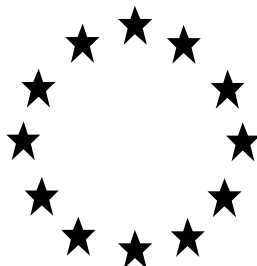


Competent Authority Report
Programme for Inclusion of Active Substances in
Annex I to Council Directive 98/8/EC



**Amines, N-C10–C16-alkyltrimethylenedi-,
reaction products with chloroacetic acid;
Ampholyt (PT 2, 3, 4)**

CAS-No. 139734-65-9

DOCUMENT IIIA (A8, A9 & A10)

Evaluation Report

Rapporteur: Ireland

April 2015

Ampholyt (PT 2, 3, 4)

Document A8-A10

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Section A8
Annex Point IIA8

Measures to be adopted to protect man, animals and the environment

Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA, 8.8.1)

Handling

Reference A8.1/01:

Anonymous (2007): Safety data sheet according to 93/112/EC – version 3.2, Ampholyt 20. Goldschmidt GmbH, May 23, 2007 (update September 1, 2006).

Handling precaution: No special precautions are necessary if used as recommended in the user instructions.

Protection against fire and explosion:

Not applicable.

Personal risk precaution:

Hygiene measures:

No smoking, eating or drinking at the place of work. Hands should be washed before breaks and at the end of the shift.

Respiratory protection:

Not required.

Hand protection:

Safety gloves of PVC.

Eye protection:

Good closing protective goggles.

Skin and body protection:

Facile protective work clothing.

Storage

Keep container close.

Storage class (VCI): 12

Official
use only

Section A8
Annex Point IIA8

Measures to be adopted to protect man, animals and the environment

		Official use only
Transport	<p><u>Land transport</u></p> <p>ADR: Class 9 Packaging group III Orange plate Hazard No. 90 UN-number 3082 Designation of goods environmentally hazardous substance, liquid, N.O.S surfactant)</p> <p>(amphoteric Transport label 9 miscellaneous dangerous goods</p> <p>RID: Class 9 Packaging group III Orange plate Hazard No. 90 UN-number 3082 Designation of goods environmentally hazardous substance, liquid, N.O.S surfactant)</p> <p>(amphoteric Transport label 9 miscellaneous dangerous goods</p> <p><u>Inland waterway transport</u></p> <p>ADNR: Class 9 Classification code M6 UN-number 3082 Designation of goods environmentally hazardous substance, liquid, N.O.S surfactant)</p> <p>(amphoteric Transport label 9 miscellaneous dangerous goods</p> <p><u>Sea transport</u></p> <p>IMDG: Class 9 Packaging group III UN-number 3082 EMS F-A-S-F Exact technical name environmentally hazardous substance, liquid, N.O.S surfactant)</p> <p>(amphoteric Transport label 9 miscellaneous dangerous goods</p> <p><u>Air transport</u></p> <p>ICAO/IATA: Class 9 Packaging group III UN-number 3082 Exact technical name environmentally hazardous substance, liquid, N.O.S surfactant)</p> <p>(amphoteric Transport label 9 miscellaneous dangerous goods</p>	

Section A8
Annex Point IIA8

Measures to be adopted to protect man, animals and the environment

		Official use only
Fire	<p>Extinguishing media: Foam, carbon dioxide, dry powder, water spray.</p> <p>Extinguishing media which must not be used for safety reasons: not applicable</p> <p>Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:</p> <p style="padding-left: 40px;">In case of fire the following can develop: Oxides of carbon; oxides of nitrogen.</p> <p>Special protective equipment for fire-fighters: Protective respirator with independent air supply.</p>	
In case of fire, nature of reaction products, combustion gases, etc. (IIA, 8.8.2)	Specific hazards: carbon monoxide, carbon dioxide, nitrogen oxides.	
Emergency measures in case of an accident (IIA, 8.8.3)		
Protection of emergency workers and bystanders	Wear protective clothing	
Accidental release measures	<p><u>Personal precautions:</u> Use personal protective clothing.</p> <p><u>Environmental precautions:</u> Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater.</p> <p><u>Methods for cleaning up or taking up:</u> Contain and adsorb using earth, sand or other inert material. Collected material disposed according to regulations.</p>	
First aid measures	<p><u>General advice:</u> Take off immediately all contaminated clothing.</p> <p><u>If inhaled:</u> Remove to fresh air.</p> <p><u>On skin contact:</u> Wash immediately with plenty of water. If irritation develops, seek medical attention.</p> <p><u>On contact with eyes:</u> Immediately wash affected eyes efficiently under running water; consult an eye specialist.</p> <p><u>On ingestion:</u> Seek medical attention and present packing or label.</p>	

Section A8
Annex Point IIA8

Measures to be adopted to protect man, animals and the environment

Possibility of destruction or decontamination following release to: (IIA, 8.8.4)

- | | |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| a) Air | Not relevant due to limited volatility. |
| b) Water | Do not allow product to reach ground water, water course or sewage system, as it is very toxic to aquatic organisms and causes adverse effects in the aquatic environment. |
| c) Soil | Avoid contamination of soil as product is not allowed to drip in the ground water. |

