Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Formaldehyde

Product type: 2

ECHA/BPC/232/2019

Adopted

10 December 2019

Opinion of the Biocidal Products Committee

on the application for approval of the active substance formaldehyde for product type 2

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 application for approval in product type 2 of the following active substance:

Common name:	**Formaldehyde**
Chemical name:	**methanal**
EC No.:	**200-001-8**
CAS No.:	**50-00-0**
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 BPC opinions

In April 2008, Germany received the so called “Formaldehyde Core-Dossier” provided as appendix to the formaldehyde releaser dossiers. The core dossier contains solely the hazard part which was discussed and harmonised by all member states responsible for the evaluation of a formaldehyde releaser dossier. The core dossier was discussed at the Technical Meeting I 2012.

Following the submission of an application by B. Braun Melsungen AG and Lysoform – Dr. Hans Rosemann GmbH on 26 June 2009 the evaluating Competent Authority of Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 29 July 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-23, BPC-33) and its Working Groups (WGs III and IV 2015). 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 http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations/-/substance-rev/5401/term on 9th February 2015, 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 10 April 2015.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the application of approval of the active substance formaldehyde in product type 2 was adopted on 13 December 2017. Due to the entry into force of Regulation (EU) 2017/2100[1] the Commission returned the BPC opinion to the Agency on 26 April 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation. The BPC opinion was then finally adopted on 10 December 2019.

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

The first version of the BPC opinion was adopted by consensus. The final version of 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.

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the formaldehyde in product type 2 may be approved. 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 formaldehyde in product type 2. Specifications for the reference source are established.

The active substance is a formaldehyde solution in water (25-55.5% formaldehyde, <7% methanol as stabilizer).

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, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices soil, water and air.

EFSA has prepared three opinions on the use of formaldehyde as a feed additive[2]. A decision by the Commission under Regulation (EC) No 1831/2003 is published[3].

A harmonized classification according to Regulation (EC) No 1272/2008 is available.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1 Muta. 2 Carc. 1B
Labelling	
Pictogram codes	GHS06, GHS05, GHS08
Signal Word	Danger
Hazard Statement Codes	H301 H311

[2] Application from Regal, opinion of 28/01/2014 : https://www.efsa.europa.eu/fr/efsajournal/pub/3561; Application from Adiveter, opinion of 28/01/2014 : https://www.efsa.europa.eu/en/efsajournal/pub/3562; Scientific Opinion on the safety and efficacy of formaldehyde as a feed hygiene substance in feed for pigs and poultry, opinion of 01/07/2014 : https://www.efsa.europa.eu/en/efsajournal/pub/3790

[3] Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjCpYq-m8blAhWSaVAKHao5BAAQFjAAegQIARAC&url=https%3A%2F%2Feur-lex.europa.eu%2Flegal-content%2FEN%2FTXT%2FPDF%2F%3Furi%3DCELEX%3A32018R0183%26from%3DEN&usg=AOvVaw375OaFnAsFmI6FQ4BsWgG5

	H331 H314 H317 H341 H350
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1; H317: C ≥ 0.2 %

The proposed classification and labelling according to Regulation (EC) No 1272/2008 is presented below. The eCA (DE) plans to submit a classification proposal to ECHA in September 2020.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Acute Tox. 3 Acute Tox. 2 Skin Corr. 1B Skin Sens. 1A Muta. 2 Carc. 1B
Labelling	
Pictogram codes	GHS06, GHS05, GHS08
Signal Word	Danger
Hazard Statement Codes	H302 H311 H330 H314 H317 H341 H350
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1A; H317: C ≥ 0.2 %
Justification for the proposal	
The changes to the existing classification are based on: • Acute oral toxicity: Category 4, based on an oral LD50 value of 640 mg/kg bw in rats, lower values reported in the literature are either not reliable or the test substance was not formaldehyde; • Acute dermal toxicity: Category 3, based on a dermal LD50 of 270 mg/kg bw in rabbits; • Acute inhalation toxicity (gases): Category 2, based on LC50 values of 1 mg/L x 0.5 h and 0.6 mg/L x 4 h in rats. • According to Regulation 1272/2008/EC, labelling as EUH071 “Corrosive to the respiratory tract” in addition to classification for inhalation toxicity is foreseen if the mechanism of toxicity is corrosivity. • Based on EC3 values of 0.33- 0.96 % in various LLNAs, an induction rate of 100 % following intradermal injection at 0.25 % a.s. in the GPMT and a high frequency of occurrence in humans at relatively low exposure, formaldehyde should be subclassified into Skin Sens. Cat. 1A (strong sensitiser) instead of category 1.	

