and technical suitability separately for each PT. Contributions that were received during the above mentioned consultations were analysed, summed up and the relevant statements included under the respective chapters (2.2, 2.4). A literature research according to the guidance on analysis of alternatives (ECHA, 2023 – Box 6) was conducted. A final conclusion was drawn taking into account all information available at the time of the assessment.

2.1 Assessment of currently available active substances extracted from R4BP3

The active substances that are subject to this analysis are introduced in the Appendix Table 8 and 9 (AT, 2022a, b). For the identification of potential alternatives for RP 3:2 and RP 1:1, respectively, all active substances currently approved for the product types (PTs) concerned were extracted from a R4BP3 research made by ECHA. The focus for the rapporteur was on active substances that were approved at the time of the AoA. These active substances are given in table 1. In table 2-6, harmonised classification was added according to the latest scientific knowledge, either C&L inventory or active substance CAR or RAC opinion. The intended uses given in the tables were extracted from the active substance CARs. The conclusion on potential alternatives and the justification was added by the rapporteur based on the overall assessment.

[7] See meeting minutes here : https://health.ec.europa.eu/system/files/2023-02/biocides_20221006_mi_en.pdf
[8] See https://www.echa.europa.eu/web/guest/potential-candidates-for-substitution-previous-consultations/-/substance-rev/72903/term (RP1:1) and https://www.echa.europa.eu/web/guest/potential-candidates-for-substitution-previous-consultations/-/substance-rev/72904/term (RP3:2)

Criteria for alternatives to be considered suitable

According to the Guidance on analysis of alternatives (ECHA, 2023), a suitable alternative should be safer (reduce the overall risk), technically and economically feasible for users in the EU and available.

Active substances that are also formaldehyde releasers were not assessed since they are or will also be classified as Carc 1B. Other candidates for substitution (CfS) or substances meeting the exclusion criteria were screened but not evaluated in detail because they were considered not to present a significantly better hazard profile (see Table 10).

The only CfS identified that was approved for similar uses compared to RP 1:1 and RP 3:2 and mentioned by stakeholders was glutaraldehyde, which is classified as Resp. Sens 1. Glutaraldehyde is also included in the REACH candidate list as a substance of very high concern (SVHC), because of the respiratory sensitisation properties, thus the respiratory sensitisation proterties of the substance are of an equivalent level of concern to category 1A or 1B CMRs or PBT/vPvB substances (ECHA, 2021a, ECHA, 2021b). Due to the severe hazardous property of glutaraldehyde the substance was not further assessed. It does not show a significant better hazard profile.

The resulting potential alternatives for all relevant PTs are given in table 1.

Table 1: Active substances approved at the time of the analysis of alternatives for the respective PTs

Active Substance	CAS	PT
2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB)	35691-65-7	PT06
2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4	PT11 PT12 PT13
3-iodo-2-propynylbutylcarbamate (IPBC)	55406-53-6	PT06 PT13
5-Chloro-2-methyl-2H-isothiazol-3-one (CIT)	26172-55-4	PT06
Active chlorine generated from sodium chloride by electrolysis	-	PT02
Active chlorine released from calcium hypochlorite	7778-54-3	PT02
Active chlorine released from chlorine	7782-50-5	PT02
Active chlorine released from hypochlorous acid	-	PT02
Active chlorine released from sodium hypochlorite	7681-52-9	PT02
Amines, N-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid	139734-65-9	PT02
Biphenyl-2-ol	90-43-7	PT02 PT06 PT13
Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime	1305-62-0	PT02
Calcium magnesium oxide/dolomitic lime	37247-91-9	PT02
Calcium magnesium tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime	39445-23-3	PT02
Calcium oxide/lime/burnt lime/quicklime	1305-78-8	PT02

Active Substance	CAS	PT
Chlorocresol	59-50-7	PT02 PT06 PT13
Citric acid	77-92-9	PT02
Copper sulphate pentahydrate	7758-98-7	PT02
Didecyldimethylammonium chloride(DDAC)	7173-51-5	PT02
Hydrochloric acid	7647-01-0	PT02
Hydrogen Peroxide	7722-84-1	PT02 PT06
L-(+)-lactic acid	79-33-4	PT02 PT06
MBIT	2527-66-4	PT06
Mixture of CMIT/MIT	55965-84-9	PT02 PT06 PT11 PT12 PT13
N-(trichloromethylthio)phthalimide (Folpet)	133-07-3	PT06
Nonanoic acid, Pelargonic acid	112-05-0	PT02
Peracetic acid	79-21-0	PT02 PT06 PT11 PT12
Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate	-	PT02
Propan-1-ol	71-23-8	PT02
Propan-2-ol	67-63-0	PT02
Reaction mass of peracetic acid and peroxyoctanoic acid	-	PT02
Sodium benzoate	532-32-1	PT06
Vinegar	8028-52-2	PT02
Ozone generated from oxygen	-	PT02 PT11

For the sake of completeness, all substances that were mentioned in addition to the assessment of the rapporteur in the public consultation or stakeholder consultation and were deemed unsuitable are listed in Appendix 1, Table 10. Reasons for unsuitability are most of all the lack of availability since some of the active substances are not approved yet under BPR and the missing reduction of the overall risk since no significantly better hazard profiles were identified.

Substances included in Annex I of the BPR were assessed separately. Substances considered as food or food stuff as well as gases, natural oils and acids were found to be no potential alternative for RP 1:1 and RP 3:2, as these substances are considered not to achieve the same efficacy and technical suitability as RP 1:1 and RP 3:2, in terms of spectrum and application rate and particular requirements for the intended use.

The other substances listed in Table 1 were checked regarding their authorised biocidal products, respective PTs and intended use. Where a similar intended use and a potential suitability of the active substance was indicated in the CAR and related authorised products[9] were available, the PARs were checked whether the authorised uses are similar to the ones of RP1:1 and RP 3:2.

[9] Information retrieved from ECHA website.

No potential alternatives were identified for the respective PTs 2, 6, 11, 12 and 13.

In general, four criteria have to be assessed in the analysis of alternatives: technical feasibility, economic feasibility, reduction of the overall risk and availability. This dossier focusses mainly on technical feasibility, reduction of overall risk and availability since an assessment of economic feasibility would require more detailed information about the industry processes and strategies which was not provided by the stakeholders and cannot be evaluated based on the lacking sources of information.

The assessment was proceeded per PT, where (harmonized) classification and intended use of the active substance in the PT were analysed and compared to RP 3:2 and RP 1:1, respectively. Physico-chemical properties and therefore technical feasibility were also taken into account to the extent known. A good potential alternative would show a significant lower hazard profile and is already approved for the same intended use. If so, technical feasibility should be assessed.

2.1.1 PT2

Intended uses of RP 1:1 *and* RP 3:2

The biocidal product (AS as manufactured) can be used within formulations as system cleaner of metal working systems. This application can be assigned to product type 2 as it is intended as disinfectant of the inner surface of vessels and tubes.

System cleaner formulations may contain emulsifiers, surfactants and biocidal active substances. The intention of the application of the product is to clean the system at areas that are difficult to access, such as vessels, pipes, filters, etc. which cannot be reached by standard cleaning operations, before new metal working fluids will be inserted in the single or the central system.

It is important to note that for the sake of disinfection and corrosion protection, system cleaner of metal working systems have to act and be stable at pH 9.5-12.

Table 2: Overview of potential alternatives for PT2 (Disinfectants and algaecides not intended for direct application to humans or animals)

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
Active chlorine generated from sodium chloride by electrolysis	-	-	Treatment of waste water including municipal waste water before and after the Waste water Treatment Plant; Disinfection of dental lines; Treatment of public and private pools	No	Technically not feasible. An increase of pH substantially decreases the biocidal activity of active chlorine
Active chlorine released from calcium hypochlorite	7778-54-3	Ox. Sol. 2 H272; Acute Tox. 4* H302; Skin Corr. 1B H 314; Aquatic Acute 1 H 400; EUH031; GHS03; GHS07; GHS05; GHS09; Dgr;	Treatment of waste water including municipal waste water before and after the Waste water Treatment Plant; Treatment of public and private pools	No	Technically not feasible. See above
Active chlorine released from	7782-50-5	Press. Gas; Ox. Gas 1 H270; Skin Irrit. 2 H315; Eye Irrit. 2 H319;	Treatment of waste water including municipal waste water before and after the	No	Technically not feasible. See above

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
chlorine		Acute Tox. 3* H331; STOT SE 3 H335; Aquatic Acute 1 400; GHS03; GHS09; GHS04; GHS05; Dgr;	Waste water Treatment Plant, Treatment of swimming pools		
Active chlorine released from hypochlorous acid	-	-	Disinfection of surfaces in hospitals and care homes; Disinfection of dental lines	No	Technically not feasible. See above
Active chlorine released from sodium hypochlorite	7681-52-9	Skin Corr 1B H314; Eye Dam 1 H318; Aquatic Acute 1 H400; Aquatic Chronic 1 H410; EUH031; GHS09; GHS05; Dgr;	Treatment of waste water including municipal waste water before and after the Waste water Treatment Plant, Surface disinfection, disinfection of swimming pools, disinfection of textiles during washing	No	Technically not feasible. See above
Amines, N-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid	139734-65-9	Acute Tox 4, *H302 Skin Corrosion, 1, *H314 STOT RE 1, *H372 Repr. 2, *H361f Aquatic Acute 1, *H400 Aquatic Chronic 1, *H410 M = 10 (acute), M = 1 (chronic)	Disinfection treatments for surfaces, walls, and floors in various areas in industry (i.e. the food/feed industry) as well as in public health or veterinary areas.	No	Comparison of the hazard shows no significant reduction of the overall risk
Biphenyl-2-ol	90-43-7	Skin Irrit. 2 H315; Eye Irrit. 2 H319; STOT SE 3 H335; Aquatic Acute 1 H400; GHS07; GHS09; Wng;	Surface disinfection in health care settings.	No	Technical feasibility questionable, intended use indicates unsuitability. Efficacy against bacteria cannot be confirmed
Calcium dihydroxide/ calcium hydroxide/caustic lime/hydrated lime/slaked lime	1305-62-0	Skin Irrit. 2 H315; Eye Dam. 1 H318; STOT SE 3 H335;	Disinfectant for the treatment of sewage sludge.	No	Technical feasibility questionable, intended use indicates unsuitability. Limited efficacy indicated, fluctuations in pH
Calcium magnesium oxide/dolomitic lime	37247-91-9	Skin Irrit. 2 H315; Eye Dam. 1 H318; STOT SE 3 H335;	Disinfection in private area and public health area disinfectant. Burnt dolomitic lime is mixed into sewage sludge to control bacteria, viruses and parasites.	No	See Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Calcium magnesium	39445-23-3	Skin Irrit. 2 H315; Eye Dam. 1 H318 ;	Disinfection in private area and public health	No	See Calcium dihydroxide/ca

