Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)

Product type: 12

ECHA/BPC/337/2022

Adopted

08 June 2022

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) for product type 12

In accordance with Article 89(1) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 12 of the following active substance:

Common name:	**Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)**
	RP 3:2
Chemical name:	**Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)**
EC No.:	**not applicable**
CAS No.:	**not applicable**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by Task Force Lubrizol Deutschland GmbH and Schülke & Mayr GmbH. on 31 October 2008, the evaluating Competent Authority Austria submitted an assessment report and the conclusions of its evaluation to the European Chemicals Agency on 29 September 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-21) and its Working Groups (WG-II-2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://echa.europa.eu/de/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations/-/substance-rev/15204/term on 4 November 2016, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 3 January 2017.

In May 2018 a request from DG SANTE according to Article 75(1)(g) of Regulation (EU) No 528/2012 to the BPC regarding an ED-assessment according to the scientific criteria set out in Commission Delegated Regulation (EU) 2017/2100 was forwarded by ECHA to the eCA. Therefore, the evaluation of “RP 3:2” was amended accordingly with an ED-assessment based on the available data. The revised evaluation report including the ED assessment was submitted on 15 September 2021 in ECHA Process flow 43 (WG-I-2022 and BPC-43) for review and discussion.

Adoption of the BPC opinion

Rapporteur: Austria

The BPC opinion on the approval of the active substance reaction products of paraformaldehyde and 2-hydroxy-propylamine (ratio 3:2) in product type 12 was adopted on 8 June 2022.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

Since RP 3:2 fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012, the overall conclusion of the BPC is that RP 3:2 in product type **12** should normally not be approved, unless one of the conditions for derogation in Article 5(2) is met. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC[1]. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), furthermore addressed as RP 3:2 in product type 12. RP 3:2 was originally notified as 3,3'-methylene-bis(5-methyl¬oxazolidine) – MBO[2]. RP 3:2 is a formaldehyde-releaser. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use and materials suitable for storage and transport of the active substance and biocidal product. Regarding the explosive properties the justification for non-submission of data has not been accepted. An experimental test has to be conducted as the substance contains of unknown constituents and therefore the waiving cannot be justified by structural considerations.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. With regard to the methods submitted for determination of the hydrolysis product 2-hydroxypropylamin in water and soil the data has been considered as not sufficient. The classification and labelling for RP 3:2 according to Regulation (EC) No 1272/2008 (CLP Regulation) as agreed by RAC (December 2015)[3] and published in Regulation (EC) No 2017/776 (10th adaption to technical progress):

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H302 Acute Tox. 3, H311 Acute Tox. 4, H332 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Eye dam. 1, H318

[1] See document: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2) (CA-Nov14-Doc.4.5-Final).
[2] The renaming of 3,3'-methylene-bis(5-methyl¬oxazolidine) – MBO into Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) is not regarded as a redefinition according to Article 11 of Regulation (EU) No 1062/2014.
[3] https://echa.europa.eu/documents/10162/96051139-f376-4da3-b25a-130668d6db45

	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%.
Labelling	
Pictograms	GHS 05, GHS 06, GHS 08, GHS 09
Signal Word	Danger
Hazard Statement Codes	H302: Harmful if swallowed H311: Toxic in contact with skin H332: Harmful if inhaled H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H373 May cause damage to organs (gastrointestinal tract and respiratory tract) H341: Suspected of causing genetic defects H350: May cause cancer H411: Toxic to aquatic life with long-lasting effects
Suppl. Hazard Statement Code	EUH071: Corrosive to the respiratory tract
Specific Concentration limits, M-Factors	M = not applicable

b) Intended use, target species and effectiveness

Biocidal products containing “Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio of 3:2)” can be used directly for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds.

The biocidal product tested inhibited growth of organisms’ representative for bacteria in oil-drilling muds such as sessile general heterotrophic bacteria (GHB), acid-producing general heterotrophic bacteria (APB) and sulphate reducing bacteria (SRB). RP 3:2 showed efficacy at 800 ppm against sessile bacteria in laboratory testing. Experience of the oil field industry indicated that a concentration of 1500 ppm RP 3:2 would be necessary to preserve the drilling mud under practical conditions.