b) Intended use, target species and effectiveness

Formaldehyde is used by professionals as a disinfectant in private and public health areas (PT2) by wiping and mopping (prophylactic purposes) as well as by fogging/fumigation in cases of danger of an epidemic. After fogging/fumigation formaldehde is neutralised with ammonia. As neutralisation product white powdered methenamine is formed and deposits on the surfaces.

The general use is assumed to take place on a daily basis whereas the use in a case of danger of an epidemic is assumed to take place only once a year.

Formaldehyde interacts with proteins, DNA and RNA in vitro. The interaction with proteins results from a reaction with the primary amide and the amino groups. It reacts with carboxyl, sulfhydryl and hydroxyl groups. Furthermore, formaldehyde reacts with nucleic acid (e.g. DNA of bacteriophages or viruses). It inhibits viral DNA synthesis by forming DNA cross-links (e.g. in SV40) and can modify viral proteins (e.g. HBsAg and HBcAg of HBV). It penetrates bacterial spores and fungal conidia, acts sporostatic and inhibits germination.

The efficacy studies performed are sufficient at the approval stage. Tests performed with the active substance show that formaldehyde has a bactericide and fungicide activity at a concentration of ≥ 0.5% within short term contact time (60min) and at concentration of 0.05% within long term contact time (24h). Further tests using formaldehyde show a sufficient disinfecting efficacy against viruses at concentrations between ≥ 0.064 and ≥ 0.92 after 120 min exposure. The proposed application rates of 0.05% - 12% of formaldehyde seem reasonable if formulated to a product.

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

Human health

Formaldehyde is of high chemical reactivity, causing local irritation or corrosion at exposed epithelia. There is also convincing evidence for skin sensitation by the a.s.. Formation of DNA-protein links is thought to lead to clastogenic effects. At concentrations causing cytotoxicity in the respiratory tract with induction of regenerative cell proliferation, formation of nasopharyngeal cancer has been established in rats.

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[4]**
Wiping and mopping of surfaces (general) in patients' rooms	Primary inhalation and dermal exposure occur during: - dilution of b.p. (40% a.s.) - mopping and wiping of surfaces in patients' rooms to 0.05% a.s. (for some purposes ≤ 0.2% water based solution) - pouring of residues for disposal (0.2% or 0.05% a.s.) **PPE:** protective gloves, protective coverall, mop changing technique[5]	Professional user	**Not acceptable with PPE** RPE is not appropriate in hospitals.
Wiping and mopping of surfaces (general) in operating theatres	Primary inhalation and dermal exposure occures during: - dilution of b.p. (40% a.s.) - mopping and wiping of surfaces in operating theatres (0.2% a.s.) - pouring of residues for disposal (0.2% a.s.) **PPE:** protective gloves, protective coverall, mop changing technique[5]	Professional user	**Not acceptable with PPE** RPE is not appropriate in hospitals.
Disinfection of surfaces (epidemic)	Primary inhalation and dermal exposure occures during: - dilution of b.p. (40% a.s.) - mopping and wiping of surfaces in patients' rooms (1.2% a.s.) - pouring of residues for disposal (1.2% a.s.) **RMM:** PPE (protective gloves, protective coverall, mop changing technique[5]) and RPE	Professional user[6]	**Not acceptable with RMM**
Disinfection of rooms by fogging (epidemic)	Primary inhalation and dermal exposure occures during dilution of b.p. (40% a.s.). Due to the self-acting of the fogging (controlled from outside) and neutralisation with ammonia no dermal and inhalation exposure to 12% a.s. is expected. **RMM:** protective gloves, RPE[5], automated fogging system and neutralisation with ammonia	Professional user[6]	**Acceptable with RMM**
Secondary exposure	Due to a waiting period inhalation and dermal exposure is not expected after	Professional	**Acceptable with RMM**

