Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Amines, N-C_{10}–C_{16}-alkyltrimethylenedi-, reaction products with chloroacetic acid

Product type: 4

ECHA/BPC/077/2015

Adopted

8 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid for product type 4

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 4 of the following active substance:

Common name:	**Amines, N-C_{10}–C_{16}-alkyltrimethylenedi-, reaction products with chloroacetic acid**
Chemical name(s):	**Amines, N-C_{10}–C_{16}-alkyltrimethylenedi-, reaction products with chloroacetic acid**
EC No.:	**N/A**
CAS No.:	**139734-65-9**
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

Following the submission of an application by Evonik Industries AG (formerly Goldschmidt GmbH) on 30th July 2007, the evaluating Competent Authority Ireland submitted an assessment report and the conclusions of its evaluation to the Commission on 30th 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_{10}–C_{16}-alkyltrimethylenedi-, reaction products with chloroacetic acid in product type 4 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_{10}–C_{16}-alkyltrimethylenedi-, reaction products with chloroacetic acid in product type 4 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-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid, which is also known under the synonym Ampholyt, in product type 4. 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, amphotheric 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_{10}-C_{16} with C_{12} and C_{14} 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 submission to ECHA will be submitted in 2016 by the evaluating CA.

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

Classification according to the CLP Regulation	
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
Labelling	
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
Specific Concentration limits, M-Factors	M = 10 (acute) M = 1 (chronic)

b) Intended use, target species and effectiveness

Ampholyt is used as a hard surface disinfectant in treatments to surfaces, walls, and floors in industrial food and feed preparation 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 viruicide 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 amphoterics, 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.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Safe use for scenario**
Spraying: Mixing and loading	Primary exposure: handling containers and diluting with water for low pressure spraying. Low-pressure spraying: Spray Model 1 (TNsG 2002) incorporates mixing and loading with an exposure time combining mixing and loading and application of 120 min. Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	No acceptable use identified at 120 mins and Tier II PPE
Spraying: Application	Primary exposure: application by low pressure spraying. Application time assumed: 120 minutes (mixing and loading and application combined). Tier I with no PPE. Tier II with PPE (coveralls and gloves, 10%).	Prof.	No acceptable use identified at 120 mins and Tier II PPE
Spraying: Post Application	Primary exposure (low-pressure spraying): 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.	Acceptable 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 acceptable 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. Application: Model TNsG Consumer Spraying and Dusting Model 2 – hand held 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 (Surface disinfection model 1): 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

In the tier II assessment for low-pressure spraying, considering the use of appropriate PPE (coveralls and gloves, 10%) acceptable risk were identified for post-application processes; but risks were identified for individual phases of the scenarios for mixing and loading, and application. Risks were identified for professionals when all phases were combined (mixing/loading, application and post-application) for the spraying scenario.

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

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

- Mopping application

For mopping the combined application of all phases of the scenario was assessed for professionals only; the timing of 135 minutes was calculated for mixing and loading (10 minutes), application and post application (125 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 application combined application of all phases of the scenario were assessed for professionals; the timing of 220 minutes was calculated for mixing and loading, application and post application. Risks were identified for the wiping tier II assessment, considering all the scenario steps and the use of PPE (coveralls and gloves, 10%).

Currently there is no guidance available for conducting dietary risk assessments and it is proposed that issues relating to dietary risk are undertaken at product authorisation.

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. However, for industrial application scenarios this situation of a crawling child is not considered appropriate.

Environment[1]

The table below summarises the exposure scenarios assessed.

[1] 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**
Food, drink and milk industries (FDM): on-site STP	Waste water emission to on-site STP (sewage treatment plant). Emission to surface water via on-site STP.	No acceptable use identified for large-scale application (e.g. spraying)
Food, drink and milk industries (FDM): off-site STP	Waste water emission to STP. Emission to surface water, soil and groundwater via STP.	No acceptable use identified for large-scale application (e.g. spraying)
Slaughterhouses	Waste water emission to STP. Emission to surface water, soil and groundwater via STP. RTU spot treatment application was carried out at 10% of the default surface area, equivalent to 1000 m^2.	No acceptable use identified for the RTU product and large-scale application (e.g. spraying)
Large scale catering kitchens	Waste water emission to STP. Emission to surface water, soil and groundwater via STP. RTU spot treatment application was carried out at 10% of the default surface area, equivalent to 200 m^2.	Acceptable use identified for RTU. No acceptable use identified for large-scale application (e.g. spraying)
Milking parlour system	Waste water emission to STP. Emission to surface water, soil and groundwater via STP.	No acceptable use identified for large-scale application (e.g. spraying)

- FDM industries (with on-site and off-site STP)

Risks were identified for FDM industries where there is an on-site STP for the surface water and sediment. Where waste water is released from FDM industries to an off-site STP risks were identified for surface water, sediment and the soil compartments.

As such, biocidal products containing the active substance, Ampholyt, should not be applied in FDM industries where safe releases of the active substance to the relevant environmental compartments cannot be identified.

- Slaughterhouses/butcheries and large-scale catering kitchens/canteens

Risks were identified for the STP, surface water, sediment and soil compartments when the product is used in slaughterhouses (including butcheries) and large-scale catering kitchens. However, an acceptable risk was identified for the STP for emissions from large-scale catering kitchens/canteens.