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.

c) Overall conclusion of the evaluation including need for risk management measures

A common core dossier was developed for formaldehyde, which was agreed at a Biocides Technical Meeting. This core dossier forms the basis of the hazard assessment of formaldehyde for all formaldehyde releasing active substances.

Human health

The toxicity of the active substances is dominated by skin sensitization and local irritation and local (in vitro) genotoxicity (but negative systemic in vivo genotoxicity) and the hydrolysis study and efficacy mode of action support that the equilibrium within the RP 3:2 quickly shifts towards formaldehyde and 2-hydroxypropylamine by dilution and by the reaction of formaldehyde with biological media. This is essentially the basis for reading across the classification of formaldehyde for germ cell mutagenicity category 2 and carcinogenicity category 1B. However the risk assessment provided below for local and for systemic effects includes also the potential for carcinogenic effects.

RP 3:2 is also intended to be used as PT12 slimicide for offshore drilling processes, in a typical concentration of 0.1 to 0.15% within the drilling mud. This is done by direct application of the biocidal product (a.s. as manufactured) to the mud. RP 3:2 is added via closed automatic dosage systems as 100% concentrate (task = connecting tubes). Due to the expected and required closed systems technology exposure might occur just from exposure to the dBut thenrilling mud containing RP 3:2 and the hydrolysis products. Due to the high dilution of RP 3:2 in the mud it is assumed that RP3:2 is fully hydrolysed to formaldehyde and 2-hydroxypropylamine. Furthermore due to the high vapour pressure of formaldehyde and due to the similar AEL of formaldehyde and RP 3:2 (AEL was read across on a molar basis) the risk assessment for PT12 is based just on the consideration of formaldehyde. The second hydrolysis product 2-hydroxypropylamine is not further considered since the respective AEL is much higher and volatility, i.e. exposure potential, is lower compared to formaldehyde. Drilling muds contain a wide range of other substances including base fluids, weighting agents (e.g. barite), viscosifers (e.g. bentonite), surfactants (e.g. imidazolines) and biocides (e.g. glutaraldehyde). They may also contain contaminants from formations (e.g. oil, condensate and H_2S). Health effects included dermatitis, respiratory irritation, narcosis and cancer. For example, H_2S is a very toxic gas that can irritate the eyes and throat but also unconsciousness and death.

Human exposure to the biocide in the shaker house is calculated for formaldehyde that has been released in the used mud. The risk for local and systemic effects appears acceptable since personal protective equipment, including respiratory protective equipment and gloves are standard in this specific working environment.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusions**
PT12: Slimicide use in offshore processes	Primary exposure covering offshore tasks like mixing and loading, activities in the shaker room, sampling, analysis Exposure to active substance and drilling before and after application Acceptable with efficient 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.	Professionals	Acceptable with RMM and PPE

Considering that local irritation is a condition for the development of tumours and applying a deterministic threshold AEC and AEL, also the risk for potential carcinogenic effects appears acceptable.

No exposure of general public, no exposure of pets and no dietary exposure is expected due to the intended PT12 use. Dermal contact against dried concentrates in dirty clothes in home laundry of working clothes is assumed to be not relevant as RP 3:2 residues will quickly hydrolyse and generate gaseous formaldehyde, which is transferred to the gaseous phase and will not remain on the clothes.