[4] This column refers to the overall conclusion of both systemic and local risk assessment.
[5] In addition safety goggles have to be worn due to local effects if no full face mask as respiratory protective equipment (RPE) is worn. Personal protective equipment (PPE) shall be substituted by engineering, technical and/or administrative equipment according to Dir.98/24/EC and Dir.2004/37/EC if possible.
[6] Professionals adequately trained (the assessment is based on professionals with a profound knowledge and experience of the efficacy and hazards of formaldehyde including adequate first aid measures, functionality of personal protective equipment, legal basis and instructions for use, e.g. room sealing, installation of a danger area of adequate size, protection measures including engineering and procedural measures as well as correct selection and proper use of effective PPE, exact dosage, safeguarding of sufficient concentration and clearance measurement, in order to avoid a critical exposure of themselves and/or bystanders and/or subsequent workers).

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusions[4]**
	regular mopping and wiping. In epidemic cases the access to the treated area is restricted. **RMM:** waiting period		
Inhalation of vapours from freshly treated surfaces	Secondary exposure: inhalation of vapours from treated surfaces	Patients, general public (infants and adults)	For freshly treated (wet) surfaces: **Not acceptable** (ventilation not considered). For dried treated surfaces: **acceptable**
Dermal contact	Secondary exposure: dermal hand contact with treated surfaces	Patients, general public (adults)	For freshly treated (wet) surfaces: **not acceptable** for dilutions of 1.2 % and above For dried treated surfaces: **acceptable**
Dermal contact	Secondary exposure: dermal contact with treated surfaces	Infants	For freshly treated (wet) surfaces: **Not acceptable** for dilutions above 0.10 % a.s. For dried treated surfaces: **acceptable**
Exposure after fogging	Secondary exposure: exposure after fogging treatment **RMM:** no entry during treatment; re-entry only after appropriate waiting period; closed premises during both treatment and waiting period	General public	**Acceptable with RMM**

The occupational risk assessment for formaldehyde takes into account systemic effects as well as local effects of the active substance. In addition to the systemic risk characterisation which is carried out with the AEL approach a risk characterisation for local effects after inhalation exposure is performed with an AEC as reference value. To assess the local dermal effects of formaldehyde a qualitative risk assessment according to the Guidance for Human Health Risk Assessment, Volume III – Part B was carried out.

For the disinfection of rooms by automated fogging (epidemic case) scenario an acceptable risk was found taking into account the above prescribed mitigation measures. The risks for all other scenarios are unacceptable for the professional user despite the described risk mitigation measures.

Non-professional use of the representative products is not intended. Therefore, primary non-professional esposure can be excluded.

Residues in food or feed are not expected from the intended use.

After treatment of surfaces, secondary exposure of the genral public may occure through inhalation of vapours from freshly treated surfaces or by dermal contact with freshly treated surfaces. For both scenarios, risks have been identified. However, theses risks can be mitigated if contact to freshly treated (wet) surfaces is avoided through appropriate RMM, such as excluding presence of the general public during treatment and setting an appropriate waiting period for re-entry. Secondary exposure after fogging is acceptable if exposure is prevented by adherence to RMM (no entry during the treatment, re-entry only when air concentration is below 0.1 ml/m^3, closed premises during both treatment and waiting period).

