PUBLIC VERSION

ANALYSIS OF ALTERNATIVES

to biocidal active substances meeting the substitution criteria under the Biocidal Products Regulation

Legal name of submitter:	Vink Chemicals GmbH & Co. KG
Date:	26.05.2023
Substance candidate for substitution:	Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (short: RP 1:1) (HPT)

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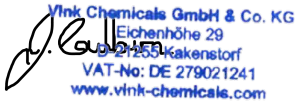
LIST OF ABBREVIATIONS

[Please insert here manually the list of abbreviations]

DECLARATION

The applicant is aware of the fact that evidence might be requested by ECHA or the relevant Member State Competent Authority to support information provided in this document.

Also, we request that the information redacted in the public version of the analysis of alternatives is not disclosed. We hereby declare that, to the best of our knowledge as of today ([DATE]) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature: 

Date, Place:

25/05/23 Kakenstorf

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Senior Regulatory Affairs Manager

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1. SUMMARY

“RP 1:1” is a CfS due to the carcinogenicity of the releasing formaldehyde. In brief its intended uses include system cleaning of metal working systems (PT2), in-can preservation of diesel fuels (PT6), preservation in closed cooling water systems (PT11), and preservation of metal working or cutting fluids (PT13). Active substances, which are approved for use in biocidal products of these product types and are not listed as CfS, were considered as potential alternatives. These active substances with formally equal intended uses were investigated more closely for the equivalence of their applicability with respect to the intended uses of “RP 1:1” and for their hazard profile. Relevant data was searched in publicly available tools and databases. Databases featuring relevant information regarding intended uses of biocidal products and active substances therein included the ECHA biocides database, German Blue Angel products database, the ChemSec Marketplace and the CORDIS database. For PT6, PT11, and PT13 potential alternative active substances with intended uses resembling those of “RP 1:1” were identified among the approved biocidal active substances listed by ECHA for the respective PTs (and not labelled as CfS). However, detailed analyses of the physical chemical properties and hazard profiles of these alternatives showed that none of them is suitable as true alternative.

2. SCOPE OF THE ASSESSMENT AND OVERVIEW OF THE APPROACH

"RP 1:1" is a candidate for substitution (CfS) due to the carcinogenicity of the releasing formaldehyde (category 1B). In brief its intended uses include system cleaning of metal working systems (PT2), in-can preservation of diesel fuels (PT6), preservation in closed cooling water systems (PT11), and preservation of metal working or cutting fluids (PT13). Active substances, which are approved for use in biocidal products of these product types and are not listed as CfS were considered as potential alternatives and screened for equivalence of their intended use. Active substances with equal intended uses were investigated more closely for the equivalence of their applicability with respect to the intended uses of "RP 1:1" and for their hazard profile.

A list of customers has been provided who have been contact by Vink Chemicals and asked to submit relevant information to this public consultation, either direct to ECHA's, or through a statement submitted by with this form on their behalf.

Further information will be submitted to show the research and development conducted by Vink Chemicals in the search for alternatives and technologies to improve efficacy.

3. ANALYSIS OF THE SUBSTANCE FUNCTION(S), TYPES OF USES, TECHNICAL REQUIREMENTS AND MARKETS FOR THE PRODUCTS

3.1. CfS active substance identification and properties

Chemical Substance

Substance identity	
ISO name	Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) notified under the name α,α′,α″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (shortly named HPT)
IUPAC or EC name	Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio 1:1)
EC number	n.a.
CAS number	n.a.
Molecular formula	n.a.
Structural formula	n.a.
Molecular mass	261 g/mol

Physico-chemical properties	
Appearance	"RP 1:1": Liquid; colourless to yellow HPA: 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 1:1" (Lubrizol): <-30°C; no endothermic signals recognizable between -30°C and +30°C "RP 1:1" (Schülke&Mayr): -36°C to -38°C

