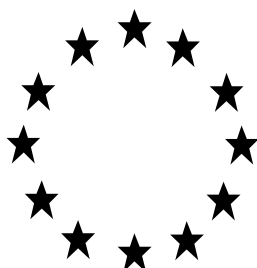


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**DRAFT RISK ASSESSMENT OF A BIOCIDAL
PRODUCT (FAMILY) FOR NATIONAL
AUTHORISATION APPLICATIONS**



Product Family name: Premium Biocidal Product Family

Product names: AquaNet Premium, AquaNet Boost

Product type(s) 21

Dicopper oxide and tralopyril

Case Number in R4BP3: BC-HJ036502-49

Evaluating Competent Authority: Norway

Date: [XX/January/2022]

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1 CONCLUSION

The biocidal product family Premium contains the active substances dicopper oxide and tralopyril. The product family is intended for treatment of fish nets to prevent fouling of the nets during use. The treatment of the net is performed in specialised facilities, and the user categories are industrial users.

It is concluded by the eCA that sufficient data have been provided to fulfil the conditions of Article 19 of regulation (EU) 528/2012. When using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

Toward the end of the evaluation phase, a risk for human health was identified for the product named AquaNet Boost. Therefore, the product named AquaNet Boost was modified, and the amount of active substance content was reduced to an acceptable level. The active substance dicopper oxide was reduced from 24.83%_(w/w) to 21.95%_(w/w). Please note that the studies performed on the old version of AquaNet Boost may be used for some endpoints. It is specified in the text whether the new or old formulation has been used, and the postfix "old" has been added to the name (i.e. "AquaNet Boost_{old}"). In those cases, read across from the old to the new formulation has been evaluated and deemed acceptable. The composition of AquaNet Boost_{old} can be found in the confidential annex.

The identity, physico-chemical properties and analytical methods were adequately addressed. The biocidal product family contains 9.99-21.95%_(w/w) dicopper oxide and 1.96-1.999%_(w/w) tralopyril. The representative products are red in colour with a pH of 8.1. The density of the products is 1.27 g/cm³ for the in-use concentrations. The products have a shelf life of 6 months when stored protected from frost.

The efficacy of the products has been demonstrated through field trials, assessing the efficacy of the net treatment under realistic conditions. The products are deemed to be sufficiently efficacious.

Exposure to human health from the use of the Premium BPF (net treatment as well as net deployment) has been assessed in a tiered approach.

The risk to industrial workers involved in net impregnation activities was assessed using the Dipping model 4 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net dipping tasks. The risk was demonstrated to be acceptable for AquaNet Premium provided that the workers wear coated coveralls and gloves. Safe use could not be demonstrated for AquaNet Boost_{old} even with use of double coveralls and gloves (see above). An acceptable risk was demonstrated with AquaNet Boost with the use of double coveralls and gloves.

The risk to professional workers involved in net deployment activities was assessed using the Handling model 2 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net deployment activities. The risk was demonstrated to be acceptable for AquaNet Premium and AquaNet Boost provided that the workers wear gloves (the indicative hand exposure value in the exposure model was actual measured values inside gloves). Acceptable risk for AquaNet Boost_{old} was demonstrated provided the use of uncoated cotton coveralls (25% penetration) in addition to gloves. Gloves are always worn when performing this task, due to mechanical strain, and in the Atlantic region usually also due to low temperatures.

An acceptable risk was demonstrated in the semiquantitative risk assessment of local effects of tralopyril by inhalation.

Due to the classification of the products for eye damage 1 (H318), protective goggles or similar eye protection should be used for the tasks where the workers may be at risk to be exposed to the product.

Exposure to the environment from the use of the Premium BPF has been assessed in a tiered approach. For the assessment covering use in the EU, the EU fish farm scenario was used. In addition, an assessment with special regard to Norwegian fish farms has been conducted based on the Norwegian fish farm scenario document. This represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway.

In the tier 1 calculations, $PEC_{dissolved}/PNEC_{water}$ ratios were above the trigger value for both Premium BPF products. A refined risk assessment based on PEC values calculated from field data along with a refinement of the mixture toxicity assessment resulted in PEC/PNEC ratios below 1, indicating acceptable environmental risk. As the environmental risk assessment was performed for products with a higher content of dicopper oxide, making use of the risk envelope approach, the AquaNet Boost product is considered covered by this assessment.

2 ASSESSMENT REPORT

2.1 SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1 Administrative Information

2.1.1.1 Identifier of the product / product family

Identifier ¹	Country (if relevant)
Product family: Premium products, consisting of:	NO
AquaNet Premium	
AquaNet Boost	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Steen-Hansen A/S
	Address	Ulsmågveien 24, NO-5224 Nesttun Norway
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Steen-Hansen A/S
Address of manufacturer	Ulsmågveien 24, NO-5224 Nesttun, Norway
Location of manufacturing sites	Same as manufacturer's address

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Dicopper oxide
Name of manufacturer	Spiess-Urania Chemicals GmbH
Address of manufacturer	Frankenstraße 18b 20097 Hamburg Germany
Location of manufacturing sites	c/o Aurubis AG Müggendorfer Hauptdeich 2 20539 Hamburg

Active substance	Tralopyril
Name of manufacturer	JANSEN PMP, a division of Janssen Pharmaceutica NV
Address of manufacturer	Turnhoutseweg 30 B-2340 Beerse Belgium
Location of manufacturing sites	No. 2255, Huanghai Road, Shouguang Bohai Industrial Zone, Shandong, China, 262714 77, Sanupdanji2ro, Uhmo-myeon, Gimcheon-si, Gyung-sangbuk-do, Korea

¹ Please fill in here the identifying product name from R4BP.

2.1.2 Product (family) composition and formulation

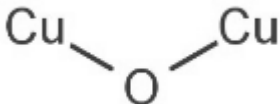
The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

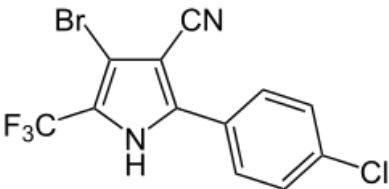
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐

No ☒

2.1.2.1 Identity of the active substances

Main constituent(s)	
ISO name	Dicopper oxide
IUPAC or EC name	Dicopper oxide, copper (1) oxide
EC number	215-270-7
CAS number	1317-39-1
Index number in Annex VI of CLP	029-002-00-X
Minimum purity / content	94.2%
Structural formula	

Main constituent(s)	
ISO name	Tralopyril
IUPAC or EC name	4-bromo-2-(4-chlorophenyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile
EC number	602-784-5
CAS number	122454-29-9
Index number in Annex VI of CLP	N/A
Minimum purity / content	97.5%
Structural formula	

2.1.2.2 Candidate(s) for substitution

None of the active substances, dicopper oxide, and tralopyril are considered as candidates for substitution.

2.1.2.3 *Qualitative and quantitative information on the composition of the biocidal product family*

2.1.2.4 *Family overview*

Overview if the whole biocidal product family

Family name	Type	Cu ₂ O, (% w/w)	Tralopyril, (% w/w)
Premium	Ready to use	9.997-21.95	1.98-1.999

Overview of the meta-SPCs

meta-SPC number	1	2
Product name(s)	AquaNet Premium	AquaNet Boost
In use concentration Cu ₂ O (% w/w)	9.997	21.95
In use concentration Tralopyril (% w/w)	1.999	1.98
Formulation type	SD – Suspension concentrate to be diluted with water (by volume)	SD – Suspension concentrate to be diluted with water (by volume)

Overview of the individual products in the family

Product name	Formulation:	Copper oxide (Cu ₂ O; % w/w)	Tralopyril (%w/w)
AquaNet Premium	Ready for use	9.997%	1.999%
Aquanet Boost	Ready for use	21.95%	1.98%

The full composition details of the formulations are contained within the confidential annex of this PAR.

2.1.2.5 *Information on technical equivalence*

Spiess-Urania Chemicals GmbH and Janssen PMP are listed as an approved supplier in accordance with Article 95 of the Biocidal Products Regulation (BPR).

2.1.2.6 Information on the substance(s) of concern

There are no substances of concern present in the products in the Premium BPF.





2.1.2.7 Type of formulation

SD – Suspension concentrate for direct application
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2.1.3 Hazard and precautionary statements





Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Meta SPC1

AquaNet Premium				
Classification				
Hazard category	Met. Corr. 1 Acute Tox. 4 (Oral) Acute Tox. 4 (inhalation: dust and mist) Eye Dam. 1 STOT RE 2 (oral) Aquatic Acute 1 Aquatic Chronic 1			
Hazard statement	H290: May be corrosive to metals H302: Harmful if swallowed H332: Harmful if inhaled H318: Causes serious eye damage H373 May cause damage to organs through prolonged or repeated oral exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects			
Labelling				
Pictogram				
	GHS07	GHS08	GHS05	GHS09

Signal words	Danger
Hazard statements	<p>H290: May be corrosive to metals</p> <p>H302 + H332: Harmful if swallowed or if inhaled</p> <p>H318: Causes serious eye damage</p> <p>H373: May cause damage to organs through prolonged or repeated oral exposure</p> <p>H410: Very toxic to aquatic life with long lasting effects</p>
Precautionary statements	<p>P234: Keep only in original packaging</p> <p>P260: Do not breathe dust, and mist</p> <p>P271: Use only outdoors or in a well-ventilated area</p> <p>P273: Avoid release to the environment</p> <p>P280: Wear eye/face protection</p> <p>P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P312: Call a POISON CENTER or doctor/physician if you feel unwell</p> <p>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P310: Immediately call a POISON CENTER or doctor.</p> <p>P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell</p> <p>P330: Rinse mouth</p> <p>P390: Absorb spillage to prevent material damage</p> <p>P391: Collect spillage</p> <p>P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation</p>
Note	This substance/mixture does not meet the PBT or vPvB criteria of REACH regulation, Annex XIII

Meta SPC2

AquaNet Boost				
Classification				
Hazard category	Met. Corr. 1 Acute Tox. 4 (Oral) Acute Tox. 4 (inhalation: dust and mist) Eye Dam. 1 STOT RE 2 (oral) Aquatic Acute 1 Aquatic Chronic 1			
Hazard statement	H290: May be corrosive to metals. H302: Harmful if swallowed H332: Harmful if inhaled H318: Causes serious eye damage H373: May cause damage to organs through prolonged or repeated oral exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects			
Labelling				
Pictogram				
	GHS07	GHS08	GHS05	GHS09
Signal words	Danger			
Hazard statements	H290: May be corrosive to metals H302+H332: Harmful if swallowed or if inhaled H318: Causes serious eye damage H373: May cause damage to organs through prolonged or repeated oral exposure H410: Very toxic to aquatic life with long lasting effects			

Precautionary statements	<p>P234: Keep only in original packaging.</p> <p>P260: Do not breathe dust and mist</p> <p>P271: Use only outdoors or in a well-ventilated area</p> <p>P273: Avoid release to the environment</p> <p>P280: Wear eye/face protection</p> <p>P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P312: Call a POISON CENTER or doctor/physician if you feel unwell</p> <p>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P310: Immediately call a POISON CENTER or doctor.</p> <p>P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell</p> <p>P330: Rinse mouth</p> <p>P390: Absorb spillage to prevent material damage</p> <p>P391: Collect spillage</p> <p>P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation</p>
Note	This substance/mixture does not meet the PBT or vPvB criteria of REACH regulation, Annex XIII

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Antifouling

Product Type	21
Where relevant, an exact description of the authorised use	The Premium BPF products are intended to be used for the protection of nets used in aquaculture against fouling.
Target organism (including development stage)	There are over 4000 fouling species from a variety of phyla <ol style="list-style-type: none"> 1. Slime, e.g. bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, e.g. barnacles, mussels and hydrozoans species
Field of use	PT 21 – Antifouling products Premium products are used in the control of fouling organisms in the marine environment.
Application method(s)	Premium products are ready for use products marketed in 1000 litre IBC HDPE containers as a liquid formulation. The products are intended to be applied by dipping or by vacuum treatment.
Application rate(s) and frequency	Application rates: 1 – 1.2 Litres per kg of net 1 treatment per net.
Category(ies) of users	Industrial use
Pack sizes and packaging material	1000 L IBC HDPE containers

2.1.4.2 Use-specific instructions for use

See section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

Meta SPC 1 (AquaNet Premium):

Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves (EN 374).

A protective coverall (at least type 6, EN-13034) shall be worn (coverall material to be specified by the authorisation holder within the product information).

Use eye protection to EN 166, designed to protect against liquid splashes.

Meta SPC 2 (AquaNet Boost)

Wear suitable gloves; i.e. Nitrile rubber gloves or natural rubber gloves (EN 374).

A double coverall, a chemically resistant (at least type 3, EN-14605) coverall which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information) shall be worn with at least a long-sleeve, long-leg cotton coverall underneath.

Use eye protection to EN 166, designed to protect against liquid splashes.

Please see also section 2.1.5.2.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please see section 2.1.5.3.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

Please see section 2.1.5.4.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please see section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

The product must be stirred well before use.

Density and viscosity must be measured prior to dipping, the measured values must be within the technical specification for the individual products. – Density and viscosity must be measured to ensure that the product is homogeneous prior to dipping. Please follow the manufacturer's directions for how to measure density and viscosity.

Dipping of nets:

Lower the net in the dipping tank using remotely operated net rollers and dip the net in the product for about 30 minutes whilst it is being held down by a weight attached to a crane.

Ensure the net to be treated is completely wetted with the product.

After treatment, remove the weight, roll back the net onto the roller and leave to dry by injecting dried air into the net rolls.

Vacuum treatment of nets:

The lid of the net-bag is opened, and the net lowered into the vacuum bag using a remotely operated net rollers or a crane. Transport a specified amount of product from

the vacuum-tank to the vacuum-bag, through the lid on the top. Start the program of "vacuuming the bag" so that the product enters through the net to be treated. Regardless of the size of the vacuum-bag, lowest pressure >0.8 bar. To ensure that the net to be treated is completely wetted with the product, run x number of cycles (≤ 4). Set on the program of "drying" so that the rest of the product left in the bag is transported back to the tank, through the bottom of the vacuum-bag. After finishing treatment, open the lid and lift the net off the bag using a crane or remote-controlled net rollers to the next process (drying-process).

Lowest pressure during vacuum cycles: 0.8 bar

Max amount of application cycles: 4

Max amount of drying cycles: 4

Avoid pushing paint above the vacuum bag

Allow leftover paint to reset for 2-3 days before re-use

2.1.5.2 Risk mitigation measures

Use in a well-ventilated area

Avoid breathing dust/mist

Avoid contact with skin and eyes.

Avoid release to the environment

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Information to Healthcare personnel/doctor:

Initiate life support measures if needed, thereafter call a POISON CENTRE

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance

Avoid release to the environment.

Emergency measures for the environment:

Discharging into rivers and drains is forbidden.

Notify authorities if liquid enters sewers or public waters.

Methods and material for containment and cleaning up:
Take up liquid spill into absorbent material and dispose of materials or solid residues at an authorized site.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product/Packaging: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Hazardous waste due to toxicity. Avoid release to the environment. Waste disposal number of unused product: UN number 3082/European waste code EWC 02 01 99.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

The product must be stored at temperatures above 5°C and below 30 °C.

The Premium products are stable, when stored in the original packaging at ambient temperatures, for up to 6 months, provided that proper measures are taken to ensure that the product is homogeneous prior to application.

Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight.

2.1.6 Other information

The label of the biocidal product must provide advise on how to perform the deployment of the treated nets. As a minimum, the label must specify that suitable chemical protective gloves and eye protection (goggles) should be used during net deployment. Other PPE should be specified according to the authorisation holder's recommendations, including those needed based on the performed risk assessment.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
IBC	1000 L	HDPE	Lid	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please see reference list

2.1.8.2 Access to documentation

The applicant has access to all the data submitted for the approval of the active substances, dicopper oxide, and tralopyril. A letter of access is provided.

The applicant is the owner of all data submitted on Premium products.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT (FAMILY)

2.2.1 *Intended use(s) as applied for by the applicant*

Table 2. Intended use # 1 – Antifouling

Product Type	21
Where relevant, an exact description of the authorised use	The Premium BPF products are intended to be used for the protection of nets used in aquaculture against fouling.
Target organism (including development stage)	There are over 4000 fouling species from a variety of phyla <ol style="list-style-type: none"> 1. Slime, e.g. bacteria and diatoms species 2. Green, red and brown algae spores 3. Animals, e.g. barnacles, mussels and hydrozoans species
Field of use	PT 21 – Antifouling products Premium products are used in the control of fouling organisms in the marine environment.
Application method(s)	Net dipping: The product is pumped to a dipping tank where the net is lowered into the product using remotely operated cranes. Vacuum treatment: The product is pumped into a sealed vacuum bag containing the net. Vacuum cycles are applied in order to evenly distribute the product into the net.
Application rate(s) and frequency	1 – 1.2 Litres of product per kg of net
Category(ies) of users	Industrial use
Pack sizes and packaging material	1000 L IBC HDPE containers

2.2.2 *Physical, chemical and technical properties*

The physical, chemical and technical properties were determined for the representative product of the Premium BPF, AquaNet Boost_{old}. Please note that all studies are performed on the old formulation of AquaNet Boost. However, this product is deemed as representative for the biocidal products family, and therefore also representative for the new version of AquaNet Boost.

