

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

Opinion on the application for approval of the active substance:

**Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with  
chloroacetic acid**

**Product type: 2**

ECHA/BPC/076/2015

Adopted

8 December 2015



## Opinion of the Biocidal Products Committee

### on the application for approval of the active substance Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid 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 approval in product type 2 of the following active substance:

<b>Common name:</b>	<b>Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid</b>
<b>Chemical name(s):</b>	<b>Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid</b>
<b>EC No.:</b>	<b>N/A</b>
<b>CAS No.:</b>	<b>139734-65-9</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 an application by Evonik Industries AG (formerly Goldschmidt GmbH) on 30<sup>th</sup> July 2007, the evaluating Competent Authority Ireland submitted an assessment report and the conclusions of its evaluation to the Commission on 30<sup>th</sup> August 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: BPC member for Ireland**

The BPC opinion on the approval of the active substance Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid in product type 2 was adopted on 8 December 2015.

The BPC opinion was adopted by consensus.

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that the Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid 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 Amines, N-C<sub>10</sub>-C<sub>16</sub>-alkyltrimethylenedi-, reaction products with chloroacetic acid, which is also known under the synonym Ampholyt, in product type 2. Ampholyt acts by a relatively unspecific mode of action. As an amphoteric surfactant part of the mode of action includes surface activity with the cell or viral surfaces. The charged character of the molecule, amphoteric agents effectively bind to cellular or viral surfaces, and disrupt the barrier that ensures impermeability. The surfactant mixture is considered to be a UVCB substance (substance of Unknown, Variable Composition, or Biological origin). The active substance is considered to be made up of ~24 individual components having long chain alkanes (C<sub>10</sub>-C<sub>16</sub> with C<sub>12</sub> and C<sub>14</sub> predominating) with amine, or amine and carboxyl functional groups. The individual components and specification ranges for the components that make up the active substance are reported. A minimum specification content of 100% w/w for total active substance was determined for the dry purified active substance material (TC). The specification range for the technical material as manufactured (TK) is 16–22% w/w (average of 19% w/w) for total active substance content in aqueous solution. 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. A number of physical and chemical properties could not be experimentally determined because of the surfactant properties of the active substance and some properties for the individual components have therefore been determined by QSAR. The substance is not considered flammable, explosive or oxidising.

Analytical methods are available for the active substance as manufactured. The HPLC-CAD method is used to determine all components of the active ingredient in Ampholyt, except the HPLC-UV method for acetic acid and a method will be required for the analysis of water content. Ampholyt is a UVCB substance and therefore does not contain impurities as such. Analytical methods are available for the relevant matrices that include soil, drinking water, food of plant and animal origin (meat, milk, fat, wine and beer), however deficiencies remain relating to some of the components of the active substance and further method validation will be required as the applicant has only used a single ion transition for method validation. The applicant should validate the lead components for an additional ion transition.

No harmonised classification for Ampholyt is available according to regulation (EC) No 1272/2008. A CLH dossier will be submitted to ECHA by the evaluating CA by 2016.

The proposed classification and labelling for Ampholyt 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 Tox Cat. 4, *H302 Skin Corrosion, Cat. 1, *H314 STOT RE Cat. 1, *H372 Repr. Cat. 2, *H361f Aquatic Acute Cat. 1, *H400 Aquatic Chronic Cat. 1, *H410
<b>Labelling</b>	
Pictograms	GHS05, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H302 Harmful if swallowed H314 Causes severe skin burns and eye damage H361f Suspected of damaging fertility H372 Causes damage to (eyes, mesenteric lymph nodes, male/female genital systems) through prolonged or repeated exposure H410 Very toxic to aquatic life with long lasting effects EUH401 To avoid risks to human health and the environment, comply with the instructions for use
<b>Specific Concentration limits, M-Factors</b>	
	M = 10 (acute) M = 1 (chronic)

