Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Reaction products of boric acid with didecylamine and ethylene oxide

(Polymeric betaine (Name used in the document))

Product type: 8

ECHA/BPC/424/2024

Adopted

29 May 2024

Opinion of the Biocidal Products Committee

on the application for approval of the active substance "Reaction products of boric acid with didecylamine and ethylene oxide" 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:

Common name:	**Polymeric betaine**
Chemical name:	**Reaction products of boric acid with didecylamine and ethylene oxide**
EC No.:	**-**
CAS No.:	**214710-34-6**
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 Rütgers Organics GmbH on March 2004, the evaluating Competent Authority Greece submitted an assessment report and the conclusions of its evaluation to the Commission on 25 February 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-51) and its Working Groups (APCP WG-III-2017, WG-I-2024). 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 *Previous consultations on potential candidates for substitution and on derogations conditions - ECHA (europa.eu)* on 03 November 2023, 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 04 January 2024. Link to submitted comments: Previous consultations on potential candidates for substitution and on derogations conditions - ECHA (europa.eu)

Adoption of the BPC opinion

Rapporteur: Greece

The BPC opinion on the application for approval of the active substance reaction products of boric acid with didecylamine and ethylene oxide in product type 8 was adopted on 29 May 2024.

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

The overall conclusion of the BPC is that the "reaction products of boric acid with didecylamine and ethylene oxide", herein after referred to as "polymeric betaine" 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 polymeric betaine in product type 8. Specifications for the reference source are established.

The physico-chemical properties of the active substance and 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 and for impurities.

No suitable analytical methods were submitted for monitoring the active substance in the soil, surface and drinking water. However, a residue definition for soil, water and air is not required based on the intended uses. Therefore, no analytical methods for monitoring purposes are required for these uses. Analytical methods for monitoring in soil, surface and drinking water must be provided if uses are applied for at product authorisations, that could lead to emissions or leaching of the active substance to these compartments.

No analytical methods for animal and human body fluids and tissues were submitted. As the active substance is not considered toxic, there is no requirement for analytical methods for monitoring of the active substance in animal or human body fluids or tissues.

No analytical methods were submitted for monitoring in food and feeding stuff of plant and animal origin, nor are required based on the intended uses.

The CLH dossier was submitted to ECHA on 9 October 2019 for accordance check. The dossier submitter will consider the outcome of the discussions on classification in WG-I-2024 while revising the CLH dossier for final submission.

The proposed classification and labelling for polymeric betaine according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Skin Corr. 1C Serious Eye Dam. 1 Skin Sens. 1A Repr. 2 (development) STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1

Labelling	
Pictogram codes	GHS05 GHS07 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H361d - Suspected of damaging the unborn child H373 - May cause damage to organs through prolonged or repeated exposure. H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects
Suppl. Hazard statement Codes	EUH071 - Corrosive to the respiratory tract
Specific Concentration limits, M-Factors	ATE = 500 M = 1 (acute & chronic)
Justification for the proposal	
Based on the results from studies presented in the dossier, classification of polymeric betaine was proposed according to the criteria set out in the CLP Regulation (with amendments).	

b) Intended use, target species and effectiveness

Efficacy of polymeric betaine is supported by 1 representative biocidal product, namely Impra-TSK 16 containing 100% active substance.

The product is a liquid concentrated wood preservative (PT8) with preventive action against wood boring beetle *Hylotrupes bajulus* (house longhorn beetle) and wood rotting fungi. The product is intended for industrial/professional use indoors for preventive treatment of wood in Use Classes (UC) 1 and 2, by vacuum pressure treatment of timber. The retention rates of the product (active substance) in the treated wood are 3.5 kg/m^3 for UC 1 and 5.8 kg/m^3 for UC 2. The concentration of the product (active substance) in the aqueous working solution for vacuum pressure is 0.5-0.8%.

The efficacy data on the representative product Impra-TSK 16, containing 100% active substance, demonstrates sufficient efficacy of the product and the active substance against the target organisms as follows:

UC 1: Wood boring beetle *Hylotrupes bajulus* (house longhorn beetle) – with retention of 2.74 – 4.32 kg/m^3 (biological reference value is the mid-toxic value 3.5 kg/m^3). The retentions are expressed in undiluted product.

UC 2: Brown and white rot fungi, and wood boring beetle *Hylotrupes bajulus* (house longhorn beetle) – with retention of 5.8 kg/m^3. The retention is expressed in undiluted product.