Physico-chemical properties	
	HPA: 1.7°C Formaldehyde: -118°C to -92°C (formaldehyde gas) -15 °C (formalin (37%))
Boiling point	"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	195 °C
Vapour pressure	"RP 1:1": Not relevant. The exposure assessment is based on formaldehyde. 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 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 (Calculated) Formaldehyde: 0.034 Pa*m³/mol at 25☐C (methanol-free formaldehyde, prepared from 37% formalin)
Relative density	"RP 1:1" (Lubrizol): D204=1.0867±0.29 g/cm3 "RP 1:1" (Schülke&Mayr): D204=1.11 g/cm3 HPA: 0.9611 g/cm3 at 20°C Formaldehyde: 0.815 at - 20☐C (formaldehyde gas) 1.1346 g/cm3 at 25☐C (aqueous solution: 50% formaldehyde, 7% methanol)
Solubility in water	"RP 1:1" (Lubrizol): Miscible with buffer solution at pH 5; 7.and 9 (20°C) "RP 1:1" (Schüle&Mayr): is miscible with water. HPA:37g/L at 11°C Formaldehyde: pH 5 at ___ ºC: not determined

Physico-chemical properties	
	pH 9 at ___ ºC: not determined up to 55% (formaldehyde gas)
Partition coefficient (n-octanol/water)	"RP 1:1" -0.4767 ± 0.06 (based on formaldehyde) -0.6108 ± 0.04 (based on 2-hydroxypropylamine)

Hazard properties	
Harmonised classification according to CLP	Acute Tox. 4, H302 Acute Tox. 4, H332 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 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%.	
PBT/vPvB or ED properties	RP 1:1 does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1). No conclusion can be drawn whether RP 1:1 fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1).
Hazard properties having led the active substance to be considered as a candidate for substitution under Article 10 of the BPR	Since the eCA concluded that "RP 1:1" does meet the conditions laid down in Article 10(1)(a) of Regulation (EU) No 528/2012, and should therefore be considered as a candidate for substitution by meeting the exclusion criteria a public consultation in accordance with Article 10(3) of BPR has been launched by ECHA

3.2. Description of the function provided by the CfS active substance

The active substance is a formaldehyde-releasing substance with bactericidal and fungicidal properties.

The effectiveness of the active substance in biocidal products against the intended target organisms (obligate or facultative pathogenic bacteria and fungi which might contaminate and spoil materials or subjects) has been demonstrated in basic experimental studies. These studies demonstrate that this formaldehyde-releaser is effective in inhibiting and irreversibly inactivating Gram negative (including *Legionella sp.*) and Gram-positive bacteria (including *Mycobacteria sp.*) as well as fungi and yeasts which are representative for the organisms in the intended field of use.

Since the representative product for PT2 is a 10% aqueous solution of the active substance and the representative products for PT6, 11 and 13 are the active substance as manufactured.

The active substance is a formaldehyde-releaser. The biocidal activity of the active substance is due to the interaction of the released formaldehyde with protein, DNA and RNA. The interaction

with protein results from a combination with the primary amide and the amino groups. It reacts with carboxyl, sulfhydryl and hydroxyl groups.

As formaldehyde is not specific for one cellular target, the development of resistance is unlikely, if sufficiently high formaldehyde concentrations are guaranteed that exceed the capacity of the innate detoxification systems. For this reason, sublethal and accordingly subinhibitory formaldehyde concentrations – which may originate through dilution effects particularly in consumer products – must be avoided.

Due to the low number of active substances effective under these PT uses which have a broad balanced spectrum of effect (incl. sulphate-reducing bacteria), anticorrosion properties it provides industries with the valuable choice needed when using biocidal products.

Although other substances may provide similar effects eliminating this biocide from the already small number of effective products would reduce the choice efficacious substances to a risky level as resistance to biocides is always a potential.

ECHA has previously held a public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012 which took place from 4 November 2016 to 3 January 2017. Three general observations are made in the industry contributions:

- First, it is stated that other formaldehyde releasers are not considered as alternatives as it can be foreseen that these will also be classified as carcinogen category 1B and subsequently meet the exclusion criteria. Several other formaldehyde releasers are under evaluation.

- Second, it is stated that for an effective preservation of many water-based products a bactericide and fungicide is needed. Subsequently, fungicide active substances cannot be regarded as suitable alternatives.

- Last, it is stated that another class of bactericides are the isothiazolinones. Although these do not meet the substitution criteria it should be considered that these are all classified as strong skin sensitisers. This triggers several obligations for the user making this class of active substances not suitable alternatives.

For PT2 with respect to the use as a system cleaner for metal working fluid systems it is stated in one of the industry contributions that the pH of the system cleaner is 9.5 to 12 to guarantee corrosion protection against steel. This limits the availability of alternatives. The only alternative indicated is glutaraldehyde which is however also a CfS as it is a respiratory sensitiser.