Property	Guideline and Method	Results	Reference
Physical state at 20°C and 101.3 kPa	EPA OPPTS 830.6303	Liquid aqueous suspension concentrate T=6 months: Liquid aqueous suspension concentrate. Clumping and some phase	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost,

Property	Guideline and Method	Results	Reference
		separation could be observed (green liquid phase on the top). T=12 months: Liquid aqueous suspension concentrate. Clumping and some phase separation could be observed (green liquid phase on the top). Some clumping could be observed after stirring for 5 minutes with an impeller attached to a drilling machine.	2018 report number 7P04987-04b
Colour at 20°C and 101.3 kPa	EPA OPPTS 830.6302	Red No significant change after 6 or 12 months storage.	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Odour at 20°C and 101.3 kPa	EPA OPPTS 830.6304	Odourless to slight damp odour No significant change after 6 or 12 months storage.	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
pH	CIPAC MT 75.3	T=0 months: pH = 8.1 T=6 months: pH = 8.0 T=12 months: pH = 8.4	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Acidity/alkalinity	Not Performed due to pH result		
Relative density	ISO 2811-1	T=0 months: Density = 1.27 g/cm ³ T=6 months:	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04

Property	Guideline and Method	Results	Reference
		Density = 1.25 g/cm ³ T=12 months: Density = 1.20 g/cm ³	Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Storage stability test – accelerated storage	Not performed		
Storage stability test – long-term storage at ambient temperature	ACCORDING TO REQUIREMENTS OF REGULATION 528/2012	Active substances contents: T=0 months: Cu ₂ O 24% w/w, Tralopyril 2.1% w/w T=6 months: Cu ₂ O 22% w/w, Tralopyril 1.8% w/w T=12 months: Cu ₂ O 22% w/w, Tralopyril 2.0% w/w	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Storage stability test – low-temperature stability test for liquids	Not performed		
Effects on content of the active substance and technical characteristics of the biocidal product – light	Storage condition under Artificial light 24 h/day	No effect of light on active ingredient content was observed	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Not performed		

Property	Guideline and Method	Results	Reference				
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	No guideline followed	No significant change was observed during long-term storage test. No reactivity towards container material is expected.	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b				
Wettability	Not performed as not applicable to this product						
Suspensibility, spontaneity and dispersion stability	CIPAC MT 184	<table><tr><td>Cu2O</td><td>Tralopyril</td></tr><tr><td>104</td><td>104</td></tr></table> T=6 months: Suspensibility: Cu2O = 103%, Tralopyril = 102% Spontaneity of dispersion: Cu2O = 87%, Tralopyril = 80% T=12 months: Suspensibility: Cu2O = 100%, Tralopyril = 100% Spontaneity of dispersion: Cu2O = 83%, Tralopyril = 92%	Cu2O	Tralopyril	104	104	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
Cu2O	Tralopyril						
104	104						
Wet sieve analysis and dry sieve test	Not performed as not applicable to this product						
Emulsifiability, re-emulsifiability and emulsion stability	Not performed as not applicable to this product						
Disintegration time	Not performed as not applicable to this product						
Particle size distribution, content of dust/fines, attrition, friability	Not performed as not applicable to this product						
Persistent foaming	Not performed as not applicable to this product						
Flowability/Pourability/Dustability	CIPAC MT 148	T=0 months: Pourability= 1.53% Rinsability= 0.3% T=6 months: Pourability= 1.53%, Rinsability= 2.31%	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b				

Property	Guideline and Method	Results	Reference
		T=12 months: Pourability= 4.49%, Rinsability= 1.62%	
Burning rate — smoke generators	Not performed as not relevant for this product		
Burning completeness — smoke generators	Not performed as not relevant for this product		
Composition of smoke — smoke generators	Not performed as not relevant for this product		
Spraying pattern — aerosols	Not performed as not relevant for this product		
Physical compatibility	Aquanet Boost is intended to be used as dipping product. Therefore, no physical constraint is expected. This study is considered as not relevant to this product		
Chemical compatibility	The product is not intended to be mixed with other chemical product. The study is therefore not considered as relevant for this product.		
Degree of dissolution and dilution stability	Not performed as not relevant for this product		
Surface tension	EC A5 1.6.4 (OECD 115), using the Wilhelmy Plate method.	37.1 mN/m (at 25°C) (Average of 15 measurements)	AquaNet Premium 2020 draft final report number RH/20/001
Viscosity	ISO 2431	T= 0 months:	Interim report 6 months AquaNet Premium Boost, 2018 report number 7P04987-04 Final report 12 months AquaNet Premium Boost, 2018 report number 7P04987-04b
		20°C Cup ISO 3	
		40°C Cup ISO 3	
		> 100	
		> 100	
		20°C Cup ISO 4	
		40°C Cup ISO 4	
		40	
		34	
		T= 6 months:	
		20°C Cup ISO 3	
		40°C Cup ISO 3	
		68	
		55	
		20°C Cup ISO 4	
		40°C Cup ISO 4	
		24	
		20	
		T=12 months:	
		20°C Cup ISO 3	
		40°C Cup ISO 3	
		56	
		52	

Property	Guideline and Method	Results		Reference
		20°C Cup ISO 4	40°C Cup ISO 4	
		23	21	

Conclusion on the physical, chemical and technical properties of the product

AquaNet Boost_{old} is a red liquid aqueous suspension concentrate at room temperature with a relative density of about 1.27, a pH of 8.1 and a pourability of 1.53%. Its viscosity at 20°C (ISO3) is >100 s and at 20°C (ISO4) is 40 respectively.

The AquaNet Boost_{old} product shows clumping in the product after both 6 and 12 months. The clumping can be removed by stirring for the first 6 months of storage. The active substance concentration shows less than 10% decrease after 12 months. However, the concentration of tralopyril shows a decrease of 14% after 6 months but increases between 6 and 12 months of storage. The results after 6 months seem erroneous, and it seems like this may be due to difficulties in sample analysis. Based on the irreversible clumping of the product after 12 months, it is suggested to allow for 6 months storage stability.

The pourability of the product is within the requirements, but the rinsability is outside after 6 and 12 months. However, the products in this product family is ready to use products, thus eliminating the risk of wrong dilutions caused by too much product remaining in the packaging. Furthermore, residues in the empty packaging should not cause a concern, as the product container in any case should be regarded as hazardous waste and must be disposed of according to local regulations.

The other physical, chemical and technical properties are considered acceptable.

2.2.3 Physical hazards and respective characteristics

The physical hazards and respective characteristics were determined for the representative product of the Premium BPF, AquaNet Boost_{old}.

Property	Guideline and Method	Results	Reference
Explosives	Differential scanning calorimetry	The total heat of decomposition was found to be < 500 J.g-1. The sample is therefore not considered to have explosive properties.	Hazardous Properties Testing on a Sample of AquaNet Boost, 2017 report number GLP3016001671AR1V1/2017
Flammable gases	Not performed as not relevant for this product		
Flammable aerosols	Not performed as not relevant for this product		
Oxidising gases	Not performed as not relevant for this product		

Property	Guideline and Method	Results	Reference
Gases under pressure	Not performed as not relevant for this product		
Flammable liquids	ASTM D93	The closed-cup flash point temperature of AquaNet Boost _{old} has been determined to be 'No Flash to Boiling'.	Hazardous Properties Testing on a Sample of
Flammable solids	Not performed as not relevant for this product		
Self-reactive substances and mixtures	Not performed	The study does not need to be conducted because the exothermic decomposition energy is less than 300J/g and hence, the classification procedure does not need to be applied	Hazardous Properties Testing on a Sample of
Pyrophoric liquids	Not performed	No ignition of the product by air is expected. The product is a liquid use for net dipping. The product has already been sold previously under the old directive and no Pyrophoric property has been saw.	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017
Pyrophoric solids	Not performed as not relevant for this product		
Self-heating substances and mixtures	Differential scanning calorimetry	A sample is a candidate for classification as a UN Class 4, Division 4.1 self-reactive substance if the heat of decomposition is > 300 J.g-1. Aquanet Boost _{old} has a heat of decomposition < 300 J.g-1.	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017

Property	Guideline and Method	Results	Reference
		So the product is not considered as a self-heating product.	
Substances and mixtures which in contact with water emit flammable gases	Not performed	The product is intended to be diluted with water and/or already contains water as a solvent. No flammable gases occurred after dilution.	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017
Oxidising liquids	Calculation based on components properties	In every respect of the oxidising liquids exemption procedure, AquaNet Boost _{old} does not show any evidence of possessing oxidising properties.	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017
Oxidising solids	Not performed as not relevant for this product		
Organic peroxides	Not performed as not relevant for this product		
Corrosive to metals	UN Manual of Tests and Criteria: Part III, 37.4: Test methods for corrosion to metals	The percentage mass losses on steel and aluminum were found to be < 13.5% over 7 days, however, the maximum pit depth on the aluminum coupons was > 120 µm. The sample is, therefore, a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations).	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017
Auto-ignition temperatures of products (liquids and gases)	ASTM E659 (Standard test method for autoignition temperature of liquid chemicals)	The autoignition temperature of AquaNet Boost _{old} has been determined to be > 600°C	AquaNet Boost, 2017 report number GLP3016001671AR1V1 /2017

Property	Guideline and Method	Results	Reference
Relative self-ignition temperature for solids	Not performed as not relevant for this product		
Dust explosion hazard	Not performed as not relevant for this product		

Conclusion on the physical hazards and respective characteristics of the product

AquaNet Boost_{old} product is a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations).

It is not explosive or oxidising and has an auto-ignition temperature of 600°C.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Methods for determining dicopper oxide in the product:

Samples are dried and digested in a mixture of nitric acid and hydrogen peroxide in closed containers that are heated using microwaves. Copper (Cu) is then determined by the resulting solutions using inductively coupled plasma – optical emission spectrometry (ICP-OES). Cu can be recalculated to Cu₂O by assuming that all Cu is present as Cu₂O (depending on the composition of the formulation). This internal method is based on several well-established standard methods: EN 13656, EPA Method 3052, and EN ISO 11885 that are fully validated. Precision (as repeatability), accuracy (as recovery), and linearity and selectivity/specificity have been investigated as described in SANCO/3030/99 rev.4 11/07/00 and all requirements have been fulfilled. The analytical method is suitable for the determination of dicopper oxide in the formulation.

Methods for determining tralopyril in the product:

Samples of paint are extracted with addition of 0.1% formic acid (FA) in acetonitrile (ACN), ultra-sonicated, decanted and diluted. The diluted samples are analysed, the analytes are separated by liquid chromatography and detected by mass spectrometry (LCMS). All analytes are quantified using external standard curve. Precision (as repeatability), accuracy (as recovery), linearity and selectivity/specificity have been investigated as described in SANCO/3030/99 rev.4 11/07/00 and all requirements have been fulfilled. The analytical method is suitable for the determination of tralopyril and 2 degradation products (CL 322 250) and CL 322 248) in the formulation.

Analytical methods used for monitoring:

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint.

Analytical methods used for soil:

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant therefore wishes to refer to the data on the active substances for this endpoint

Analytical methods used for air:

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint

Analytical methods used for water:

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint

Analytical methods used for animal and human body fluids and tissues:

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint

Analytical methods for monitoring of active substances and residues in food and feeding stuff

The applicant has letters of access issued by Spiess-Urania Chemicals GmbH and Janssen PMP to the data on the active substances. The applicant, therefore, wishes to refer to the data on the active substances for this endpoint

Conclusion on the methods for detection and identification of the product
All methods are valid and acceptable.

2.2.5 *Efficacy against target organisms*

2.2.5.1 *Function and field of use*

Function: Antifoulant

Field of use: Aquaculture

The Premium products are intended to be used for the protection of nets used in aquaculture against fouling organisms in marine environments.

2.2.5.2 *Organisms to be controlled and products, organisms or objects to be protected*

The number of fouling organisms to which an aquaculture net may be exposed is large. Over 4000 fouling species with representatives from a variety of phyla, for example; slime, diatoms species (e.g. *Achnanthes* and *Amphora* species), algae such as green, brown and red algae spores (e.g. *Enteromorpha* spp, *Polysiphonia*), animals such as barnacles, mussels, tubeworms (e.g. Serpulids), sponges.

2.2.5.3 *Effects on target organisms, including unacceptable suffering*

Cell death or inactivation, settlement inhibition or retardation by uncoupling mitochondrial oxidative phosphorylation. Target organisms are not expected to experience any unacceptable suffering.

2.2.5.4 *Mode of action, including time delay*

Dicopper oxide:

When copper from cuprous oxide leaches into marine water in presence of oxygen, the predominant form of the copper is the active substance, the cupric ion, Cu^{2+} . The cupric ion acts to retard settlement of the microscopic larvae of fouling organisms within a microlayer of water at the paint surface via two mechanisms:

- (1) the ion retards organism's vital processes by inactivating enzymes;
- (2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates.

Tralopyril:

Tralopyril is an arylpyrrole that acts by uncoupling mitochondrial oxidative phosphorylation.

2.2.5.5 *Efficacy data*

Biofouling in marine aquaculture is one of the main barriers to efficient and sustainable production (Dürr and Watson 2010), and the direct economic cost of managing biofouling in the aquaculture industry is estimated to be 5-10% of the production costs (Lane and Willemsen 2004).

No agreed guidance document on efficacy of PT21 products for use on aquaculture nets exists today. In 2017, the NO CA commissioned the development of such a guidance document in order to provide the applicants with an equal framework to base their efficacy studies upon, as well as to establish a framework to base their evaluation on (Guidelines for efficacy testing of antifouling coatings for nets in field tests; Developed by SINTEF Ocean on behalf of the Norwegian Environment Agency. Hereafter referred to as "SINTEF"). The proposed guidance document is included as a separate attachment to this PAR (Bloecher and Floerl 2018). The goal is to get this proposed guidance document included as an annex to the existing ECHA guidance document on efficacy and thereby completing the chapter on PT 21 products. The proposed guidance document has currently been discussed among the members of the ECHA working group on efficacy, but no final agreement has been reached at this point.

The proposed guidance document has been used for the evaluation this product family authorisation. However, as no agreement on its applicability has been reached some flexibility and pragmatism has been used in the assessment

The first efficacy studies performed for these products were performed in 2017 before the proposed guidance document was finalised and were thus performed according to the applicants own internal routines. After the proposed guidance document was finalised / drafted, a new set of efficacy studies was performed in 2018, where the methodology and principles given in the proposed guidance document was largely followed.

The first set of efficacy studies performed for this product family deviate from the principles in the proposed guidance document in that the samples are not tested in randomised triplicates. Only single samples of each product were tested. This was reported to be due to capacity problems at the fish farms due to the commercial activities, such as boat traffic and other farm operations taking place. The applicant therefore chose to use larger sample panels (80 x 40 cm) than the minimum size recommended in the proposed by SINTEF (25 x 25 cm). The total tested areas are thus larger in these studies than recommended in the SINTEF document. The samples were scored in accordance with the applicants own internal procedure which is presented in the individual study reports.

The submitted photo evidence from the 2017 efficacy tests were unfortunately of too poor quality and resolution for a proper evaluation to be performed by the RMS. The tests are generally well performed and to a large extent follow the principles given in the SINTEF document. Due to the poor image quality, these tests have been given a reliability score of 3. They are nevertheless included in order to provide supplemental information.

The second set of efficacy test were performed largely in line with the principles given in the SINTEF document. The samples are tested in four parallels and all samples were randomised in the frames. The frames were placed in the sea at an active fish farm and were located approximately 1 meter away from an active producing fish cage. The samples were inspected and photographed approximately every 4 weeks. The applicant has also analysed the samples according to their own internal standard, and not according to the standard proposed by SINTEF.

All the submitted efficacy studies were performed at active fish farms with the test panels were placed in close proximity from an active producing fish cage. This gives very realistic conditions with regard to the natural conditions in a producing cage with respect to fouling pressure and exposure to nutrients from food spillage and faeces. The fouling pressure under such conditions is extreme and has been reported to be up to 49 times higher than in the surrounding sea (Bloecher et al 2015).

The rMS has analysed the submitted 2018 efficacy studies by quantifying the total biofouling load in accordance with the principles outlined in the SINTEF document. The submitted photo evidence was unfortunately of too poor quality to allow for a detailed analysis of the % biofouling cover (Analysis of type B according to the SINTEF document). Instead, the biofouling load was estimated (Analysis of type A according to the SINTEF document).

Basically, the submitted pictures were assigned a nominal rank score, ranging from 0 (free of biofouling) to 5 (>80% of the surface covered with biofouling organisms) by comparing them to the reference images presented in the SINTEF document, where possible. The reference pictures and the corresponding rank descriptions can be found in Bloecher and Floerl 2018.

The efficacy criterium applied by the rMS was decided based on discussions between SINTEF Ocean and The Norwegian Environment Agency. The coating is assessed to be efficacious if the biofouling load on a sample is approximately 40% lower than the untreated control, equal to a difference in two ranks.

The protection goal with the use of antifouling coats on aquaculture nets differ between areas in Europe. The main objective is, nevertheless, to ensure an adequate water flow through the nets which is essential for fish health and wellbeing. Fish farms typically have oxygen meters permanently installed in the cages to indicate when the oxygen level is starting to decline so that cleaning or a change of net can be performed.

In Norwegian waters, the main objective is to control the level of salmon lice (*Lepeophtheirus salmonis*) in the cages. Salmon lice are normally not harmful to the farmed fish but exerts a threat to wild sea trout and wild salmon fry. Acceptable levels of sea lice in a farm is therefore strictly regulated and controlled, and too high levels may result in the farmer being imposed a reduced operation volume, or even a production quarantine. The predominant strategy used today to control salmon lice is by using cleaner fish. It is believed to be essential that the level of biofouling on the nets is kept at a low level to ensure that the cleaner fish eat salmon lice and not fouling organisms on the nets.

The applicant has informed us that a fouling level of 60 - 80% normally can be tolerated in countries without salmon lice issues. A defined upper tolerable fouling level is not possible to determine, as the farmers normally initiate measures on the basis of in-situ oxygen measurements in the cages and not on observed fouling levels.

In areas with salmon lice issues, a fouling level equal to a score rank of 3 (10 – 34% of the surface) can be tolerated before measures, such as cleaning, need to be taken. In this respect, the practice between individual farms and farming companies differ.

It is important to notice in this respect, that even when a coating has been deemed as not sufficiently effective, it still can perform much better than the untreated control. It is also experienced by the farmers that the biofouling falls easier off from a treated net than from

an untreated net if the net is cleaned or at incidences with heavy weather. An untreated net in a peak fouling period can become fully overgrown in only one week.

The protection goal of the farmer is thus to postpone or delay the need for measures, such as cleaning or changing the net and to ensure fish health.

According to information from the applicant, the fish farm companies are to a large extent very professional businesses which often have a high degree of competence of the biofouling issues in the area where they operate. They have thus much experience and expertise on the farming strategies that gives the biggest production advantages in their farms.

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Premium</i>	<i>Wide range of marine fouling organisms in North European waters (Norway)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Syltøy at 70 m depth from Apr. to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 10% dicopper oxide + 2% tralopyril / 7 months (0 – 23 – 58 – 77 – 116 – 134 – 169 – 205 d	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) The nets remained free from fouling organisms (score 0) until Day 23. Thereafter, the fouling score oscillated between 1 and 2 throughout the exposure time (Score 1: slime, score 2: scarce patches of slight fouling, < 10% coverage). The fouling score remained considerably lower than the reference frame.	<i>Fagerlid, S (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Premium</i>	<i>Wide range of marine fouling organisms in North European waters (Norway)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Horgefjorden at 80 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 10% dicopper oxide + 2% tralopyril / 5 months (0 – 44 – 64 – 85 – 104 – 127 – 162 d)	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) The nets remained free from fouling organisms (score 0) until Day 85. Thereafter, only microfouling (slime) was observed throughout the exposure time (score 1). The fouling score remained considerably lower than the reference frame.	<i>Hope, B (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Premium</i>	<i>Wide range of marine fouling organisms in the Mediterranean Sea (Greece)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Galaxidi at 100 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 10% dicopper oxide + 2% tralopyril / 5 months (0 – 27 – 40 – 54 – 68 – 83 – 96 – 111 – 125 – 139 – 152 – 167 d)	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) Only microfouling (slime) was observed until Day 54 (score 1). Thereafter, scarce patches of slight fouling (score 2, < 10% coverage) were observed throughout the exposure time. The fouling score remained considerably lower than the reference frame.	<i>Fagerlid, S (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Boost_{old}</i>	<i>Wide range of marine fouling organisms in North European waters (Norway)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Syltøy at 70 m depth from Apr. to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 24.8% dicopper oxide + 2% tralopyril / 7 months (0 – 23 – 58 – 77 – 116 – 134 – 169 – 205 d	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) The nets remained free from fouling organisms (score 0) up to Day 58. Thereafter, the fouling score oscillated between 1 and 0 throughout the exposure time (Score 1: slime). The fouling score remained considerably lower than the reference frame.	<i>Ulriksen, U (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Boost_{old}</i>	<i>Wide range of marine fouling organisms in North European waters (Norway)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Horgefjorden at 80 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 24.8% dicopper oxide + 2% tralopyril / 5 months (0 – 44 – 64 – 85 – 104 – 127 – 162 d)	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) The nets remained free from fouling organisms (score 0) throughout the exposure time.	<i>Hope, B (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>AquaNet Boost_{old}</i>	<i>Wide range of marine fouling organisms in the Mediterranean Sea (Greece)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in Galaxidi at 100 m depth from May to Nov. 2017, close to high production cages where fouling pressure is higher than surrounding areas / 24.8% dicopper oxide + 2% tralopyril / 5 months (0 – 27 – 40 – 54 – 68 – 83 – 96 – 111 – 125 – 139 – 152 – 167 d)	Study not assessed by the rMS. The samples are scored by the applicant according to their internal procedures. Included to provide supplemental information. Reliability score 3 (poor picture quality) Only microfouling (slime) was observed until Day 96 (score 1). Thereafter, scarce patches of slight fouling (score 2, < 10% coverage) was observed throughout the exposure time. The fouling score remained considerably lower than the reference frame.	<i>Fagerlid, S (2017)</i>

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
AquaNet Premium	<i>Wide range of marine fouling organisms in North European waters (Norway)</i>	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests CEPE-method (antifouling coatings-methods for the generation of antifouling efficacy data)- for aquaculture nets developed by SINTEF Ocean on behalf of the Norwegian Environment Agency Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in South-West Norway at 80 m depth from April 2018 to November 2018, 1 meter from high production cages where fouling pressure is greater than surrounding areas. Test units comprised of nets on stainless steel cages treated with test substance (6 replicates) or control (7 replicates)	Active protection time 8 months Reliability score: 2	Hope, B (2018)

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism (s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
AquaNet Boost _{old}	Wide range of marine fouling organisms in North European waters (Norway)	ISO 4628/3 SINTEF Guidelines for efficacy testing of antifouling coatings for nets in field tests CEPE-method (antifouling coatings-methods for the generation of antifouling efficacy data)- for aquaculture nets developed by SINTEF Ocean on behalf of the Norwegian Environment Agency Internal procedures DOKID-1294561088-104 Internal procedures: DOKID-1294561088-103	Seawater column located in South-West Norway at 80 m depth from April 2018 to November 2018, 1 meter from high production cages where fouling pressure is greater than surrounding areas. Test units comprised of nets on stainless steel cages treated with test substance (6 replicates) or control (7 replicates)	Active protection time 8 months Reliability score: 2	Hope, B (2018)

Conclusion on the efficacy of the products

Please observe that only the efficacy studies performed in 2018 has been evaluated by the rMS and the fouling levels assigned a rank according to the SINTEF document.