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

Ampholyt is used as a hard surface disinfectant in hospitals, institutional and industrial areas (including public health areas) by professionals to prevent the spread of various micro-organisms. The spectrum of antimicrobial activity is focused on the destruction of gram-positive and gram-negative bacteria, yeasts, as well as a limited virucide activity against enveloped viruses and against the non-enveloped adenovirus. The effectiveness of Ampholyt observed in tests under a range of conditions on bacteria, moulds and viruses to demonstrate innate activity of the active substance against a selection of representative target organisms, indicative effective concentrations in the ranges 0.125-0.5%, 0.125-0.25% and 0.2-1.0% respectively.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the data provided in support of the efficacy of the accompanying product, establishes that the products containing the active substance are expected to be efficacious. Specific resistance to Ampholyt has not been recorded to date and is not expected due to the relatively unspecific mode of action of amphoteric, which is at least partly based on surface activity.

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

#### **Human health**

Ampholyt is harmful when administered by the acute oral route and was determined to have a rat oral LD50 value between 300 and 2,000 mg/kg body weight. When administered repeatedly by the oral route, repeated dose studies on the 90-day rat study, the 90-day dog study and the two year mouse study indicate Ampholyt can cause damage to organs (eyes, mesenteric lymph nodes, male/female genital systems) through prolonged or repeated exposure. Toxicological studies carried out on Ampholyt indicate that the substance is corrosive based on in vivo corrosivity and irritation studies on rabbit. Based upon the results of the 90 day dog dietary study and 18 month mouse dietary study Ampholyt may also potentially affect fertility.

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>Safe use for scenario</b>
Spraying: Mixing and loading	Primary exposure: handling containers and diluting with water for low pressure spraying.	Prof.	Safe use identified at Tier II
Spraying: Application	Primary exposure: application by low pressure spraying. Application time assumed: 30 minutes. Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	Safe use identified at Tier II
Spraying: Post Application	Primary exposure: Wash-down, disposal of the remaining cleaning solution/waste water and disposal of empty containers. Post- application time assumed: 9 minutes. Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	Safe use identified at Tier II
Spraying: Combined exposure	Primary exposure: mixing and loading, application and post application (coveralls and gloves, 10%) for low-pressure spraying.	Prof.	No safe use identified when combined with PPE
Mopping exposure	Primary exposure: application by mop. For mopping a total exposure time of 135 minutes was used to encompass all three scenarios (i.e. mixing and loading, application and post-application). Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	Acceptable use identified at Tier II
Wiping exposure	Primary exposure: application by wiping with cloth. For wiping a total exposure time of 220 minutes was used to encompass all three scenarios (i.e. mixing and loading, application and post-application). Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	No acceptable use identified
RTU: Combined exposure from spraying by RTU	Primary exposure: application and post application of ready-to-use trigger spray.. Wash-down, disposal of the remaining cleaning solution/waste water and disposal of empty containers. Application time assumed: 30 minutes (total exposure including application and post-application). Wiping step: 15 minutes. Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	Acceptable use identified at Tier II
Secondary exposure	Secondary exposure: child in contact (oral and dermal exposure) with residues following disinfection procedure.	Child	Risk identified.

Skin and eye corrosive properties were observed in the tests using Ampholyt. Therefore, the classification of Ampholyt as H314 "Causes severe skin burns and serious eye damage", according to CLP Regulation 1272/2008, warrants the incorporation of a qualitative local risk assessment to address the potential risks associated with its use to the skin and to the eye. Study data suggests that the technical active substance and products may cause corrosion to skin and eyes under the normal conditions of use through the mixing and loading phase of an application process. The use of PPE including protective eyewear is recommended because of corrosive and irritant local effects.

For professional users exposure to Ampholyt was evaluated for the scenarios summarized in the table above.

- Spraying application

For spraying, in the tier II assessment, considering the use of appropriate PPE (coveralls and gloves, 10%) acceptable risks were identified for all individual phases of the scenarios that include mixing and loading, application and post application. Unacceptable risks were identified for professionals when all phases were combined (mixing/loading, application and post-application).