Several other active substances are already approved for PT2. However, for none of these active substances the intended use was like “RP 1:1”.

For PT6 the only alternative mentioned in the industry contributions is CMIT/MIT. However, this active substance belongs to the class of isothiazolinones. In addition, it is stated that CMIT/MIT is not soluble in fuel and contains halogen which is not allowed according to German Clean Air Act.

For PT11 in the industry contributions glutaraldehyde, THPS and acrolein are indicated as possible alternatives in oilfield applications. Glutaraldehyde is also a CfS. THPS is also a formaldehyde releaser, has a more severe classification for acute aquatic toxicity compared to “RP 1:1” and its stability prevents its application for the same use as “RP 1:1”. Acrolein also has a more severe aquatic toxicity compared to “RP 1:1”.

The following active substances are already approved for PT11: CMIT/MIT, glutaraldehyde, peracetic acid and PHMB (1600; 1.8). CMIT/MIT belongs to the class of isothiazolinones, while PHMB (1600; 1.8) is also a CfS meeting two out of the three PBT criteria. Glutaraldehyde is also a CfS as it is a respiratory sensitiser.

For PT13 in the industry contributions CMIT/MIT, MIT, BIT, diamine, phenoxyethanol, MBIT and DBNPA are indicated as possible alternatives. It is concluded that isothiazolinones (CMIT/MIT, MIT, BIT and MBIT) would be the only practical alternatives, however these are classified as skin sensitizers. MIT has also limitations because of its lower stability. BIT has a gap of efficiency against *Pseudomonas* species. Diamine is an alternative to "RP 1:1" in PT13 niche applications only; phenoxyethanol has a limited use in metalworking fluids due to its low partition coefficient; and DBNPA has technical limitations (fast decomposition at pH>7 and in presence of nucleophilic compounds).

The following active substances are already approved for PT13: biphenyl-2-ol, C(M)IT/MIT, chlorocresol, IPBC, and MIT. CMIT/MIT and MIT belong to the class of isothiazolinones. Biphenyl-2-ol and IPBC are fungicides. For chlorocresol it is stated in the BPC opinion that sufficient efficacy has been demonstrated for the representative product against bacteria and fungi.

As in 2017, there is still limited information available is insufficient to conclude on the availability of suitable alternatives for the intended uses assessed.

3.3. Intended uses and products

Overview:

Biocidal products which contain the active substance are employed as microbicides for the disinfection (disinfectant system cleaner) of surfaces, materials and equipment in the metal working area (PT2: Disinfectants and algaecides not intended for direct application to humans or animals) as well as for the preservation of liquid cooling systems (PT11: Preservatives for liquid-cooling and processing systems), fuels (PT6: In-can preservatives) and metal working fluids (PT13: Working or cutting fluid preservatives).

Markets and supply chains:

The market sectors for these biocidal products and treated articles/end-products:

Industrial workers, Professionals

o countries/regions where the biocidal products, treated articles/end-products are commercialised: Europe, South America, Asia Pacific, China.

o end users are [redacted] blank #1

Application methods and rates, risk mitigation measures for each intended use:

PT2: The biocidal product is applied to system cleaners

PT6: The preservative is added during the formulation of fuels.

PT11: a.s. is mixed into the process solutions by the user

PT13: Direct application to the metal working fluid or application to a metal working fluid concentrate

For use of the active substance in **PT2** products (disinfectant system cleaners) test reports according to EN 1040 and EN 1275 were submitted to determine the basic microbicidal effect of "RP 1:1". In these quantitative suspension tests the biocidal product tested exhibited sufficient bactericidal (*S. aureus, P. aeruginosa*; RF>5) and fungicidal (*C. albicans, A. niger*; RF>4) activity at a concentration of 1% at 6 h and 0.25% at 24 h exposure (bactericidal) and 0.5% at 3 h and

0.25% at 6 h exposure (fungicidal). The requirements of both norms, to show the activity within 1 h, were not fulfilled with all of the tested strains.

Overall, a microbicidal effect of the biocidal product was demonstrated with concentrations ranging from 0.25% (=2500 ppm) up to 3% (30000 ppm) depending on the exposure time. The microbistatic effects were demonstrated by different growth inhibition test. The overall MIC is 0.05% (v/v) (Gram negative bacteria), 0.2% (v/v) (fungi).