Nonetheless, for large scale kitchens/canteens where low-pressure spraying is applied appropriate risk mitigation measures may help to reduce the identified risks to acceptable levels. As such, biocidal products containing the active substance, Ampholyt, should not be applied in large scale kitchens where safe releases of the active substance to an STP cannot be identified.

Additionally, for slaughterhouses (including butcheries) the risks identified could be mitigated against and reduced with feasible measures given the significant level of waste control from the meat processing sector (which include licensing in some MS). Mitigation measures that could be employed by large-scale slaughterhouses and butcheries, based on ECHA Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 4 (2014), may involve relevant treatment and/or disposal strategies and methods, such as separation, traps, settling, pre-treatments (digestion, neutralisation) and

containment of the emissions to the slaugtherhouse/butchery facility. As such, biocidal products containing the active substance, Ampholyt, should not be applied in areas of large-scale meat processing where safe releases of the active substance to the relevant environmental compartments cannot be identified.

- Ready-to-use (RTU) spot treatment application in slaughterhouses (including butcheries) and large-scale catering kitchens/canteens

RTU - Large-scale catering kitchens/canteens

Acceptable risks were identified for the environmental compartments where RTU spot treatment application is made in large scale catering kitchens/canteens. An unacceptable risk slightly exceeding the trigger value of one was identified for the sediment compartment at both Koc-values. 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 for sediment, the identified risk is considered acceptable even though the risk ratios are just above the trigger value of 1. Indeed, appropriate risk mitigation measures, based on ECHA Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 4 (2014), relating to the disposal of residues 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 large-scale kitchens/canteens risks were further reduced in all compartments and to acceptable levels for the sediment compartment in large-scale catering kitchens.

RTU - Slaughterhouses and butcheries

Risks were identified for the surface water (low Koc value only) and sediment compartments of the environment when RTU spot treatments are applied in slaughterhouses. Acceptable risks were identified for the STP, soil, groundwater and surface water (high Koc value only) compartments. Following the application of risk mitigation measures based on pre-treatment elimination of the active substance prior to release via drains a risk was still identified for slaughterhouses in the sediment compartment for the low Koc value. As such, biocidal products containing the active substance, Ampholyt, should not be applied in slaughterhouses where safe releases of the active substance to the relevant environmental compartments cannot be identified.

- Milking parlour systems

Acceptable risks were identified for the STP, soil and groundwater compartments for Ampholyt when used in milking parlour systems.

A risk was identified for milking parlours as a result of exposure to the surface water and sediment compartments when water is released from the milking parlour system. Risk mitigation measures could be applied for the surface water and sediment compartments of the environment by directing emissions from milking parlours to slurry/manure tanks to ensure that waste water is collected and removed to the slurry tank or manure storage. However, as this was not assessed, biocidal products containing the active substance, Ampholyt, should not be applied to milking parlours where direct releases of the active substance to surface water cannot be prevented and/or where safe releases of the active substance to an STP 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 large scale kitchens and canteens as 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 the 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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">Ampholyt does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>Repr. Cat. 2 (H361f)</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Not P or vP</td><td rowspan="3">Ampholyt does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Not B or vB</td></tr>
<tr><td>Toxic (T)</td><td>T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">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 not have endocrine disrupting properties. Ampholyt does not fulfil criterion (d) of Article 5(1)</td></tr>
<tr><td>Respiratory sensitisation</td><td colspan="3">No classification required. Ampholyt does not fulfil criterion (b) of Article 10(1)</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Ampholyt does not fulfil criterion (e) of Article 10 (1)</td></tr>
</table>

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 54th 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[2]. 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 4

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. surface water and sediment for products used in: i) food, drink and milk industry sites; ii) milking parlours; iii) slaughterhouses and butcheries and iv) large scale catering kitchens and canteens;

[2] 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)

iii. soil for products used in i) food, drink and milk industry sites; ii) slaughterhouses and butcheries and iii) large scale catering kitchens and canteens.

c. 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 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken into account to ensure that the applicable MRLs are not exceeded.

d. Products containing Ampholyt shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of Ampholyt into food or it has been established pursuant to that Regulation that such limits are not necessary.

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. When authorising products containing Ampholyt Member States will need to determine the potential risk presented following secondary exposure to contaminated food or food products.

2. Where large-scale spraying application is assessed for the FDM industry sites scenario, the technical and procedural mitigation measures for the control of residues from FDM sites 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 4 (Food and feed area) (2014) that involve disposal strategies an dpre-treatment methods, such as separation, traps, settling, pre-treatments (digestion, neutralisation) and containment of the emissions to the FDM.

3. 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 Koc values applied across the entire mixture of Ampholyt.

4. 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:

   4.1. 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.

   4.2. 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.

   4.3. If an unacceptable risk is identified for the surface water, sediment and/or soil, labels, and where provided, safety data sheets, should indicate that use of products applied by spraying shall be restricted to uses where direct release via waste water to aquatic system is prevented.

4.4. For RTU products the following has to be considered: i) where process residues resulting from RTU used for spot treatment applications in large scale catering kitchens or canteens or in slaughterhouses and butcheries, 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 used for spot treatment applications in large scale catering kitchens or canteens or in slaughterhouses and butcheries 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 RMM 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 must 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 should 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 needs to 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 should 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 full validated method of analysis for sediment, body fluids and tissue (the LOQ should allow determination at the NOAEL).

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