- Ready-to-use (RTU) trigger spray spot application

For professional users application by RTU trigger spray is acceptable for all phases (application and post-application) when combined, providing appropriate PPE (coveralls and gloves, 10%) is used.

- Mopping application

For mopping the combined application of all phases of the scenario were assessed for professionals only; the timing of 135 minutes was calculated for mixing and loading (10 minutes), application and post application (110 minutes) and wiping step (15 minutes). An acceptable risk was identified for the mopping tier II assessment, considering all the exposure scenario steps and the use of PPE (coveralls and gloves, 10%).

- Wiping application

For wiping the combined exposure of all phases of the scenario were assessed for professionals; the exposure time of 220 minutes was calculated for mixing and loading, application and post application. Unacceptable risks were identified for the wiping tier II assessment, considering all the scenario steps and the use of PPE (coveralls and gloves, 10%).

A risk of secondary exposure is identified based on the worst case exposure of a crawling child on a floor in contact (oral and dermal exposure) with residues following hard surface disinfection. For industrial application scenarios this situation of a crawling child is not considered appropriate. However, where the application is intended for institutional areas (public health areas) the scenario is considered appropriate such as in waiting rooms or other treated public areas.

## **Environment<sup>1</sup>**

The table below summarises the exposure scenarios assessed.

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<sup>1</sup> WG III Environment 2014 agreed that two Koc values should be applied from the available data across the Ampholyt mixture. The worst-case adsorptive Koc value (106 L/kg) and the worst-case ionic Koc value (15,432 L/kg) were used for the for the environmental risk assessment.

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Safe use for scenario
Industrial areas	Disinfection of surfaces by spraying or ready-to-use (RTU) trigger spray. Waste water emission to STP (sewage treatment plant). Emissions to surface water, soil and groundwater via STP. RTU spot treatment application was carried out at 10% of the default surface area, equivalent to 100 m <sup>2</sup> .	Acceptable use identified for RTU, except for the sediment compartment for the lower Koc-value.  No acceptable use identified for large-scale application (e.g. spraying)
Institutional (sanitary) areas (includes medical facilities)	Disinfection of surfaces by spraying or ready-to-use (RTU) trigger spray. Waste water emission to STP. Emissions to surface water, soil and groundwater via STP. RTU scaling approach for the tonnage-based calculations utilising tonnage data of RTU product.	Acceptable use identified for RTU, except for the sediment compartment for the lower Koc-value.  No acceptable use identified for large-scale application (e.g. spraying)

- Industrial areas

Acceptable risks were identified for the STP and groundwater compartments for Ampholyt when used in industrial areas. An acceptable risk was also identified for the soil compartment for the lower Koc-value. However, risks were identified for the surface water and sediment compartments in the environment for industrial areas. A risk was also identified for the soil compartment at the higher Koc-value.

Biocidal products containing the active substance, Ampholyt, should not be applied by low-pressure spraying to industrial areas where direct releases of the active substance to sediment, surface water and soil (high Koc) cannot be prevented and/or where safe releases of the active substance to these relevant environmental compartments cannot be identified.

- Ready-to-use (RTU) spot treatment application in industrial areas

Acceptable risks were identified for the environmental compartments where RTU spot treatment application is made in industrial areas. An unacceptable risk slightly exceeding the trigger value of one was identified for the sediment compartment at the lower Koc-value. However, given the assessment for sediment using conservative and contrasting Koc values, based on the refinement and risk mitigation measures outlined below this is considered an acceptable use.

Whilst an unacceptable risk was identified with a slight exceedance of the trigger value, this identified risk is considered acceptable even though the risk ratio is just above 1. Indeed, appropriate risk mitigation measures, based on ECHA Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 2 (2014), relating to the disposal via solid waste would minimise or eliminate releases to water and the sediment compartment. If the product is either restricted to use in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product is removed by disposable cloths or wipes that are disposed of as waste, emissions to waste water from wet cleaning of treated surfaces would be eliminated.

