

## **Biocidal Products Committee (BPC)**

Opinion on the application for approval of the active substance:

**Coco alkyltrimethylammonium chloride**

**Product type: PT 8**

ECHA/BPC/097/2016

Adopted

14 April 2016



## Opinion of the Biocidal Products Committee

### on the application for approval of the active substance coco alkyltrimethylammonium chloride for product type 8

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 **8** of the following active substance:

<b>Common name:</b>	<b>coco alkyltrimethylammonium chloride (ATMAC/TMAC)</b>
<b>Chemical name:</b>	<b>coco alkyltrimethylammonium chloride (IUPAC name)</b> <b>quaternary ammonium compounds, coco alkyltrimethyl, chlorides (CAS name)</b>
<b>EC No.:</b>	<b>263-038-9</b>
<b>CAS No.:</b>	<b>61789-18-2</b>
<b>Existing active substance</b>	

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

Following the submission of two applications by Lonza GmbH (ATMAC) and Akzo Noble Surface Chemistry AB (TMAC) on 28 March 2004, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation for the dossier submitted by Lonza GmbH and Akzo Noble Surface Chemistry AB to the Commission on 20 November 2007 and 10 June 2010, respectively. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Commission organised consultations via the Biocides Technical Meetings (TM III in 2009) and the Agency via the BPC (BPC-4 and BPC-15) and its Working Groups (WG-II-2015, APCP WG-II-2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: Italy**

The BPC opinion on the approval of the active substance coco alkyltrimethylammonium chloride in product type 8 was adopted on 14 April 2016.

The BPC opinion was adopted by consensus.

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that the coco alkyltrimethylammonium chloride in product type 8 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 coco alkyltrimethylammonium chloride (ATMAC/TMAC) in product type 8. Coco alkyltrimethylammonium chloride is a quaternary ammonium compound which acts by disruption and leakage of the membranes, leading to cell damage or lysis of the cell content. Specifications for the reference sources are established.

The physico-chemical properties of the active substance and its representative 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 (technical concentrate) and for the significant impurities. Validated analytical methods are required and available for the relevant matrices soil and water (drinking, ground and surface water), but additional confirmatory methods are still missing for one of the two applicants seeking for approval and required at product authorisation.

A harmonised classification does not exist for coco alkyltrimethylammonium chloride under the CLP Regulation. The evaluating Competent Authority (eCA) intends to submit the following harmonised classification proposal to ECHA.

The proposed classification and labelling for coco alkyltrimethylammonium chloride according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

<b>Proposed classification according to the CLP Regulation</b>	
Hazard Class and Category Codes	Acute toxicity (oral) Hazard Category 3 Acute toxicity (dermal) Hazard Category 3 Skin Corrosion Hazard Category 1B Aquatic Acute 1
<b>Labelling</b>	
Pictograms	GHS05, GHS06, GHS09
Signal Word	Danger
Hazard Statement Codes	H301: Toxic if swallowed H311: Toxic in contact with skin H314: Causes severe skin burns and eye damage EUH071: Corrosive to the respiratory tract H400: Very toxic to aquatic life
<b>Specific Concentration limits, M-Factors</b>	
	M factor=10

**b) Intended use, target species and effectiveness**

Coco alkyltrimethylammonium chloride has fair wetting properties, severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides. The field of application of coco alkyltrimethylammonium chloride includes wood preservatives for the preventive treatment against wood-discolouring moulds and fungi by industrial and professional users. Coco alkyltrimethylammonium chloride is used for preventive protection of wood and constructional timbers in areas with moderate or subtropical climate in use classes 1 to 4A as reported in the Emission Scenario Document for PT 8.

The representative product is an aqueous solution, with preventive efficacy against wood-destroying basidiomycetes, against soft rot fungi. It is used in dipping and spray tunnel application applications in wood protection.

The assessment of the biocidal activity of coco alkyltrimethylammonium chloride demonstrates that it has a sufficient level of efficacy against the target organisms. The evaluation of the summary data provided in support of the efficacy of the representative product establishes that it may be expected to be efficacious.

From practical experiences with standalone-biocides in this field of application, it is known that local formation of "resistant" fungus strains at the application site may occur. For this reason coco alkyltrimethylammonium chloride is normally not used as a unique biocide in anti sapstain formulations. Wood preservative type formulations normally consist of up of two or three different active substances to avoid resistance.

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

The main critical effects associated with coco alkyltrimethylammonium chloride are due to its corrosive properties. The active substance induces severe erythema, desquamation and corrosive eschar in the rabbit skin, and therefore it is classified as corrosive to skin. Additionally, corrosive effects in the respiratory tract are expected. No specific studies on coco alkyltrimethylammonium chloride toxicokinetics and metabolism are available, however, the read across from data on a structurally related compound, namely didecyldimethylammonium chloride (DDAC), has been accepted. No systemic effects in the absence of local effects were observed in any of the studies. Therefore, only a local risk assessment was considered necessary for the use of coco alkyltrimethylammonium chloride.