The efficacy studies performed in 2017 could not be evaluated by the rMS. These tests were evaluated and scored by the applicant according to their own internal procedure. As the applicant has used the term "score" in their assessment of the 2017 studies, this term has been kept in the description of the studies.

The referred scores do not correlate directly to the ranks given in the SINTEF document. Please see the SINTEF document and the study reports for further information.

Aquanet Premium:

Norwegian south-western coast, April to November 2018

In the efficacy test performed with Aquanet Premium on the Norwegian south-western coast in 2018 (Hope, B.; 2018), the product showed good efficiency against biofouling throughout the whole test period of 231 days. The test samples remained nearly completely free from biofouling, up to and including sample day 98. The assigned ranks of the 98 days samples were approaching 1 (<20% biofouling cover), basically based on the observation of some skeleton shrimp and a few hydroids. The control samples in this period showed a steady increase in biofouling level up to an assigned rank of 5 (>80% biofouling cover) at sample day 98.

At the sampling point at 134 days in the sea, the samples had contracted a substantial number of skeleton shrimps. A few hydroids were also observed. The test samples were assigned a rank of 3 (40-50% biofouling cover). The concurrent controls were assigned a rank of 5 at this sampling point.

At the sampling point at 176 days in the sea, the number of skeleton shrimps was somewhat reduced compared to the previous sampling date. Still only minimal occurrence of macrofouling species was observed and the samples were assigned a rank 2 (20-39% biofouling cover). The control samples remained heavily fouled at this time point, with an assigned rank of 5.

At the final sampling point after 231 days in the sea, the samples were assigned a rank of 2. At this sampling point some hydroids and skeleton shrimp was observed. The control samples retained a rank of 5 at this sampling point.

Horgefjorden on the Norwegian south-western coast, April to November 2017:

The test performed on Aquanet Premium in 2017 in Horgefjorden on the Norwegian south-western coast (Hope, B.; 2017) show good efficacy throughout the test period of 162 days. The test samples retained a low level of fouling throughout the study period of 162 days, while the control samples were heavily fouled. The samples were given a scores by the applicant, not exceeding 1 in the run of the study.

The pictures submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the assigned score values. The samples are thus evaluated by the applicant in accordance with their own internal procedure. It is, nevertheless, included to provide supplemental information.

Syltøy on the Norwegian south-western coast, April to November 2017:

In the efficacy study performed on Aquanet Premium in 2017 in Syltøy on the Norwegian south-western coast (Fagerlid, S.; 2017) show a similar result as the previous studies. The product provides good protection against biofouling throughout the whole study period of 162 days, while the control samples were heavily fouled. The test samples reached a maximum fouling score of 2 in the run of the study.

The pictures submitted with this report were of too low quality for the rMS to be able to perform an independent evaluation of the assigned score values. The samples are thus evaluated by the applicant in accordance with their own internal procedure. It is, nevertheless, included to provide supplemental information.

Galaxidi, central Greece May to November 2017:

The test with Aquanet Premium performed in Galaxidi in central Greece in 2017 (Fagerlid, S. 2017), shows good efficacy throughout the test period of 167 days. The samples are given a maximum score of 2, while the control samples were heavily fouled. The visible fouling in the pictures is described as being non-sessile algae, which is normally not regarded as fouling.

The pictures submitted with this study are unfortunately of low quality, so an independent evaluation by the rMS was not possible. The samples are thus evaluated by the applicant in accordance with their own internal procedure. It is, nevertheless, included to provide supplemental information.

Conclusion:

Based on the submitted efficacy studies on Aquanet Premium, an efficacy of 8 months in North Atlantic waters is demonstrated. It is noted that although the product demonstrated very good protection towards sessile fouling species, it did not appear to provide efficient protection against skeleton shrimp.

The applicant's own conclusion of the efficacy test performed in Greece is that the product is efficacious for at least 5.5 months in Mediterranean waters. The rMS has not been able to perform an independent assessment of this study.

Aquanet Boost_{old}:**Norwegian south-western coast, April to November 2018**

The efficacy test performed on Aquanet Boost_{old} on the Norwegian south-western coast in 2018 (Hope, B.; 2018) shows good efficiency against biofouling throughout the whole test period of 231 days. The test samples remained nearly completely free from biofouling, up to and including sample day 98. The assigned ranks of the 98 days samples were approaching 1 (<20% biofouling cover), based on the observation of some skeleton shrimp. The control samples in this period showed a steady increase in biofouling level up to an assigned rank of 5 (>80% biofouling cover) at sample day 98.

At the sampling point at 134 days in the sea, the samples had contracted a substantial number of skeleton shrimps. A few hydroids were also observed. The test samples were assigned a rank of 3 (40-50% biofouling cover), while the concurrent controls were assigned a rank of 5 at this sampling point.

At the sampling point at 176 days in the sea, the number of skeleton shrimps was somewhat reduced compared to the previous sampling date. Still only minimal occurrence of macrofouling species was observed and the samples were assigned a rank 2 (20-39% biofouling cover). The control samples remained heavily fouled at this time point, with an assigned rank of 5.

At the final sampling point after 231 days in the sea, the samples were assigned a rank of 1. At this sampling point some hydroids and skeleton shrimp was observed. The control samples retained a rank of 5 at this sampling point.

Horgefjorden on the Norwegian south-western coast, April to November 2017:

The test performed on Aquanet Boost_{old} in Horgefjorden on the Norwegian south-western coast 2017 (Hope, B.; 2017) show good efficacy against fouling throughout the test period of 162 days.

The samples have been given a score by the applicant of 0 (no fouling) throughout the entire test period of 162 days. It is noted that the applicant does not appear to take skeleton shrimp into account in their evaluation of the fouling level, although their presence is reported in the study report.

The pictures submitted with this study were unfortunately of too poor quality for the rMS to be able to perform an independent assessment of this study. The study is thus assessed by the applicant and has been scored according to the applicants own internal procedure. The study is included in order to provide supplemental information.

Syltøy on the Norwegian south-western coast, April to November 2017:

In the efficacy study performed on Aquanet Boost_{old} in 2017 in Syltøy on the Norwegian south-western coast (Ulriksen, U.; 2017) show a similar result as the previous studies. The product provides very good protection against biofouling throughout the whole study period of 205 days, while the control samples were heavily fouled. The applicant has evaluated the fouling score to no more than 1 in the run of the study.

The pictures submitted with this study were unfortunately of too poor quality for the rMS to be able to perform an independent assessment of this study. The study is thus assessed by the applicant and has been scored according to the applicants own internal procedure. The study is included in order to provide supplemental information.

Galaxidi, central Greece May to November 2017:

The efficacy study performed with Aquanet Boost_{old} in Galaxidi in central Greece in 2017 (Fagerlid, S.; 2017), the product shows very good efficacy throughout the test period of 167 days. The applicant has evaluated the samples to a maximum score of 2 in the run of the study, while the control samples were heavily fouled.

The pictures submitted with this study were unfortunately of too poor quality for the rMS to be able to perform an independent assessment of this study. The study is thus assessed by the applicant and has been scored according to the applicants own internal procedure. The study is included in order to provide supplemental information.

Conclusion:

Based on the submitted efficacy tests on Aquanet Boost_{old}, an efficacy of 8 months in North Atlantic waters is demonstrated. It is noted that although the product demonstrated very good protection towards sessile fouling species, it did not appear to provide efficient protection against skeleton shrimp.

During the evaluation of the biocidal product family the content of dicopper oxide was reduced from 24.9% to 22% for the product Aquanet Boost. As both Premium and Boost

are shown to efficacious for 8 months, the rMS considers that the new formulation of Boost is covered by the studies performed on Boost_{old}.

The applicant's conclusion of the efficacy study performed in Galaxidi in central Greece is that the product is demonstrated efficacious for at least 5.5 months in Mediterranean waters.

2.2.5.6 Occurrence of resistance and resistance management

Considering the non-selective mode of action of both active substances (dicopper oxide and tralopyril), development of resistance against Premium BPF products is unlikely.

Dicopper oxide:

As stated in the CAR (PT21, 2016), there have never been any recorded cases of resistance in populations of fouling organisms using copper based anti-fouling paints in the literature up to now.

However, some studies, in the literature, showed some impacts of copper pollution on marine life and indicate that some hull-fouling species have copper tolerance.

Tralopyril:

As stated in the CAR (PT21, 2014), the applicant has provided evidence to demonstrate that development of resistance is not an issue. This is due to the mode of action of the biocide, which is by uncoupling mitochondrial oxidative phosphorylation. Development of resistance against compounds with this mode of action can be considered unlikely and rare for a variety of reasons; a lack of target site for mutation, the need for combined mechanisms to enable detoxification or uptake decrease, and a steep concentration-dependence in uncoupling phosphorylation. It is considered that the submitted data and information on resistance are sufficient to support approval.

2.2.5.7 Known limitations

None reported

2.2.5.8 Evaluation of the label claims

The Premium BPF products are not marketed with label claims on specific protection times. Marine biofouling pressure is extremely variable with regards to season, location, temperature, sunlight, water nutrient level etc. so no specific claims are possible to make, except for reduced growth relative to an untreated net.

According to Steen-Hansen's internal procedure, nets treated with antifouling products in the Premium Biocidal Products Family cannot be used together with high pressure water jetting on site. This is detailed in the Steen-Hansen Compliance Document: 'Cleaning restrictions for treated nets' (2019).

2.2.5.9 Relevant information if the product is intended to be authorised for use with

other biocidal product(s)

Premium BPF products are not intended to be used in combination with other products.

2.2.6 Risk assessment for human health

The toxicology of the active substances dicopper oxide (Cu₂O) and tralopyril was examined according to standard requirements in the review programme under BPR. The toxicological properties of the active substances are summarised in the respective CA reports:

- Assessment report on dicopper oxide (CAS-no: 1317-39-1), Product type 21, eCA FR, January 2016 (ECHA, 2016a)
- Assessment report on tralopyril (CAS-no: 122454-29-9), Product type 21, eCA UK, 2014 (ECHA, 2014b)

Toxicological testing (acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation) have not been performed for the products in the Premium biocidal product family.

In the absence of such test results, the products are classified based on information on the ingredients in the products using the conventional calculation method in Regulation 1272/2008 (CLP) (cf. 2.2.6.1.).

Based on the classification of the individual ingredients, the products included in the Premium biocidal product family are classified for acute oral toxicity (Cat 4, H302), Acute inhalation toxicity (cat. 4; H332), serious eye damage (Cat 1, H318), and STOT RE (Cat 2, H373 (oral)).

The composition of the products and CLP classification of the co-formulants are presented in the confidential Annex to this PAR.

Background information on the active substances:

Dicopper oxide is approved for use in product-type PT21 in the context of Regulation (EU) No.528/2012 by Implementing Regulation (EU) 2016/1089. To support the decision on approval, the hazard assessment of cuprous oxide was conducted in line with the assessment of copper compounds dossiers for PT21 (ECHA, 2016a).

A harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) of the active substance is available (17 ATP). The human hazards related to this substance are the following Acute Tox. (Cat 4, H332, Inhalation), Acute Tox. (Cat 4, H302, oral) and Eye Dam. (Cat 1, H318) (ECHA, 2014a).

No repeated toxicity study by oral route was provided for dicopper oxide. However, it was decided that read across to other relevant copper compounds (e.g., copper sulphate pentahydrate) was applicable. Further information can be found in the assessment report (ECHA, 2016a), as further elaborated in the competent authority report of dicopper oxide.

Copper is a micronutrient, essential for life and necessary for all living cells. It is essential for a normal physiological function such as cellular respiration, free radical defense,

synthesis of melanin, connective tissue, iron metabolism, regulation of gene expression, and normal function of the heart, brain and immune system. On the other hand, copper transport mechanisms in the organism form part of the system of homeostasis, i.e., the body can maintain a balance of dietary copper intake and excretion that allows normal physiological processes to take place. Deficiency in copper is associated with growth retardation, anaemia, skin lesions, impaired immunity, intestinal atrophy, impaired cardiac function, reproductive disturbance, neurological defects and skeletal lesions. Additionally, copper is present in almost all foods and some products. Most human diets naturally include between 1 and 2 mg/person/day of copper, with some containing up to 4 mg/person/day. Copper intake which exceeds the capacity of the endogenous homeostasis results in toxicity, or excess copper disease. Chronic copper toxicity is very rare, and the upper limit of homeostasis has never been strictly defined (ECHA, 2016a).

Based on the CA report on dicopper oxide, the key health effects to consider in the risk assessment are the kidney and forestomach-damages observed in the 90-day dietary study in rats (with the test material copper sulphate pentahydrate). A NOAEL of 1000 ppm (16.3 and 17.3 mg Cu/kg bw/day in male and female rats respectively) was established based on the kidney effects. The lowest of these NOAEL values was used when deriving the short-term and long term AEL values (ECHA, 2016a).

Tralopyril is approved for use in product-type PT21 in the context of Regulation (EU) No.528/2012. No harmonised classification in accordance with Regulation (EC) No 1272/2008 is available. The proposed classification published in the Assessment report for tralopyril has been used as a basis for the risk assessment (ECHA, 2014b).

The proposed human classification of the active substance tralopyril by the evaluating Competent Authority, based on Regulation (EC) No 1272/2008 is Acute Tox. (Cat 2, H300, oral), Acute Tox. (Cat 3, H311, dermal), Acute Tox. (Cat 2, H330, inhalation), STOT RE (Cat 1, H372, oral), and STOT RE (Cat 2, H373, inhalation) (ECHA, 2014b).

In the assessment report for tralopyril, some toxicological data on the active substance is presented. However, most of the properties of tralopyril is predicted by read across from a metabolic precursor of tralopyril, CL 303,630. The endpoints addressed by studies conducted with CL 303,630 (at least in part) are toxicokinetics, sub-chronic toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, and neurotoxicity. There appears to be quantitative differences in the dose levels in the repeated dose toxicity studies on tralopyril and CL 303,630, which are the only directly comparable studies. Hence, only data on tralopyril were used to derive route specific AELs. The studies comprise a rat developmental toxicity study for acute oral exposure scenarios, a 90 day rat study for medium term and chronic oral exposure scenarios, a 90 day dermal study for all dermal exposure scenarios and a 90 day inhalation study for all inhalation exposure scenarios. In addition, AECs were derived for the local risk characterisation of inhalation exposure scenarios (ECHA, 2014b).

ARfD and ADI were not derived in the assessment of the active substance. However, the reference values are needed for the dietary risk assessment of the use of tralopyril in these aquaculture products. Hence, reference values have been derived by the RMS in agreement with the principles for ARfD and ADI setting. The same studies have been used as the ones used for deriving the AEL short term (oral) and AEL long term (oral), not correcting for oral absorption.

Reference values to be used in the Risk Characterisation

(ref: Assessment reports for dicopper oxide (ECHA, 2016a) and tralopyril (ECHA, 2014b))

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral/dermal/ inhalation absorption	Value
Reference values for copper (from dicopper oxide)					
AEL _{short-term}	90-day rat study	16.3 mg Cu/kg bw/day	50	25%	0.082 mg Cu/kg bw/day
AEL _{medium-term}	90-day rat study	16.3 mg Cu/kg bw/day	50	25%	0.082 mg Cu/kg bw/day
AEL _{long-term}	90-day rat study	16.3 mg Cu/kg bw/day	100	25%	0.041 mg Cu/kg bw/day
ARfD	n.a.				
ADI	EFSA (2008)	-			0.15 mg Cu/kg bw/day
Reference values for tralopyril					
AEL _{short-term} (Dermal)	90-day rat study	300 mg/kg bw/day	100	2%	0.06 mg/kg bw/day
AEL _{medium-term} (Dermal)	90-day rat study	300 mg/kg bw/day	100	2%	0.06 mg/kg bw/day
AEL _{long-term} (Dermal)	90-day rat study	300 mg/kg bw/day	200	2%	0.03 mg/kg bw/day
AEL _{short-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	100	100%	0.058 mg/kg bw/day
AEL _{medium-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	100	100%	0.058 mg/kg bw/day
AEL _{long-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	200	100%	0.029 mg/kg bw/day
AEL _{short-term} (Oral)	rat developmental study	10 mg/kg bw/day	100	80%	0.08 mg/kg bw/day
AEL _{medium-term} (Oral)	90-day rat study	5 mg/kg bw/day (LOAEL)	300	80%	0.013 mg/kg bw/day
AEL _{long-term} (Oral)	90-day rat study	5 mg/kg bw/day (LOAEL)	600	80%	0.007 mg/kg bw/day
Acute AEC local	90-day rat study	20 mg/m ³ (LOAEC)	75	100%	0.27 mg/m ³
Medium term AEC local	90-day rat study	20 mg/m ³ (LOAEC)	75	100%	0.27 mg/m ³
Long term AEC local	90-day rat study	20 mg/m ³ (LOAEC)	150	100%	0.13 mg/m ³
ARfD ¹	Rat developmental study (oral)	10 mg/kg bw/day	100	n.a.	0.10 mg/kg bw
ADI ¹	90-day rat study (oral)	5 mg/kg bw/day (LOAEL)	600	n.a.	0.0083 mg/kg bw day

¹ Not included in the AR of tralopyril, but derived for the purpose of this risk assessment

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No studies for the assessment of skin irritation/corrosion of Premium products are available.

The additivity principle of the CLP Regulation applies for the hazard class skin corrosion/irritation with a generic cut off for when the substances should be taken into account of 1 % point (Table 1.1, in Annex I to Reg. no 1272/2008).

The active substance, dicopper oxide, present at levels ranging between 10 and 22% (w/w) in this product family, is not classified with skin irritation/corrosion. Also, tralopyril present at levels of approximately 2% in the Premium products is not proposed classified for skin irritation/corrosion.

In agreement with Annex III of BPR regulation (point 8.1, column 3), as sufficient information is available for the active substance and the co-formulants, a study investigating the skin irritating effects of Premium products is not considered necessary.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin
Justification for the value/conclusion	None of the components in the Premium biocidal product family that are classified for skin corrosion or irritation are present above the SCL or GCL that would lead to a classification.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Skin corrosion or skin irritation
Justification	Waiving according to Annex III, point No. 8.1, Column 3 of the BPR: There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected.

Eye irritation

No studies for the assessment of eye irritation/corrosion of Premium products are available. A classification for "Causes serious eye damage" (Cat 1, H318) is proposed.