For use of the active substance in **PT11** growth inhibition for some bacteria and fungi was determined in accordance to DGHM-standard methods. The biocidal product tested completely inhibited growth of the 8 strains tested at a concentration of 0.05% within 3 days *(Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Pseudomonas putida, Pseudomonas fluorescens* and *Klebsiella oxytoca*), 7 days (L*egionella longbeachea*) and 14 days (Mycobacterium avium) exposure. The overall MIC and or growth inhibition concentration is 0.05% (v/v) (only for bacteria and only valid for closed cooling water systems) and 0.2% (v/v) if growth of fungi should be prohibited also.

For use of the active substance in **PT13** tests in metal working fluids showed that “RP 1:1” completely inhibited growth of the tested bacterial (including *Mycobacterium sp.*), yeasts and fungal strains at >=0.15 % w/w.

“RP 1:1” containing biocidal products are used as bactericides for the preservation of fuels (**PT6**) which are prone to bacterial decay. The product is intended to be incorporated by industrial users into fuels during the formulation process, which is carried out automatically, to act as a preservative with bactericidal activity. Formulation is performed in closed systems with a high degree of automation resulting in a final concentration of the active substance of 0.005%. The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against gram negative bacteria such as Pseudomonas aeruginosa, Enterobacter aerogenes and Acinetobacter spec. at the concentrations mentioned.

Risk mitigation measures:

The use of a biocidal product containing “RP 1:1” shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment is minimised as far as possible.

PT2: Health, technical and organisational RMM and PPE (like gloves, coveralls, masks) for high local hazard category (loading) and RMM and PPE for medium local hazard category for other tasks. Environment: The cleaner is not discharged but diluted in the metalworking fluid (MWF) and will then be used as preservative. Therefore, possible releases into the environment during use of system cleaners are covered by the emission scenario for metalworking fluids (PT13).

Waste treatment is done by end-users who treat their waste on-site and apply commonly used emulsion splitting techniques based on the partition coefficient K_{ow} (e.g. chemical splitting, ultrafiltration). All waste waters resulting from the use of water miscible MWF will be led to biological treatment before discharge into the environment.

PT6: automatic dosing system, technical and organisational RMM and PPE (like gloves, coveralls, masks) for high local hazard category (loading, mixing) and RMM for standard industrial workplace for other tasks. Exposure to fuels acceptable with vapour recovering which is standard at filling stations.

PT11: automatic dosing system, technical and organisational RMM and PPE (like gloves, coveralls, masks) for high local hazard category (loading, dosing) and RMM for standard industrial workplace for other tasks.

PT12: local exhaust ventilation (LEV), automatic dosing system and organisational RMM and PPE (like gloves, coveralls) including RPE for high local hazard category (dosing, mixing) and standard RMM including PPE (gloves, coveralls, and mask) for offshore workplace for other tasks.

Spend drilling muds are not discharged overboard and the drilling mud is treated on land, re-injection, on-site dewatering or treatment in an off-site wastewater treatment facility.

PT13: local exhaust ventilation (LEV), automatic dosing system, technical and organisational RMM and PPE (like gloves, coveralls) for high local hazard category (dosing, mixing) and LEV and RMM for standard industrial workplace for other tasks.

Combinations with other active substances

The active substance is not intended to be used in combination with other active substances.

In addition to the information above, for a given product type (PT), the core identification elements of an intended use can be summarised in a table such as below:

1	Product Type	PT2 Private area and public health area disinfectant and other biocidal products
2	Where relevant, an exact description of the authorised use	Generally, the biocidal product (a.s. as manufactured) and other substances can be added by downstream users to base oils to get concentrates, which can be used to prepare a metal working fluid. The biocidal product containing “RP 1:1” is applied as preservative for water-based metal working fluids. In addition, the biocidal product can be used within formulations as system cleaner of metal working systems. This application can be assigned to product type 2 as it is the disinfection 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. The system cleaner will be added to the used metalworking fluid 6h -24h before the exchange of the complete liquid. In order to achieve sufficient cleaning and sanitizing efficiency a contact time of at least 6-24 hours is typically recommended for such systems cleaners. After the residence time, the used metal working fluid containing system cleaner will be dumped and the system will be rinsed with additional water. By this treatment it is guaranteed that even the dead spaces of the tank and tubing system of the machines are cleaned and sanitized and the risk of an immediate microbial recontamination by remaining biofilms after refilling with fresh metalworking fluid is eliminated.
3	Target organism(s) (including development stage)	Gram-negative bacteria such as *P. putida, E. coli, P. aeruginosa* Gram-positive bacteria such as *Staphylococcus aureus* yeasts such as *Candida albicans*

		fungi such as *Fusarium oxysporum*.
4	Field of use	Disinfectant system cleaner for metal working: disinfection of inner surfaces of vessels and tubes
5	Category(ies) of users	Professional and industrial users
6	Application method(s)	The biocidal product is applied to system cleaners