The table below summarises the exposure scenarios assessed.

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Mixing and Loading (Automated dipping)	Primary exposure to 14% of coco alkyltrimethylammonium chloride in product concentrate Tier 1: without RMMs Tier 2: Engineering controls (e.g., full automation); Gloves and protection coveralls	Industrial users / Professionals	Acceptable with PPE and other RMMs
Automated dipping application	Primary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Automated dipping process Tier 3: Automated dipping process, gloves and coveralls	Industrial users / Professionals	Acceptable with PPE and other RMMs
Handling of wet treated wood (Automated dipping)	Secondary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Gloves and coveralls	Industrial users / Professionals	Acceptable with PPE
Maintenance and cleaning (Automated dipping)	Secondary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Gloves and coveralls	Industrial users / Professionals	Acceptable with PPE
Mixing and Loading (Spray tunnel)	Primary exposure to 14% of coco alkyltrimethylammonium chloride in product concentrate Tier 1: without RMMs Tier 2: Engineering controls (e.g., full automation); Gloves and coveralls	Industrial users / Professionals	Acceptable with PPE and other RMMs
Spraying in close tunnel application	Primary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Closed and automated process Tier 3: Closed system process; gloves and coveralls	Industrial users / Professionals	Acceptable with PPE and other RMMs
Handling of wet treated wood (Spraying in closed tunnel)	Secondary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Gloves and protection coveralls	Industrial users / Professionals	Acceptable with PPE

Maintenance and cleaning (Spraying in close tunnel)	Secondary exposure to 1.12% of coco alkyltrimethylammonium chloride in aqueous diluted concentrate Tier 1: without RMMs Tier 2: Gloves and protection coveralls	Industrial users / Professionals	Acceptable with PPE
Infants mouthing wood off-cut	Secondary exposure: Infants mouthing wood off-cut (oral exposure)	General public	Acceptable

The local risk assessment has been carried out according to ECHA guidance<sup>1</sup>. When appropriate risk mitigation measures are in place, including appropriate exposure control measures like engineering controls and PPE the potential risks associated with local effects were acceptable for all uses. No risks were identified from secondary exposure to treated wood by the general public.

## Environment

The table below summarises the exposure scenarios assessed.

<b>Summary table: environment scenarios</b>		
<b>Scenario</b>	<b>Description of scenario including environmental compartments</b>	<b>Conclusion</b>
Dipping treatment during application	Dipping process is used only to prevent surface growth of organisms for short term storage of wood used internally for buildings and similar applications. Compartments assessed: sewage treatment plant (STP), surface water and sediment.	Unacceptable for surface water and sediment. Acceptable for STP.
Dipping treatment during storage	Treated wood is stored in appropriate locations of the treatment plant following the treatment process. Compartments assessed: surface water, sediment and groundwater.	Unacceptable for surface water, sediment and groundwater.
Bridge over pond (UC 3)	Treated wood in service. Compartment assessed: surface water.	Acceptable for surface water and sediment.
Noise barrier (UC 3)	Noise barrier is made of poles with planks in between. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: STP, surface water, sediment, soil and groundwater.	Unacceptable for surface water and sediment at Time 1 (short term) while acceptable at Time 2 (long term). Unacceptable for soil. Acceptable for STP and groundwater.

<sup>1</sup> Guidance on the BPR: Volume III Human Health, Part B Assessment (2015)



Fence (UC 3)	A fence is made of poles with planks in between. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: soil and groundwater.	Unacceptable for soil and groundwater.
House cladding (UC 3)	The house scenario describes a timber or timber clad house. For the calculations, the default value for the height of the claddings is 2.5 m and the circumference of the house is 50 m. For the Use Class 3, wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting. Compartments assessed: soil and groundwater.	Unacceptable for soil and groundwater.
Fence post (UC 4a)	The fence post scenario describes a rectangular fence post of 10 by 10 cm and a length of 2 m, which is buried to a depth of 0.5 m. For the Use Class 4a, wood in contact with ground. Compartments assessed: soil and groundwater.	Acceptable for soil and groundwater.
Transmission pole (UC 4a)	The scenario describes a transmission pole with a default diameter of 25 cm and a default length of 9 m, which is buried to a depth of 2 m. For the Use Class 4a, wood in contact with ground. Compartments assessed: soil and groundwater.	Acceptable for soil and groundwater.