Environment

Formaldehyde was shown to be ready biodegradable fulfilling the 10d-window criterion. Hydrolysis of formaldehyde can be excluded because of the absence of a hydrolysable group in the molecule. Accumulation and long range transport in the atmosphere are not expected. Formaldehyde is also not expected to accumulate in the environment as the estimated BCF values in aquatic and terrestrial indicator species are both below 1. Formaldeyhde is toxic to aquatic organisms with the lowest available NOEC of 1.04 mg/L derived from a long-term study on the reproduction of *Daphnia magna.*

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Surface disinfection in industrial and health care areas by wiping and mopping (general and epidemic)	Emission to atmosphere as a result of volatilization from treated surfaces Emission to waste water due to excess of disinfection solution (sewage treatment plant (STP), aquatic compartment (surface water and sediment) and terrestrial compartment (soil and groundwater)	**Acceptable**

Room disinfection by fumigation (epidemic)	Emission to atmosphere due to residues in the disinfected room air. Releases of a.s. into the air compartment are negligible compared to releases into the air during surface disinfection. After fumigation and incubation time formaldehyde is neutralised by fumigation of ammonia solution which reacts to form methenamine. Only this reaction product reaches the waste water following wet wiping after the neutralization. Subsequently it reaches the STP. In surface water it slowly hydrolysis to formaldehyde and ammonia. **RMM:** Residues of methenamine are removed by wet mopping and use of damp cloths. Mopping water as well as damp cloths are disposed of as hazardous waste (only applicable for epidemic use).	**Unacceptable risks for aquatic organisms, acceptable with RMM**

No unacceptable risks were identified for any environmental compartment when formaldehyde is being used as a surface disinfectant.

In case of (epidemic) room disinfection the risk assessment results in a PEC/PNEC ratio > 1 for surface water, indicating that formaldehyde poses an unacceptable risk to aquatic organisms when used as a fumigant. For all other compartments no unacceptable risks have been identified for this application. The risk for the aquatic compartment (PEC/PNEC = 1.92) is primarily caused by lacking data on ready biodegradability for the neutralisation product methenamine resulting in the assumption that methenamine is not degraded in the STP and that 100 % is hydrolysed to formaldehyde and ammonia in surface water.

To reduce the risk to an acceptable level, emission of methenamine to waste water should be prevented. In epidemic cases, it is assumed that residues of methenamine (small quantities of solid white powder) can be removed by wet mopping and use of damp cloths. Both, mopping water and damp cloths are disposed of as hazardous waste. It has to be highlighted that this RMM is only applicable for the epidemic case (low quantities of waste, rare event) whereas thit is not deemed applicable for standard disinfection purposes.

At product authorisation the risk for aquatic organisms can be refined by submission of further data (i.e. an algae test according to OECD 201 for formaldehyde as well as further information on the ready biodegradability of methenamine).

No aggregated risk assessment for formaldehyde in product type 2 has been carried out because the biocidal uses of formaldehyde are less than 10 % of the total tonnage produced.

Overall conclusion

An acceptable risk for human health and environment has only been identified for the scenario “disinfection of room **by automated fogging** in an epidemic case”. Regarding this use, an acceptable risk for the surface water compartment was only found when appropriate RMM are applied.

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	Formaldehyde fulfils 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 and not vP	Formaldehyde does neither fulfil criterion (e) of Article 5(1) nor criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and not vB	
	Toxic (T)	not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data.	No conclusion can be drawn whether formaldehyde 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	No conclusion can be drawn based on the available data.	
	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. Hence, formaldehyde does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	For formaldehyde no concerns regarding critical effects according to Article 10(1)(e) are identified.		
Proportion of non-active isomers or impurities	Formaldehyde is not considered to have a significant proportion of non-active impurities. That means formaldehyde does not fulfil criterion (f) of Article 10(1).		

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"[7], with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[8] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[9] 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).

Consequently, the following is concluded:

Formaldehyde does meet the exclusion criteria laid down in Article 5(1)(a) of Regulation (EU) No 528/2012 by being classified as Carc 1B.

Formaldehyde 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. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of formaldehyde for PT 2 was submitted before 1 September 2013.

According to the "Note on the principles for taking decisions on the approval of active substances under the BPR"[7] for draft assessment report and the conclusions of its evaluation submitted by the evaluating Competent Authorities before 1 September 2013, the exclusion and substitution criteria as defined in the BPR have to be assessed, but the principles of the Biocidal Products Directive will apply for the decision-making. This means that though formaldeyhde fullfills Article 5(1)(a) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision.

2.2.2. POP criteria

As formaldehyde is not P, B or vB, it does not meet the criteria for being a persistent organic pollutant.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

During public consultation 2 confidential and 11 non-confidential comments were received from third parties.