The additivity principle of the CLP Regulation applies for the hazard class serious eye damage/eye irritation with a generic cut off for when the substances should be taken into account of 1 % point (Table 1.1, in Annex I to Reg. no 1272/2008).

Since dicopper oxide is contained in the products in a range of concentrations between 10 and 22%(w/w), this triggers a classification for the products with Cat 1, H318 "Causes

serious eye damage”, irrespective of the co-formulants (Table 3.3.3 in Annex I to Reg. no 1272/2008).

One co-formulants is classified as an eye irritant (Cat.2, H319) and another as serious eye damaging (Cat.1, H318). However, the concentration of the latter is below the cut off concentration for when the substances should be taken into account. Thus, none of these co-formulants contribute to the overall classification of the products as eye damaging.

According to Annex III, point 8.2, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the eye irritating effects of Premium products is not considered necessary.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage
Justification for the value/conclusion	Classification of this product family is based on the classification of the active ingredient dicopper oxide.
Classification of the product according to CLP	Eye Damage Cat 1, H318

Data waiving	
Information requirement	Eye irritation or damage
Justification	Waiving according to Annex III, point No. 8.2, Column 3 of the BPR: There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected

Skin sensitisation

No studies for the assessment of skin sensitisation of Premium products are available. The active substances, dicopper oxide is not classified for skin sensitisation (17 ATP to CLP). Neither is tralopyril proposed classified for this endpoint (ECHA, 2014b). One co-formulant does however contain two substances which are classified for skin sensitisation with specific lower concentration limits (SCL). The concentrations of these substances in the two Premium products are below the SCL's, as well as below the concentration limit for elicitation (Please see the confidential annex for details). Thus, neither classification for sensitisation nor the additional labelling provision apply for these products.

According to Annex III, point 8.3, Column 3 of the BPR, as sufficient information is available for the active substances and the co-formulants, a study investigating the skin sensitizing effects of Premium products is not considered necessary.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	The active substances are neither classified nor proposed classified for skin sensitisation. One co-formulant contains two substances which are classified for skin sensitisation. However, the concentrations of these substances in the products in the

	Premium biocidal product family are below the concentration that trigger classification for skin sensitisation as well as additional labelling provisions (EUH 208).
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Skin sensitisation
Justification	Waiving according to Annex III, point No. 8.3, Column 3 of the BPR: There are sufficient data available on the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected.

Respiratory sensitisation (ADS)

No studies for the assessment of respiratory sensitisation of Premium products are available. The active substances, dicopper oxide and tralopyril, are not classified (ECHA 2016a) or proposed classified (ECHA 2014b) for this end point. In addition, none of the co-formulants is classified for this endpoint. A study investigating the respiratory sensitising effects of Premium products is not considered necessary.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No data available
Justification for the value/conclusion	No substances present in the Premium Product Family are classified for respiratory sensitisation. Therefore, this BPF is not classified for this endpoint.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Not a core data requirement
Justification	No test guideline available The toxicity of the active substances and of the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP).

Acute toxicity

Acute toxicity by oral route

No studies for the assessment of acute oral toxicity of Premium products are available. Harmonised CLP classification exists for dicopper oxide with regard to this endpoint (Acute Tox 4, H302, ATE of 500 mg/kg bw, 17 ATP to CLP). As for tralopyril, no harmonised classification, nor CLH proposal exists. A classification as Acute tox 2; H300 was proposed by the eCA in the CAR (ECHA 2014b)

One co-formulant is also classified for acute oral toxicity (Acute Tox 4; H302), but should not be taken into account in the calculation of ATE value for acute oral toxicity as it is present in a concentration below the generic cut of value of 1% for Acute Tox 4 classified substances (Table 1.1, in Annex I to Reg. no 1272/2008).

Due to the contribution of dicopper oxide and tralopyril to the classification of the mixture using the ATE calculation method, classification for this endpoint is required for the Premium biocidal product family members (see the confidential annex for details).

According to Annex III, point 8.5.1, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the acute toxic effects of Premium BPF is not considered necessary.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Acute oral toxicity
Justification for the selected value	The products are classified for acute oral toxicity based on the classification of the active substances.
Classification of the product according to CLP	Acute Tox. 4 (H302, oral)

Data waiving	
Information requirement	Acute oral toxicity
Justification	<p>Waiving according to Annex III, point No. 8.5.1., Column 3 of the BPR:</p> <p>There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected.</p>

Acute toxicity by inhalation

No studies for the assessment of acute inhalation toxicity of Premium BPF are available.

A harmonised classification exists for dicopper oxide with a classification for acute inhalation toxicity (Acute Tox 4, H332, ATE of 3.34 mg/l (dusts or mists), 17 ATP to CLP). As for tralopyril, a classification for Acute Tox 2, H330 was proposed by the eCA (ECHA, 2014b). None of the co-formulants are classified for this endpoint.

Due to the contributions of dicopper oxide and tralopyril to the classification of the Premium family members for acute inhalation toxicity (using the ATE calculation method), classification for this endpoint is required (please see the confidential annex for details).

According to Annex III, Point 8.5.2, Column 3 of the BPR, as sufficient information is available for the active substances and the co-formulants, a study investigating the acute toxic effects after inhalation of Premium products is not considered necessary.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Acute inhalation toxicity
Justification for the selected value	The active substances are classified for acute inhalation toxicity, and the classification of the biocidal product family is based on the classification of these substances.
Classification of the product according to CLP	Acute Tox. 4 (H332, Inhalation: dust/mist)

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Waiving according to Annex III, point No. 8.5.2, Column 3 of the BPR: There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected.

Acute toxicity by dermal route

No studies for the assessment of acute dermal toxicity of Premium products are available. Dicopper oxide (ECHA, 2014a) and the co-formulants are not classified for this endpoint. Tralopyril was proposed classified for this endpoint by the eCA with Acute Tox 3; H311 (ECHA,2014b). According to calculations using the ATE method, no classification for this endpoint is required for the Premium family members (please see the confidential annex for further details).

According to Annex III, point 8.5.3, Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants, a study investigating the acute dermal toxicity of Premium products is not considered necessary.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No acute dermal toxicity
Justification for the selected value	Tralopyril is proposed classified for acute dermal toxicity. However, no classification of the BPF is necessary based on this constituent.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute dermal toxicity
Justification	<p>Waiving according to Annex III, point No. 8.5.3., Column 3 of the BPR:</p> <p>There are sufficient data available on each of the components in the mixture to allow classification of the mixture. No relevant synergistic effects are expected.</p>

Respiratory tract irritation

No studies for the assessment of respiratory tract irritation of Premium BPF are available. None of the ingredients of the product mixture including the co-formulants in Premium BPF products are classified as respiratory tract irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Not irritating
Justification for the value/conclusion	No substances are classified as respiratory tract irritation. Therefore, this BPF is not classified.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory tract irritation.
Justification	No study required for this endpoint according to Annex III to BPR.

Specific target organ toxicity, single or repeated exposure

The active substance tralopyril was proposed classified STOT RE 1; H372 (oral) and STOT RE 2; H373 (inhalation) by the eCA (ECHA 2014b) on the basis of histopathological changes in the CNS seen in rats in the 90 day and 1-year studies. None of the other ingredients of the Premium BPF products are classified for specific target organ toxicity.

As tralopyril is present in a concentration of 2% (w/w) in the Premium BPF products, this substance triggers a classification of the products as STOT RE 2; H372 (oral).

Conclusion used in the Risk Assessment – Specific target organ toxicity, single or repeated exposure	
Value	Specific target organ toxicity, repeated exposure (oral)
Justification for the selected value	Tralopyril is classified for Specific target organ toxicity, repeated exposure and classification of the BPF is based on this substance.
Classification of the product according to CLP	STOT RE cat 2; H372 (oral)

Information on dermal absorption

Two *in vitro* dermal absorption studies through human skin, performed in accordance with OECD test guideline 428, were initially conducted on Aquanet Premium as a representative product in this product family; one examining the dermal absorption of copper (Bernal, J. 2018a) and one examining the dermal absorption of radiolabelled (^{14}C) tralopyril (Bernal, J. 2018b) through human skin. The former study measured the total amount of copper (non-radiolabelled) using ICP-MS as it is not technically feasible for copper to be radiolabelled. Both studies were performed on split thickness human skin samples using static diffusion cells.

The product is a paint formulation which dries on the skin and is difficult to remove by washing without damaging the skin sample. The test formulation was therefore left on the skin samples for the whole test period of 24 hours, as recommended by the PT21 dermal absorption guidance (ECHA 2016c). The *stratum corneum* was removed with up to 15 and 11 successive tape strips respectively. All tape strips were photographed and analysed separately.

In the studies, the receptor fluid was sampled six times at 1h, 2h, 4h, 8h, 12h and 24h from the commencement of the application.

In the study on (^{14}C) tralopyril, less than 75% of the total absorption was recovered at half of the study duration (i.e., 12 hours). Hence, it could not be concluded that the absorption was essentially complete at half of the study duration. Consequently, a potential absorbable dose was calculated including tape strips 3+, in agreement with the EFSA guidance (EFSA, 2017).

Based on the photos, it could be observed that almost all the paint was removed at the very first tape strip. Some splinters were also sometimes observed in the following tape strips. However, it was decided by the study director to exclude only the first strips in agreement with the EFSA guidance.

Due to deficiencies identified in the first study on copper (analytical problems resulting in a lack of exposed skin samples) this study was considered invalid and was repeated (Wallace, J. 2020). In the study, the paint was removed after 8-hours. To demonstrate the extent of paint removal, one photograph of each skin sample was taken before and one after the washing procedure was complete. After a 16-hour post-dose monitoring period, the *stratum corneum* was removed with 20 successive tape strips. Photographs were taken after each tape strip of the skin and tape strips (unless no paint was present on pre-tape stripping image) until all the paint formulation had been removed from the skin surface.

Four-hourly fractions of the receptor fluid from 0 to 24h post dose were collected. The test system, especially the cell apparatus, can contain levels of endogenous copper that must be accounted for to ensure reliable data. Hence, a second undosed group of skin samples from the same donors was set up, washed, terminated, and analysed using the same methods described for those exposed to the test preparation. Based on the undosed group results (and the results of blank sample analysis), it was not considered necessary to adjust the data to account for intrinsic copper content since low background levels of Cu was measured.

An adjustment was nevertheless made for the receptor wash samples. Small, but measurable levels of copper (all values above LOQ) were found for the undosed group at around the same levels as the ones in the test material treated group. It was concluded that the copper present in the receptor wash sample is very unlikely to come from the test material and should not contribute to the risk assessment figures. Hence, the mean receptor wash value from the undosed group (0.11%) was subtracted from each individual cell in the test material treated group. The impact on the dermal absorption value of this adjustment was minor.

Since all measurements in the receptor fluid for skin samples with applied test material were below the LOQ, it was not possible to determine the extent of absorption as defined in the EFSA guidance. Hence, it could not be concluded that the absorption was essentially complete at half of the study duration. Furthermore, based on the available photo evidence of the tape strips, there was no convincing evidence for disregarding tape strips 3+. Consequently, a potential absorbable dose was calculated including tape strips 3+, in agreement with the EFSA guidance.

Where values measured were below LOQ, this value was used in calculations. An additional set of results were generated on the request of the applicant (report amendment 1) for which all values for the test material treated group were corrected for the background/LOQ values seen in the undosed group. However, it was stressed in the report that these values represent the very best case for absorption. The real amount of absorbed copper is likely to be somewhere in between the two sets of calculated values. Keeping in mind the uncertainties in the figures and the aim of the risk assessment, i.e., to ascertain safe use of the workers, the RMS is of the opinion that the calculated best-case values would not be sufficiently protective.

The results found in the studies were evaluated to be applicable to both products in this product family. The tested formulation has the lowest content of Cu₂O, and the concentration of tralopyril in the family members is almost identical. Further details on the composition of the family members are described in the confidential annex.

Based on these *in vitro* studies on human skin, the dermal absorption values for dicopper oxide (copper) and tralopyril to be used in the risk assessment of the products in the Premium biocidal product family are 1.1% for copper and 1.1% for tralopyril.

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	Species, Number of skin samples tested per dose, Other relevant information about the study	Test substance, Doses	Absorption data for each compartment and final absorption value		Remarks (e.g. major deviations)
<i>In-vitro</i> human skin penetration of ¹⁴ C-tralopyril in AquaNet Premium PT21 biocide product OECD TG 428 (2004) GLP Reliability 1 Bernal, J (2018b)	<i>In vitro</i> , split thickness human skin, abdomen, 8 samples from 4 donors, absorption of tralopyril measured static diffusion cells 24h exposure (no washing; paint left on skin) Sampling of receptor fluid at 1h, 2h, 4h, 8h, 12h and 24h Tape stripping (max 11). Photo evidence.	AquaNet Premium dicopper oxide 10% and tralopyril 2%	Compartment	Concentrate	
			Tape strips 1 & 2	99.22±3.51	
			Tape-strips 3+	0.47±0.60	
			Skin (exposed + surrounding skin)	0.06±0.06	
			Receptor fluid (incl. receptor compartment rinsing)	0.02±0.01	
			Dermal delivery*	0.08±0.06	
			Potentially absorbable dose**	0.54±0.61	
			Total absorption*** (mean + 0.84* SD)	1.05	
			Total recovery	99.76±3.57-	
			*Skin + receptor fluid **Skin + receptor fluid + tape-strips 3+ (absorption not complete) *** n = 8		
Final dermal absorption value: correcting for variability according to EFSA, 2017 (mean value + 0.84 x standard deviation; n=8): 1.1%					

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	Species, Number of skin samples tested per dose, Other relevant information about the study	Test substance, Doses	Absorption data for each compartment and final absorption value	Remarks (e.g. major deviations)	
The <i>In Vitro</i> Percutaneous Absorption of Dicopper Oxide in AquaNet Premium antifouling paint formulation through Human Split-Thickness Skin OECD TG 428 (2004) GLP Reliability 1 Wallace, J (2020)	In vitro, split thickness human skin, abdomen, 12 samples from 4 donors (8 processed) Additional 8 samples from 4 donors (blank controls to account for intrinsic copper levels in the matrices). Blank samples: (4 receptor fluid, 4 skin, 4 tape strips, 4 skin washes, 4 tissue swabs, 8 donor and 8 receptor chamber washes). Flow-through diffusion cells, 8 h exposure (paint removed with Swarfega® Paint Pro), 16 h post exposure monitoring. Photos	AquaNet Premium dicopper oxide 10% and tralopyril 2%	Compartment	Concentrate	Non-radio-labelled (copper cannot be radio-labelled) Absorption of total copper measured LOQ used in the calculations for values below LOQ
			Tape strips 1 & 2	1±0.73	
			Tape-strips 3+	0.65±0.10	
			Exposed skin	0.23±0.05	
			Receptor fluid	0.07±0.00	
			Receptor wash	0.01±0.01	
			Total absorbed dose*	0.08±0.01	
			Dermal delivery**	0.30±0.05	
			Potential absorbable dose ***	0.95±0.12.	
			Total recovery	104.84±5.26	
			*cumulative receptor fluid + receptor chamber wash (excluding mean value from the undosed group from the latter). **absorbed dose + exposed skin. *** Dermal delivery + <i>stratum corneum</i> 3-20		
			Final dermal absorption value correcting for variability according to EFSA, 2017 (mean value + 0.84 x standard deviation; n=8): 0.4% (excluding tape strips) – 1.1% (including tape strips 3-20)		

	demonstrating extent of paint removal.			
	4h fractions of receptor fluid (0 to 24h post dose).			
	Tape stripping (20). Photo-evidence.			

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Dicopper oxide (copper)	Tralopyril
Value(s)	1.1%	1.1%
Justification for the selected value(s)	The <i>In Vitro</i> Percutaneous Absorption of Dicopper Oxide in AquaNet Premium Paint Formulation through Human Split-Thickness Skin (Wallace, J. 2020)	<i>In vitro</i> human skin penetration of ¹⁴ C-tralopyril in AquaNet Premium PT21 biocide product (Bernal, J. 2018b)

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

Toxicological information on the co-formulants is summarized in a separate report (see further information in the confidential annex).

Available toxicological data relating to a mixture

Not relevant

Endocrine disrupting potential

According to the assessment performed according to the draft document "*Practical approach for the assessment of ED properties of a biocidal product by RMS/eCA*", none of the formulants contained in the products of the Premium family are identified as endocrine disruptors.

However, there might be indications that one co-formulant shows alerts for endocrine disruption potential from in vitro assays and in silico models. An Endocrine Disruption Screening Program (EDSP) 21 search was done, and the substance tested positive in 5 of 26 estrogen receptor (ER) bioactivity assays; 8 of 16 androgen receptor (AR) bioactivity assay, 5 of 10 thyroid bioactivity assays and 2 of 2 steroidogenesis assays. According to a

ToxCast model prediction for the co-formulant, it seems to be an ED alert at least for anti-androgenicity, that should be further explored. No evidence of endocrine disruption effects has been observed in standard in vivo regulatory studies or in the published literature. Based on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. The co-formulant is a biocidal active substance currently under evaluation as an active substance. If the substance is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

The complete assessment is presented in the confidential annex to this PAR (1.6).

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substances and substances of concern from its use in biocidal product

Nets used to house fish in aquaculture are coated with an antifouling product before being used on fish farms. The treatment process is undertaken industrially by specialised service companies. This document assesses the risks to the operators and workers involved in the treatment and deployment of nets when using the products in the Aquanet 360 biocidal product family, in compliance with Regulation (EU) No. 528/2012. The relevant work tasks for industrial and professional workers dealing with antifouling coating nets are described below.

Mixing and loading

Under normal working procedures, the product is pumped directly from the 1000 litre IBC containers into larger storage tanks. From here the product is pumped to the treatment unit using integrated systems. After a treatment episode, the unused product is pumped back to the storage tank for re-use. Internal circulation pumps in holding/storage tanks are also common. Since there is no pouring or mixing by hand, no physical contact is expected. However, as a worst-case scenario, some dermal exposure may occur during the fixing/removing of the pump lines to the IBC (**Feil! Fant ikke referansekilden.**).



Figure 1: Mixing and loading operations with Premium products (Figure: Steen-Hansen)

Treatment of nets

In general, there are two methods in use for the treatment of aquaculture nets; crane assisted dipping in open tanks and vacuum treatment.

Crane assisted dipping

Crane assisted dipping is performed by lowering the net into a vat containing the product. The net is left submerged in the product for approximately 20 minutes whilst being held down by a weight attached to a crane. After treatment, the weight is removed, and the net is either rolled back onto the roller or is gradually lifted by the crane to allow unattached product to drain off the net (**Feil! Fant ikke referansekilden.**). It is assumed that no more than two nets are treated during a working day, and that this task is performed 2-3 times pr. week.

There is a potential for dermal exposure through contact with contaminated surfaces/equipment.