<u>Mode of action</u>

Polymeric betaine reacts with wood to bind the quaternary moiety permanently to the wood structure. This quaternary ammonium compound is absorbed at interfaces of biological membranes resulting in lysis of cell membranes.

The active substance polymeric betaine contains two active substance components, namely the borate esters of quaternary ammonium compounds and boric acid.

Due to the low ability of the borate-ester form to interact with the treated wood, the borate esters can penetrate deeply into wood. In the wood the pH is normally low, which shifts the equilibrium towards the quaternary ammonium form, which then strongly binds through the OH-groups to the wood (fixation). Diluting with water shifts the equilibrium towards the quaternary ammonium ion form and frees the boric acid. Both the quaternary ammonium compounds as well as the boric acid exert biocidal properties within the wood. While the quaternary ammonium compounds bind to the wood, which reduces their leaching potential, the boric acid can easily be leached out.

The biocidal activity of boric acid is in the first place insecticidal, while the quaternary ammonium compounds exert primarily a fungicidal activity.

Resistance

No resistance cases of insects and fungi to polymeric betaine and its active substance components (boric acid and quaternary ammonium compounds) are reported in the Arthropod Pesticide Resistance Database as compiled by Michigan State University (MSU) in conjunction with the Insecticide Resistance Action Committee (IRAC) (https://www.pesticideresistance.org/index.php), as well as in the FRAC code list by Fungicide Resistance Action Committee (https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2024.pdf). Moreover, according to the applicant, no resistance was noted up to now, after using polymeric betaine in the impregnation of wood for 30 years in Europe.

Hence, due to the lack of resistance cases of the target organisms to polymeric betaine and its active substance components, no specific resistance management strategies are deemed necessary.

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

Human health

Polymeric betaine is rapidly but not extensively absorbed after single oral administration (oral absorption accounts for 16% of administered dose); it is excreted effectively, mainly *via* faeces. It is widely distributed in the body and there is no potential for accumulation.

Polymeric betaine is corrosive to skin and eyes and it is a potent skin sensitizer. It is harmful by the oral route.

Polymeric betaine is not considered to be neurotoxic, immunotoxic, carcinogenic, genotoxic, reproductive toxicant for effects on fertility, endocrine disruptor and it does not have specific target organ toxicity following single exposure. It is toxic to reproduction for effects on development, based on absence of phalangeal ossification in rats in the absence of maternal toxicity. After repeated exposure, polymeric betaine may cause squamous hyperplasia of the stomach (local effects) at non-corrosive concentrations.

Since systemic effects in the absence of local effects were observed in the available studies, both systemic and local risk characterisation have been performed.

Polymeric betaine does not meet the endocrine disruption (ED) criteria for the EATS-modalities in humans based on detailed assessment performed by the eCA according to the ECHA/EFSA guidance on endocrine disruptors (2018).

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Automated mixing and loading	Primary Exposure	Industrial user	Acceptable with personal protective equipment (PPE)
Application: Vacuum pressure	Primary Exposure	Industrial user	Acceptable with PPE
Post-application: Maintenance / Disposal	Primary Exposure	Industrial user	Acceptable with PPE
Infant chewing treated wood cut-off	Secondary Exposure	General public (infant)	Acceptable
Sanding treated wood by non-professionals	Primary Exposure	Non-professionals	Acceptable
Sanding treated wood by professionals	Secondary Exposure	Professionals	Acceptable with PPE
Adult and toddler – Inhalation of volatilised residues indoors	Secondary Exposure	General public	Acceptable

Systemic effects

With regard to primary exposure, an acceptable risk has been identified for the industrial user with the use of personal protective equipment (PPE), gloves, coverall.

For secondary exposure to the treated wood during sanding, the risk is acceptable without the use of PPE for non-professionals, while for professionals the risk is acceptable provided that PPE is used. No risk has been identified for an infant chewing a treated wood cut-off. For exposure to volatilised residues from indoor polymeric betaine-treated timber, the risk is acceptable.

Local effects

When appropriate risk management measures are in place, including appropriate exposure control measures like engineering controls and PPE (gloves), the potential risks associated with local effects are acceptable for the industrial user.

For secondary exposure, no risk is identified due to local effects *via* the dermal route for any exposed population group.