Environment

The risk characterisation was based on the hydrolysis products 2-hydroxypropylamine and formaldehyde as during the use as slimicide for offshore drilling processes and due to the high dilution of RP 3:2 in the mud it is assumed that RP 3:2 is fully hydrolysed. The parent compound itself is therefore not expected to reach any environmental compartment. 2-Hydroxypropylamine and formaldehyde are expected to be readily biodegradable in the environment and are unlikely to bioaccumulate in biota. For acute toxicity algae is the most sensitive species with a 72h-E_rC50 of 5.7 mg/L (geometric mean, *Desmodesmus subspicatus*) for formaldehyde and a 96h-E_bC50 of 118.4 mg/L (nominal, buffered, *Pseudokirchneriella subcapitata*) for 2-hydroxypropylamine. Both compounds are not classifiable towards environmental hazards based on the available data.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Drilling chemicals - Continuous discharge	The biocidal products (a.s. as manufactured) are mainly applied as slimicide in the oil industry (offshore) for the preservation of drilling muds. Continue discharge refers to the fraction that could not be extracted and discharged overboard bound to the cuttings. This is therefore only a fraction of the total volume of drilling fluids initially added. **Affected environmental compartment:** sea water	Acceptable
Drilling chemicals – Batch wise discharge	Batch wise discharge occurs during drilling operations when the mud needs to be diluted. Some of the drilling mud may have to be discharged and the remainder in the system diluted. Batch wise discharges also occur at the end of a section where a new or different mud will be required in the next section. Finally, these discharges will also occur at the end of the well drilling when all operations are finished and the rig is to be moved to a new location. These discharges are larger both in volume and rate of discharge **Affected environmental compartment:** sea water	Acceptable if spend drilling muds are not discharged overboard and the drilling mud is treated.

The risk for slimicides in offshore processes for the application in drilling muds with continuous discharges is acceptable.

For batch wise discharge the risk is acceptable only if risk mitigation measures (RMM) are applied such as application of the spent drilling mud to land, re-injection, on-site dewatering or treatment in an off-site wastewater treatment facility.

Overall conclusion

Overall a safe use has been identified for the use of RP 3:2 as a slimicide for offshore drilling processes in PT12 provided adequate RMM and PPE are considered for human health and environment.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	Cat 1B	RP 3:2 does 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 does 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 fulfils 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	

Property		Conclusions	
		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 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 does 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 does fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	The substance does not contain a significant proportion of non-active isomers or impurities. RP 3:2 does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) does meet the exclusion criteria laid down in Article 5(1) of Regulation (EU) No 528/2012 by the released formaldehyde being a carcinogen Cat 1B.

Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) does meet the conditions laid down in Article 10(1)(a) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution by meeting the exclusion criteria.

The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR”[4] and in line with “Further guidance on the application of the substitution criteria set out under article 10(1) of

[4] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

the BPR"[5] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment"[6] agreed at the 54th , 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

An ED assessment for RP 3:2 has been carried out taken the EFSA/ECHA (2018) guidance for the identification of endocrine disruptors into account. The ED assessment has been also discussed in the ED expert group via a written procedure, followed by an ad hoc meeting in June 2021. The advice of the experts was considered for the ED assessment.

For the T-modality the ED criteria are not met for human health. For non-target organisms no conclusion can be drawn on T-modality based on the available data. For EAS modalities no conclusion can be drawn for human health and non-target organisms based on the available data. Further testing with the active substance is not considered appropriate in that specific case because 'testing does not appear scientifically necessary' (first heading of Annex IV of Regulation (No) 528/2012 and because 'testing is technically challenging' (referring to second heading on Annex IV), as detailed below.

- It is uncertain, if further mechanistic studies, particularly with mammals with RP 3:2 would allow establishing a mode of action, keeping in mind that endocrine mediated endpoints may be impacted secondary to general, non-endocrine toxicity and that in vivo apical endpoints can be triggered by several modes of action, including endocrine and non-endocrine modalities. Also for aquatic species it would be challenging to get meaningful results in further tests as correct dose setting and detangling the ED mode of action from non-ED modes of action are hampering the performance and interpretation of such tests. For birds no agreed and adequate study protocols are available to determine endocrine modes of action.

- Due to the properties of RP 3:2 as skin corrosive, skin sensitising and local acting genotoxic carcinogen and the corresponding low effect concentration(s), it is difficult to select an appropriate test system to get meaningful results, at least for mammals.

- The main hydrolysis product formaldehyde of RP 3:2 is an endogenously formed substance with a high turn-over rate in mammals and potentially also other non-target organisms. Exogenous FA due to biocidal product use might be a minor contributor to total systemic exposure.

Hence, a final conclusion on the exclusion criteria related to Article 5(1)(d), and on whether RP 3:2 shall be considered a candidate for substitution related to possible ED effect to Article 10(1)(e) is not possible for RP 3:2.