1	Product Type	PT6 In-can preservative
2	Where relevant, an exact description of the authorised use	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. The evaluated use of the preserved fuel is use by professional and non-professionals/general public during the refuel of engines.
3	Target organism(s) (including development stage)	Gram-negative bacteria such as *Pseudomonas aeruginosa, Enterobacter aerogenes* and *Acinetobacter spec.*
4	Field of use	The preservative is added automatically during the formulation of Diesels fuels.
5	Category(ies) of users	Professional
6	Application method(s)	The preservative is added during the formulation of fuels.

1	Product Type	PT11 Preservatives for liquid-cooling and processing systems
2	Where relevant, an exact description of the authorised use	Generally, the biocidal product (a.s. 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 applicants. 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” are used only in closed systems. They are not intended to be applied in once-through cooling systems or large open recirculating cooling systems. Therefore, in the following the closed recirculating cooling system will be considered for release estimation as representative application in product type 11.

		In closed recirculating cooling water systems cooling water recirculates in a closed loop. The cooling water is not discharged after cooling. These systems have minimal loss of water, since there is no direct contact with the atmosphere. Process heat is transferred to the cooling water in one heat exchanger, and in a second heat exchanger the cooling water is cooled off by air or water. The cooled water is then returned to the heat exchanger that cools the process.
3	Target organism(s) (including development stage)	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*
4	Field of use	Used as preservative only for closed recirculating cooling water systems
5	Category(ies) of users	Professional and industrial users
6	Application method(s)	a.s. is mixed into the process solutions by the user

1	Product Type	PT13 Working or cutting fluid preservatives
2	Where relevant, an exact description of the authorised use	Generally, the biocidal product (a.s. as manufactured) and other substances can be added by downstream users to base oils to get concentrates, which can be used to prepare a metal working fluid. However, the applicants are only the manufacturers of the biocidal products, not of the concentrates for metal working fluids. As this formulation step is done by downstream industry, the applicants have only limited information. Nevertheless, some general assumption can be made which might fulfil the requirements for exposure information. Biocidal products containing “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 application can 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.

		In the present document for active substance evaluation, the estimation of the exposure and emissions is restricted to the exemplary use as preservative in emulsifiable metal working fluids.
3	Target organism(s) (including development stage)	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)* fungi such as *Fusarium, oxysporum Aspergillus niger*
4	Field of use	1. Use in lubricant concentrate 2. Ready to Use concentration in water based emulsifiable metalworking fluids
5	Category(ies) of users	Professional and industrial users
6	Application method(s)	Direct application to the metal working fluid or application to a metal working fluid concentrate

3.4. Description of the technical requirements that must be achieved by the product(s)

- Broad, balanced spectrum of effect (incl. sulphate-reducing bacteria)
- Good immediate effect
- Good anticorrosion properties
- Fully soluble in water and in most polar organic solvents.
- Contains no nitrate, nitrosing agents or organically bound chlorine (has no effect on the AOX value)
- pH-Range: 8 - 12
- Temperature: < 80°C

4. ANNUAL TONNAGE

10-100 tonnes per year

We've observed [redacted] blank #2 [redacted].

5. IDENTIFICATION OF POTENTIAL ALTERNATIVES

(See Guidance section 3.3)

5.1. Description of efforts made to identify possible alternatives

5.1.1. Stakeholders' involvement

Refer to submitted confidential document named: "Stakeholder Involvement Section 5.1.1"

Downstream users / focus groups were contacted (refer to attached confidential document) regarding the public consultant for alternatives of MBO ("RP 3:2") and HPT ("RP 1:1") asked to provide information direct to ECHA through consultation link, or statement to be included with our own submission.

Reasons for the request were given, and they were directed to ECHA information on the consultation process and submission portal.