For industrial application by dipping, including storage, for all scenarios, unacceptable risks are identified for aquatic organisms in surface water. No risk is predicted for micro-organisms in the sewage treatment plant. For the groundwater compartment, unacceptable risks have been identified only following storage. Therefore, risk mitigation measures are proposed to restrict the storage of pre-treated timber to areas of impermeable hard standing or under shelter, so as to prevent direct exposure of the water compartment and allow the recovery of the losses for recycling or appropriate disposal. Moreover, it is proposed to restrict the dipping treatment allowing it only to those plants where significant losses can be contained (e.g. no drain connections to storm drains or STP) and appropriately recycled/disposed. The spraytunnel application assessed for human exposure was with respect to environmental risks considered to be covered by the dipping scenario. No release is expected to the environment following this application.

Due to the unacceptable risks identified for the terrestrial compartment, the use of products for treatment of wood in contact with fresh water or for treatment of wood that will be continually exposed to the weather or subject to frequent wetting should be restricted. For authorizing products in use class 3 a safe use could be demonstrated by providing a leaching study at product authorization stage. The leaching data currently used for the derivation of the predicted environmental concentrations (PECs) were generated from a leaching study simulating worst-case conditions: wooden blocks continuously submerged in water for a period of 14 days (also considering the high water solubility of coco alkyltrimethylammonium chloride).

## Overall Conclusion

Both automated dipping and spraying in closed tunnel application were acceptable for professional users when appropriate risk mitigation measures are considered. These industrial applications, including storage was only acceptable for the environment when appropriate risk mitigation measures are in place. For the in-service life of treated wood exposed to frequent weathering, an unacceptable risk for soil and groundwater is identified in use class 3 (house and fence scenario). With regards to human health and environment safe use for use classes 1, 2 and 4A were identified when appropriate risk mitigation measures are in place.

## 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)	no classification required	Coco alkyltrimethylammonium chloride does not fulfil criterion (a), (b) and (c) of Article 5(1).
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P	Coco alkyltrimethylammonium chloride 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	
	Toxic (T)	T	
Respiratory sensitisation	No classification required. Coco alkyltrimethylammonium chloride does not fulfil criterion (b) of Article 10(1)		
Endocrine disrupting properties	Not considered to have endocrine disrupting properties. Coco alkyltrimethylammonium chloride does not fulfil criterion (d) of Article 5(1)		
Concerns linked to critical effects	Coco alkyltrimethylammonium chloride does not fulfil criterion (e) of Article 10(1)		
Proportion of non-active isomers or impurities	As the proportion of impurities is below 20% coco alkyltrimethylammonium chloride does not fulfil criterion (f) of Article 10(1)		

Consequently, the following is concluded:

Coco alkyltrimethylammonium chloride does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Coco alkyltrimethylammonium chloride does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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"<sup>2</sup> and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"<sup>3</sup> agreed at the 54<sup>th</sup> and 58<sup>th</sup> 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).

### **2.2.2. POP criteria**

Coco alkyltrimethylammonium chloride does not meet the PBT criteria. No potential for long-range environmental transport is expected, either. Subsequently, it is concluded that coco alkyltrimethylammonium chloride is not expected to meet the POP criteria.

### **2.3. BPC opinion on the application for approval of the active substance coco alkyltrimethylammonium chloride in product type 8**

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

1. Specification: minimum purity of the active substance evaluated:  $\geq 96.6\%$  w/w (dry weight)
2. The authorisation of biocidal products are subject to the following conditions:
  - 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. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
    - i. industrial and professional users;
    - ii. soil and groundwater for wood in service that will be exposed to frequent weathering.
  - c. In view of the risks identified for soil, surface and ground water, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

<sup>2</sup> 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>)

<sup>3</sup> 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](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))

Coco alkyltrimethylammonium chloride meets the criteria for classification according to Regulation (EC) 1272/2008 as skin corrosive of category 1B. Therefore, coco alkyltrimethylammonium chloride does not meet the conditions in Article 28(1) to allow inclusion in Annex I of Regulation (EU) 528/2012.

#### **2.4. Elements to be taken into account when authorising products**

1. Where use of the product may lead to contamination of food and feeding stuffs, an assessment of the risk in food and feed areas may be required at product authorisation. Analytical methods for residues in/on food and/or feedstuffs may be required, too.
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 for industrial and professional users is identified, 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.
  - b. An unacceptable risk for soil and groundwater is identified for treated wood exposed to frequent weathering. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

#### **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 coco alkyltrimethylammonium chloride. However, the following information should be provided to the evaluating Competent Authority (Italy) as soon as possible but not later than 6 months before the date of approval of the active substance:

- additional highly-specific confirmatory methods for coco alkyltrimethylammonium chloride residues in soil and water (both drinking and surface water) for the applicant Lonza GmbH.