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime		STOT SE 3 H335;	area disinfectant. Burnt dolomitic lime is mixed into sewage sludge to control bacteria, viruses and parasites.		lcium hydroxide/caustic lime/hydrated lime/slaked lime
Calcium oxide/lime/burnt lime/quicklime	1305-78-8	Skin Irrit. 2 H315; Eye Dam. 1 H318 ; STOT SE 3 H335;	Disinfection in private area and public health area disinfectant. Burnt dolomitic lime is mixed into sewage sludge to control bacteria, viruses and parasites.	No	See Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Chlorocresol	59-50-7	Acute Tox. 4 H302; Skin Corr. 1C H 314; Eye Dam 1 H318; Skin Sens. 1B H317; STOT SE 3 H 335; Aquatic Acute 1 H 400; Aquatic Chronic 3 H 412; GHS07; GHS05; GHS 09; Gdr; M=1;	Disinfection in health care. Application in hospitals, surface application, in clean conditions, in private areas.	No	Technical feasibility questionable, intended use indicates unsuitability. Efficacy is questionable in consideration of the intended uses of RP 1:1 and RP 3:2
Citric acid	77-92-9	Eye Irrit. 2 H319; STOT SE 3 H 335; GHS 07; Wng;	Impregnation of facial tissues	No	Technically not feasible: limited efficacy of acids at high pH
Copper sulphate pentahydrate	7758-99-8	Acute Tox 4 H 302; Eye dam 1 H 318; Aquatic Acute 1 H400; M=10; Aquatic. Chronic 1 H410;	Incorporated into products used with washing machines to reduce the bacterial contamination of clothing or overalls, Algaecide	No	Technically not feasible: limited efficacy (bactericide)
Didecyldimethylammonium chloride (DDAC)	7173-51-5	Acute Tox 4* H302; Skin Corr. 1B H314; GHS07; GHS05; Dgr;	Disinfection of surfaces, inanimate objects and materials and equipment in several sectors: Private area and public health area disinfectant and other biocidal products. Disinfectants for medical equipment, for accommodation for man or in industrial areas, swimming pools disinfection, chemical toilets, treatment of waste water or treatment of hospital waste, laundry disinfection	No	Technical feasibility questionable: stability at high pH not confirmed at AS level
Hydrochloric acid	7647-01-0	Skin Corr. 1B H314; STOT SE 3 H335	Surface disinfectant for toilet bowls in private	No	Technically not feasible:

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
			and domestic situations.		limited efficacy of acids at high pH
Hydrogen Peroxide	7722-84-1	Ox. Liq. 1; Acute Tox. 4; Skin Corr. 1A; Acute Tox. 4; Aquatic chronic 3; (ENV WG)	Surface disinfection by vaporized hydrogen peroxide. Vaporization of closed rooms (e.g., in hospitals, emergency vehicles, biological laboratories).	No	Technical feasibility questionable: oxidizer, highly reactive
L-(+)-lactic acid	79-33-4	Skin Corr 1C H 314; Eye Dam. 1 H318; EUH071; GHS05; Dgr;	Disinfection of surfaces in bathrooms (general public) in order to prevent growth of bacteria and fungi.	No	Technically not feasible: limited efficacy of acids at high pH
Mixture of CMIT/MIT	55965-84-9	Acute Tox. 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; C ≥ 0,6 % Eye Dam. 1 H318; C ≥ 0,6 % Eye Irrit. 2 H319; 0,06 % ≤ C < 0,6 % **Skin Sens. 1A H317**; C ≥ 0.0015 % Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic Chronic 1 H410; M=100;** EUH071; GHS09; GHS05; GHS06; Dgr;	Preservation of air conditioning and air washing systems, and for chemical toilets.	No	Comparison of the hazard shows no reduction of overall risk; not stable at high pH
Nonanoic acid	112-05-0	Skin Irrit. 2 H315; Eye Irrit. 2 H319; Aquatic Chronic 3 H412; GHS07; Wng	Algaecide for masonry such as walls, facades, paved paths or terraces and fences (other than wood), gravestones.	No	Technically not feasible: limited efficacy of acids at high pH
Peracetic acid	79-21-0	Org. Perox. D, H242; Acute Tox. 2, H330; Acute Tox. 2, H310; Acute Tox. 3, H301; Skin Corr. 1A, H314; Aquatic Acute 1, H400; M=10 Aquatic Chronic 1, H410; M=100;	Laundry disinfection, disinfection of sewage/waste water, disinfection of surfaces in industrial, public and health care areas, CIP (Clean-in-Place) in pharmaceutical and cosmetic industry.	No	Technically not feasible: limited efficacy of acids at high pH
Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate	-	-	Laundry disinfection in household, and in industrial and institutional use, and also for surface disinfection in industrial, public and and health care area.	No	Technically not feasible: limited efficacy of acids at high pH
Propan-1-ol	71-23-8	Flam.Liq 2; Eye Irrit. 1; STOT SE 3;	Disinfection of surfaces, inanimate objects, material, and	No	Technical feasibility questionable:

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
			equipment in private, public health and industrial areas.		high increase in application rate to achieve efficacious concentration.
Propan-2-ol	67-63-0	Flam.Liq 2; Eye Irrit. 2; STOT SE 3;	Disinfection of surfaces, inanimate objects and materials and equipment in private, public health and industrial areas	No	Technical feasibility questionable: high increase in application rate to achieve efficacious concentration.
Reaction mass of peracetic acid and peroxyoctanoic acid	-	CAR: Org. Perox. C; Skin Corr. 1A; Eye Dam. 1;	Cleaning in Place (CIP) systems for cosmetics and pharmaceutical industry.	No	Technically not feasible: limited efficacy of acids at high pH
Vinegar	8028-52-2	Not harmonised	E.g. Algaecide Removal of green surface contamination from hard porous surfaces.	No	Technically not feasible: limited efficacy at high pH
Ozone generated from oxygen	-	Ox. Gas 1, H270; Acute Tox. 1, H330; STOT SE 1, H370; STOT RE 1, H372; Muta. 2; H341; Carc. 2; H351; Aquatic acute 1; H400, M=100; Aquatic chronic 1; H410, M=1	Disinfection of surfaces (walls, floors, ceilings), textile disinfection by ozone in water, disinfection of swimming pools	No	Technical feasibility questionable: intended use and use of a generating system indicates unsuitability; Comparison of the hazard indicates no reduction of the overall risk, strong oxidiser

All of the active substances for PT2 are approved for typical intended uses like disinfection in health care settings, in private and public areas for surface disinfection or disinfection of public and private swimming pools as well as treatment of wastewater and therefore do not resemble the intended use of RP 1:1 and RP 3:2.
Nevertheless, active substances approved for more general uses like ‘surface disinfection’, ‘disinfection in industrial area’ or ‘CIP in pharmaceutical and cosmetic industry’ might spawn biocidal products revealing the same uses as RP 1:1 and RP 3:2.

Therefore, the technical/economic feasibility and reduction of the overall risk by using these substances were assessed.

In terms of **technical feasibility:**

It is highlighted by industry in the required technical specifications that only formaldehyde-releasing active substances are stable and active under the respective conditions for metalworking fluid installations which includes e.g. pH values between 9.5 and 12 to ensure corrosion protection. As generally acids work at lower pH-values these substances are not

appropriate for the in-use conditions (high pH values would also affect the efficacy). The same issue applies for AS releasing active chlorine. At high pH values, only OCl^- is present in the solution which reveals only very little antimicrobial activity. Additionally, it is a strong oxidiser which is also counterproductive with regards to corrosion protection.

Propan-1-ol and Propan-2-ol, which might be stable at the required conditions have a significantly higher efficacious concentration (up to 70% w/w) compared to RP 1:1 and RP 3:2 (max. up to 2% w/w). Thus, the technical feasibility of these two substances is questionable and this might also raise an issue of economic feasibility if far higher amounts of the substance have to be used. Therefore, Propan-1-ol and Propan-2-ol are also not expected to be suitable alternatives.

Concerning the **reduction of overall risk:**

For the active substance Amines, N-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid (– Ampholyt) an assessment report is available (IR, 2015). According to the assessment and the entry in the CLH register, the substance meets the CLP criteria for Acute Tox 4 H302, Skin Corr. 1C H314, Repr 2 H361f and STOT RE 1 (eyes, mesenteric lymph nodes, male/female genital systems. The eCA (IR) has submitted a CLH dossier. It is noted that endocrine organs are impacted by Ampholyt application to laboratory rodents, but an ED assessment according to the ED EFSA/ECHA (2018) guidance has not been conducted yet.

The derived AELs of Ampholyt are low (AEL long-term 0.0035 mg/kg bw/d, AEL medium-term 0.0085 mg/kg bw/d, AEL acute 0.027 mg/kg bw/d). No AEC values are available. Compared to the AELs of RP 3:2 and RP 1:1 these toxicological reference values are about ten-fold lower, which together with the ED concerns questions the suitability as less severe alternative in regard to human health. Moreover, the substance meets the classification criteria for Aquatic Acute 1, M-factor =100 and Aquatic Chronic 1, M-factor =1, and thus also poses a higher risk for the environment compared to RP 1:1 and RP 3:2.

From the information available about ozone generated from oxygen it was concluded that technical feasibility is questionable due to the intended use and the need of a generating device that has to be included in the system.

Since no related biocidal products are available on the market, it is not clear if these devices could be compatible with the systems where RP 1:1 and RP 3:2 are applied.

Moreover, ozone is a strong oxidiser and highly reactive gas which makes it incompatible with some (organic) matrices /matrix components which limits the applicability for the intended uses.

Additionally, for ozone there is no indication of existence of NOAECs/NOAELs from relevant epidemiological studies. It is a suspected genotoxic carcinogen, and thus a minimal effect level (MEL) is proposed. The MEL is 50 $\mu g/m^3$ (10 % extra mortality risk at 25 ppb). In addition, to assess the risk for professional form respiratory irritation during short-term peak, a NOAEC short-term of 120 $\mu g/m^3$ is proposed based on human volunteer studies. For RP 3:2 and RP 1:1 a threshold mode of action is assumed and threshold values have been derived, since formaldehyde, although it is a genotoxic carcinogen, has a mode of action based threshold. Thus, in contrast to ozone for RP 3:2 and RP 1:1 a safe level can be defined. From that perspective, ozone cannot be considered as a safer alternative.