[5] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[6] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx)

2.2.2. POP criteria

A PBT assessment was performed for RP 3:2 and its hydrolysis products. Based on the available data RP 3:2, 2-hydroxypropylamine and formaldehyde are neither vPvB, nor PBT substances. Furthermore, none of the 3 substances meets two of the PBT criteria. Therefore, neither the parent nor its hydrolysis products meet the criteria for POPs either.

2.2.3. Public consultation for potential candidates for substitution and alternative substances or technologies

As RP 3:2 is considered a candidate for substitution ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012. The public consultation took place from 4 November 2016 to 3 January 2017. Four contributions were submitted: one by an industry stakeholder association, two by individual companies and one by a member state. The same contributions were submitted in the consultation on the structurally and toxicologically related substance RP 1:1.

In the member state contribution it is stated that no information on alternatives is available as the product types are not covered by their national authorisation scheme. This may be the case for more member states.

In the three industry contributions information is submitted on the importance of formaldehyde releasers in the control of microbial growth in water-containing products or equipment. In addition, information on alternatives is submitted for all product types.

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. In total 10 other formaldehyde releasers are under evaluation and one (formaldehyde released from N,N-Methylenebismorpholine or MBM for PT6 and 13) is already approved.
- 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 are not meeting 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 PT11 and 12 in the industry contributions glutaraldehyde, THPS and acrolein 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 3:2 and its stability prevents its application for the same use as RP 3:2. Acrolein also has a more severe aquatic toxicity compared to RP 3:2 and its stability limits its use to water injection.

The following active substances are already approved for PT12: C(M)IT/MIT, glutaraldehyde and peracetic acid. C(M)IT/MIT belongs to the class of isothiazolinones. Glutaraldehyde is also a candidate for substitution as it is a respiratory sensitiser. For peracetic acid the

intended use in the evaluation of PT12 was use as a slimicide in the paper and pulp industry.

The limited information available is insufficient to conclude on the availability of suitable alternatives for the intended uses assessed.

2.3. BPC opinion on the application for approval of the active substance RP 3:2 in product type 12

As the exclusion criteria are met, RP 3:2 should normally not be approved unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is met.

If RP 3:2 is approved and included in the Union list of approved active substances, the approval shall be subject to the following specific conditions:

1. Specification:

   The active substance has to be considered as substance of Unknown or Variable composition or Complex reaction products (UVC). Therefore the minimum purity is 1000 g/kg (100% by wt)

2. RP 3:2 is considered a candidate for substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012.
3. The authorisations of biocidal products are subject to the following condition:
   a. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. Measures shall ensure that exposure of the user and the environment is minimised as far as possible.
   b. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
   c. In the view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
      i. Professionals
      ii. Sea water
4. The placing on the market of treated articles is subject to the following condition:

   The person responsible for the placing on the market of a treated article treated with or incorporating RP 3:2 shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

RP 3:2 does not fulfil the criteria according to Article 28(1) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is classified as Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1A, STOT RE 2, Muta 2, Carc. 1B.

2.4. Elements to be taken into account when authorising products

1. The active substance RP 3:2 is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.

2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. The use of a biocidal product containing RP 3:2 shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment is minimised as far as possible.

    b. If an unacceptable risk for professional users is identified for the product, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.

    c. Unacceptable risks were identified for the sea water for the batch wise discharge during drilling operations when the mud needs to be diluted. Labels and, where provided, safety data sheets shall indicate that the spent drilling muds shall not be directly discharged into sea water and appropriate risk management measures shall be taken (on-site or off-site treatment of drilling muds), unless it can be demonstrated at product authorisation that risks to the environment can be reduced to an acceptable level by other means.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of RP 3:2. However, further data shall be required as detailed below. Data must be provided as soon as possible but not later than 6 months before the date of approval to the evaluating Competent Authority (Austria):

a. Regarding the explosive properties of the active substance an experimental test has to be conducted as the substance contains of unknown constituents and therefore the waiving cannot be justified by structural considerations.

b. A specific or highly specific and fully validated analytical method for the determination of the hydrolysis product 2-hydroxypropylamin in water.

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