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[7] 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)

[8] 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)

[9] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details).

In all of the received comments it is said, that formaldehyde is effective against a wide varity of microbiological organisms like bacteria, fungi, enveloped and non-enveloped viruses, yeasts and spores.

The authors of the documents describe the different applications of formaldehyde disinfection of air, surfaces, materials and equipement in private and public health areas. Another application in the received documents is the hot water treatment of flowerbulbs to kill nematodes in the Netherlands.

As stated in the received documents formaldehyde is effective against a broad antimicrobial spectrum. Formaldehyde is non-corrosive and exhibits good material compartibility towards wooden surfaces, bricks, electronic and mechanical equipment. Formaldehyde has superior penetration properties and the restistance to inactivation by blood and organic matter is low. The fumigated substance can reach all inaccessible areas and crevices in the facility. It enables a high control of infectious diseases.

The third party information received for PT 2 also presents some alternative substances for formaldehyde which are e.g. hydogen peroxide, peracetic acid, chlorine dioxide, ozone, chlorine and sodium hypochlorite. Chlorine is not suitable for the disinfection of porous surfaces and surfaces contaminated with blood or organic matter. Preparations containing active oxygen or peracids and peroxides are highly reactive and rapidly disintegrating oxidants. They must be kept protected from heat and light and are susceptible to protein, blood and organic matter.

At the moment, there are 25 active substance which have already been approved for PT 2. Only one of these active substances, hydrogen peroxide, is considered as vaporizable and was evaluated for room disinfection by fogging. The other active substance were mostly evaluated as surface disinfectant (e.g. propan-2-ol, glutaraldehyde, peracetic acid, CMK, etc.) or completely different uses (e.g. treatment of sewage sludge, swimming pool treatment, etc.).

Based on the information available from the public consultation, any alternative identified was neither comparably effective nor practicable to inactivate harmful organisms (no distinction has been made between prophylactic purposes and the use in case of danger of an epidemic).

The BPC could not further assess potential alternative substances, due to lack of information received during public consultation.

2.3. BPC opinion on the application for approval of the active substance substance formaldehyde in product type 2

In view of the conclusions of the evaluation, it is proposed that formaldehyde shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: 25 – 55.5% formaldehyde in aqueous solution (minimum purity 87.5% w/w with regard to formaldehyde)
2. Methanol is identified as relevant impurity (stabilizer) with a maximum content of 7%.
3. Formaldehyde is considered a candidate of substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012.
4. The authorisations of biocidal products are subject to the following condition(s):

a. 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.

b. 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.

c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

i. professional users for products used in the disinfection by mopping and wiping of surfaces

ii. the general public and children following secondary exposure

iii. the aquatic environment for products used for room disinfection by fumigation in epidemic cases

5. The placing on the market of treated articles is subject to the following condition(s):

a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance formaldehyde 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.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. Formaldehyde gives rise to concern for human health, i.e. it is acute toxic by oral, dermal and inhalation route, it is carcinogenic of category 1B as well as mutagenic category 2. It is skin corrosive category 1B as well as skin sensitising category 1. In addition, Formaldehyde is considered a candidate of substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

1. The active substance formaldehyde 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. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

b. An unacceptable risk for professional users is identified for products applied by wiping and/or mopping. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures, these uses should not be authorised.

c. An unacceptablee risk for human health is identified as consequence of secondary exposure to vapours and to freshly treated (wet) surfaces from wiping/mopping. The risk can be mitigated by setting appropriate re-entry times (1 hour based on submitted data or value based on product-specific data).

d. An unacceptable risk for human health is identified as consequence of secondary exposure after fogging. The risk can be mitigated by ensuring the air concentration of formaldehyde is below the AEC of 0.1 ml/m^3.

e. An unaccepatble risk for the aquatic compartment is identified for room disinfection by fumigation in epidemic cases. To mitigate the risk residues of the neutralisation product methenamine shall be removed by wet mopping and use of damp clothes. Both, mopping water and cloths shall be disposed of as hazardous waste.

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 formaldehyde in product type 2.

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