A similar issue applies for the mixture of CMIT/MIT. CMIT/MIT has a strong skin sensitization potential. It is harmonized classified as Skin Sens 1A with a very low specific concentration

limit of C ≥ 0.0015 %. A comparison of important toxicological information of CMIT/MIT, MIT and RP 3:2 and RP 1:1 is provided in appendix I table 11.

The carcinogenicity and mutagenicity properties of RP 3:2 and RP 1:1 have been determined based on the read across to formaldehyde. It is considered that based on the reactivity and poor systemic availability, local genotoxic effects for which a threshold is assumed (SCOEL, 2016, RAC/SEAC, 2020) are of concern. It is considered that the toxicological reference values derived from the most sensitive effect (irritative properties) does cover the mutagenic and carcinogenic concern.

As provided in the table 11 in appendix I the acute toxicological classification for CMIT/MIT is more severe and also the reference values derived for CMIT/MIT are lower than for RP 3:2 and RP 1:1, indicating that CMIT/MIT exposure already at low concentrations has an adverse impact on human health. Thus, based on these considerations it is not considered to have a significant better hazard profile.

With respect to the environment CMIT/MIT shows a more severe classification compared to RP 3:2 and RP 1:1 with a classification of aquatic acute 1 (M=100) and aquatic chronic 1 (M=100).

Thus, also based on the comparison of acute acceptable exposure levels, CMIT/MIT cannot be considered as a safer alternative in respect to human health and the environment.

Therefore, no suitable alternative was identified for the intended uses of RP 1:1 and R3:2 in PT2.

2.1.2 PT6

Intended uses of RP 1:1 *and* RP 3:2

The biocidal product (AS as manufactured) can be used as in-can preservative in fuels, added automatically during the formulation of diesel fuels (PT6), against Gram-negative bacteria such as *Pseudomonas aeruginosa, Enterobacter aerogenes* and Acinetobacter spps.

The product is intended to be incorporated by industrial users into fuels to act as a preservative. The biocidal product is incorporated into fuels during the formulation process.

Table 3: Overview of potential alternatives for PT6 (Preservatives for products during storage)

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB)	35691-65-7	Acute Tox. 4 (oral); H302 Acute Tox. 2 (inhalation); H330 Skin sens. 1; H317 Eye Dam. 1; H318, Aquatic Chronic 2; H411;	Antimicrobial preservative for water based paints intended for decorative brush/roller-painting indoors.	No	Technically not feasible: contains halogens, data on solubility in fuel/ combustion process not available
3-iodo-2-propynylbutylcarbamate (IPBC)	55406-53-6	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Sens. 1 H317, Acute Tox. 3 H331, STOT RE 1 H372 (larynx), Aquatic Acute 1	In-can preservative covering washing and cleaning fluids and other detergents, paints and coatings, fluids used in textile production and glues	No	Comparison of hazards indicates no reduction of the overall risk; technically not feasible: limited

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
		H400, Aquatic Chronic 1 H410, GHS08, GHS05, GHS09, GHS06, Dgr, M=10, M(Chronic)=1;	and adhesives for indoor use.		efficacy (fungicide)
5-Chloro-2-methyl-2H-isothiazol-3-one (CIT)	26172-55-4	Acute Tox 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; Eye Dam. 1 H318; **Skin Sens. 1A H317**; Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic Chronic 1 H410;** EUH071; GHS09; GHS05; GHS06; Dgr;	Preservation of household cleaning products, cleaning products for professionals, textile washing products and softener, Preservation of paints and coatings, preservation of additives in paper production, glues and adhesives, pigment paste, colorants and polymer dispersions	No	Technically not feasible: contains halogens; no reduction of overall risk
Biphenyl-2-ol	90-43-7	Skin Irrit. 2 H315; Eye Irrit. 2 H319; STOT SE 3 H335; Aquatic Acute 1 H400; GHS07; GHS09; Wng;	In-can preservation of detergents and household cleaning products; Preservation of paper additives.	No	Technical feasibility questionable: intended use indicates unsuitability. Data on solubility in fuel/ combustion process not available; efficacy against bacteria cannot be confirmed
Chlorocresol	59-50-7	Acute Tox. 4 H302; Skin Corr. 1C H 314; Eye Dam 1 H318; Skin Sens. 1B H317; STOT SE 3 H 335; Aquatic Acute 1 H 400; Aquatic Chronic 3 H 412; GHS07; GHS05; GHS 09; Gdr; M=1;	Preservatives for detergents used in many applications (e.g.: liquid for manual/machine dishwashing, floor waxes, car polishes, detergents, laundry softeners, etc.); Preservatives for fluids used in paper production.	No	Technically not feasible: contains halogens
Hydrogen Peroxide	7722-84-1	Ox. Liq. 1; Acute Tox. 4; Skin Corr. 1A; Acute Tox. 4; Aquatic chronic 3; (ENV WG)	Preservative for paper additives to preserve them during storage and transport.	No	Technical feasibility questionable: strong oxidizer, highly reactive
L-(+)-lactic acid	79-33-4	Skin Corr 1C H 314; Eye Dam. 1 H318; EUH071; GHS05; Dgr;	Preservation of liquid detergents such as e.g. fabric conditioners and dishwashing liquids.	No	Technically not feasible: limited efficacy at pH > 3.8
MBIT	2527-66-4	Acute Tox. 3 H301; Acute Tox. 4 H312; Skin Corr. 1C H314;	In-can preservation of e.g. polymer latex, adhesive, ink, mineral slurries, fluids used in	No	Comparison of hazards indicates no reduction of

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
		Eye Dam. 1 H318; **Skin Sens. 1A H317**; C ≥ 0,0015 % Aquatic Acute 1 H400; Auqatic Chronic 2 H411; M=1 dermal: ATE = 1100 mg/kg bw (-) oral: ATE = 175 mg/kg bw (-) EUH071; GHS09; Hs05; GHS06; Dgr;	leather and textile production, paints, plasters, or detergents.		overall risk
Mixture of CMIT/MIT	55965-84-9	Acute Tox. 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; C ≥ 0,6 % Eye Dam. 1 H318; C ≥ 0,6 % Eye Irrit. 2 H319; 0,06 % ≤ C < 0,6 % **Skin Sens. 1A H317**; C ≥ 0.0015 % Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic Chronic 1 H410; M=100;** EUH071; GHS09; GHS05; GHS06; Dgr;	In-can preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers by the control of microbial deterioration to ensure their shelf life during storage. **Fuel preservation included.**	No	Technically not feasible: contains halogens - not suitable for use throughout the European Union – see reasoning below; comparison of hazards indicates no reduction of the overall risk
N-(trichloromethylthio)phthalimide (Folpet)	133-07-3	Eye Irrit. 2 H319; Skin Sens. 1 H317; Acute Tox. 4* H332; Carc. 2 H351; Aquatic Acute 1 H400; GHS08; GHS07; GHS09; Wng;	In-can preservative in paints.	No	Technically not feasible: contains halogens
Peracetic acid	79-21-0	Org. Perox. D, H242; Acute Tox. 2, H330; Acute Tox. 2, H310; Acute Tox. 3, H301; Skin Corr. 1A, H314; Aquatic Acute 1, H400; M=10 Aquatic Chronic 1, H410; M=100;	In-can preservation in the paper production.	No	Technical feasibility questionable: intended use, intrinsic properties – see below
Sodium benzoate	532-32-1	Not harmonised	In-can preservation of dishwashing liquids, laundry products and	No	Efficacy and technical suitability

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
			cleaning liquids.		questionable, data on solubility in fuel/ combustion process not available

Most of the listed active substances in table 3 do not show intended uses equal or similar to the intended use of RP 3:2. The most common intended uses are as preservatives in paints and coatings, detergents and household products such as dishwashing liquids, as well as in paper production.

The only substance which is also approved for the use in fuel preservation is CMIT/MIT. No products are identified which include the use as fuel additive and are authorised in the whole European Union. In concrete, an Union Authorisation of a BPF was found including the use as fuel additive, but this BPF will not be authorised in Denmark and Belgium in general and also shall not be used in Germany for non-rail bound on-road motor vehicles since dioxins might be formed from halogenated organic compounds such as CMIT/MIT during fuel combustion which might have an impact on human and environmental health (for more information see *Commission Implementing Regulation (EU) 2023/402 of 22 February 2023*). Beside the concern that dioxins might be formed during fuel combustion which might have negative consequences, CMIT/MIT does not show a significantly better hazard profile compared to RP 1:1 and RP 3:2. Please also see 2.1.1 and Appendix 1 table 11 on this issue.

For MBIT, the same reasoning as for MIT and CMIT/MIT applies. Due to the high skin sensitizing potential (SCL: C ≥ 0,0015 %), the low acute exposure concentration values and the environmental hazards, MBIT does not show a significantly better hazard profile. The exact values and comparison are added in Appendix 1, table 11.

It cannot be determined by the rapporteur whether or not other substances are suitable alternatives based on the information available at the time of the assessment. E.g. Biphenyl-2-ol shows a similar solubility in solvents and water and similar efficacy but there is no data available on solubility in fuel, the combustion process (formation of harmful residues) and compatibility with the technical system. Since no biocidal products are authorised for fuel preservation for other active substances, these points cannot be evaluated and therefore, no clear conclusion can be drawn on the question of a suitable alternative.

Sodium benzoate is an Annex I substance and therefore, it is considered not to achieve the same efficacy and technical suitability as RP 1:1 and RP 3:2, in terms of spectrum and application rate and particular requirements for the intended use.

Peracetic acid is produced by reacting with hydrogen peroxide and acetic acid. It shows oxisiding as well as explosive properties, depending on the concentration (Finland, 2015).

Peracetic acid is evaluated for in-can preservation of pigment slurries and coating products in the paper industry only. No data about the combustion process and potential byproducts/combustion products is available. Moreover, there are currently no biocidal products authorised under BPR for PT6 and therefore, based on the intended uses, suitability cannot be confirmed. Based on the intrinsic properties of the active substance and the lack of data on suitability for this specific use, peracetic acid is not considered a suitable alternative.

Therefore, based on the information available, no suitable alternative for the use in PT6 was identified.

2.1.3 PT11

Intended uses of RP 1:1 and RP 3:2

Generally, the biocidal product (AS as manufactured) can be used directly for preservation of liquid cooling systems. For this application the biocidal product is applied as manufactured, i.e. it is mixed into the process solutions by the user.

Three types of cooling systems are distinguished: once-through cooling, open recirculating cooling systems, and closed recirculating cooling systems. The biocidal products containing RP 1:1 and RP 3:2 are used only in closed systems.