The option was provided that Vink could submit their statement on their behalf.

No responses were provided information to Vink on suitable alternatives.

Due to the short period of this public consultation further surveys were not possible.

5.1.2. Research and development

Refer to confidential statement submitted **"Vink Chemicals Topic Alternatives.pdf"**

5.1.3. Data searches

SOURCE OF INFORMATION ON BIOCIDES AND THEIR ALTERNATIVES: DATABASES AND RESOURCES CONSIDERED

- The list of active substances included into the Union list or Annex I, or under examination (under the review programme set up in Article 89 of the BPR or outside the review programme applied for a new active substance) for the same product type, and similar uses (pattern of use, target organism, etc.) – see ECHA biocides database;
    - See excel table: "HPT_CfS_Alernatives_Screening_Vink.xlsx"
- Any information available to Member States Competent Authorities, including on biocidal products still placed on the market under the transitional period set up under Article 89 of the BPR (only available to Member States Competent Authorities);
    - Information from eCAs (not for ITEM)
- Outcome of consultations of interested third parties in accordance with Article 10(3) of the BPR (if available);
- German Blue Angel products database: gathering more than 20 000 products and services labelled as environmentally friendly
    - No information on alternatives was found in the German Blue Angel products database regarding relevant biocidal product types and intended uses. [The database focuses on non-industrial uses and finished products to which biocidal products may have been applied. Search terms included 'fuel', 'system cleaner', 'cooling water', 'slimicide', 'metal working', 'cutting', 'preserv')

- ECHA's substitution pages: contains links to several databases, tools and methodologies relevant for the different steps of an analysis of alternatives and substitution projects
    - The PRIO Inventory tool lists hazardous or priority risk substances, with the goal of facilitating phasing them out. Therefore it was not considered a priority source of information on alternatives.
    - OECD eChemPortal provides information on the properties of chemicals, but does not allow searching chemicals by uses, so it was considered inappropriate to help identify alternatives
    - RISCTOX, a database on risks and hazards of substances, provides information on the properties of chemicals, but does not allow searching chemicals by uses, so it was considered inappropriate to help identify alternatives
    - Further sources are listed but were not considered so far as they are designed similarly as eChemPortal
- SCOTTY platform: information on biocides and their alternatives
    - No information regarding specific potential alternatives or relevant biocidal product types and intended uses was found at the SCOTTY platform.
- SUBSPORTplus: substitution portal with lists of assessed alternatives, tools and guidance for substance evaluation and substitution management
    - The Portal offers information supporting efforts in substituting hazardous substances and assists in searching safer alternatives but does not feature access to any database of such alternatives.
- ChemSec Marketplace: online platform with alternatives to substances of concern, enabling buyers and sellers of alternatives to hazardous chemicals to interact
    - Searching biocides resulted in **one hit**: NatSurFact All Natural BioSurfactant, which is a **surfactant**, id est not relevant.
- CORDIS database of projects under the EU Research and Innovation funding programmes: information on all EU-supported R&D activities, including programmes (H2020, Horizon Europe, FP7 and older), projects, results, and publications
    - Search terms included 'alternative,' 'candidate' 'of' 'substitution,' 'biocide'. **14 results** were obtained, but **none aligned with the intended** use of the active substance of interest.
- OECD substitution toolbox: a compilation of resources relevant to chemical substitution and alternatives assessments
    - https://www.oecd.org/chemicalsafety/risk-management/substitution-alternatives-assessment-tools-data-sources.htm
    - Several substitution and alternatives assessment tools and data sources (incl. IFA column model, green chemistry assistant, …) potentially applicable, based on availability of detailed data regarding intended uses and alternatives

5.2. Identification of alternatives

5.2.1. Screened alternatives and selection for further assessment

Table 1: Initial list of chemical and non-chemical alternatives and outcome of the selection for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number	Description of the alternative	Reason for selection/rejection for further assessment
PT2		N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (BDA)	2372-82-9		Not suitable alternative: Still under review for approval and as a CfS, but a known alternative in the industry. Bad environmental profile, H410 - Very toxic to aquatic life with long lasting effects. 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 9degreeC - difficult to manage at harsh weather conditions.
PT6 / PT11 / PT13		Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)	55965-84-9		CMIT/MIT is not suitable alternative: it is not soluble in fuel and contains halogens. Skin sensitising / classified Danger! According to the harmonised classification and labelling (ATP13)