Environment

Polymeric betaine is not readily biodegradable. The hydrolysis test could be waived based on the nature of the active substance (reaction mass in equilibrium) and the fact that the main forms are dependent on dilution and pH. No relevant absorbance over the UV-VIS wavelength range of 200 to 800 nm was observed, thus no direct photolysis is expected. Over 64 days the mineralisation was measured <50% (35-45%) in three different soil types. The determined DT50 values in soil are 241.7 days to 399.5 days at 12°C in two soils (sandy loam and sandy clay loam). One major metabolite (M-1) was formed in the terrestrial compartment with maximum occurrence of 23.7% and a DT50 value of 932 days at 12^0C. Both the active substance and its soil metabolite are characterized as very persistent (vP). Polymeric betaine is immobile in soil with a Koc value of 96449.2 L kg^{-1} (geometric mean, n=5). Furthermore, polymeric betaine has high vapour pressure (150 Pa).

Monomer 5, boric acid and metabolite M-1 have been considered for the risk assessment. The active substance is not B/vB. Bioaccumulation criterion is not fulfilled.

Based on aquatic studies with fish, daphnia and algae (short-term and long-term) it can be concluded that the substance is very toxic to all aquatic organisms. Polymeric betaine is classified as very toxic to aquatic life and can cause long lasting effects.

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100 no conclusion can be drawn for the environment (non-target organisms) 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**
Scenario 1: Vacuum pressure – Industrial application (UC1 and UC2)	Industrial preventive treatment; Direct exposure of STP and indirect (through STP) to fresh water, sediment, soil and groundwater from draining facilities after application.	Monomer 5: risk identified: aquatic/terrestrial compartment, however acceptable with RMM. Boric acid: acceptable. Metabolite M-1: risk identified: terrestrial compartment, however acceptable with RMM.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Scenario 2: Vacuum pressure – Storage (UC1 and UC2)	Industrial preventive treatment; Direct exposure to soil and groundwater from draining facilities during storage.	Monomer 5: risk identified: aquatic/terrestrial compartment, however acceptable with RMM. Boric acid: risk identified: terrestrial compartment, however acceptable with RMM. Metabolite M-1: risk identified: terrestrial compartment, however acceptable with RMM.

Scenarios for "treated wood in service" are not relevant, because the intended uses for the representative product are for UC1 and UC2 industrial application only.

Unacceptable risks were identified for aquatic and sediment dwelling organisms and for the terrestrial compartment as well at industrial application and storage. However, the risk can be addressed with the application of appropriate risk management measures, as follows:

- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- During the application phase: Prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);
- Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.

Overall conclusion

For vacuum pressure applications and regarding human health, a safe use has been demonstrated when appropriate risk management measures are considered.

For the environment for industrial processes (vacuum pressure treatment) the use of polymeric betaine will not pose unacceptable risks for the environmental compartments as long as appropriate risk management measures are considered.

Therefore, combining the assessment for human health and the environment, safe use can be identified for use classes 1 and 2, when appropriate risk management 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.	Polymeric betaine does not fulfil criterion (a), (b) and (c) of Article 5(1) BPR.
	Mutagenicity (M)	No classification required.	
	Toxic for reproduction (R)	Cat 2	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP	Polymeric betaine does not fulfil criterion (e) of Article 5(1) BPR but fulfils criterion (d) of Article 10(1) BPR
	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	No	Polymeric betaine does not fulfil criterion (d) of Article 5(1) BPR. No conclusion possible, on fulfilling Article 10(1)(e) BPR.
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Further data need to be generated at renewal to conclude on ED potential	
	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	Polymeric betaine does not fulfil criterion (b) of Article 10(1). No classification required.		
Concerns linked to critical effects other than those related to endocrine disrupting properties	No other concerns are identified.		
Proportion of non-active isomers or impurities	Polymeric betaine does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Polymeric betaine does not meet the exclusion criteria laid down in Article 5 of the BPR.

Polymeric betaine meets the conditions laid down in Article 10(d) of the BPR and it is therefore considered as a candidate for substitution since it is vP and T.

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"[1], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] and 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[3]. This implies that the assessment of the exclusion criteria is based on Article 5(1) of the BPR and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f) of the BPR.

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, polymeric betaine is not an endocrine disruptor for human health and mammals; no conclusion can be drawn for the environment (non-target organisms) based 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 Polymeric Betaine for PT 8 was submitted before 1 September 2013.[4]

2.2.2. POP criteria

Polymeric betaine is not B and has no potential for long-range transport. Therefore, the substance does not meet the POP criteria (persistent organic pollutant (POP) under Regulation (EC) No 850/2004).