Table 4: Overview of potential alternatives for PT11 (Preservatives for liquid-cooling and processing systems)

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4	Acute Tox. 3 H301, H311, Skin Corr. 1B H314, Eye Dam. 1 H 318, Skin Sens. 1A H317, C ≥ 0.0015 % Acute Tox. 2 H330, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, M=10, M(Chronic)=1 EUH071, GHS05, GHS09, GHS06, Dgr,	Preservation of open and closed liquid cooling and processing systems	No	Comparison of hazards indicates no reduction of the overall risk
Mixture of CMIT/MIT	55965-84-9	Acute Tox. 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; C ≥ 0,6 % Eye Dam. 1 H318; C ≥ 0,6 % Eye Irrit. 2 H319; 0,06 % ≤ C < 0,6 % **Skin Sens. 1A H317**; C ≥ 0.0015 % Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic Chronic 1 H410; M=100;** EUH071; GHS09; GHS05; GHS06; Dgr;	Preservation of liquid cooling and industrial processing systems: (open and closed recirculating cooling towers, industrial process water, air washers, air conditioning systems, humidifiers, nonfood pasteurizers/sterilizers/can warmers, non-medical/nonpotable reverse osmosis (RO) and ultrafiltration (UF) membranes, wastewater treatment systems, water rinse baths, and conveyor lubricants). Preservation of	No	Comparison of hazards indicates no reduction of the overall risk, technically not feasible: not stable at high pH

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
			photo-processing systems, print fountain solutions, textile systems/spinning fluids, electrodeposition coating systems, paint spray booths, wood treatment solutions, and industrial cleaning in place.		
Peracetic acid	79-21-0	Flam. Liq. 3 H226; Org. Perox. D**** H242; Acute Tox. 4* H302; Acute. Tox4* H312; Skin Corr. 1A H314; Acute Tox. 4* H332; Aquatic Acute H400; GHS02; GHS07; GHS05; GHS09; Dgr;	Treatment of cooling water in open recirculating systems and once-through cooling systems (shock dosing).	No	Technically not feasible: limited efficacy of acids at high pH
Ozone generated from oxygen	-	Ox. Gas 1, H270; Acute Tox. 1, H330; STOT SE 1, H370; STOT RE 1, H372; Muta. 2; H341; Carc. 2; H351; Aquatic acute 1; H400, M=100; Aquatic chronic 1; H410, M=1	Preservatives for water in open circuit liquid cooling systems and in closed process water systems. E.g. for Cooling water systems / cooling towers / process water systems	No	Comparison of the hazard indicates no reduction of the overall risk; Technical feasibility questionable

Only four potential alternatives were identified for the use in PT11, the isothiazolinones MIT and CMIT/MIT as well as peracetic acid and ozone generated from oxygen.

According to industry, the typical pH-value for cooling liquids in closed circulation systems is in the pH range between 8.0 – 10.0 for the reason of corrosion protection. Therefore, this is an essential feature for active substances in this use.

Based on the information on physico-chemical properties of CMIT/MIT given in the active substance CAR, CMIT/MIT is not stable under alkaline conditions. For MIT it is not clearly stated in the CAR whether or not the substance is stable at high pH.

Furthermore, both, CMIT/MIT and MIT do not show a significant better hazard profile compared to RP3:2 and RP1:1. Please also see 2.1.1 and Appendix 1 table 11 on this issue.

Peracetic acid is highly unstable at high pH according to the active substance CAR and only used in open systems or once-through systems (shock dosing). It is not approved for the use in closed recirculating systems. Additionally, no related biocidal products are authorised so far for this use.

As already stated in 2.1.1 PT2 ozone generated from oxygen does not show a significantly better hazard profile compared to RP 1:1 and RP 3:2. Additionally, based on its intrinsic properties (strong oxidizer) it is not considered to be a suitable alternative for RP 1:1 and RP 3:2.

No suitable alternative was identified for PT11 based on the information available.

2.1.4 PT12

Intended uses of RP 3:2

- Use as slimicide (bactericide) in the oil industry (offshore) for the preservation of drilling muds (PT12), against sessile general heterotrophic bacteria (GHB), acid-producing general heterotrophic bacteria (APB) and sulphate reducing bacteria (SRB);
- Generally, biocidal products containing "RP 3:2" can be used directly for the prevention or control of slime growth on materials, equipment and structures in industrial processes. The biocidal products (AS as manufactured) are mainly applied as slimicide in the oil industry (offshore) for the preservation of drilling muds.

Table 5: Overview Intendent Use PT12 (Slimicides)

Active Substance	CAS	C&L	Intended Use according to the active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4	Acute Tox. 3 H301, H311, Skin Corr. 1B H314, Eye Dam. 1 H 318, Skin Sens. 1A H317, C ≥ 0.0015 % Acute Tox. 2 H330, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, EUH071, GHS05, GHS09, GHS06, Dgr, Skin Sens 1A, H317: C ≥ 0,0015 %, M=10, M(Chronic)=1;	Slimicide for preservation of aqueous products in paper mills	No	Comparison of hazards indicates no reduction of the overall risk;
Mixture of CMIT/MIT	55965-84-9	Acute Tox. 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; C ≥ 0,6 % Eye Dam. 1 H318; C ≥ 0,6 % Eye Irrit. 2 H319; 0,06 % ≤ C < 0,6 % **Skin Sens. 1A H317**; C ≥ 0.0015 % Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic Chronic 1 H410; M=100;** EUH071; GHS09; GHS05; GHS06; Dgr;	1: The biocide is used in the wet end of paper mills 2: Oilfield Injection Systems – The biocide is used to control the growth of target organisms in injection water lines and raw materials used in processing for enhanced oil recovery (drilling muds and fracture fluids).	No	Comparison of hazards indicates no reduction of the overall risk; Technically not feasible: not stable at high pH

Active Substance	CAS	C&L	Intended Use according to the active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
Peracetic acid	79-21-0	Flam. Liq. 3 H226; Org. Perox. D**** H242; Acute Tox. 4* H302; Acute. Tox4* H312; Skin Corr. 1A H314; Acute Tox. 4* H332; Aquatic Acute H400; GHS02; GHS07; GHS05; GHS09; Dgr;	Use as slimicide in the pulp and paper industry.	No	Technicalfeasibility questionable: not stable at high pH, decomposition strongly exothermic

As it was indicated by stakeholders, a crucial property for active substances used in this field is their stability above a pH of 8 for reasons of efficacy and corrosion protection. Peracetic acid (PAA) is an organic acid which is not stable at high pH an reacts strongly exothermic when decomposing. Furthermore, PAA is only approved as slimicides in paper production and therefore not considered as suitable alternative.

The mixture of CMIT/MIT is approved for the preservation of polymers used in processing for enhanced oil recovery (like in (bio-)polymers in drilling muds etc.). Biocidal products were identified which are used in this area but this turned out to be a different use area for PT11, as preservative for liquids in processing systems.

Furthermore, both, CMIT/MIT and MIT do not show a significant better hazard profile compared to RP 3:2 and RP 1:1. Please also see 2.1.1 and Appendix 1 table 11 on this issue.

Thus, CMIT/MIT cannot be considered as a safer alternative in respect to human health and the environment.

In conclusion, no suitable alternative was identified for the use in PT12 based on the information available.

2.1.5 PT13

Intended uses of RP 1:1 and RP 3:2

Biocidal products containing RP 1:1 and RP 3:2 are applied as preservative for water-based metal working fluids. In general, these metal working fluids can be divided in two application fields, emulsifiable and water-soluble metal working fluids. In addition, the biocidal products can be used within formulations as system cleaner of metal working systems. This application could be assigned to product type 2. However, the application is in the field of metal working industry, and thus, the exposure to workers and the emission to the environment during application of the system cleaner are nearly identical with the application in PT13.

Table 6: Overview Intended Use PT13 (Working or cutting fluid preservatives)

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4	Acute Tox. 3 H301, H311, Skin Corr. 1B H314,	Preservative for metalworking fluid systems.	No	Comparison of hazards indicates no

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
		Eye Dam. 1 H 318, **Skin Sens. 1A H317, C ≥ 0,0015 %** Acute Tox. 2 H330, **Aquatic Acute 1 H400, Aquatic Chronic 1 H410,** EUH071, GHS05, GHS09, GHS06, Dgr, Skin Sens 1A, **H317: C ≥ 0,0015 %, M=10, M(Chronic)=1;**	These systems include but are not limited to the emulsifiable and water soluble metalworking fluids, metal cleaners, and water-based hydraulic fluids.		reduction of the overall risk
3-iodo-2-propynylbutyl-carbamate (IPBC)	55406-53-6	Acute Tox. 4 H302, Eye Dam. 1 H318, **Skin Sens. 1 H317,** Acute Tox. 3 H331, **STOT RE 1 H372 (larynx), Aquatic Acute 1 H400, Aquatic Chronic 1 H410,** GHS08, GHS05, GHS09, GHS06, Dgr, **M=10, M(Chronic)=1;**	Preservative for emulsifiable and water soluble metal working fluids	No	Comparison of hazards indicates no reduction of the overall risk; Technically not feasible: limited efficacy (fungicide)
Biphenyl-2-ol	90-43-7	Skin Irrit. 2 H315; Eye Irrit. 2 H319; STOT SE 3 H335; **Aquatic Acute 1 H400;** GHS07; GHS09; Wng;	Preservation of metal working fluids (cooling lubricants).	No	Technical feasibility questionable: intended use indicates unsuitability, Efficacy against bacteria cannot be confirmed, no biocidal products on the market
Chlorocresol	59-50-7	Acute Tox. 4 H302; Skin Corr. 1C H 314; Eye Dam 1 H318; **Skin Sens. 1B H317;** STOT SE 3 H 335; **Aquatic Acute 1 H 400;** Aquatic Chronic 3 H 412; GHS07; GHS05; GHS 09; Gdr; M=1;	Antimicrobial preservative for aqueous metal working fluids (MWF).	No	Technical feasibility questionable: no data available, no biocidal products on the market
Mixture of CMIT/MIT	55965-84-9	Acute Tox. 3 H301; Acute Tox. 2 H310; Skin Corr. 1C H314; C ≥ 0,6 % Eye Dam. 1 H318; C ≥ 0,6 % Eye Irrit. 2 H319; 0,06 % ≤ C < 0,6 % **Skin Sens. 1A H317; C ≥ 0.0015 %** Acute Tox. 2 H330; **Aquatic Acute 1 H400; Aquatic**	Preservation of water-based metalworking fluids prepared from water soluble or emulsifiable concentrates.	No	Comparison of hazards indicates no reduction of the overall risk; Technically not feasible: not stable at high pH

Active Substance	CAS	C&L	Intended Use according to active substance CAR	Potential Alternative (Yes/No)	Justification by the rapporteur
		Chronic 1 H410; M=100; EUH071; GHS09; GHS05; GHS06; Dgr;			

In total, five active substances were identified which are approved for PT 13 and show a similar use compared to RP3:2 and RP1:1, respectively. IPBC has also a classification for Skin Sens. 1 and the systemic AELs are in the same order of magnitude as for RP 3:2 and RP 1:1. For the environment the classification of IPBC is more servere as for RP 3:2 and RP 1:1. Thus, it is assumed that IPBC also shows no significantly better hazard profile. Furthermore, the substance is predominantly used as fungicide and does not possess the same high bactericidal efficacy compared to RP 3:2 and RP 1:1. Therefore, IPBC cannot be considered as suitable alternative.