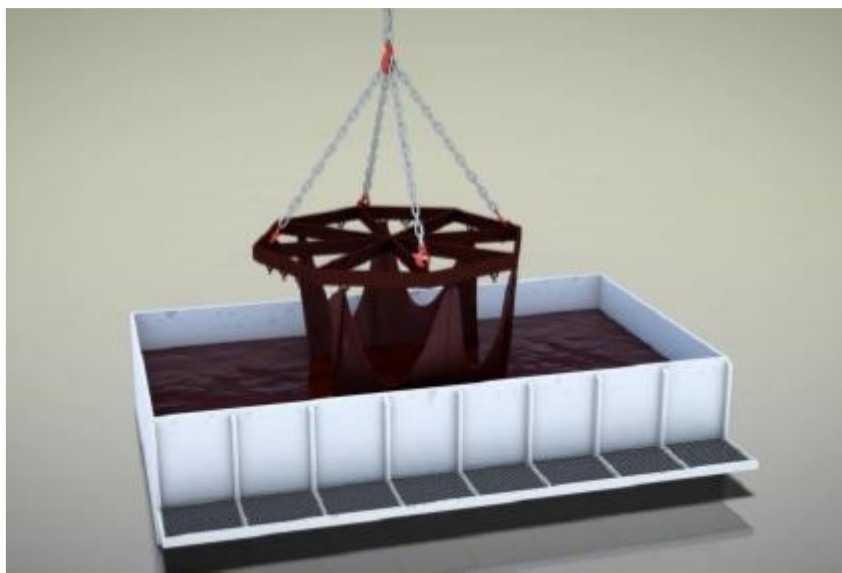


Figure 2: Net dipping procedure using dipping tanks (Figure: Steen-Hansen)

Vacuum treatment

Vacuum treatment is performed by placing the net inside a special bag. The bag is then sealed tight and is filled with product. Repeated vacuum cycles are then applied to "suck" the product into the net, and later to remove excess product from the net. At the end of the treatment, excess product is pumped out from the bottom of the bag. The drip-dry net is then hoisted out of the bag by crane or winch.

There is a potential for exposure to the body and hands through direct contact with the treated nets when manually reconnecting the nets from the hoist after impregnation.

The applicant Steen-Hansen recommends dip treatment with their products, as they are of the opinion that this method gives the best quality of the treatment. It can nevertheless not be excluded that some service stations choose to apply their products using the vacuum method.

Net drying

After treatment, the net can be left hanging freely over the dipping tank to dry in ambient temperature. The drying may also be accelerated by exposing it to dried heated air. Net drying may also be done in a separate drying station. An alternative method in use is when the net is wound up on a net roller which is injected in the centre with dried heated air.

When the net is totally dry, it is transferred to a compression/packing unit where it is tightly packed in a sealed waterproof bag. The transfer of the treated net is performed using winches or cranes. In a worst-case scenario, the drip-free net is suspended in a drying tower or left dry freely using outside freestanding cranes (**Feil! Fant ikke referansebildet.**).

Exposure may occur when the treated net is connected to the crane or drying roller in the drying station and by manual assistance when the net is wound up on the roller.



Figure 3: Net drying procedure (Figure: Steen-Hansen)

Cleaning of dipping vats

Cleaning of dipping vats is normally performed once pr year. All product is pumped out of the vat and the metal inlay is hoisted out and is left to dry overnight. Residues in the bottom of the vat is removed manually and transferred to an empty IBC. The inlay is then scraped free of dry product.

The task is performed by the same personnel as performs the net dipping. Some contact with wet surfaces will occur and single-use coveralls, boots, gloves and a face shield are used when cleaning is performed.

Inspection and repair of used nets

Net service companies typically treat both new and used nets. Used nets are returned to the service station by boat or truck in closed containers. The nets are then cleaned and disinfected before they are thoroughly inspected and repaired, if necessary.

The net is lifted using an electrically operated hoist/crane and manoeuvred into a tumble washer containing seawater. It is washed for 3 – 5 hours where the biofouling and old coating are removed primarily through mechanical action. The cleaning is conducted in a closed loop process with the wash water being reused after extraction of the solid waste. The solid waste is incinerated or is sent for recovery of the metals. The washed nets are then submerged in disinfectant fluids in an aseptic zone (**Feil! Fant ikke referansekilden.**). No physical contact is expected during the net cleaning procedures.



Figure 4: Net washing and disinfection procedure (Figure: Steen-Hansen)

Inspection/repair of cleaned nets

The entire net must be inspected for damage and the breakage strength is tested in several places, depending on the size of the net (**Feil! Fant ikke referansekilden.**). Any damaged areas are repaired manually. This activity requires physical handling of the nets. The nets will, however, at this point contain a very small amount of remaining product. Personnel involved in the inspection and repair process may thus be exposed to a very small amount of product residues by dermal contact with the net and through inhalation of formed dust.

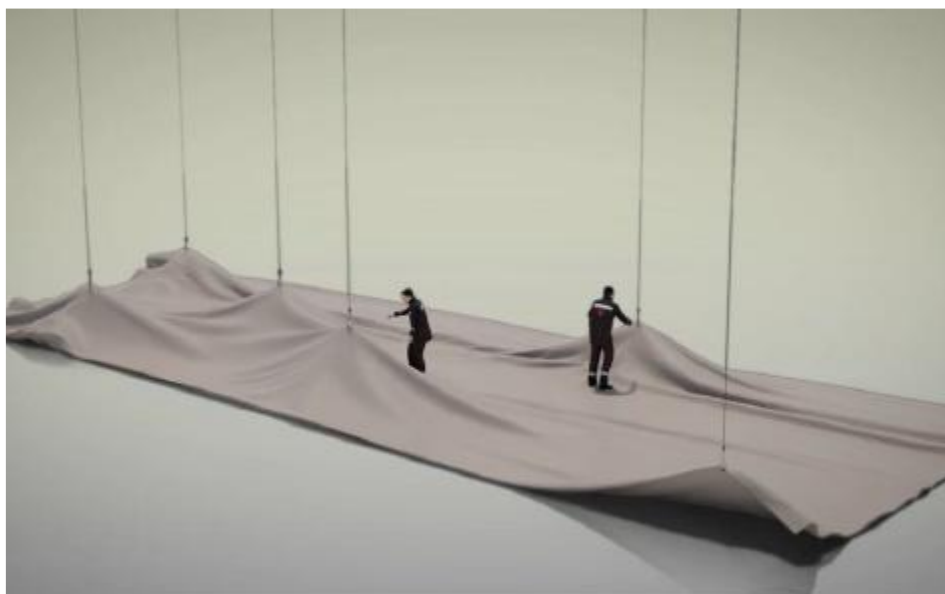


Figure 5: Net inspection procedure (Figure: Steen-Hansen)

Deployment/removal of nets

The treated net is hoisted by a crane into a service boat. The net is attached to one side of a floating frame and then pulled towards the other side of the frame. Remotely controlled weights and supports are lowered into the water. The net is attached to floats and its upper part is tied to the cage fence. These activities require handling the nets and although limited, physical contact is expected, and workers would be exposed via the dermal route. Removal of the net is the opposite process of deployment. Up to 6 people are involved in the deployment of one net and the operators may deploy up to 3-7 nets in a day. As nets are normally changed with 5 – 10 months intervals, the involved personnel perform this task infrequently.

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure (treatment of nets)			Secondary (indirect) exposure (deployment and washing of nets)			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	Non-professional use	Via food
Inhalation	Yes	n.a.	n.a.	n.a.	Negligible	n.a.	n.a.
Dermal	Yes	n.a.	n.a.	n.a.	Yes	n.a.	n.a.
Oral	No	n.a.	n.a.	n.a.	No	n.a.	yes

List of scenarios.**Mixing and loading**

Minimal risk of exposure is expected as the mixing and loading process is automated and occurs in a closed system. Some accidental exposure can occur during fixing/removal of the pump lines. Mixing and loading is included in Dipping model 4 and is not assessed separately.

Inspection and repair of used nets

A scenario to assess exposure from the task of inspecting and repairing used nets does not exist. At the end of the service life of a net, it is in the risk assessment for the environment assumed that approx. 80% of the active substances has leached out. Before being inspected, the nets have also been thoroughly washed in a tumble washing machine with the aim to remove all remaining coating and attached debris and have been disinfected. It can thus reasonably be expected that the small amount of product residues that may still be found in the nets at this point represents a negligible exposure compared to e.g., deployment of nets. This task is thus not further assessed.

Treatment of nets – semiautomatic dipping

A scenario to assess exposure from dip treatment of aquaculture nets, Dipping model 4, is found in the Biocides Human Health Exposure Methodology (page 311, ECHA, 2015a). The scenario includes dispensing product from IBC (mixing and loading), stirring and crane assisted dipping of both solvent-based and water-based products. Indicative values for this scenario are further given (page 199). The indicative values are the maximum values due to the low number of measurements and the large variation.

The scenario is based on survey data from different dipping processes.

According to the guidance document, the results reflect the true nature of the net dipping activity, i.e., an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated immersion of the nets in large vats of fluid and similar retrieval at the conclusion of the process. This work is then followed by the drying and preparation of the nets and wrapping prior to transportation to the ultimate customer.

The survey reports it is based on are, however, rather old (from 1999), and the number of measurements is very low (n=9). The dipping techniques used differ between the sites included in the survey with different degrees of automatization and hence potential for dermal exposure. Dermal exposure resulted from manually connecting/disconnecting of treated nets to hoists/forklifts/drums, contact with contaminated surfaces, manually immersion of buoyant nets using sticks (where relevant, two sites only) and particularly from physical contact when transferring the nets to the drying stations.

Several of the measurements (n=5) are from dipping and packing of nets treated with solvent-based products. Nets treated with solvent-based products need to be packed and deployed in a damp state and might therefore result in a high exposure to the involved personnel. Solvent based net impregnation products are no longer on the market in Europe. Nets treated with water-based products on the contrary must be completely dry before they

can be packed. The packing process does no longer involve any manual handling as the nets are transferred directly by winch into a special waterproof net bag in a compression unit for packing.

The dipping process has been developed in the last 20 years, as both the aquaculture business and its service providers has grown significantly and professionalised in this period. The service stations use, to our knowledge, treatment processes which involve very little degree of physical contact with the nets during the treatment process.

The recommendation in the Biocides Human Health Exposure Methodology for this exposure model is that the maximum value is used, due to the low number and the variability of the data. This is obviously a very conservative approach, and the exposure calculations must therefore be regarded as conservative.

Treatment of nets – Vacuum treatment

No scenario exists for the assessment of exposure from vacuum treatment of nets. Many of the tasks involving potential exposure to treated nets and contaminated surfaces are, however, identical as for dipping, such as connecting/disconnecting of nets to cranes/winches and transferring the nets to the drying station.

It is assumed that the Dipping model 4 also covers treatment using the vacuum method.

Cleaning of dipping vats

No scenario exists for the assessment of exposure from cleaning of dipping vats. Cleaning is normally performed once pr. year and is performed using single-use coveralls, gloves, boots and face shields. The exposure is assessed as being covered by the dipping 4 model.

Deployment of treated nets

A scenario to assess exposure from deployment and installation of a net at a fish farm, Handling model 2, is found in the Biocides Human Health Exposure Methodology (page 303, ECHA, 2015a). Indicative values for this scenario are further given (page 198) and are the 75 percentile values.

The situation is similar for the exposure scenario for deployment of a treated net as for treatment of nets. The scenario is titled "installing fish cages using lifting equipment and handling nets damp with sticky product". The original surveys the scenario is based upon are rather old, and the number of data is very low. For several of the data points, the workers are employing nets treated with solvent based antifouling products, requiring that the nets are still damp with product at deployment. This will inevitably result in a higher risk for exposure than if the nets are treated with a water-based product which is completely dry before the net is installed. The assessment must therefore be regarded as being conservative.

Summary table: Scenarios			
Scenario number	Scenario (e.g. mixing/loading)	Primary (direct) or secondary (indirect) exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Dipping Model 4; Net Dipping	Describes the process of mixing and loading antifouling product into reservoirs for net dipping, crane assisted net dipping and the packing of treated nets for shipment out to the customer. The model covers the use of both water-based and solvent based products. Hand exposure is actual values inside gloves. Indicative values are maximum values.	Industrial workers
2.	Handling model 2; Net deployment/removal	Describes the process where the treated net is hoisted by a crane from a service boat and employed in the sea at an aquaculture farm. It will also cover the process of changing a net which is still in service in an active fish farm. These activities require handling the nets and although limited, physical contact is expected, and workers would be exposed via the dermal route. Removal of the net is the opposite process of deployment. Hand exposure is actual values inside gloves. Indicative values are 75 percentile values.	Professional operators

Description of Scenario 1		
Dipping model 4		
	Parameters	Value
Tier 1	Body ¹	221 mg/min
	Hands ¹ (hand exposure values are actual measurements inside gloves)	16.7 mg/min
	Inhalation ¹	0.20 mg/min
	Inhalation rate ²	1.25 m ³ /h
	Duration ¹	60 min.
	Body weight ²	60 kg
	Dermal absorption ⁴	copper: 1.1% tralopyril: 1.1%
Tier 2a	Clothing penetration (coated coverall) ³	10%
	Hand exposure ¹	Hand exposure values are actual

		measurements inside gloves.
Tier 2b	Clothing penetration (impermeable coverall) ³	5%
	Hand exposure ¹	Hand exposure values are actual measurements inside gloves.
Tier 2 c	Clothing penetration (Double coverall) ³	1%
	Hand exposure ¹	Hand exposure values are actual measurements inside gloves.

¹) Dipping model 4; Biocides Human Health Exposure Methodology, maximum values (ECHA, 2015a)

²) Ad hoc Working Group Recommendation 14: Default human factor values for use in exposure assessments for biocidal products (ECHA, 2017b)

³) HEEG opinion 9, Default protection factors for protective clothing and gloves

⁴) Dermal absorption studies (Wallace, 2020; Bernal, 2018b)

Description of Scenario 2		
Handling model 2		
	Parameters	Value
Tier 1	Body ¹	7.55 mg/min
	Hands ¹ (hand exposure values are actual measurements inside gloves)	0.21 mg/min
	Duration ¹	300 min
	Body weight ²	60 kg
	Dermal absorption ³	copper: 1.1%. tralopyril: 1.1%
Tier 2	Clothing penetration Uncoated cotton coveralls (dry) ²	25% penetration from dry substances
	Hand exposure ¹	hand exposure values are actual measurements inside gloves

¹) Handling model 2; Biocides Human Health Exposure Methodology. 75th percentile values (ECHA, 2015a)

²) Ad hoc Working Group Recommendation 14: Default human factor values for use in exposure assessments for biocidal products (ECHA, 2017b).

³) Dermal absorption studies (Wallace, 2020; Bernal, 2018b)

General assumptions:

The systemic exposure of each active substance via the dermal and inhalation routes were estimated using default physiological values (body weight, breathing rate, etc.) and either default or refined model input values for each scenario. After estimation of the systemic exposure, the occupational risks were estimated by comparing the level of systemic exposure with the relevant toxicological reference value for each active substance (see

2.2.6). The long-term Acceptable Exposure Level values (AEL) of 0.041 mg Cu/kg bw/day for dicopper oxide and 0.03 mg/kg bw/day (dermal) and 0.029 mg/kg bw/day (inhalation) for tralopyril, respectively were used in the assessment of net treatment based on the description of the frequency of use. Personnel involved in net treatment may perform this task 2-3 days per week the whole year.

In the assessment of net deployment, the medium term AEL values of 0.082 mg Cu/bw/day for dicopper oxide and 0.06 mg/kg bw/day (dermal) for tralopyril, respectively, were used as this task is performed infrequently. These values are reported in the respective Assessment Reports for the approval of the use of these active substances as biocides.

An initial screening assessment (Tier-1) using default assumptions and only minimal clothing as well as gloves (hand exposure being actual values inside gloves) was conducted. Since the Premium products are for professional use only, this was considered the "extreme" worst-case scenario and is unlikely to be representative of the normal workplace. A Tier-2 assessment was used applying representative PPE for the estimation of a more realistic systemic exposure where necessary.

Active substances present in the members of the Premium biocidal product family			
Representative product	Aquanet Premium	Aquanet Boost ^{old2}	Aquanet Boost
Active ingredient (% w/w)	9.99% dicopper oxide + 2.00% tralopyril	24.83% dicopper oxide + 1.96% tralopyril	21.95 dicopper oxide + 1.98% tralopyril
Formulation (Ready-for-use or concentrate)	Ready for use	Ready for use	Ready for use
Ionic equivalents (in-use conc. of copper; % w/w) ¹	Total Cu: 8.87% Total tralopyril: 2.00%	Total Cu: 22.05% Total tralopyril: 1.96%	Total Cu: 19.49% Total tralopyril: 1.98%

¹ Conversion factors: ($[\text{Cu}_2\text{O}] \cdot 0,888$)

²Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Industrial exposure

Scenario [1] Industrial use: Net treatment

The modelling input parameters of Dipping model 4 were used to calculate the exposure values for the Premium biocidal product family members.

Summary table: Estimated systemic exposure from professional use					
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw)	Estimated dermal intake (mg/kg bw)	Estimated oral intake (mg/kg bw)	Estimated total systemic uptake (mg/kg bw)
Scenario 1: Net dipping					
Aquanet Premium					
Copper					
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	3.7e-04	0.23	-	0.23
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	3.7e-04	0.038	-	0.038
Tralopyril					
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	8.4e-05	0.052	-	0.052
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	8.4e-05	8.5e-03	-	8.6e-03
Aquanet Boost^{old}					
Copper					

Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	9.3e-04	0.58	-	0.58
	Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves)	9.3e-04	0.094	-	0.095
	Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves)	9.3e-04	0.067	-	0.068
	Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves)	9.3e-04	0.046	-	0.047
Tralopyril					
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	8.2e-05	0.051	-	0.051
	Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-05	8.4e-03	-	8.5e-03

	Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-05	6.0e-03	-	6.1e-03
	Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-05	4.1e-03	-	4.2e-03
AquaNet Boost					
Copper					
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	8.2e-04	0.51		0.51
	Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-04	0.083		0.084
	Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-04	0.060		0.060
	Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.2e-04	0.041		0.041
Tralopyril					

Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	8.3e-05	0.052	-	0.052
	Tier 2a; Coated coverall (10 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.3e-05	8.4e-03	-	8.5e-03
	Tier 2b; Impermeable coverall (5 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.3e-05	6.0e-03	-	6.1e-03
	Tier 2c; Double coverall (1 % penetration) and gloves (hand exposure is actual exposure inside gloves)	8.3e-05	4.1e-03	-	4.2e-03

¹Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Professional exposure

Scenario [2] Professional use: Net deployment

The modelling input parameters of Handling model 2 were used to calculate the exposure values for the Premium biocidal product family members.

Summary table: Estimated systemic exposure from professional use				
Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw)	Estimated dermal intake (mg/kg bw)	Estimated total systemic uptake (mg/kg bw)

Scenario 2: Net deployment				
Aquanet Premium				
Copper				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	0.038	0.038
Tralopyril				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	8.5e-03	8.5e-03
Aquanet Boost_{old}¹				
Copper				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	0.094	0.094
	Tier 2; Uncoated cotton coverall (dry) (25% penetration). Gloves (hand exposure is actual exposure inside gloves)	-	0.025	0.025
Tralopyril				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	8.4e-03	8.4e-03
	Tier 2; Uncoated cotton coverall (dry) (25% penetration). Gloves (hand exposure is actual exposure inside gloves)	-	2.3e-03	2.3e-03

Aquanet Boost				
Copper				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	0.083	0.083
Tralopyril				
Professional deployment of aquaculture nets; Handling model 2	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	-	8.4e-03	8.4e-03

¹ Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

2.2.6.3 Risk characterisation for human health

Reference values to be used in the Risk Characterisation

(ref: Assessment reports for dicopper oxide (ECHA, 2016a) and tralopyril (ECHA, 2014b))

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral/dermal/inhalation absorption	Value
Reference values for copper (from dicopper oxide)					
AEL _{short-term}	90-day rat study	16.3 mg Cu/kg bw/day	50	25%	0.082 mg/kg bw/day
AEL _{medium-term}	90-day rat study	16.3 mg Cu/kg bw/day	50	25%	0.082 mg/kg bw/day
AEL _{long-term}	90-day rat study	16.3 mg Cu/kg bw/day	100	25%	0.041 mg/kg bw/day
ARfD	n.a.				
ADI	EFSA (2008)	-			0.15 mg Cu/kg bw/day

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral/dermal/inhalation absorption	Value
Reference values for tralopyril					
AEL _{short-term} (Dermal)	90-day rat study	300 mg/kg bw/day	100	2%	0.06 mg/kg bw/day
AEL _{medium-term} (Dermal)	90-day rat study	300 mg/kg bw/day	100	2%	0.06 mg/kg bw/day
AEL _{long-term} (Dermal)	90-day rat study	300 mg/kg bw/day	200	2%	0.03 mg/kg bw/day
AEL _{short-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	100	100%	0.058 mg/kg bw/day
AEL _{medium-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	100	100%	0.058 mg/kg bw/day
AEL _{long-term} (Inhalation)	90-day rat study	5.8 mg/kg bw/day	200	100%	0.029 mg/kg bw/day
AEL _{short-term} (Oral)	rat developmental study	10 mg/kg bw/day	100	80%	0.08 mg/kg bw/day
AEL _{medium-term} (Oral)	90-day rat study	5 mg/kg bw/day (LOAEL)	300	80%	0.013 mg/kg bw/day
AEL _{long-term} (Oral)	90-day rat study	5 mg/kg bw/day (LOAEL)	600	80%	0.007 mg/kg bw/day
Acute AEC local	90-day rat study	20 mg/m ³ (LOAEC)	75	100	0.27 mg/m ³
Medium AEC local	90-day rat study	20 mg/m ³ (LOAEC)	75	100	0.27 mg/m ³
Long term AEC local	90-day rat study	20 mg/m ³ (LOAEC)	150	100	0.13 mg/m ³
ARfD ¹	Rat developmental study (oral)	10 mg/kg bw/day	100	n.a.	0.10 mg/kg bw
ADI ¹	90 day rat study (oral)	5 mg/kg bw/day (LOAEL)	600	n.a.	0.0083 mg/kg bw day

¹ Not included in the AR of tralopyril, but derived for the purpose of this risk assessment

Industrial use

Scenario [1] Industrial use: Net dipping

The predicted levels of systemic exposure of operators to copper and tralopyril when undertaking net dipping activities are summarised and compared with the relevant AEL-values below.