Procedures for waste management of the active substance for industry and professional users (IIA, 8.8.5)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Possibility of re-use or recycling (IIA, 8.8.5.1) | Re-use or recycling is not foreseen. |
| Possibility of neutralisation of effects (IIA, 8.8.5.2) | Rinsing with plenty of water is appropriate to neutralise the effects of Ampholyt 20. |
| Conditions for controlled discharge including leachate qualities on disposal (IIA, 8.8.5.3) | Ampholyt 20 is washed off after use and directed to the STP, where it is readily biodegraded. Avoid disposal of the product in soil, water and canalisation. All attempts should be made to use this product completely, in accordance with its intended use and its recommended application rate, than no significant failures in ecological process and balance are expected. |
| Conditions for controlled incineration (IIA, 8.8.5.4) | Mixing with combustible liquids and supply to a suitable incineration plant. |
| Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms (IIA, 8.8.6) | When applied according to use instructions, the usage of Ampholyt 20 is considered to be safe.
No cases of observations on undesirable or unintended side-effects of the product Ampholyt 20 are known to the applicant. |

Official
use only

Section A8
Annex Point IIA8

Measures to be adopted to protect man, animals and the environment

Identification of any substances falling within the scope of List I or II of the Annex to Directive 80/68/EEC (IIIA, 8.1)	None	Official use only
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Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
Date	EVALUATION BY RAPPORTEUR MEMBER STATE (*) <i>01/07/2013</i>	
Materials and Methods	Not applicable	
Results and discussion	Not applicable	
Conclusion	Not applicable	
Reliability	Not applicable	
Acceptability	Not applicable	
Remarks	The RMS has examined the recommendations put forward by the Applicant and has not found any parts that in light of the assessment of the hazards of the active substance require amendment. However it is the responsibility of the Applicant to comply with legislation relating to labelling for transport etc. Although the RMS has not identified any specific errors in the text, it accepts no responsibility for the accuracy of any of the advice or labelling instructions	
Date	COMMENTS FROM ...	
Materials and Methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A9
Annex Point IIA9

Classification and labelling

Official
use only

Classification proposal

Classification proposal

Symbol(s) and indication of danger:

“Xi” Irritant
“N” Dangerous for the environment

Risk Phrases:

R38 Irritating to skin
R41 Risk of serious damage to eyes
R50 Very toxic to aquatic organisms

Safety Phrases:

S24/25 Avoid contact with skin and with eyes
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S39 Wear eye/face protection
S60 This material and its container must be disposed of as hazardous waste
S61 Avoid release to the environment. Refer to special instructions/safety data sheet

Justification of the proposals

Symbol(s) and indication of danger:

Xi Required as the substance is “irritating to skin” (R38), recover the “risk of serious damage to eyes”(R41)
N Required as the aquatic toxicity is < 1 mg/l for fish, daphnia and algae.

Risk Phrases:

R38 Derives from results of skin irritation testing in rabbits (A6.1.4) according to classification criteria of Commission Directive 2001/59/EC (OJ L 225)
R41 Derives from results of eye irritation testing in rabbits (A6.1.4) according to classification criteria of Commission Directive 2001/59/EC (OJ L 225)
R50 Derives from observed toxicity to *Brachydanio rerio*, *Daphnia magna* and *Selenastrum capricornutum* (A7.4.1)

Section A9
Annex Point IIA9**Classification and labelling****Labelling proposal****Labelling proposal**

Hazard Symbol(s): Xi, N
Indication of Danger: Irritant, Dangerous for the environment
Risk Phrases: R38, 41, 50
Safety Phrases: S24/25, 26, 39, 60, 61

Packaging**Description of packaging**

Ampholyt 20 is a “product by process”. The active substance as manufactured is a 20% (w/w) aqueous solution of the active ingredient, whereby the pure/technical active substance never occur in another form than as an aqueous solution. The “product by process” is filled automatically from the manufacturing system (batch reactor) via filling machines into polyethylene containers (5, 10, 20, 200 and 1000 kg volume).

Suitability of packaging

Polyethylene containers have been used for the supply of the 20% solution (active substance/ the biocidal product) for decades without any signs of reactions or interaction between container and Ampholyt 20 solution.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Date	EVALUATION BY RAPPORTEUR MEMBER STATE (*) 09/07/2013
Materials and Methods	Not applicable.
Results and discussion	Not applicable
Conclusion	Adopt applicant's version with appropriate revisions outlined in Doc IIA
Reliability	1
Acceptability	acceptable
Remarks	N/A
Date	COMMENTS FROM ...
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 10		SUMMARY AND EVALUATION OF SECTIONS 2 TO 9	
Annex Point IIB, X			
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified []	
Limited exposure []	Other justification [X]		
Detailed justification:	Refer to Document IIA for a summary and evaluation of the data presented in Sections 2 to 9.		
Undertaking of intended data submission []			
Evaluation by Competent Authorities			
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	09/07/2013		
Evaluation of applicant's justification	Agree with applicants justification		
Conclusion	Applicants justification is acceptable		
Remarks	N/A		
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>			
Date	<i>Give date of comments submitted</i>		
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>		
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>		
Remarks			