Based on the intended use and the harmonized classification, Biphenyl-2-ol would be a potential alternative. The harmonized classification of Biphenyl-2-ol might be significantly better compared to RP 1:1 and RP 3:2; also, the derived toxicological reference values are lower. However, similar to IPBC, the bactericidal efficacy of Biphenyl-2-ol is quite limited according to the CAR (ES, 2015), where it is stated that "*Efficacy against bacteria was not demonstrated and should be shown at product authorization stage*". Since currently no biocidal product for the use in PT13 is authorised on the market and the respective evaluations are still in progress, no clear conclusion on the suitability of this substance can be drawn at the moment.

A similar issue applies for Chlorocresol, which shows mainly fungicidal activity.

The harmonized classification and labelling of Chlorocresol might be considered as less severe than RP 3:2 and RP 1:1. No CMR classification is proposed, and the skin sensitizing potential is less severe. The AEC values for the active substances for medium and long-term effects, as well as the AELs (acute, medium and long term) are in the same order of magnitude, the AEC for acute toxicity is lower for RP 3:2 and RP 1:1. However it needs to be considered that no ED assessment according to ECHA/EFSA guidance is available for Chlorocresol. Currently, there are no biocidal products authorised on the market. Therefore, a comparison as suitable alternative is not possible since the exact field of use and spectrum of bactericidal activity cannot be evaluated.

For the mixture of CMIT/MIT, 10 BPs are authorised on the market for the respective use. Similar to PT 11, it was stated by the industry that the typical pH-value for metal working fluids is in the pH range of 8.5 – 9.5. Therefore, this is an essential feature for active substances in this use. CMIT/MIT (3:1) is stable in acidic and neutral conditions but lacks stability at higher pH values which makes it inadequate as alternative for RP 3:2 and RP1:1.

Furthermore, both, CMIT/MIT and MIT do not show a significant better hazard profile compared to RP 3:2 and RP 1:1. Please also see 2.1.1 and Appendix 1 table 11 on this issue.

Thus, CMIT/MIT cannot be considered as a safer alternative in respect to human health and the environment.

Therefore, no suitable alternative was identified for the use in PT13.

2.2 Biocidal products on the EU market under the transitional period (Article 89) and the BPR (528/2012) – Infformation received from Member States consultation

In the member states consultation, in total 6 countries contributed, including Denmark, Estonia, Belgium, Switzerland, Luxemburg and the Netherlands. In most of the countries only biocidal products containing RP 3:2 and RP 1:1 are placed on the market and used according to the transitional measures of Article 89 in the respective uses. In some of the products the active substances are used in combination with 2-pyridinethiol, 1-oxide, sodium salt. Biocidal products containing FARs like 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT) and Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5 (1H,3H)-dione (TMDA) as well as other candidates for substitution/ substances meeting the exclusion criteria were not considered in the assessment.

Denmark stated that there was no national authorisation system covering most of the uses in the respective PTs prior to the BPD/BPR so information was collected from stakeholders. In Denmark, “RP 3:2” is used in paint industry (as PT11), in diesel fuels after cases of ‘diesel plague’ and in offshore oil industry. These products are placed on the market and used according to the transitional measures of article 89.

The same applies for Estonia, which also only listed biocidal products containing RP 3:2 and RP 1:1 (in combination with 2-pyridinethiol, 1-oxide, sodium salt).

Belgium stated that it was not always possible to identify whether potential alternatives are authorised on the market in Belgium (PT2). No alternatives were found for the use in PT6. Results given for PT11 are not divided by use, therefore it is not possible to make any statement about the availability of suitable alternative for PT11 on the Belgian market under the transitional period. The same applies for PT13. Active substances used in PT12 are CMIT/MIT and Bronopol and authorised products show a similar use but the suitability of these active substances has already been discussed in the rapporteur’s evaluation, for CMIT/MIT in paragraph 2.1.1, and for Bronopol in the Appendix, Table 10.

Contributions from Switzerland did not include any statement on potential alternatives, only biocidal products containing RP 3:2 and RP 1:1.

According to the contribution of Luxemburg, no suitable alternative is authorised in Luxemburg for PT2. For PT6, one biocidal product was identified that is used for “*diesel-powered vehicles, decommissioned or in low use (construction machinery), storage tanks or disinfection of contaminated tank systems*”. The active substance of the product is 1,2-benzisothiazolin-3-one (BIT, CAS No. 2634-33-5) - an isothiazol – with high skin sensitizing potential. A CLH report has been already submitted by the Rapporteur Member State and, according to the RAC opinion (RAC, 2021), the Annex VI entry should be revised also for the skin sensitizing properties, resulting in Skin Sens. 1A, C ≥ 0.036%. Although the concentration limit is higher compared to other isothiazoles such as MIT or CMIT/MIT (C ≥ 0.0015%), the specific concentration limit of BIT still indicates higher sensitizing potential compared to RP 3:2 and RP 1:1. For RP 3:2 and RP 1:1 no specific concentration limit has been derived, and the generic concentration limit of ≥ 0.1% for Skin Sens. 1A applies. Also, the environment classification for Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=1) is more severe than for RP 3:2 and RP 1:1. Thus, BIT does not have a significantly better hazard profile. Therefore, this active substance is not considered to be an appropriate alternative.

For PT11, the intended use of potential alternatives is not specified as well – A few potential alternatives were identified, e.g. products containing the active substance (review

programme) DBNPA, which also fulfills exclusion criteria and is therefore no suitable. Again, BIT is mentioned as potential alternative, but not enough information is given in the contribution to evaluate the exact use and thus the suitability. No information about the product were found during internet research. No CAR/BPC opinion is available for BIT in PT11.

Most of the substances listed in PT13 are used in combination with one or two other active substances. Some products are listed containing BIT but not enough information could be found about the use of the products to make a clear statement on suitability. Furthermore, the regulatory status of BIT was already discussed above.

Biocidal products provided by the Netherlands do not reveal any new potential alternatives.

2.3 Non-chemical alternatives

No non-chemical alternatives were identified during the analysis.

2.4 Stakeholder consultation on alternatives 2023

The following chapter only reflects the stakeholder contribution and not all the information could be verified by the rapporteurduring this analysis.

As indicated previously, another consultation on alternatives to RP1:1 and RP3:2 was initiated in March 2023. In addition to the standard advertising of the consultation via ECHA communication channels, based on a prior internet research, 64 stakeholders including individual industries or industry associations which could have an interest in the consultation have been identified by the rapporteur and the ECHA secretariat and informed directly about the consultation.

In total, 44 comments of stakeholders including downstream users, manufacturers and industry associations were submitted for RP 3:2 and RP 1:1. Most of the received statements only supported the opinion of the applicants. In the following, only the view of the contributors of this consultation is summarised.

In general, the potential alternative substances discussed by the industry are the same as the active substances evaluated by the Competent Authority. In addition to the chemical alternatives discussed, no other non-chemical alternatives for the use of RP 3:2 or RP 1:1, respectively, were identified in the contributions that are currently available on the market. All contributions emphasized the need to continue the approval of RP 3:2 and RP 1:1, respectively, to keep them on the market and pointed out the enormous impact on various sectors of the economy as well.

The contributors did not include any other formaldehyde-releasers in their discussion as alternatives for RP 3:2 and RP 1:1, since these substances will probably also be classified as carcinogenic and will therefore fulfil exclusion criteria. Other active substances (e.g. glutaraldehyde) which are flagged as Candidates for Substitution due to other reasons were also not included in the discussion. The active substance family of isothiazolinones including MIT, CMIT/MIT and BIT were highly discussed in most of the contributions, especially CMIT/MIT, which is approved for all relevant PTs. CMIT/MIT was not confirmed to be a suitable alternative by the stakeholders for any of the respective PTs: CMIT/MIT has a harmonised classification as skin sensitizer Cat. 1 and is also very toxic for the environment (with long lasting effects). Therefore, in general, it cannot be stated that CMIT/MIT shows a significantly better hazard profile compared to RP 3:2and RP 1:1. The substance is not stable above a pH of 8, which is a crucial factor for the intended use in PT 11 and PT12. The efficacious concentration needed for the use in PT 13 would also exceed the limit of labelling with H317

about 2-4 times. Additionally, due to the German Clear Air Act, biocidal products containing halogens, such as CMIT/MIT, will not be authorised in Germany in PT6 for the use as fuel additives.

The same might apply for chlorocresol, which is approved for PT 1, 2, 3, 6, 9 and 13. This AS is also classified as skin sensitizer and is therefore also not considered to be a suitable alternative for RP 2:3 and RP 1:1 by the contributors.

One substance, that was previously considered as potential alternative for PT11 is tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (THPS). This substance is also a formaldehyde releaser and is therefore no longer considered as suitable alternative. Additionally, it has a more severe classification for acute aquatic toxicity compared to RP 3:2 and RP1:1and its stability prevents its application for the same use as RP 3:2 and RP1:1.

For PT13, in the March 2023 stakeholder consultation, CMIT/MIT, MIT, BIT, diamine, phenoxyethanol, MBIT and DBNPA were indicated as potential alternatives. Despite the classification as skin sensitizer of the isothiazolinones that was already discussed, MIT has also limitations because of its lower stability under alkaline conditions. BIT shows a lack of efficiency against *Pseudomonas* species which is essential in the use for PT13. Diamine is an alternative to RP 3:2 and RP 1:1 in PT13 niche applications only and would therefore not fully substitute the active substances of concern. The other substances mentioned above have not been approved since.

Other substances approved for the use in PT13 are: biphenyl-2-ol, chlorocresol and IPBC. Biphenyl-2-ol and IPBC are fungicides, so deemed not a suitable alternative since both, bactericidal and fungicidal properties are needed. Chlorocresol is also classified as skin sensitizer and is, just like the isothiazolinones, not deemed suitable as an alternative.