Where pre-treatment/disposal risk mitigation measures are carried out for industrial areas risks were further reduced in all compartments and to acceptable levels for the sediment compartment in industrial areas.

- Institutional areas (includes medical facilities)

Acceptable risks were identified for the STP, soil and groundwater compartments for Ampholyt when the substance is used in institutional areas (including medical facilities). At the higher Koc value an additional safe use was also identified for surface water in

institutional areas. However, risks were identified for the sediment compartment following application in institutional facilities and also for surface water for the lower Koc value.

The risks identified for the institutional areas may be mitigated against and reduced with feasible measures given the control of waste from areas such as hospitals and other sanitary sectors (which include licensing in some MS). Such mitigation measures identified based on ECHA Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 2 (2014) involve disposal strategies and pre-treatment methods, such as separation, traps, settling, pre-treatments (digestion, neutralisation) and containment of the emissions to the institutional facility.

Biocidal products containing the active substance, Ampholyt, should not be applied by low-pressure spraying to institutional areas where direct releases of the active substance to sediment and surface water (low Koc) cannot be prevented and/or where safe releases of the active substance to these relevant environmental compartments cannot be identified.

- Ready-to-use (RTU) Institutional areas (includes medical facilities)

Acceptable risks were identified for the environmental compartments where RTU spot treatment application is made in institutional areas when based on the scaling of tonnages, except for a risk identified for the sediment compartment for the low Koc value.

Indeed, appropriate risk mitigation measures, based on ECHA Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 2 (2014), relating to the disposal via solid waste would minimise or eliminate releases to water and the sediment compartment. If the product is either restricted to use in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product is removed by disposable cloths or wipes that are disposed of as waste, emissions to waste water from wet cleaning of treated surfaces would be eliminated. As such, biocidal products containing the active substance, Ampholyt, should not be applied by low-pressure spraying to institutional areas where direct releases of the active substance to sediment and surface water (low Koc) cannot be prevented and/or where safe releases of the active substance to these relevant environmental compartments cannot be identified.

The risk of secondary poisoning after the application of Ampholyt in all scenarios is not considered to be of concern for the aquatic or terrestrial food chain owing to Ampholyt being both highly water-soluble and readily biodegradable in the environment.

## **General conclusion**

A safe use for human health and environment is identified only for ready-to-use (RTU) products used in industrial and institutional areas provided the product is used in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product is removed by dry or damp cloths that are disposed of as waste. Where process residues resulting from RTU use occur in wet cleaned areas these process wastes have to be transferred to an on-site facility pre-treatment processes before discharge into on-site or municipal STPs.

## **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	Ampholyt does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	Repr. Cat. 2 (H361f)	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	Ampholyt 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	Effects on organ systems in studies with Ampholyt suggest a systemic toxicity mediated by perturbations in the lymphatic system. The male and female genital systems are not selectively impacted but rather are part of a group of organs impacted by Ampholyt's systemic toxicity. Ampholyt is not considered to have endocrine disrupting properties. Ampholyt does not fulfil criterion (d) of Article 5(1)		
Respiratory sensitisation	No classification required. Ampholyt does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects	Ampholyt does not fulfil criterion (e) of Article 10 (1)		
Proportion of non-active isomers or impurities	A minimum specification content of 100% w/w for total active substance was determined for the dry purified active substance material. Given this, Ampholyt does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Ampholyt 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" agreed at the 54<sup>th</sup> meeting 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<sup>2</sup>. 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**

Ampholyt does not fulfil criteria for being a persistent organic pollutant (POP).

Ampholyt does not have potential for long-range transboundary atmospheric transport.