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

Seven (7) confidential and two (2) non confidential contributions by interested parties were received during the consultation period. All contributors agreed that polymeric betaine is essential in the timber treatment business because of (a) the critically low availability of products with other PT8 active substances and (b) the successful and long-term wood protection that has been achieved having used that active substance for more than two decades. Two contributors also stated that due to its unique structure, polymeric betaine forms a film on the metal surfaces which prevents corrosion of the metal parts that it may get in contact with (such as impregnating systems, hinges and screws that will be fixed on the treated wood etc). Besides corrosion prevention, another contributor stated that polymeric betaine exhibits intrinsic emulsification properties because it contains an aliphatic

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/efada790-f874-4667-b3cf-d15a09060ac8/details).
[2] 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/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/c6bf2c1b-e281-4955-93f1-56b0422425ab/details).
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100
[4] 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/5ac61098-3765-48a7-800c-74ae41960ba0/details).

(a positively charged and a negatively charged molecule part). Hence, polymeric betaine enables good interaction with a variety of wood-specific chemical ingredients, so the use of additional emulsifiers in the final solution is limited or not needed at all. Overall, most of the contributors agreed that the anti-corrosive properties provide to polymeric betaine a technical and economical advantage over the remaining PT8 active substances.

Potential alternative active substances

There are 28 PT8 active substances approved. Some of those substances act against only wood rotting fungi, some other act only against wood boring insects, while there are also substances that act against both fungi and insects infesting wood. Polymeric betaine has been found to be efficacious against both wood rotting fungi and wood infesting insects. Ten (10) out of the 28 approved PT8 active substances act against both fungi and insects infesting wood and could be explored as potential alternatives to polymeric betaine. Those substances are listed below:

- Boric acid
- Creosote
- Cu-HDO
- ADBAC/BKC
- Copper (II) oxide
- Copper (II) hydroxide
- Granulated copper
- Basic copper carbonate
- DDAC
- DDACarbonate

In relation to the above active substances, creosote and boric acid are candidates for substitution (CFS), while the CFS criteria for the remaining substances are currently under assessment. In addition, creosote is not allowed for UC1 and UC2, while Cu-HDO is not allowed for UC1. Hence, and pending the finalization of the assessment of the CFS criteria of the potential alternative active substances, the following substances could be further explored as potential alternatives to polymeric betaine:

- Copper compounds (Copper II oxide, Copper II hydroxide, granulated copper, basic copper carbonate)
- DDAC
- ADBAC/BKC
- DDACarbonate

It is to be noted that there are no PT8 authorized products (against both wood infesting insects and fungi) containing a single active substance that belongs to the above list. On the contrary, the above active substances are contained only in mixtures with other approved active substances in the PT8 authorized products.

Though it can be concluded that none of the above listed active substance can substitute polymeric betaine alone, considering the authorised products, a combination of two or more of these active substances, covering the same target organisms/uses as polymeric betaine, may be an alternative.

2.3. BPC opinion on the application for approval of the active substance polymeric betaine in product type 8

In view of the conclusions of the evaluation, it is proposed that polymeric betaine be approved

and included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 100% w/w (UVCB)

2. Polymeric betaine is considered a candidate for substitution in accordance with Article 10(d) of the BPR.

3. The authorisations 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. STP, surface water, sediment, soil and groundwater for UC1 and UC2.

    c. In view of the risks identified for surface water, sediment, soil and groundwater during industrial impregnation and storage of wood intended for UC1 and UC2, labels and, where provided, safety data sheets of biocidal products shall indicate that:

        i. All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

        ii. During the application phase: Prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);

        iii. Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.

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 polymeric betaine shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the BPR.

5. Member States competent authorities or, in the case of a union authorisation, the Commission shall specify in the summary of the biocidal product characteristics of a biocidal product containing polymeric betaine the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of the BPR.

6. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 and Regulation (EC) No 396/2005 shall be verified, and any appropriate risk

management measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance does not fulfil the criteria according to Article 28(2)(a)(b) to enable inclusion in Annex I of the BPR, since polymeric betaine meets the criteria for classification according to Regulation (EC) No 1272/2008 as corrosive of category 1C, skin sensitiser, human reproductive toxicant of category 2, toxic to aquatic life of acute category 1 and fulfils substitution criteria set out in Article 10(1) of the BPR as it is vP and T.

2.4. Elements to be taken into account when authorising products

1. The active substance polymeric betaine 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 either national or Union authorisation.

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

    - If an unacceptable risk is identified for industrial and/or 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.

3. For products that may lead to residues in food or feed a dietary risk assessment has to be performed at product authorization level.

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 polymeric betaine.

o0o