For substances in the review programme it was stated:
„[…]. *The limited information available on other active* [substances] *within the review program is insufficient to conclude on the availability of suitable alternatives for the intended uses assessed*. […]."

In table 7 below, a short analysis of alternatives was performed by an industry representative on the substances that show the highest potential for being a suitable alternative.

Table 7: Overall assessment on suitability of alternatives concerning safety and health issues as well as technical and economical issues, as provided by Vink Chemicals GmbH & Co. KG

	PT2	**PT6**	**PT11**	**PT12 "RP3:2" only**	**PT13**
Description	Use as microbicidal system cleaner (bactericide and fungicide) of metal working systems (disinfection of the inner surface of vessels and tubes) (PT 2), against gram-negative bacteria such as	Use as in-can preservative (bactericide) in fuels, added automatically during the formulation of diesel fuels (PT 6), against gram-negative bacteria such as *Pseudomonas aeruginosa*, *Enterobacter aerogenes* and *Acinetobacter*	"RP3:2": Use as preservative (bactericide) for closed recirculating cooling water systems (PT 11), against gram-negative bacteria such as *Pseudomonas putida*, *Proteus sp.*; "RP 1:1": as preservative (bactericide)	Use as slimicide (bactericide) in the oil industry (offshore) for the preservation of drilling muds (PT 12), against sessile general heterotrophic bacteria (GHB), acid-producing general heterotrophic bacteria (APB)	Use as preservative (bactericide and fungicide) for water-based metal working or cutting fluids (PT 13), against gram-negative bacteria such as *Pseudomonas spec.*; gram-positive bacteria such

	PT2	PT6	PT11	PT12 "RP3:2" only	PT13
	Pseudomonas putida, *Escherichia coli*; gram-positive bacteria such as *Staphylococcus aureus* and *Mycobacterium immunogenum* ; yeasts such as *Candida albicans*, and fungi such as *Fusarium oxysporum*;	*spec.*;	for closed recirculating cooling water system (PT 11), against gram-negative bacteria such as *Pseudomonas putida, Pseudomonas fluorescens., Pseudomonas aeruginosa, Escherichia coli, Klebsiella oxytoca, Legionella longbeachea;* gram-positive bacteria such as *Staphylococcus aureus and Mycobacterium avium.*	and sulphate reducing bacteria (SRB);	as *Bacillus spec.* and *Mycobacterium sp.*; yeasts such as *Candida albicans* and *Rhodotorula mucilaginosa (rubra)*, and fungi such *as Fusarium oxysporum*. "RP1:1": as preservative (bactericide and fungicide) for emulsifiable and water-soluble metal working fluids (PT 13), against gram-negative bacteria such as *Pseudomonas spec., Klebsiella pneumoniae, Escherichia coli*; gram-positive bacteria such as *Bacillus spec. and Mycobacterium sp.*; yeasts such as *Candida albicans and Rhodotorula mucilaginosa* (rubra); and fungi such as *Fusarium oxysporum, Aspergillus niger*
Alternate Substance	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (BDA) (CAS 2372-82-9) (Still under review for approval and as a CfS, but known alternative in the industry)	CMIT/MIT	2-methyl-2H-isothiazol-3-one (MIT) (CAS #2682-20-4) CMIT/MIT	CMIT/MIT	Chlorocresol, (CAS# 59-50-7) Biphenyl-2-ol, (CAS#90-43-7) CMIT/MIT, MIT
Health &	Bad	Sensitizing	**MIT:**	Sensitizing	**MIT:**

	PT2	PT6	PT11	PT12 "RP3:2" only	PT13
Safety issue of alternates	environmental profile, H410 - Very toxic to aquatic life with long lasting effects.	GHS05: Corrosive GHS06: Acute Toxicity GHS09: Hazardous to the environment Classified Danger! According to the harmonised classification and labelling (ATP13) Due to the classification of CMIT/MIT its use as a substitution would not reduce overall risk to human health, animal health and the environment.	Sensitizer, toxic and bad environmental profile, potentially carcinogenic. **CMIT/MIT:** Sensitizing GHS05: Corrosive GHS06: Acute Toxicity GHS09: Hazardous to the environment Classified Danger! According to the harmonised classification and labelling (ATP13) Due to the classification of CMIT/MIT its use as a substitution would not reduce overall risk to human health, animal health and the environment.	GHS05: Corrosive GHS06: Acute Toxicity GHS09: Hazardous to the environment Classified Danger! According to the harmonised classification and labelling (ATP13) Due to the classification of CMIT/MIT its use as a substitution would not reduce overall risk to human health, animal health and the environment.	Sensitizer, toxic and bad environmental profile, potentially carcinogenic. **Chlorocresol:** sensitizing and potentially carcinogenic **Biphenyl-2-ol:** bad environmental profile **CMIT/MIT:** Sensitizing GHS05: Corrosive GHS06: Acute Toxicity GHS09: Hazardous to the environment Classified Danger! According to the harmonised classification and labelling (ATP13) Due to the classification of CMIT/MIT its use as a substitution would not reduce overall risk to human health, animal health and the environment.
Technical issue with alternatives	Foaming issues, cationic in nature, interacts with anionics, which is a big issue for MW fluid as most of them are anionic. Freezing point of 9°C - difficult to manage at harsh weather conditions	Contains AOX (org. halogens) Not stable at pH >8 Deactivated by sulphur. Not readily biodegradable Contains water, must be blended with methanol or glycol to avoid freezing. Does not avoid corrosion (unlike "RP3:2" and "RP1:1"). Not Soluble in oil ("RP3:2"	**CMIT/MIT:** Contains AOX (org. halogens) Not stable at pH >8 Deactivated by sulphur. Not readily biodegradable Contains water, must be blended with methanol or glycol to avoid freezing. Does not avoid corrosion (unlike "RP3:2" and "RP1:1"). Not effective	Contains AOX (org. halogens) Not stable at pH >8 Deactivated by sulphur Not readily biodegradable Contains water, must be blended with methanol or glycol to avoid freezing. Does not avoid corrosion (unlike "RP3:2" and "RP1:1"). Not Soluble in oil ("RP3:2" and "RP1:1"	**MIT:** not stable at pH>8, decomposition in the presence of sulphide. **Chlorocresol** only 4% water soluble. Primarily fungicidal action only. **Biphenyl-2-ol:** mainly a fungicide. very low water solubility (0.7g/l, 20°C) **CMIT/MIT:** Contains AOX (org. halogens) Not stable at

	PT2	PT6	PT11	PT12 "RP3:2" only	PT13
		and "RP1:1" are soluble is oil). Not effective against anaerobic bacteria, particularly SRB's. In presence of H2S CMIT/MIT & MIT degrades. Not an ashless additive for fuel ("RP3:2" is ashless additive in fuel)	against anaerobic bacteria, particularly SRB's. In presence of H2S CMIT/MIT & MIT degrades. **MIT:** not stable at pH>8. decomposition in the presence of sulphide.	are soluble is oil). Not effective against anaerobic bacteria, particularty SRB's. In presence of H_2S CMIT/MIT & MIT degrades.	pH >8 Deactivated by sulphur. Not readily biodegradable Contains water, must be blended with methanol or glycol to avoid freezing. Does not avoid corrosion (unlike "RP3:2" and "RP1:1"). Not Soluble in oil ("RP3:2" and "RP1:1" are soluble is oil). Not effective against anaerobic bacteria, particularty SRB's. In presence of H2S CMIT/MIT & MIT degrades.
Economical and/or supply chain issue with alternatives	Active product is more expensive than "RP3:2""RP 1:1": Not known	If "RP3:2" is not approved CMIT/MIT would be the <u>only</u> fuel biocide approved in Europe, and CMIT/MIT banned in some EU countries (DK, BE, DE and RO) for use is fuel. CMIT/MIT is not seen as a replacement, and in many uses this AS is the only other substance available for use and often only used in complimentary manner with "RP 3:2". With the implementation of the BPR, the number of technically suitable	Not known	CMIT/MIT is not seen as an alternative for many PT uses, and in many uses this AS is the only other substance available for use and often only used in complimentary manner with "RP 3:2". With the implementation of the BPR, the number of technically suitable candidates for fuel and oil treatment has reduced significantly, the costs of regulatory approval, and approvals by relevant system Original Equipment Manufacturers (OEMs), would	Not known

	PT2	PT6	PT11	PT12 “RP3:2” only	PT13
		candidates for fuel and oil treatment has reduced significantly, the costs of regulatory approval, and approvals by relevant system Original Equipment Manufacturers (OEMs), would be disproportionally high.		be disproportionally high.	

No suitable alternative was identified by the industry contributors.

All active substances that were finally analysed by the stakeholders were also analysed by the rapporteur and the same conclusion was drawn. Most of the arguments could be substantiated, although not all of them. Only data and arguments that were used for the rapporteur’s assessment were checked for reliability. The assessment was carried out in accordance with the Guidance and accepted by the rapporteur AT.

2.5 Literature research

Literature research was performed according to the guidance on analysis of alternatives (ECHA, 2023 – Box 6). Different pages and data bases were searched for chemical and non-chemical alternatives. Important search criteria and keywords were based on the intended use mainly.

1) ECHA biocides database

Literature research on ECHAs biocides database was performed and already summed up under 3.1.1 to 3.1.5.

2) Member states and interested third parties consultation

Information on this topic are given under the respective points above.

3) German Blue Angel product Database

The website was searched for “preservatives”, “system cleaners”, “metalworking fluids”, “fuel”, “fuel additive”, “cooling”, “liquid cooling systems”, “oil industry”, “drilling muds”.

Neither a chemical nor a non-chemical alternative was identified.

4) ECHAs substitution website

ECHA substitution website provides several links of databases that can be used for search for alternatives:

- PRIO Platform: is about identifying hazardous substances prior to product development and therefore not useful for this assessment. Searching for the active substance names and their variations did not lead to any result.

- All other webpages and databases mentioned on this website focus mainly on listing hazardous substances for manufacturers/industry for reasons of information before product development and are not considered useful in the frame of this research.

5) SCOTTY platform

The SCOTTY platform mainly focuses on product types like insecticides and rodenticides and other products for pest control and therefore no information on alternatives for the intended uses searched for could be found.

6) SUBSPORTplus

This website mainly provides information on lists of hazardous substances identified by different regulatory regimes and also a case data base where research on substitutes of different hazardous substances are discussed. No alternative was identified in this research.

7) ChemSec Marketplace

On this website, it was searched for alternatives using the technical functions “biocide”, “disinfectant”, “fuel”, “fuel additive” and “hydraulic (functional) fluids”. 10 hits in total were found, but none of them was found a suitable alternative due to the different uses.