Risk characterisation of industrial use				
Exposure scenario	Tier/PPE	Estimated total systemic uptake (mg/kg bw)	AEL _{long term} (mg/kg bw/day)	Exposure/AEL
Aquanet Premium				
Copper				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration) Gloves (hand exposure is actual exposure inside gloves)	0.23	0.041	5.7
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.038	0.041	0.93
Tralopyril				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), Gloves (hand exposure is actual exposure inside gloves)	0.052	0.029 (inhalation), 0.03 (dermal)	1.8
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	8.6e-03	0.029 (inhalation), 0.03 (dermal)	0.29
Aquanet Boost_{old}¹				
Copper				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	0.58	0.041	14
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.095	0.041	2.3
	Tier 2b; Impermeable coverall (5% penetration) and gloves (hand	0.068	0.041	1.7

Risk characterisation of industrial use				
	exposure is actual exposure inside gloves)			
	Tier 2c; Double coverall (1% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.047	0.041	1.14
Tralopyril				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	0.051	0.029 (inhalation), 0.03 (dermal)	1.7
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	8.5e-03	0.029 (inhalation), 0.03 (dermal)	0.28
	Tier 2b; Impermeable coverall (5% penetration) and gloves (hand exposure is actual exposure inside gloves)	6.1e-03	0.029 (inhalation), 0.03 (dermal)	0.20
	Tier 2c; Double coverall (1% penetration) and gloves (hand exposure is actual exposure inside gloves)	4.2e-03	0.029 (inhalation), 0.03 (dermal)	0.14
Aquanet Boost				
Copper				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing(100% penetration), gloves (hand exposure is actual exposure inside gloves)	0.051	0.041	13
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.084	0.041	2.1
	Tier 2b; Impermeable coverall (5% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.060	0.041	1.5

Risk characterisation of industrial use				
	Tier 2c; Double coverall (1% penetration) and gloves (hand exposure is actual exposure inside gloves)	0.041	0.041	1.01
Tralopyril				
Industrial dipping of aquaculture nets; Dipping model 4	Tier 1; Light clothing (100% penetration), gloves (hand exposure is actual exposure inside gloves)	0.052	0.029 (inhalation), 0.03 (dermal)	1.7
	Tier 2a; Coated coverall (10% penetration) and gloves (hand exposure is actual exposure inside gloves)	8.5e-03	0.029 (inhalation), 0.03 (dermal)	0.28
	Tier 2b; Impermeable coverall (5% penetration) and gloves (hand exposure is actual exposure inside gloves)	6.1e-03	0.029 (inhalation), 0.03 (dermal)	0.20
	Tier 2c; Double coverall (1% penetration) and gloves (hand exposure is actual exposure inside gloves)	4.2e-03	0.029 (inhalation), 0.03 (dermal)	0.14

¹. Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Values in bold represent exposure/AEL values >1.

Conclusion:

The risk from systemic exposure to copper and tralopyril to industrial workers performing net treatment activities using AquaNet Premium is acceptable in Tier 2a. Safe use requires the use of coated coveralls and gloves. Safe use could not be demonstrated for Aquanet Boost_{old} even with use of double coveralls and gloves. Consequently, the product was modified (new name: AquaNet Boost). reducing the amount of active substance content to an acceptable level. Safe use of the modified product necessitates use of double coveralls and gloves.

Professional use

Scenario 2: Net deployment

The predicted levels of systemic exposure of operators to copper and tralopyril when performing net deployment activities are summarised and compared with the relevant AEL-values below.

Risk characterisation of professional use				
Exposure scenario	Tier/PPE	Estimated total systemic uptake (mg/kg bw)	AEL _{medium term} (mg/kg bw/day)	Exposure/AEL
Aquanet Premium				
Copper				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	0.038	0.082	0.46
Tralopyril				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	8.5e-03	0.06 (dermal)	0.14
Aquanet Boost_{old}¹				
Copper				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	0.094	0.082	1.2
	Tier 2; Uncoated coverall (dry) (25% penetration). Gloves (Hand exposure is actual exposure inside gloves)	0.025	0.082	0.31
Tralopyril				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	8.4e-03	0.06 (dermal)	0.14

Risk characterisation of professional use				
	Tier 2; Uncoated coverall (dry) (25 % penetration). Gloves (Hand exposure is actual exposure inside gloves)	2.3e-03	0.06 (dermal)	0.04
Aquanet Boost				
Copper				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	0.083	0.082	1.01
Tralopyril				
Professional deployment of nets	Tier 1; Light clothing (100% penetration) gloves (hand exposure is actual exposure inside gloves)	8.4e-03	0.06 (dermal)	0.14

¹. Due to an identified risk in the human health risk assessment (net treatment), the product was modified (the amount of active substance content reduced to an acceptable level). The postfix "old" has been added to the name.

Values in bold represent exposure/AEL-values >1.

Conclusion:

The risk to workers involved in deployment activities of nets treated with AquaNet Premium and Aquanet Boost was demonstrated to be acceptable in the Tier 1 assessment.

The risk to workers involved in net deployment activities of nets treated with AquaNet Boost_{old} was demonstrated to be acceptable in a tier 2 assessment, assuming the use of an uncoated coverall and gloves. Gloves are normally worn, also due to physical strain and in the North Atlantic region due to low temperatures.

Combined scenarios

Not applicable

Local effects

A classification for Eye damage 1 (H318) is proposed for all products in the Premium biocidal product family; therefore, consideration of a local risk assessment is required. No relevant quantitative information is available to conduct a quantitative risk assessment, and so in this case a qualitative risk assessment is considered appropriate in accordance with the BPR Guidance (Chapter 4.3, ECHA, 2017a).

Most of the net treatment process is remotely operated and does not involve physical contact with the dipping vat/vacuum impregnation bag or the treated net. The tasks where the workers may be at risk to be exposed to splashes or dripping of product that may come into their eyes, thus constitute a limited part of the whole treatment process. By requiring that protective goggles or similar eye protection is used during the performance of these tasks, the risk of serious eye damage will be minimal.

AEC_{inhalation} values of 0.13 mg/m³ (long term) and 0.27 mg/m³ (acute and medium term) have been derived for tralopyril. The indicative inhalation exposure value in the dipping model 4 is 0.2 mg/m³ product. This equals approximately 0.004 mg/m³ tralopyril for both AquaNet Premium, AquaNet Boost_{old} and AquaNet Boost, which is acceptable.

Hazard		Exposure						Risk
Hazard category	Effects in terms of c&L	Who is exposed	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM and PPE	Conclusion on risk
High	Eye dam. Cat 1, H318	Industrial workers	Net treatment	Skin Eye (splashes, hand to eye transfer)	2-3 days per weeks Only a few minutes potential exposure due to automated processes. Intermittent handling of treated nets at various stages of dryness, (mainly due to connecting/disconnecting of treated nets to hoist/drums), incidental contact with contaminated surfaces	n.r.	<ul style="list-style-type: none"> – Minimisation of manual phases (automatization; crane assisted lifting of nets) – Avoidance of contact with contaminated tools and objects – Training for staff on good practice; instructions for use – Regular cleaning of equipment and work area – Good standard of personal hygiene – Coveralls, gloves, eye protection (goggles) – Labelling as H318 	Acceptable +Automated processes; Minimal potential for exposure +No aerosol formation +trained workers +use of appropriate PPE
		Professionals	Net deployment	Skin Eye (dust, hand to eye transfer)	Infrequent task Dermal contact with dry treated nets Practically no exposure to eyes. due to the use of goggles during net deployment	n.r.	<ul style="list-style-type: none"> – Training for staff on good practice; instructions for use – Good standard of personal hygiene – Coveralls, gloves, googles* <p><i>*goggles are according to the applicant worn during net deployment because of risk of debris from nets (e.g. dried microorganisms)</i></p>	Acceptable +Exposure to dry nets +trained workers +use of appropriate PPE

Conclusion

Industrial exposure

Net treatment activities:

The risk to industrial workers involved in net impregnation activities was assessed using the Dipping model 4 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net dipping tasks.

The risk was demonstrated to be acceptable in the Tier 2a assessment for AquaNet Premium, provided that the workers wear coated coveralls and gloves.

For AquaNet Boost_{old}, no safe use was demonstrated even in the Tier 2c assessment, assuming use of double coveralls and gloves. An acceptable risk was estimated for the modified product Aquanet Boost.

An acceptable risk was demonstrated for all products in the family in the semiquantitative risk assessment of local effects of tralopyril by inhalation.

Due to the classification of the products for Eye damage 1 (H318), protective goggles or similar eye protection should be used for the tasks where the workers may be at risk to be exposed to the product.

Professional exposure

Net deployment activities:

The risk to professional workers involved in net deployment activities was assessed using the Handling model 2 in the Biocides Human Health Exposure Methodology, based on surveys of personnel performing aquaculture net deployment activities.

The risk was demonstrated to be acceptable in the Tier 1 assessment for AquaNet Premium and Aquanet Boost. The risk for workers involved in net deployment activities of nets treated with AquaNet Boost_{old} was demonstrated to be safe in tier 2, assuming the use of an uncoated coverall in addition to gloves. The indicative hand exposure values in the exposure model are actual measured values inside gloves. Gloves are always worn when performing this task, due to mechanical strain, and in the Atlantic region usually also due to low temperatures. The use of gloves when performing this task should be required.

Risk for non-professional users

The products are not used by non-professionals.

Risk for the general public

The products are only for professional use, and no exposure to the general public is possible.

Dietary risk assessment

Copper

Copper is naturally present in the environment and also essential for many metabolic functions and reactions for both plants and animals. Copper is authorised as a feed additive under EU Reg. 479/20064 for nutrition of livestock including fish and shellfish and is routinely added to fish feed to prevent copper deficiency. The maximum content in the complete feeding stuffs is 25 mg/kg for fish and 50 mg/kg for crustaceans. It is also present in many food supplements for human consumption, according to Directive 2002/46/EC. Acceptable risks due to potential exposure of copper via food contamination was identified in the competent authority report for dicopper oxide based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force (ECHA, 2016a). However, it was indicated that exposure via food contamination might need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

There is currently no harmonized methodology to assess the level in foodstuff of a PT21 active substance. The most relevant general approach available to estimate levels in fish and shellfish is based on a rough calculation using the highest Predicted Environmental Concentration (PEC) calculated from the marine environment with a Bio Concentration Factor (BCF). However, for copper this approach is not relevant. In the case of copper, the potential bioaccumulation cannot be established from the BCF values. This is due to copper being an essential metal for many organisms where a feedback regulation mechanism of the uptake exists. No concern is identified for copper, also due to its physico-chemical properties (high solubility/dilution in sea water, low bioaccumulation). See the Risk Assessment for the Environment section 2.2.8. for further information.

The levels of copper (Cu), as well as other metals and environmental pollutants, were analysed in a standardised muscle sample from both farmed (n=100) and wild (n=87) Atlantic salmon caught or produced in Norway in 2012 (Lundebye *et al.*, 2017). The farmed Atlantic salmon were sampled at fish farms by inspectors from the Norwegian Food Safety Authority (NFSA) in 2012 (for the annual monitoring programme laid down in Directive 96/23 EC). Sampling locations represent regions with aquaculture activity along the Norwegian Coast accounting for at least 10 % of the total number of farm sites each year. The Wild Atlantic salmon were caught by nets in Norwegian northern coastal waters by commercial fishermen in 2012. Filets from the farmed salmon contained less copper than wild salmon. The mean copper value \pm SD from the farmed salmon was 0.38 ± 0.09 mg/kg w.w. (with a min- max range of 0.27 – 0.95) and the mean value for the wild salmon was 0.57 ± 0.15 mg/kg w.w (with a min – max range of 0.4 – 1.8). The findings in Lundebye *et al.* (2017) gives no indication of elevated copper levels in farmed fish compared to wild caught fish.

Copper levels in farmed Atlantic salmon filets were also given in an annual report for 2019 provided by the Norwegian Institute of Marine Research. This report is part of the monitoring program for pharmaceuticals, illegal substances and contaminants in farmed fish (Bernhard *et. Al.*, 2020). Samples were taken from fish farms or slaughterhouses in all fish-producing regions in Norway by official inspectors from the NFSA. The sampling plan was randomised according to season and region. When analysing the Atlantic salmon filets from the fish included in this report (n = 52), the median value was 0.4 mg/kg w.w. and the max vale was 0.7 mg/kg w.w. copper.

No information was given regarding the biocide(s) used for net treatment. However, given that the samples were taken from different farms, and considering that copper containing antifoulants is the most frequently used antifoulant in Norway, it is reasonable to believe that nets treated with such products were used in a number of the selected farms. The results from both 2012 and 2019 seem to be in the same range with the mean of 0.38 vs a median of 0.4 mg/kg w.w.

If the maximum copper value in filets of 0.95 mg/kg w.w. given in the Lundebye study is used in a reverse reference exposure calculation, a 15-kilo child would have to consume approximately 2.4 kilos of salmon per day to exceed the ADI of 0.15 mg Cu/kg bw/day. The corresponding amount for an adult of 60 kg using the same maximum value, is 9.5 kilo salmon per day.

$$\begin{aligned} (0.15 \text{ mg/kg bw/day} \times 15 \text{ kg bw}) / 0.95 \text{ mg /kg w.w.} &= 2.4 \text{ kg w.w./day} \\ (0.15 \text{ mg/kg bw/day} \times 60 \text{ kg bw}) / 0.95 \text{ mg /kg w.w.} &= 9.5 \text{ kg w.w./day} \end{aligned}$$

Based on the information above, no concern regarding exposure via food is identified. However, when a uniform methodology to assess dietary exposure induced by an antifouling application is available, this assessment may need to be updated.

Tralopyril

The potential for residues of tralopyril in food and feed of marine origin was not assessed during the evaluation of the active substance (ECHA,2014b). Thus, the potential for food/feed residues of tralopyril should be assessed as part of a dietary risk assessment at product authorisation for products for which a risk of food/feed contamination is possible due to the intended use.

A multisite trial to determine the risk of bioaccumulation of tralopyril in tissue of Atlantic Salmon was conducted for the Premium biocidal product family at four commercial fish farms in South-West Norway (3 fiords and one open water/island system) in 2016 and 2017 (Ulriksen, 2021a and b). The nets were treated with AquaNet Premium or AquaNet Protect, both products containing approximately 2% tralopyril. The time from net deployment to collection of fish was short (1-6 ½ months) and not representative for the time from deployment to harvesting of fish. Two to six salmons were collected at each site, in total 19 fish. Analysis of tralopyril was performed of edible (filet), non-edible (organs) and skin parts of the fish using LC/MS. The individual fish were apparently not tagged, and the analytical results were only partly possible to retrieve (13 out of 19 fish, see results below, Ulriksen, 2021b). Thus, there are some uncertainties related to the trial and the provided results.

Another trial to test long term accumulation of tralopyril in Atlantic Salmon was performed at one fish farm in Western Norway (Trommo). All nets were treated with AquaNet Boost, containing 2% tralopyril (Hope, 2021 and Bjarnemark, 2019). The net and fish (approximately 200-300 g) were deployed in April 2018 and fish were collected in mid-March 2019 (3.0-3.3 kg); before net change and well before harvesting of fish (week 34-42 in 2019). According to the applicant (personal communication), the reason for sampling of fish before net change was that the new net was not treated with a product containing tralopyril. Fish were therefore collected before the net was changed at a timepoint when they still were exposed to the tralopyril containing product.

Nine fish were sampled (3 fishes from 3 different cages) and analysed for tralopyril using LC/MS. The main degradation products in marine water (CL 332 250 and CL 322 248) were not analysed in fish tissue samples as intended by the study director (IUCLID end point

study record 8.10.02). Analysis of the main degradation products in marine water (CL 332 250 and CL 322 248) was not considered necessary as the metabolites are orders of magnitude less toxic than tralopyril. The fate and behaviour of tralopyril in the aquatic compartment (including sediment) is described in the assessment report of tralopyril (ECHA, 2014b) as reflected in the environmental part of the PAR (see page 88).

The fishes were, individually, separated into three fractions: edible (filet), non-edible (organs) and skin. Average and max concentrations of tralopyril in the different parts of the fish are included in the table below.

No information about in situ cleaning of nets were provided in the referred studies.

Fish tissue fraction (ng tralopyril/g fish tissue)					
	Edible (filet)	Nonedible (intestines)	Skin	Total	Reference
Mean	0.051	0.062	1.524		Ulriksen, 2021a and b
Max	0.186	0.10	4.1		
Mean	0.029	0.319	0.157	0.504	Hope, 2021/ Bjarnemark, 2019
Max	0.07	0.51	0.24	0.73	

Values below LOQ were set at LOQ for calculating average values.

In the active substance evaluation of tralopyril, ADI and ARfD values were not established since no dietary exposure to tralopyril was foreseen based on the supported intended uses. However, for this assessment, ARfD and ADI values have been derived by RMS, as described in section 2.2.6; i.e., an ARfD of 0.10 mg/kg bw and ADI of 0.0083 mg/kg bw/day.

Assuming a conservative dietary consumption of fish of 235g/day for adults (highest EU consumption value of 235g/day, Malta, taken from the EU Commission publication "The EU Fish Market") and a proportion of skin to edible flesh in a composite salmon fillet of 15/85% (Janssen, 2021) and the max residues of tralopyril from the two surveys ($0.186 \times 0.85 + 4.1 \times 0.15 \approx 0.77$ ng/g and $0.07 \times 0.85 + 0.24 \times 0.15 \approx 0.096$ ng/g) results in a dietary exposure of $3.0\text{E-}06$ and $3.8\text{E-}07$ mg/kg bw/day respectively, which are far below the derived ADI and ARfD.

In addition, a simplified assessment of the risk to food consumers due to contamination of fish based on the predicted environmental concentration (PEC) of tralopyril in fish and the proposed Acceptable Daily Intake (ADI) was undertaken. The highest $\text{PEC}_{\text{Coral, predator}}$ from the EU scenario (including in situ cleaning) was used in the assessment, i.e., $1.28\text{E-}04$ mg/kg = 0.13 µg/kg (see page 116).