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

In view of the conclusions of the evaluation, it is proposed that Amines, N-C10-C16-alkyltrimethylenedi-, reaction products with chloroacetic acid (Ampholyt) 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: The active substance as manufactured is an aqueous solution of 160-220 g/kg (16-22 %, by wt) solution of Ampholyt. The theoretical (calculated) dry weight specification: minimum purity of Ampholyt is 1000 g/kg (100.0 %, by wt).
2. 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 use 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. professional users;
    - ii. children for products used in institutional areas;
    - iii. surface water and sediment for products used in industrial or institutional areas;
    - iv. soil for products used in industrial areas.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

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

1. Where large-scale spraying application is assessed for the industrial scenario, the technical and procedural mitigation measures for the control of residues from industrial areas should be considered; this may include the licensing of facilities in some Member States. It may also include such mitigation measures identified in the ECHA Transitional Guidance on Evaluation of Environmental Risk Mitigation Measures for Disinfectants Product Type 2 (Disinfectants and algaecides not intended for direct application to humans or animals) (2014) that involve disposal strategies and pre-treatment methods, such as separation, traps, settling, pre-treatments (digestion, neutralisation) and containment of the emissions to the industrial facility.

<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>)

2. Risks identified in the sediment compartment during the environmental assessment may need to be re-considered based on additional data that is likely to be available at product authorisation and which may alleviate the risk to sediment. This is especially the case since in addition the sediment assessment was based on equilibrium partitioning with low and high K<sub>oc</sub> values applied across the entire mixture of Ampholyt.
3. 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:
  - 3.1. If an unacceptable risk for industrial and professional users is identified for the concerned 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.
  - 3.2. An unacceptable risk for professional users is identified for products applied by spraying or wiping. 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.
  - 3.3. If an unacceptable risk is identified for children following secondary exposure in institutional areas, labels, and where provided, safety data sheets, should indicate that products used in institutional areas shall be restricted to areas not accessible to children.
  - 3.4. If an unacceptable risk is identified for surface water, sediment and soil labels, and where provided, safety data sheets, should indicate that use of products for disinfection of institutional areas (including medical facilities) and/or of industrial areas shall be restricted to uses where direct release via waste water to aquatic system is prevented. In addition, the use of products shall be restricted to uses in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product shall be removed by dry or damp cloths that are disposed of as waste. The effectiveness of these risk mitigation measures should be demonstrated by supporting information.
  - 3.5. For RTU products the following has to be considered: i) where process residues resulting from RTU use occur in wet cleaned areas it should be ensured that these process wastes are transferred to the on-site facility pre-treatment processes before discharge into on-site or municipal STPs unless it can be demonstrated that risks (to the surface water and sediment) can be reduced to an acceptable level; and ii) RTU products should be used in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product is removed by disposable cloths or wipes that are disposed of as waste unless it can be demonstrated that risks (to the surface water and sediment) can be reduced to an acceptable level. The effectiveness of these risk mitigation measures should be demonstrated by supporting information.

## **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 Ampholyt. However, further data shall be required as detailed below:

The data should be provided to the evaluating Competent Authority (Ireland) as soon as possible but no later than 6-months before the date of approval of the active substance.

### **2.5.1. Physical and chemical properties**

The applicant needs to confirm their specification proposals for the C10 components

(including C10-diGly) in the active matter. The C10 components were not analysed as part of the 7-batch analysis.

The applicant shall provide a study or make a statement in relation to the corrosivity of Ampholyt to metals.

### **2.5.2. Methods of analysis**

The applicant should provide further validation of the active substance in the technical material as manufactured regarding the HPLC-CAD method. Following deficiencies should be addressed: the use/synthesis of certain reference standards for method validation and the lack of validation data for a number of components which are considered to be part of the active substance.

The applicant shall provide a validated method of analysis for water in the technical material as manufactured. The applicant should also experimentally determine the LOQ of acetic acid down to a level of 0.9% w/w for the HPLC-UV method.

The applicant shall provide validation data for a second ion transition for the "three lead components" included in the residue analysis method and definition for monitoring in soil and drinking water. Additionally, the applicant needs to provide a validated method of analysis for sediment, body fluids and tissue (the LOQ should allow determination at the NOAEL).