8) CORDIS database

The platform was searched with the keywords “biocide”, “alternative” and “substitution”, in total 35 hits were listed, but none of them identified a suitable alternative approved for the respective uses.

2.6 Overall conclusion

In the present document, the potential alternatives to substances RP3:2 and RP1:1 were examined. In particular, the intended uses, classification and physicochemical properties of the potential alternatives were evaluated in a first step.

The intended uses per PT according to the active substance CAR (AT, 2022) are as follows:

- PT2: Generally, the biocidal product (AS as manufactured) and other substances can be added by downstream users to base oils to get concentrates[10] which can be used to prepare a metal working fluid. The biocidal products containing the active substances RP 3:2 or RP 1:1 are applied as preservatives for water-based metal working fluids. In addition, the biocidal products can be used within formulations as system cleaner of metal working systems. This application can be actually assigned to product type 2 as it is considered to be the disinfection of the inner surface of vessels and tubes[11]

- PT6: The products are intended to be incorporated by industrial users into fuels to act as a preservative. The biocidal products are incorporated into fuels during the formulation process. The evaluated use of the preserved fuel is used by professional and non-professionals/general public during the refuel of engines.

[10] The concentration in the concentrate is typically 10% w/w, the final dilution in the ready to use solution is 0.25% w/w up to 3% w/w depending on the duration of the disinfectant cleaning process

[11] The active substances RP 1:1 and RP 3:2 are applied for PT2 at the time of the analysis of alternatives and the discussion on the distinction between PT2 and PT13 is still pending. At SCBP 77 in October 2022, a newsgroup was announced to which two Member States contributed but no final conclusion was drawn on this topic.

- PT11: Generally, the biocidal products (AS as manufactured) can be used directly for preservation of liquid cooling systems. For this application the biocidal product is applied as manufactured, i.e. it is mixed into the process solutions by the industrial user.

  Three types of cooling systems are distinguished: once-through cooling, open recirculating cooling systems, and closed recirculating cooling systems. The biocidal products containing “RP 3:2” or “RP 1:1” are used only in closed systems.

- PT12 („RP 3:2“only): Generally, biocidal products containing “RP 3:2” can be used directly for the prevention or control of slime growth on materials, equipment and structures in industrial processes. The biocidal products (AS as manufactured) are mainly applied as slimicide in the oil industry (offshore) for the preservation of drilling muds.

- PT13: Biocidal products containing the active substance “RP 3:2” or “RP 1:1” are applied as preservative for water-based metal working fluids. In general, these metal working fluids can be divided in two application fields, emulsifiable and water-soluble metal working fluids. In addition, the biocidal products can be used within formulations as system cleaner of metal working systems. This particular application can be actually assigned to product type 2. However, the application is in the field of metal working industry, and thus, the exposure to workers and the emission to the environment during application of the system cleaner are nearly identical with the application in PT13.

Active substances that were approved for the respective PTs according to R4BP3 at the start of the assessment were taken into account. Furthermore, a survey for Member States was conducted and contributions and statements from relevant stakeholders were included. For comparison, contributions from the public consultation from November 2017 and the SCBP discussion 55, 56 and 77 were also considered. With regard to non-chemical alternatives, a literature search was carried out according to the current AoA guidance (ECHA, 2023).

In general the conclusion should be drawn against four criteria (as far as possible): technical feasibility, economic feasibility, availability and reduction of the overall risk. The focus was put on the technical feasibility and the reduction of the overall risk since information for evaluation of these point was available from the active substance CARs and the stakeholder consultations. Availability and economic feasibility could not be estimated based on the information available.

Referring to the question of technical feasibility, the areas of application of the substances RP 3:2 and RP 1:1 are very specific and few other substances are intended for the same areas of application. In most applications, there are certain conditions that must be met, such as a high pH value to ensure efficacy and corrosion protection or the active substance must reveal efficacy against certain target organisms. To meet these requirements, the active substance must be stable and effective under the given conditions which is not the case for certain acids and in situ active chlorine and in general substances that degrade in certain ways at high pH. For use in PT6, the preservative must not contain halogens such as chlorine to prevent the formation of harmful combustion products which is e.g. the case for CMIT/MIT.

Concerning the reduction of the overall risk for humans and the environment, substances that could come into question do not have a hazard profile that can be described as significantly better. Even if a substance is neither a candidate for substitution nor does meet the exclusion criteria, the entire harmonized classification was used for assessing the overall picture. As explained e.g. under 3.1.2 for CMIT/MIT, the classification for the environment and thresholds

in the hazard assessment for humans play a major role, especially since no risk was calculated for the user when using RP 3:2 and RP 1:1.

A problem that frequently arose during the evaluation was that some substances from the review programme have still not been fully evaluated and there is no data on the specific application and sufficient details on the substance itself available. For other substances that show a very similar area of application and are approved, no products have yet been authorised and their exact field of use could not be compared. In case RP 3:2 and/or RP 1:1 would be approved, an important point for their potential renewal would therefore be to analyse these potential alternative substances and to include in an potential updated AoA, any products that may have been authorised at that point in time.

No details can be given for future active substances or substances currently not on the market. Substances that are currently approved but do not have any related biocidal products revealing the same use were assessed on their suitability. In most of the cases, active substances were not considered being potential alternatives even in the future since the reasons for unsuitability were about their intrinsic properties such as stability or efficacy, which cannot be changed without changing the system or the process.

The questions on obstacles for industry to develop suitable chemical and non-chemical alternatives, as mentioned in the mandate for the AoA item 14), are not easy to answer. No or hardly any comments were made on this by the stakeholders. To the Rapporteur's knowledge, only one company is currently researching on a new biocidal active substance that might be used as alternative for PT2. However, the greatest obstacles are considered to be, among other things, the high financial outlay and the lack of pressure from the regulatory side. Also not to be neglected is the time-consuming research and development process and the approval requirements themselves.

Based on the available information, the conclusion can be drawn that, at the time of the assessment, no active substance (including a related biocidal product) has been identified being on the market that unequivocally represents a suitable alternative for RP1:1 and RP 3:2.

2.7 Uncertainties

The BPC highlights the fact that this opinion only reflects the current state of knowledge based on the information that could be collected at the time of writing the opinion.

The performance of an analysis of alternatives at the level of active substance approval involves inherent challenges, for example, when there are a large number of uses involved or if access to information on alternative substances and non-chemical methods of control is limited, This is especially the case when not all active substances have yet been evaluated in accordance with Regulation (EU) 528/2012 and therefore not all products have been authorised in accordance with the same regulation. Additional and more specific information that becomes available may affect the outcome of future analyses. The analysis in this opinion was one of the first carried out based on the documents CA-June22-Doc.5.4a[12], CA-Oct22-Doc.5.5[13] and in ECHA's guidance on analysis of alternatives v1.0[14]. The BPC notes that the methodology of these analyses will probably develop as more experience is gained and more

[12] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/eb8644d5-0545-4240-a0ef-87573d0c871b/details
[13] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/38b336bd-8558-4b40-be2b-aa8631cb25a3/details
[14] https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternatives_biocides_en.pdf

information becomes available. The BPC furthermore underlines the need to address some methodological issues in the appropriate scientific or policy fora.

2.8 References

AT (2022a). Assessment Report of Reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1), [notified as α,α′,α″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol – HPT] for Product-type 2, 6, 11 & 13, Austria, 2017, revised 2022

AT (2022b). Assessment Report of Reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 3:2), [notified as 3,3'-methylene-bis(5-methyl¬oxazolidine) – MBO] for Product-type 2, 6, 11, 12 & 13, Austria, 2017, revised 2022

ES (2015). Assessment Report of Biphenyl-2-ol for Product–type 13, Spain, 2015

ECHA (2021a). Agreement of the member state committee on the identification of glutaral as a substance of very high concern according to articles 57 and 59 of Regulation (EC) 1907/20067. Adopted on 3 June 2021.

ECHA (2021b). Member state committee support document for identification of glutaral as a substance of very high concern because of its respiratory sensitising properties (article 57 (F) – Human Health Properties. Adopted on 3 June 2021.

ECHA (2023). Guidance on "Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance", ECHA, 2023

Finland (2015). Assessment Report of Peracetic acid for Product types 1-6, Finland, 2015

SCOEL (2016). Recommendation from the scientific committee on occupational exposure limits. SCOEL/REC/125 Formaldehyde

RAC & SEAC (2020). Committee of risk assessment (RAC)/Committee for Socio-economic Analysis (SEAC). Opinion on an Annex XV dossier proposing restrictions on Formaldehyde and formaldehyde releasers.

RAC (2021). Committee for Risk Assessment. Opinion proposing harmonised classification and labelling at EU level of 1,2-benzisothiazol-3(2H)-one CAS: 2634-33-5

2.9 Appendix

Table 8: Identity of the active substances subject to the analysis of alternatives

Substance Identity RP3:2	
IUPAC name	Formaldehyde released from reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)
CAS number	n.a.
EC number	n.a.
Molecular and structural formula	n.a. (UVCB substance)
Molecular mass	n.a. (UVCB substance)
Substance Identity RP1:1	
IUPAC or EC name	Formaldehyde released from reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio 1:1)
EC number	n.a.
CAS number	n.a.
Molecular and structrual formula	n.a.
Molecular mass	n.a.
Physico-chemical properties	
Appearance	RP 3:2: colourless to yellowish liquid and an amine like odour RP 1:1: Liquid; colourless to yellow HPA[15]: colourless liquid and a slight ammonia odour Formaldehyde: colourless gas, pungent suffocating odour (formaldehyde gas) colourless liquid, irritating, pungent odour (formaldehyde solution (30-55% w/w))
Melting point	RP 3:2:-60.5°C; RP 1:1: <-30°C (-36°C to -38°C), no endothermic signals recognizable between -30°C and +30°C HPA: 1.7°C Formaldehyde: -118°C to -92°C (formaldehyde gas), -15°C (formalin (37%))
Boiling point	RP 3:2: endothermic effect up to 195°C (boiling); exothermal effect at 186 °C (decomposition). RP 1:1 endothermic effect between 40 – 195°C (boiling); exothermal effect at 195 °C (decomposition) HPA: 160°C Formaldehyde: -19.5 °C (1013 hPa) (formaldehyde gas) 96 °C (formalin (37w/w% aqueous solution, containing 10-15% methanol))
Temperature of decomposition	RP 3:2: - RP 1:1: -
Vapour pressure	RP 3:2/RP 1:1: Not relevant. The exposure assessment is based on formaldehyde.