$(0.0083 \text{ mg/kg bw/day} \times 60 \text{ kg bw}) / 1.28\text{E-}04 \text{ mg/kg w.w} = 3891 \text{ kg w.w/day}$
 $(0.0083 \text{ mg/kg bw/day} \times 15 \text{ kg bw}) / 1.28\text{E-}04 \text{ mg/kg w.w} = 973 \text{ kg w.w/day}$

Based on these calculations, a 15 kg child would have to consume 973 kg and an adult 3891 kg fish a day to exceed the threshold level. Hence, a risk to consumers from consumption of fish contaminated by tralopyril is not expected.

However, it should be noted that when a uniform methodology to assess dietary exposure induced by an antifouling application is available, this assessment may need to be updated.

2.2.7 Risk assessment for animal health

Not relevant for these products.

2.2.8 Risk assessment for the environment

The environmental risk assessment covers the two active substances dicopper oxide (Cu_2O) and tralopyril. The Premium BPF does not contain any substances of concern (SoC) for the environment.

2.2.8.1 Effects assessment on the environment

Dicopper oxide

An evaluation of the effect data for the active substance with relevance to the aquatic compartment can be found in the Competent Authority Report for dicopper oxide (PT21, France, 2016).

Regarding the exposure to the environment from the use of the Premium BPF, the harmonised scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms (NO, 2015), hereafter referred to as the EU fish farm scenario, has been used for a first tier assessment at the EU level. In addition, an exposure assessment for Norwegian fish farms has been carried out, following the Norwegian environmental emission scenario for nets used in fish farms (NO, 2019), hereafter referred to as the Norwegian fish farm scenario. The latter represents an adjustment of the EU scenario to better reflect Norwegian fish farm conditions.

The relevant ecotoxicological data and the calculated Predicted No Effect Concentrations (PNECs) are summarized below:

Predicted no effect concentrations for dicopper oxide used for the risk characterisation

PNEC	Result	Reference
PNEC _{marina}	2.6 µg Cu/L	CAR dicopper oxide PT21, 2016
PNEC _{surrounding waters}	1.15 µg Cu/L	CAR dicopper oxide PT21, 2016
PNEC _{sea}	0.65 µg Cu/L	CAR dicopper oxide PT21, 2016
PNEC _{sediment}	98.8 mg Cu/kg sediment (dry weight)	CAR dicopper oxide PT21, 2016.

For the marine compartment, 56 chronic NOEC/EC₁₀ values, resulting in 24 different species-specific NOEC values covering different trophic levels (fish, invertebrates, algae), were

retained for the PNEC derivation. NOEC values were related to the organic carbon (DOC) concentrations of the marine test media and species-specific NOECs were calculated after DOC normalizing of the NOECs. These species-specific NOECs were used for the derivation of species sensitivity distributions (SSD) and HC₅₋₅₀ values, using statistical extrapolation methods. PNECs were derived for three different areas with differing DOC concentrations using an assessment factor of 2: harbours/marinas with a typical DOC concentration of 2 mg/L, surrounding waters with a typical DOC concentration of 0.5 mg/L and open sea with a typical DOC concentration of 0.2 mg/L. The emission scenario for fish nets (NO, 2015) assumes that the fish farm is located in coastal waters with low water flow velocities. Further, this emission scenario assumes water characteristics typical of more open waters. Therefore, for the purpose of the risk assessment, a PNEC_{surrounding water} of 1.15 µg Cu/L is considered the most relevant for the fish farm scenario.

For the marine PNEC_{sediment} derivation, as no reliable toxicity data are available for the marine sediment compartment, the PNEC_{marine sediment} was calculated according to the equilibrium-partitioning concept based on a PNEC_{water} using the 10th percentile of the K_d value for marine sediment according to the Guidance for environmental risk assessment for metals and metal compounds. The marine PNEC_{sediment} was determined to be 98.8 mg Cu/kg dw sediment (corresponding to 21.48 mg Cu/kg ww sediment)

Tralopyril

An evaluation of effect data for the active substances with relevance to the aquatic compartment can be found in the Competent Authority Report for tralopyril (PT 21, UK, 2014).

Predicted no effect concentrations for tralopyril used for the risk characterisation

PNEC	Result	Reference
Marine PNEC _{surface water}	0.0017 µg/L	CAR tralopyril PT21, 2014
Marine PNEC _{sediment}	0.00079 mg/kg (dry weight)	CAR tralopyril PT21, 2014

For the marine PNEC_{surface water} derivation, the available data show that the Zebra fish is the most sensitive following chronic exposure. The AF needed to calculate a PNEC in the marine environment requires endpoints from 2 additional invertebrate taxonomic groups, in order to establish the most sensitive invertebrate species. Without this the TGD recommends an additional factor of 10 compared to the freshwater AF derivation. For tralopyril, only an endpoint from one additional marine taxonomic group is available. Unfortunately, the available chronic endpoints include only the marine and freshwater crustaceans, while the marine mollusc was the most sensitive species tested (acute exposure). However, the reproducibility and reliability of chronic studies against molluscs and other marine invertebrates is relatively unknown for regulatory purposes. Overall, the fish data has been shown to be the most sensitive, and whilst the lack of chronic data against molluscs may be of concern, it is important to note that such organisms are also the target organism, and so the sensitivity observed is to be expected. . An assessment factor of 100 has been applied to the lowest available chronic endpoint (Zebra fish: NOEC_{larval weight} (33d) = 0.17 µg/L) in order to derive a marine PNEC_{surface water} of 0.0017 µg/L

For the marine PNEC_{sediment} derivation, only acute toxicity endpoints were available. According to the TGD, where only acute toxicity results are available, the risk assessment is performed on the basis of the test result of the most sensitive species using an assessment factor of 1000 and on the Equilibrium Partitioning Method. This gives marine PNEC_{sediment} of 0.00017 mg/kg (wet weight). However, as the MAMPEC model used to derive exposure concentrations

expresses these values on a dry weight basis, the $PNEC_{\text{sediment}}$ has been revised, resulting in a marine $PNEC_{\text{sediment}} = 0.00079 \text{ mg/kg sediment (dry weight)}$.

Co-formulants

Available effect data for the co-formulants are documented in the separate file "Environmental hazards of co-formulants in Premium BPF 2017". The available data allow the first evaluation of co-formulants and a classification of the biocidal product family.

Considering the concentrations of each active ingredient, Premium products are classified into aquatic acute or chronic toxicity. None of the co-formulants are regarded as substances of concern (SoC), since they do not affect the overall classification of Premium products. Thus, no specific risk assessment of co-formulants has been carried out.

Further Ecotoxicological studies

No further ecotoxicological studies on Premium products are available. According to Annex III, point 8.5(1), Column 3 of the BPR, as sufficient information is available for the active substance and the co-formulants (see separate report "Section 13 of the IUCLID file: "Environmental hazards of co-formulants in Premium BPF 2017.pdf"), further ecotoxicology studies on Premium BPF products are not considered necessary.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

There are no indications of specific environmental risk due to specific properties of the biocidal product or information on non-target organisms believed to be at risk, which would justify further testing.

Supervised trials to assess risks to non-target organisms under field conditions

No supervised field trials to assess the risks to non-target organisms have been conducted.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No studies to assess the avoidance or palatability of the biocidal products have been conducted.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Biocides from antifouling paints applied on aquaculture nets enter the marine environment because of direct leaching from the paint while a treated net is in service on a fish farm. The Emission Scenario Document presents a default scenario for the calculation of environmental exposure from antifouling active substances from nets used in farms using the MAMPEC model.

Further studies on fate and behaviour in the environment (ADS)

Fate and behaviour of dicopper oxide

The CAR for the active substance dicopper oxide (PT21, 2016) states that, because of the unique fate of copper in water, soil, sediment, and sludge, many of the data requirements

listed in Section A7 of the Technical notes for Guidance are not applicable for inorganic compounds and metals; in particular e.g. hydrolysis, photodegradation and biodegradation. It is not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation. Subsequently, dicopper oxide, which is an inorganic salt, cannot be transformed into related degradation products other than copper ions (Cu^{2+}) and water in solution. As with all metals, copper becomes complexed to organic and inorganic matter in waters, soil, and sediments and this affects copper speciation, bioavailability and thus toxicity, which mainly depends on the abundance of the copper ion. An important parameter determining the distribution of copper in the aquatic and soil environment is the adsorption onto solid materials and therefore partitioning coefficients. The concepts of octanol-water partitioning coefficient (K_{ow}) and organic carbon partitioning coefficient (K_{oc}) are not applicable to metals. Instead, the distribution of metals between the aqueous phase and soil/sediment/suspended matter could be described in terms of measured soil/water, sediment/water and suspended matter/water equilibrium distribution coefficients.

Fate and behaviour of tralopyril

The CAR for the active substance tralopyril (PT21, 2014) states that [^{14}C]-tralopyril was shown to be hydrolytically unstable, with the rate of hydrolysis increasing as the pH value increased (the most rapid was found at pH 9). In all tests, the main metabolite CL322,250 was identified. A DT_{50} of 16 hours was calculated for artificial seawater at 9°C in order to reflect the EU acceptable temperatures for marine risk assessment.

The evaluated photolysis study suggested that tralopyril is unlikely to persist in waters where sunlight is able to penetrate and as a conservative approach, the impact of photolysis on the breakdown of parent tralopyril was not taken into account in the environmental exposure assessment at active substance approval.

Tralopyril cannot be regarded as readily biodegradable but degradation under both aerobic and anaerobic sediment-water conditions was demonstrated, with degradation being shown to be more rapid in the marine than the freshwater systems. In the marine systems, tralopyril which remained largely associated with the sediment, was shown to hydrolyse to CL322,250 and CL322,248 which remained largely in the aquatic phase. For the purpose of risk assessment, a marine aquatic total system DT_{50} of 0.74 d (at 20 °C) was determined. For the sediment compartment a default DT_{50} of 1000 d is proposed. Data have been provided that indicate that both tralopyril and its metabolite CL322,250 have a strong potential to adsorb to soil/sediments and that this process is largely irreversible with K_{aOC} of 4585 l/kg and 2074 for marine sediments respectively.

Fate and behaviour of co-formulants

Biodegradability data of the co-formulants are documented in the environmental background documentation for co-formulants attached to section 13 of the IUCLID file.

Testing for distribution and dissipation in soil (ADS)

No data available.

Testing for distribution and dissipation in water and sediment (ADS)

No data available.

Testing for distribution and dissipation in air (ADS)

No data available.

Dicopper oxide is an inorganic compound and as such has negligible volatility. Hence, the amount emitted to air is expected to be very low and no risk assessment is carried out for the atmosphere compartment.

Aquatic bioconcentration

Dicopper oxide

The CAR of the active substance dicopper oxide (PT21, 2016) states that because of the homeostasis of metals, BCF values are not indicative of the potential bioaccumulation. There is therefore limited evidence of accumulation and secondary poisoning of inorganic forms of metals, and biomagnification in food webs.

Tralopyril

According to the CAR of the active substance tralopyril, the log K_{ow} is pH dependant with values of 4.4, 3.5 and 2.4 reported for pH 4, 7 and 9, respectively. A bioconcentration study was conducted in carp (*Cyprinus carpio*). Data on the uptake of tralopyril indicated that mean measured tissue concentrations were below the level of detection of 0.15 ng g⁻¹. As the steady state BCF for tralopyril was less than 3.2 ml g⁻¹ neither the uptake nor depuration rate constants were determined.

If the biocidal product is to be sprayed outside or if potential for large-scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

The biocidal product is not sprayed outside, and no large-scale formation of dust is expected.

2.2.8.2 Environmental exposure assessment and risk characterisation

Exposure to the environment from the use of the Premium BPF has been assessed in two tiers:

1. The first tier assessment is based on the EU fish farm scenario document agreed at EU level.
2. A second tier assessment with special regard to Norwegian fish farms has been conducted based on the Norwegian fish farm scenario document (available as an annex under section 3.7). This represents an adjustment of the EU scenario to reflect a realistic worst case fish farm in Norway. The most notable adjustments made in the Norwegian fish scenario as compared to the EU fish farm scenario, are that the net size (area) and sea depth is increased, the flow velocity is very slightly increased, and the parameters related to (suspended) organic matter have been adjusted. All the adjustments have been done following an investigation of information for 232 fish farm facilities which were considered relevant, i.e. they are marine salmon, trout and rainbow trout farms, and they have a moderate to high production capacity (in order to capture the trend towards larger fish farms). Please see the scenario document for details on the data gathering and selection of final values.

General information on the exposure assessment is given in the table below

General information

Assessed PT	PT 21
Assessed scenarios	Environmental emissions from nets used in fish farms, during the deployment time of the nets in the sea. Only professional uses of the Premium products are envisaged and have been assessed.
Emission Scenario Document	<p>For the assessment covering use in the EU, the EU fish farm scenario was used, as a tier 1 assessment:</p> <p><i>Scenario document for the calculation of environmental exposure from antifouling active substances from nets used in fish farms. ECHA, 2015.</i></p> <p>For the assessment representative for Norway (i.e. a tier 2 assessment for the use in Norway), the Norwegian fish farm scenario was used:</p> <p><i>A Norwegian environmental emission scenario for fish farms - Adjustment of the EU scenario (2015) to better represent national conditions. Norwegian Environmental Agency, 2019</i></p>
Approach	<p>MAMPEC v.3.1 was used for the modelling.</p> <p>For the active substances, agreed values from the CARs were used as input. For other environmental parameters, default values for the environmental parameters given in the above-mentioned scenario documents were used, in addition to product-specific values where applicable.</p>
Distribution in the environment	The PEC values in water and sediment were calculated with MAMPEC v.3.1 based on the input described above.
Life cycle steps assessed	<p>Production: No information</p> <p>Formulation: No information</p> <p>Use</p> <p>Service life</p>

Emission estimation

In the following tables, some of the input parameters used for the calculations of daily local emissions (E_{local}) and predicted environmental concentrations (PECs) are given. E_{local} was calculated as follows, in accordance with the scenario documents:

$$E_{\text{local}} \text{ (g/d)} = (N_{\text{net}} \cdot \text{AREA}_{\text{net}} \cdot W_{\text{net}} \cdot \text{COVERAGE} \cdot C_{\text{a.i.}} \cdot F_{\text{a.i.}}) / T_{\text{deployment}}$$

Subsequently, the E_{local} values were entered into MAMPEC for the modelling of PECs. In the first table, E_{local} input parameters and some input parameters for the PEC modelling are given, for both the EU fish farm scenario and the Norwegian fish farm scenario (for a full list of all input parameters and reasoning behind them, see the respective scenario documents).

The second table lists the active substance input parameters, and the third table gives the concentrations of active substances used for the E_{local} calculation of the different products.

All calculations of E_{local} , and details on the MAMPEC modelling, can be found as annexes under section 3.2.1.

Parameters for emission (E_{local}) and PEC calculations

Parameter	EU fish farm scenario ¹ (tier 1)	Norwegian fish farm scenario ² (tier 2)
Concentration of a.i. in product, $C_{\text{a.i.}}$	See table below	See table below
Number of nets per fish farm area, N_{net}	10	10
Area of each net, Area_{net}	5103 m ²	7770 m ²
Weight per m ² of net, W_{net}	0.36 kg/m ²	0.36 kg/m ²
Coverage of product (amount of product used per kg net)	1 L/kg	1 L/kg
Fraction of released a.i. per deployment time of nets, $F_{\text{a.i.}}$	0.8	0.8
Time net is deployed in water, $T_{\text{deployment}}$	180 days	180 days
Fish farm area (length [x] × width [y])	300 × 450 m	280 × 610 m
Sea depth	30 m	60 m
Flow velocity	3 cm/s	3.2 cm/s
Salinity	34 psu	33.2 psu
Temperature	9 °C	8.6 °C

¹ Please see the [Emission scenario for nets used in fish farms \(ECHA, 2015\)](#) available from ECHA's webpage for the full set of parameters.

² Please see the [Norwegian fish farm scenario \(NO, 2019\)](#) for the full set of parameters.

Active substances input parameters

Active substance	Parameter	Unit	Value	Reference
Copper (total)	Molecular mass	g/mol	63.5	PT 21 ESD excel copper
	Saturised vapour pressure at 20°C	Pa	0	
	Solubility at 20°C	g/m ³	0.001	
	Kd	m ³ /kg	132	
Tralopyril	Molecular mass	g/mol	349.5	PT 21 ESD excel tralopyril
	Saturised vapour pressure at 20°C	Pa	1.9E-08	
	Solubility at 20°C	g/m ³	0.16	
	Hydrolysis DT ₅₀ at 20°C	days	infinity	
	Photolysis DT ₅₀ at 20°C	days	Infinity	
	Water DT ₅₀ at 20°C	days	0.737	
	Sediment DT ₅₀ at 20°C	days	1000	
	Octanol-water partition coefficient, K _{ow}	-	2.75	
	Partition coefficient, K _{oc}	L/kg	3.66	
	Henry's constant at 20°C	Pa. m ³ /mol	4.15E-005	

Concentration of active ingredients in Premium products

*Toward the end of the evaluation phase, a risk for human health was identified for the product named AquaNet Boost. Therefore, the product AquaNet Boost was modified, and the amount of active substance content was reduced from 24.83% to 22% (w/w). Please note that the environmental risk assessment has been performed on the old version of AquaNet Boost (hereafter referred to as AquaNet Boost_{old}) and is considered to cover the Boost product as a risk envelope approach.

Product	Concentration of a.i. in product (%, w/w)		Concentration of a.i. in product (g/L)	
	Copper ¹	Tralopyril	Copper ¹	Tralopyril
AquaNet Premium	9.99	2.00	100.24	22.59
AquaNet Boost _{old}	24.83	1.96	280.02	24.90

¹ Copper equivalent from dicopper oxide = 88.8%

Following the approach described above, E_{local} values were calculated for all the products. The table below gives the E_{local} for both the EU fish farm scenario (tier 1) and the Norwegian fish farm scenario (tier 2).

Daily emission outputs (E_{local})

Product	EU fish farm scenario (tier 1)		Norwegian fish farm scenario (tier 2)	
	Copper	Tralopyril	Copper	Tralopyril
AquaNet Premium	8184 g/d	1844 g/d	12462 g/d	2808 g/d
AquaNet Boost _{old}	22867 g/d	2033 g/d	34818 g/d	3096 g/d

Background concentrations for Cu

Background concentrations for Cu in water and sediment of **1.1 µg/L and 16.1 µg/g**, respectively, should be added to the predicted environmental concentrations. This is in line with the EU-agreed background concentrations used for the active substance evaluation for the marina scenarios for antifouling paints on recreational crafts, including the regional Atlantic marina scenario. It is not considered suitable to use the background values for open sea (0,5 µg/L for water and 3,5 µg/g for sediment), since the open sea background concentrations represent areas that are further away from the sources for release of Cu. The background concentrations can be integrated in the MAMPEC modelling or they can be added manually after calculating the steady-state PECs (without background concentrations) in MAMPEC. We chose the latter approach.

Calculated PEC values and risk characterisation – Tier 1: the EU fish farm scenario

AquaNet Premium Average PEC values calculated by MAMPEC v3.1 (without Cu background concentrations)				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	0.11	0.09	14.21	0.14
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	0.04	23.65	0.01	13.96

¹ PEC/PNEC ratios above 1 (values in bold) indicate unacceptable environmental risks.

AquaNet Premium Average PEC values with Cu background concentrations				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	1.21	1.05	30.31	0.31
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	0.04	23.65	0.01	13.96

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

AquaNet Boost_{old} Average PEC values calculated by MAMPEC v3.1 (without Cu background concentrations)				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	0.50	0.26	39.70	0.40
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
EU fish farm scenario	0.04	25.97	0.01	15.33

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

AquaNet Boost _{old}				
Average PEC values with Cu background concentrations				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
EU fish farm scenario	1.40	1.22	55.80	0.56
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
EU fish farm scenario	0.04	25.97	0.01	15.33

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risk for the environment.