					Reacts with amine and sulphur containing proteins. Contains water, so must be blended with methanol or glycol to avoid freezing. Does not avoid corrosion in use.
PT11 / PT13		2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4		Not suitable alterative: not stable at pH > 9, complete decomposition in the presence of amines and alkanol-amines. High use level in MWF, >10 times above H317 labelling Classified: Skin sensitising / Danger! According to the harmonised classification and labelling (ATP13)
PT13		Chlorocresol	59-50-7		Not suitable alternative: Skin sensitising, primarily fungicidal action only.
PT13		Biphenyl-2-ol	90-43-7		Not suitable alternative: primarily fungicidal action only, efficacy not shown at active approval, no product approved yet / Classified: Danger! According

					to the harmonised classification and labelling.

Table 2: Shortlisted chemical and non-chemical alternatives for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of alternative
See table above				

[Add any figure, if relevant]

Figure 1

6. SUITABILITY AND AVAILABILITY OF POTENTIAL ALTERNATIVES

Due to the short period of time allowed to do the assessment, only minimal information can be supplied.

Only once all actives are approved should a comparison, under similar uses, be taken as those still under the review process will have the advantage of being the last active available if all other candidates are removed.

For PT2 use as a disinfectant of metal working systems, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS no.: 2372-82-9) is a commonly used alternative, although this active substance is not yet approved. No known PT2 actives have been approved with similar use in metal working industries, this makes comparison difficult.

For PT 6, 11, and 13 uses the most common alternative used is Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT, ratio 3:1).

Please refer to the attached table for further information.

6.1. INTENTED USE 1

6.1.1. Chemical alternatives

6.1.1.1 Alternative substance 1

6.1.1.1.1 Substance ID and properties (or Description of alternative technique)

Please refer to the table below.

6.1.1.1.2 Reduction of overall risk

Please refer to the table below.

6.1.1.1.3 Technical feasibility

Please refer to the table below.

6.1.1.1.4 Economic feasibility

Please refer to the table below.

6.1.1.1.5 Availability

Widely available

6.1.1.1.6 Other relevant information

6.1.1.1.7 Conclusion on the suitability and availability of alternatives

	PT2	**PT6**	**PT11**	**PT13**
Description	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 *Pseudomonas putida*, *Escherichia coli, Pseudomonas aeruginosa*; gram-positive bacteria such as *Staphylococcus aureus*; yeasts such as *Candida albicans*; and mould such as *Fusarium oxysporum*;	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 spec.*	as preservative (bactericide) 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.*	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	Chlorocresol, (CAS# 59-50-7) Biphenyl-2-ol, (CAS#90-43-7) CMIT/MIT, MIT
Health & Safety issue of alternates	Bad environmental profile, H410 - Very toxic to aquatic life with long lasting effects.	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 over risk to human health, animal health and the environment.	**MIT:** 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 over risk to human health, animal health and the environment.	**MIT:** 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 over 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 9degreeC - 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 MBO/HPT). Not Soluble in oil (MBO/HPT are soluble is oil). Not effective against anaerobic bacteria, particularty SRB's. In presence of H2S CMIT/MIT & MIT degrades.	**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 MBO/HPT). Not effective 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.	**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 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 MBO/HPT). Not Soluble in oil (MBO/HPT 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	Not known	CMIT/MIT is not seen as an alternative for many PT uses,	Not known	Not known

with alternatives		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 be disproportionally high.		

6.1.2. Non-chemical alternatives

None reported.

6.1.3. Overall comparison of alternatives for intended use 1 (summary table)

6.2. INTENTED USE 2

Please refer to the table above

7. EFFORTS TAKEN BY THE APPLICANT TO DEVELOP NEW ALTERNATIVES

Please refer to confidential document **"Vink Chemicals RD topic Alternatives.pdf"**

8. OVERALL CONCLUSION

ECHA has previously held a public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012 which took place from 4 November 2016 to 3 January 2017. Three general observations are made in the industry contributions:

- First, it is stated that other formaldehyde releasers are not considered as alternatives as it can be foreseen that these will also be classified as carcinogen category 1B and subsequently meet the exclusion criteria.

- Second, it is stated that for an effective preservation of many water-based products a bactericide and fungicide is needed. Subsequently, fungicide active substances cannot be regarded as suitable alternatives.