[15] HPA,: 2-Hydroxypropylamine (starting material).

	Therefore, the vapour pressure of formaldehyde was used for further calculations and not the value of the substance or one of its constituents HPA: 0.63hPa at 25°C Formaldehyde: 5490 hPa, 300 K (formaldehyde gas) 187 Pa, 25°C (formalin (37%))
Henry's Law constant	RP 3:2/ RP 1:1: Not relevant. The exposure assessment is based on formaldehyde. Therefore, the Henry's law constant of formaldehyde was used for further calculations and not the value of the substance or one of its constituents HPA:4.94·10-5 Pa m3 mol-1 at 25°C Formaldehyde: 0.034 Pa*m³/mol at 25°C (methanol-free formaldehyde, prepared from 37% formalin)
Relative density	RP 3:2: 1.05 at 20°C RP 1:1: D204 =1.11 g/cm3
Solubility in water	RP 3:2: completely miscible in water at room temperature, 2800g/L at 30°C and pH 9.77 RP 1:1: Miscible with buffer solution at pH 5; 7.and 9 (20°C) and miscible with water. HPA: 37g/L at 11°C Formaldehyde: up to 55% (formaldehyde gas)
Partition coefficient (n-octanol/water) and its pH dependency	RP 3:2: -0.043 RP 1:1: -0.4767 ± 0.06 (based on formaldehyde) -0.6108 ± 0.04 (based on 2-hydroxypropylamine)
Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H302 Acute Tox. 3, H311 ("RP 3:2" only) Acute Tox. 4, H332 Skin Corr. 1B, H314 (Skin Corr. 1C for "RP 1:1" Skin Sens. 1A, H317 Eye dam. 1, H318 STOT RE 2, H373 Muta 2, H341* Carc. 1B, H350** Aquatic Chronic 2, H411
	* The classification as a mutagen need not apply if it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 1%. ** The classification as a carcinogen need not apply if it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0.1%.
Specific Concentration limits, M-Factors	M = not applicable

Table 9: Assessment of exclusion and substitution criteria concerning RP 1:1 and RP 3:2

Assessment of exclusion and substitution criteria			
Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	Cat 1B	RP 3:2 and RP1:1 do fulfil criterion (a) of Article 5(1)
	Mutagenicity (M)	Cat 2	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	RP 3:2 and RP1:1 do not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	An assessment of the endocrine disrupting properties was conducted: - the ED criteria for the T modality are not met; - for EAS modalities no conclusion can be drawn based on the available data. However, considering the known severe hazard properties of this substance and based on scientific reasons, further data will not be requested in this special case.	No conclusion can be drawn whether RP 3:2 and RP1:1 fulfil criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1).
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	An assessment of the endocrine disrupting properties was conducted: for EAS modalities as well as for T-modality no conclusion can be drawn based on the available data. However, considering the hazard profile of this substance and the anticipated difficulties to determine the mode of action, further data will not be requested in this special case based on	

Assessment of exclusion and substitution criteria			
Property		**Conclusions**	
		scientific reasons.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. RP 3:2 and RP1:1 do not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Based on the available data it cannot be concluded if RP 3:2 and RP1:1 do fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	The substances do not contain a significant proportion of non-active isomers or impurities. RP 3:2 and RP 1:1 do not fulfil criterion (f) of Article 10(1).		

Table 10: Substances listed in the public / stakeholder consultation that were deemed unsuitable for the AoA discussion and screening results for candidates for substitution (CfS)

Active Substance	CAS	PT	Classification	Reason for exclusion
2-pyridinethiol, 1-oxide sodium salt	3811-73-2	2, 6, 13	Acute Tox. 4, H302; Acute Tox. 2, H311; Skin Irrit. 1, H315; Eye Irrit., H319: Skin Sens.1, H317; Acute Tox. 3, H331; STOT RE 1, H372; Aquatic acute 1, H400, M=100; Aquatic chronic 2, H411; **inhalation:** ATE = 0.5 mg/L (dusts or mists) **dermal:** ATE = 790 mg/kg bw (-) **oral:** ATE = 500 mg/kg bw (-)	Not approved at the time of the assessment; No reduction of overall risk
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	4719-04-4	6, 11, 12, 13	Acute Tox. 4, H302; Skin Sens. 1, H317; Skin Sens. 1; H317: C ≥ 0,1 %	Not approved at the time of the assessment; formaldehyde

Active Substance	CAS	PT	Classification	Reason for exclusion
(HHT)				releaser
Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMDA)	5395-50-6	6, 11, 12, 13	No harmonized classification	Not approved at the time of the assessment; formaldehyde releaser
Bronopol	52-51-7	2, 6, 11, 12	Acute Tox. 4, H302; Acute Tox. 4; H312; Skin Irrit. 2, H315; Eye Dam. 1, H318; STOT SE 3, H335; Aquatic Acute 1, H400, M=10;	Not approved at the time of the assessment;
BIT	2634-33-5	2, 6, 11, 12, 13	Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Dam. 1, H318; Skin Sens. 1, H317; Aquatic Acute 1, H400; Skin Sens. 1; H317: C ≥ 0,05 %	No reduction of the overall risk
DBNPA	10222-01-2	6, 11, 12	Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Dam. 1, H318; Skin Sens. 1, H317; Acute Tox. 2, H330; STOT RE 1, H372; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; M=1 M(Chronic)=1 **inhalation:** ATE = 0.24 mg/l (dusts or mists) **oral:** ATE = 118 mg/kg bw (-)	No reduction of the overall risk: Exclusion criteria fulfilled - ED HH, ED ENV
THPS	55566-30-8	6, 11, 12	No harmonized classification	Not approved at the time of the assessment; formaldehyde releaser
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (BDA)	2372-82-9	2, 6, 11, 12, 13	No harmonized classification	Not approved at the time of the assessment
2-Phenoxyethanol	122-99-6	2	Acute Tox. 4, H302; Eye Dam. 1, H318; STOT SE 3, H335; **oral:** ATE = 1394 mg/kg bw (-)	Not approved at the time of the assessment
Glutaraldehyde	111-30-8		Acute Tox. 3, H301; Skin Corr. 1B, H314; Skin Sens. 1A, H317; Acute Tox. 2, H330; STOT SE 3, H335; Resp. Sens. 1, H334; Aquatic Acute, H400; Aquatic Chronic, H410; STOT SE 3; H335: ,5 % ≤ C < 5 %	No reduction of the overall risk: Resp. Sens 1 - CfS
polyhexamethylene biguanide hydrochloride with a mean number-average	1802181-67-4	2	Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1B, H317; Acute Tox. 2, H330; Carc. 2, H351; STOT RE 1, H372, Aquatic Acute 1, H400; Aquatic Chronic 1, H410;	No reduction of the overall risk: vP, T - CfS

Active Substance	CAS	PT	Classification	Reason for exclusion
molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7 (PHMB(1415;4.7))			M=10 M(Chronic)=10	
polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8 (PHMB(1600;1.8))	27083-27-8	2, 11	Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1B, H317; Acute Tox. 2, H330; Carc. 2, H351; STOT RE 1, H372, Aquatic Acute 1, H400; Aquatic Chronic 1, H410; M=10 M(Chronic)=10	No reduction of the overall risk: vP, T - CfS
Formaldehyde	50-00-0	2	Acute Tox. 3, H301; Acute Tox. 3, H311; Skin Corr. 1B, H314; Skin Sens. 1, H317; Acute Tox. 3, H331; Muta 2, H341; Carc. 1B H350; Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0,2 %	No reduction of the overall risk: Carc. 1B – Exclusion substance
5-chloro-2-(4-chlorphenoxy)phenol (DCPP)	3380-30-1	2	Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic chronic 1, H410; M=10 M(Chronic)=10	No reduction of the overall risk: (metab: vB), T - CfS

Table 11: Comparison between toxicological properties of CMIT/MIT, MIT, MBIT, RP 3:2 and RP 1:1

Active Substance	CMIT/MIT	MIT	MBIT	RP3:2	RP 1:1
CAS Nummer	55965-84-9	2682-20-4	2527-66-4	-	-
C&L	Acute Tox. 3 H301 Acute Tox. 2 H310 Acute Tox. 2 H330	Acute Tox. 3 H301 Acute Tox. 3 H311	Acute Tox. 3 H301 Acute Tox. 4 H312 dermal: ATE = 1100 mg/kg bw oral: ATE = 175 mg/kg bw	Carc. 1B H350 Muta. 2 H341 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 4 H332 STOT RE 2 H372	Carc. 1B H350 Muta. 2 H341 Acute Tox. 4 H302 Acute Tox. 4 H332 STOT RE 2 H372

Active Substance	**CMIT/MIT**	**MIT**	**MBIT**	**RP3:2**	**RP 1:1**
CAS Nummer	55965-84-9	2682-20-4	2527-66-4	-	-
	Skin Corr. 1C H314; C ≥ 0,6% Eye Dam. 1 H318 C≥0,6% Eye Irrit. 2 H319 0,06 % ≤C< 0,6% Skin Sens. 1A H317; C≥0.0015% Aquatic Acute 1; H400 Aquatic Chronic 1 H410; M=100 EUH071	Skin Corr. 1B H314 Eye Dam. 1 H318 Skin Sens. 1A H317; C≥0,0015% Aquatic Acute 1; H400 M=10 Aquatic Chronic 1 H410; M=1	Skin Corr. 1C H314 Eye Dam. 1 H318 Skin Sens. 1A H317; C≥0,0015% Aquatic Acute 1 H400 Aquatic Chronic 2 H411; M=1 EUH071 GHS09; Hs05; GHS06; Dgr	Skin Corr. 1B H314 Eye Dam. 1 H318 Skin Sens. 1A H317 Aquatic Chronic 2 H411 EUH071	Skin Corr. 1C H314 Eye Dam. 1 H318 Skin Sens. 1A H317 Aquatic Chronic 2 H411 EUH071
Acceptable Exposure Level (mg/kg bw/d)					
AEL acute	0.11	0.053	0.42	0.33	0.54
AEL mid term	0.11	0.053	0.42	0.33	0.54
AEL long-term	0.09	0.027	0.21	0.33	0.54
Accptable Exposure Concentration (mg/m^3)					
AEC acute	0.04	0.043	-	0.25	0.43
AEC mid term	0.04	0.043	0.024	0.25	0.43
AEC long term	0.02	0.021	0.011	0.25	0.43
ARfD (acute reference dose, mg/kg bw/d)	0.02	0.1	0.56	n.a.	n.a.
ADI (acceptable daily intake, mg/kg bw/d)	0.004	0.05	0.14	n.a.	n.a.