- Last, it is stated that another class of bactericides are the isothiazolinones. Although these do not meet the substitution criteria it should be considered that these are all classified as strong skin sensitisers. This triggers several obligations for the user making this class of active substances not suitable alternatives.

For PT2 with respect to the use as a system cleaner for metal working fluid systems it is stated in one of the industry contributions that the pH of the system cleaner is 9.5 to 12 to guarantee corrosion protection against steel. This limits the availability of alternatives. The only alternative indicated is glutaraldehyde which is however also a candidate for substitution as it is a respiratory sensitiser.

Several other active substances are already approved for PT2. However, for none of these active substances the intended use was like "RP 1:1".

For PT6 the only alternative mentioned in the industry contributions is CMIT/MIT. However, this active substance belongs to the class of isothiazolinones. In addition, it is stated that CMIT/MIT is not soluble in fuel and contains halogen which is not allowed according to German Clean Air Act.

For PT11 in the industry contributions glutaraldehyde, and THPS are indicated as possible alternatives in oilfield applications. Glutaraldehyde is also candidate for substitution. THPS is also a formaldehyde releaser, has a more severe classification for acute aquatic toxicity compared to RP 1:1 and its stability prevents its application for the same use as "RP 1:1".

The following active substances are already approved for PT11: CMIT/MIT, glutaraldehyde, peracetic acid and PHMB (1600; 1.8). CMIT/MIT belongs to the class of isothiazolinones, while PHMB (1600; 1.8) is also a candidate for substitution meeting two out of the three PBT criteria. Glutaraldehyde is also a candidate for substitution as it is a respiratory sensitiser.

For PT13 in the industry contributions CMIT/MIT, MIT, BIT, and diamine are indicated as possible alternatives. It is concluded that isothiazolinones (CMIT/MIT, MIT, BIT) would be the only practical alternatives, however these are classified as skin sensitizers. MIT has also limitations because of its lower stability. BIT has a gap of efficiency against pseudomonas species. Diamine is an alternative to "RP 1:1" in PT13 niche applications only.

The following active substances are already approved for PT13: biphenyl-2-ol, CMIT/MIT, chlorocresol, IPBC, and MIT. CMIT/MIT and MIT belong to the class of isothiazolinones. Biphenyl-2-ol and IPBC are fungicides. For chlorocresol it is stated in the BPC opinion that sufficient efficacy has been demonstrated for the representative product against bacteria and fungi.

As in 2017, there is still limited information available is insufficient to conclude on the availability of suitable alternatives for the intended uses assessed.

9. REFERENCES

[Provide list of references]

ANNEX I – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[1]

[Include justifications for each item that you have claimed as confidential in the "public version" of the AoA. Give a clear numbered reference to each piece of information claimed confidential. Redacted items should be limited to a minimum and cover only that information for which disclosure presents a direct threat to commercial interests. The size of redacted text/figure should correspond to the actual size of the text/figure which has been redacted (e.g., if an entire page has been redacted, it should be visible in the "public version" that an entire page has been blanked out). Use the table below to report the blanked-out references, corresponding page number and justification.].

Redacted item reference	Page number	Justification for confidentiality
Blank # 2: Section 4	15	Specific annual tonnage is confidential business information
Blank # 1	10	Specific end users / customers are confidential business information
…	…	…

ANNEX II – STAKEHOLDERS' INVOLVEMENT

Refer to confidential document entitled "Stakeholder_Involvement_Section5_1_1" submitted separately.

ADDITIONAL ANNEXES

Refer to documents submitted separately:

Position paper from the Union of the European Lubricants Industry ("UEIL Position – Biocides for Metalworking fluids – February 2023. pdf")

[1] This annex will not be made publicly available on ECHA's website as part of the BPR Art.10(3) third party consultation.

Position paper from the European Council of the Paint, Printing Ink, and Artist's Colours Industry (CEPE); "CEPE_Position-paper-on-preservatives-2.pdf"

"Vink Chemicals RD Topic Alternatives.pdf"

"Stakeholder_Involvement_Section5_1_1.pdf"

"HPT_CfS_Alternative Screenings_Vink.xlsx"

Stakeholder statements:

"FABI_pc_mbo_hpt_2017_comment.pdf"

"Schulke_MBO_HPT_Alternatives_Submission_2017"