Calculated PEC values and risk characterisation – Tier 2: the Norwegian fish farm scenario

AquaNet Premium				
Average PEC values calculated by MAMPEC v3.1 (without Cu background concentrations)				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario	0.04	0.03	5.25	0.05
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario	0.01	6.15	6.37E-03	8.06

¹ PEC/PNEC ratios above 1 (values in bold) indicate unacceptable environmental risks.

AquaNet Premium				
Average PEC values with Cu background concentrations				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario	1.14	0.99	21.35	0.22
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario	0.01	6.15	6.37E-03	8.06

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

AquaNet Boost_{old} Average PEC values calculated by MAMPEC v3.1 (without Cu background concentrations)				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
Norwegian fish farm scenario	0.11	0.10	14.7	0.15
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
Norwegian fish farm scenario	0.01	6.75	7.00E-03	9.01

¹ PEC/PNEC ratios above 1 (values in bold) indicate unacceptable environmental risks.

AquaNet Boost_{old} Average PEC values with Cu background concentrations				
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
Norwegian fish farm scenario	1.21	1.05	30.78	0.31
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water} ¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment} ¹
Norwegian fish farm scenario	0.01	6.75	7.00E-03	9.01

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risk for the environment.

2.2.8.3 Risk characterisation

Atmosphere

No exposure to the atmosphere as the active ingredients do not volatilise.

Sewage treatment plant (STP)

The proposed uses of the Premium BPF products as antifouling coatings for nets used in aquaculture would not result in any direct or indirect exposure to STPs.

Aquatic compartment

Risk characterisation for the EU fish farm scenario (tier 1)

The PEC/PNEC ratios based on PEC values calculated with the EU fish farm scenario are summarised in the following table.

Summary table of PEC/PNEC values*		
	PEC _{dissolved} /PNEC _{water}	PEC _{suspended matter} /PNEC _{sed}
AquaNet Premium		
Copper	1.05	0.31
Tralopyril	23.65	13.96
Combined	24.79	14.26
AquaNet Boost_{old}		
Copper	1.22	0.56
Tralopyril	25.97	15.33
Combined	27.19	15.89

*with background concentrations of copper

In tier 1 calculations, the PEC/PNEC ratios are above the trigger value for all Premium products, indicating unacceptable risk for the aquatic environment.

Risk characterisation for the Norwegian fish farm scenario (tier 2)

The PEC/PNEC ratios based on PEC values calculated with the Norwegian fish farm scenario are summarised in the following table.

Summary table of PEC/PNEC values*		
	PEC _{dissolved} /PNEC _{water}	PEC _{suspended matter} /PNEC _{sed}
AquaNet Premium		
Copper	0.99	0.22
Tralopyril	6.15	8.06
Combined	7.14	8.28
AquaNet Boost_{old}		
Copper	1.05	0.31
Tralopyril	6.75	9.01
Combined	7.80	9.32

*with background concentrations of copper

With the Norwegian fish farm scenario, the PEC/PNEC ratios are above the trigger value for both Premium products, indicating unacceptable risk for the aquatic environment.

Leaching behavior

Dicopper oxide

The applicant has submitted field and farm studies to determine the release of dicopper oxide from aquaculture nets coated with Aquanet antifouling products. These studies aim to determine the loss of biocide during commercial conditions with or without high water jetting (in-situ cleaning).

<p align="center">Study Overview Biocide release from Aquaculture nets</p>

DOKID-794567110-370			
Test matrix and test substance	Method	Compartment, pH, Temp [°C]	Reference
Field Study AquaNet North Sea Ultra	Bespoke method	Norwegian Coastal Seawater (submerged at 6 metres depth), pH not measured, 8.7 to 17.8°C	Ulriksen, U (2020) IUCLID 10.3.2
Farm Study AquaNet North Sea Ultra	Bespoke method	Nets deployed in Norwegian Coastal Seawater, pH not measured, Temperature not measured	Ulriksen, U (2020) IUCLID 10.3.2

Study summaries
<p>Field Study - Ulriksen, U (2020) Egersund nylon net dipped in AquaNet Ultra was used to determine the amount of copper released into coastal waters by comparing nets deployed with Day 0 samples.</p> <p>Using a destructive analysis technique (method SP5458) the remaining copper content in the nets was determined at different time points. The change in copper content was calculated, this represents the fraction of biocide release ($F_{a.i.}$).</p> <p>The lack of triplicate data points and limited duration of the trial introduces some uncertainty regarding its results. There is a relatively good correlation with findings in the Farm study (see below).</p> <p>Farm Study - Ulriksen, U (2020) Commercial nets treated with North Sea Ultra were deployed throughout 2016 to 2019 in aquaculture farms in the West coast of Norway. Some of the nets were cleaned in-situ, some were not cleaned in-situ.</p> <p>The nets have been used for regular commercial farming. A majority of the nets have been cleaned at sea using high pressure water jetting. Time to first cleaning has been on average 3 months, with subsequent cleanings averaging every 2 weeks for the net walls. The net bottom has been cleaned less efficiently due to machine limitations when cleaning the coned floor. Seasonal variation of cleaning includes a higher frequency from June to October and lesser with low sea temperatures. This is due to the variation of fouling pressure related to sea temperatures in the Norwegian coastal areas. The dataset consists of several types of high effect cleaning equipment all operated with pressure between 100 and 300 bar. Deployment data such as time in sea, cage id and location were recorded.</p> <p>Samples of net were taken before and after use, dissolved in nitric acid and analysed for copper using ICP-MS (method NS-EN ISO r7294-2).</p>

Data for a total of 62 nets were analysed. Copper release was compared with nets cleaned in-situ and nets without cleaning at sea. The farm and field studies use North Sea Ultra, this is the AquaNet product with the highest concentration of copper. It is therefore possible to use these values for $F_{a.i.}$ as a surrogate in all AquaNet products as it represents a worst-case scenario and worst-case leaching into the coastal waters. Real life aquaculture conditions are used, representative for farmers in Norway with an operational practice including with and without in-situ cleaning of treated nets. There is some uncertainty due to the small sample size for the nets that were not in-situ cleaned (farm study), ($n = 13^*$)

* Samples from 7 nets, 7 samples of the net bottom, 6 samples of the net wall

The Norwegian Environment Agency has evaluated the Ulriksen, 2020 study and has defined the following fraction of release a.i. per deployment time of nets ($F_{a.i.}$) for refined emission (E_{local}) and PEC calculations:

Scenario	Sample set	Refined $F_{a.i.}$	Number of samples (n)
1: not in-situ cleaned nets	"Farm study:" 90 th percentile value from nets that were not in-situ cleaned	0.28	13
2: both cleaned and not in-situ cleaned nets	"Farm study:" Average of wall and bottom samples from all nets that were deployed at sea during summer months*	0.44	113 Samples from 58 nets, 58 samples of the net bottom, 55 samples of the net wall

*4 nets were excluded from the data set since they were only deployed at sea during winter months and are therefore not considered to represent realistic worst case conditions in terms of fouling.

Daily Cu emission outputs (E_{local})

Product/Scenario	Refined $F_{a.i.}$	EU fish farm scenario	Norwegian fish farm scenario
AquaNet Premium / 1: not in-situ cleaned nets	0.28	2865	4362
AquaNet Premium / 2: both cleaned and not in-situ cleaned nets	0.44	4501	6854
AquaNet Boost _{old} / 1: not in-situ cleaned nets	0.28	8602	12186
AquaNet Boost _{old} / 2: both cleaned and not in-situ cleaned nets	0.44	12575	19150

Tralopyril

The applicant has submitted several laboratory release rate studies for tralopyril. For copper, the fraction of biocide release ($F_{a.i.}$) was refined using data from aquaculture nets used in real fish farms. This is possible as elemental copper can be quantified after destructive extraction and analysis techniques.

This study design is not suitable for tralopyril due to the requirement for destructive sampling. Tralopyril is an organic chemical and would breakdown to its elemental components. Extracting tralopyril from a used aquaculture net using non-destructive techniques is very difficult due to the nature of the net and the growth of biofilms and seaweed.

The test methods (ASTM D6903-07 and ISO 15181) are designed to determine the rate at which organic biocides are released from an antifouling coating exposed in substitute ocean water. They are normally used to estimate the release rate of biocides from antifouling paints on ships' hulls into the environment. In the absence of any other suitable studies they have been used here to determine the release rate of coatings from aquaculture nets. The test guidelines were not designed for aquaculture netting, however, these studies are the closest possible relevant test guideline.

There are implications of using a coated polycarbonate cylinder study to estimate release rates from a coated aquaculture net:

- Using the resulting release rates from a coated polycarbonate cylinder as a surrogate for fish nets does require additional caution and justification, as the materials and application are fundamentally different.
 - To address this point the Applicant has conducted a study using a coated net fixed to the polycarbonate cylinder to fully account for any differences in release rate due to differences in material and coating application
 - This addresses:
 - the difference in fixation of paints on aquaculture nets versus fixation on ship hulls.
 - the difference in leaching behaviour of coatings on aquaculture nets versus fixation on ship hulls i.e. it is multi-directional from fish nets
 - the difference in surface material i.e. how a hard surface influences the leaching as compared to a fibrous surface

The ASTM D6903-07 and ISO 15181 methods were specifically developed to measure the release of antifouling active substances, under prescribed laboratory conditions, from antifouling coatings designed for use on ships' hulls and other marine structures. Such structures are typically made of metal (although smaller boat hulls may, of course, be made from fibreglass, polycarbonate, or other polymeric materials), and may be painted with a primer coat before the application of the antifouling coating. Thus, the polycarbonate test cylinder to which the antifouling coating is applied, may be considered representative of the substrate to which the coating is applied in practice. The substrate is a continuous, smooth and impervious surface, and the antifouling coating is applied to a thickness which is typical for in-use conditions. It may be expected, therefore, that an antifouling coating designed for application by spray, or brush/roller, to a ship's hull will apply and adhere satisfactorily to the test cylinder, when painted on. Release of an active substance from such a coating is, of course, uni-directional.

In contrast, antifouling coatings used in aquaculture are applied to fibrous nets, manufactured from knotted twine, usually of nylon, and no primer is used. The Premium BPF coatings used are formulated very differently from those used for ships' hull (and they have a much higher water content than ship paints) and, whilst a full coating of the netting surface is achieved, a significant proportion of the coating is 'absorbed' into the twine's fibre

structure as a result of the dipping/immersion process used to treat the nets, and a thick outer layer of coating is not, therefore, produced. Good adhesion to the finer, fibrous structure of the nylon netting is an important attribute of the coatings, whereas good adhesion to a continuous, smooth and impervious surface is not important, and not considered in the design parameters for such a coating. In addition, the nylon fibres can act as reinforcement to the coating once applied, in a similar way to glass fibres in resin. Release of an active substance from an aquaculture coating applied to a net in service may occur in all directions; the design of the adapted study performed, where the net is affixed to the cylinder by a light application only of glue at each node, ensures that the vast majority of the surface area of the netting remains exposed to the artificial sea water.

Recognising the differences in formulation type and treated substrate highlighted above, it may be more meaningful to study the release of an active substance from an aquaculture coating when applied to the appropriate substrate, i.e. an aquaculture net, rather than a cylinder. Of course, there would also be uncertainties if release of active substance from a ship paint were studied by applying the ship paint to a sample of aquaculture net.

As stated in the test guidelines, the results of these tests do not reflect environmental biocide release rates for antifouling products and are not suitable for direct use in environmental risk assessments.

- To address this point the Applicant has considered actual environmental factors such as temperature and flow rate that are specific to where the products are used in Norway
 - This allows the test to be more reflective of environmental conditions

The ASTM/ISO test guidelines also state that 'where the results of this test method are used in the process of generating environmental-risk assessments, producing environmental-loading estimates or for regulatory purposes, it is most strongly recommended that the relationship between *laboratory release rates* and *actual environmental inputs* be taken into account to allow a more accurate estimate of the biocide release rate from antifouling coatings under *real-life* conditions to be obtained. This can be accomplished through the application of appropriate correction factors'. This is because the test methods are known to overestimate release rates of biocides under in-service conditions.

The studies were conducted with a salinity range that is appropriate for Norway and meets test guideline requirements. The salinity of the seawater in supply tanks and holding tanks in one of the studies (Andreyko II, M. 2020a & b) were maintained between 33-34 ppt (equivalent to 33-34 psu). In 'A Norwegian environmental emission scenario for nets used in fish farms' (Norwegian Environment Agency, 2019) the yearly average temperature and salinity along the Norwegian coast, from the surface to a maximum of 300 m, is 8.3°C and 33.7 psu, respectively. Looking at the data sampled from the surface to a maximum of 100 m, which is seen as more relevant, the corresponding numbers are 8.6°C and 33.2 psu, respectively.

The table below presents a comparison of salinity in MAMPEC scenarios, test guidelines and Andreyko II, M. (2020a & b).

Parameter	Norwegian scenario (2019)	EU scenario (2019)	Andreyko II, M. (2020a & b)	ISO 15181	ASTM D6903-07
Salinity	33.2 psu	34 psu	33-34 ppt	33-34 psu	33-34 ppt

Note: Salt concentration is often described in units of parts per thousand (ppt), parts per million (ppm), milligrams per liter (mg/L) or percent. The relationship between these units is: 1 ppt = 1,000 ppm = 1000 mg/L = 0.1 percent. Salinity is also expressed in practical salinity units (psu), a measure of conductivity at a constant pressure and temperature that is about equivalent to ppt.

In 'A Norwegian environmental emission scenario for nets used in fish farms' (Norwegian Environment Agency, 2019) there are data presented from a range of Norwegian Fish Farms for flow velocity. From this dataset, the 90th percentile flow velocity measured on Norwegian fish farms around the static net (9 cm/s) was used in the studies instead of the value in the test guidelines (20 cm/s). This reflects the actual environmental conditions in Norwegian Aquaculture. The cylinder rotational speed in the ISO/ASTM guideline is thought to be representative of sea current in the MAMPEC boat scenarios. The proportion of ships moving and at berth is dealt with in the MAMPEC Emissions input page.

Comparison of Flow velocity			
Norwegian fish farms	ISO 15181	ASTM D6903-07	Andreyko II, M. (2020a & b)
6.1 cm/s (Mean) 9.1 cm/s 90 th percentile (n = 140)	60 ± 5 r/min (0.2 ± 0.02 m/s ≡ 20 ± 2 cm/s)	60 ± 5 rpm (0.2 ± 0.02 m/s ≡ 20 ± 2 cm/s)	19 rpm (0.09 m/s ≡ 9 cm/s)

In MAMPEC the release rate from the study is inputted into the 'Leaching rate' 'at berth' parameter, this is used as a surrogate for static aquaculture nets. The 'berth scenario' is used as it is representative of a static aquaculture net rather than the moving scenario which is designed to represent a moving ship. The surface area of the nets and the number of nets is parameterised in MAMPEC by entering for example: 7770 (7770 m² is from AREA_{net})¹ in the 'Service Life' 'Surface Area' parameter and 10 (10 is the number of nets N_{net}) in the #Ships at berth box.

Studies conducted with a coated polycarbonate cylinder versus a coated net attached a polycarbonate cylinder

The leaching rate study using a coated net was conducted alongside the cylinder studies to provide a more relevant and realistic leaching rate for the aquaculture nets. There were uncertainties regarding the novel test design, however, these were successfully overcome and the study was subsequently performed. The study is a better reflection of the real-world leaching of tralopyril for several reasons, including that the paint is specifically designed to coat fibres and form a stronger coating with them compared to the flat surface of the cylinder (which represents a ship's hull). The net study is the most appropriate way to obtain a relevant and meaningful release rate for use in the risk assessment.

Justification for use of the net study includes:

- The paint system is designed to adhere on net fibres of nylon, not solid surfaces of polycarbonate.
- The curing time for high water content paint like this is very high, and it can take longer to achieve curing of thicker layers such as that used on the cylinders. The ISO/ASTM study guideline does not account for this.
- The net filaments add strength to the paint system, acting in a similar way to fibre glass. The paint is designed to penetrate between the fibres and not form a thick outer layer. Such outer layers are avoided during the treatment process.
- Because self-adhesion of the paint, and adhesion of the paint to the polycarbonate cylinder is poor there is a high risk of paint flakes or particles being released during the extraction process.

Release rate studies have been submitted by the applicant, using the ISO 15181-1, 15181-6 and ASTM D6903-07 test guidelines. The applicant has proposed to use leach rates derived from these studies in the refined risk assessment.

Three release rate studies have been submitted by the applicant (in addition, one study using painted cylinder was submitted but this study was found not to be compliant with ISO 15181-1 & 15181-6 and not suitable for use in risk assessment):

1) Determination of release rate of Tralopyril from antifouling paint according to ISO 15181-1 and -6. Pinori, E. (2020). Study Number: 2P01843-2, RISE Research Institutes of Sweden AB.

2) Leach Rate Determination of Tralopyril and Metabolites from AquaNet Boost Study. Andreyko, M. (2020a). Study Number: No. 3990-04. Case Laboratories, Inc.

3) Leach Rate Determination of Tralopyril and Metabolites from Net Coated with AquaNet Boost. Andreyko, M. (2020b). Study Number: No. 3990-05. Case Laboratories, Inc.

Leaching rates used for the risk characterisation

Summary endpoints - leaching behaviour for tralopyril			
Study Number:	Test Matrix	Reported R _{21,end} (µg/cm ² /day)	Reference
2017-05-05*	Cylinder	-	Pinori, E. (2017), IUCLID 10.3.1
2P01843-2	Cylinder	0.301	Pinori, E. (2020), IUCLID 10.3.3
3990-04	Cylinder	0.572	Andreyko II, M. (2020a), IUCLID 10.3.4
Average of 2P01843-2 & 3990-04	Cylinder	0.438 (n=2)	Calculated
3990-05	Net	0.0525	Andreyko II, M. (2020b), IUCLID 10.3.5

*Study not fully compliant with ISO 15181-1 & 15181-6 so not suitable for use in risk assessment

Release rate of tralopyril

The release rates do not follow pseudo-steady state as defined in the test guideline. The pattern of tralopyril release from the coated cylinder is continuous and variable in line with its phys-chem properties, i.e. K_{oc} of 4585 mL/g = LogK_{oc} 3.66 mL/g equates to 'Slightly Mobile' according to McCall et al 1981². Log K_{ow} is pH dependant with values of 4.4, 3.5 and 2.4 reported for pH 4, 7 and 9 respectively equating to a tendency for high to very high adsorption to organic matter in soils or sediments because of a low affinity for water. Additionally, the paint system is designed to adhere on net fibres of Nylon as well as penetrating between the net fibres. Because self-adhesion and adhesion of the paint to the polycarbonate cylinder is less than for nets there is risk of paint flakes or particles being released during the extraction process. This may also explain some of the variability in the release rate.

² McCall P.J., Laskowski D.A., Swann R.L., and Dishburger H.J., (1981), "Measurement of sorption coefficients of organic chemicals and their use, in environmental fate analysis", in Test Protocols for Environmental Fate and Movement of Toxicants. Proceedings of AOAC Symposium, AOAC.

Study summaries - leaching behaviour for tralopyril					
Test Substance	Title, Guideline	Compartment, pH, Temp [°C]	Release rate, R _{21, end} [µg/cm ² /day]	Remarks	Reference
<i>AquaNet Boost_{old}</i>	<i>Determination of release rate of Tralopyril from antifouling paint according to ISO 15181 -1 and -6,</i>	<i>Artificial seawater (Coastal waters), pH – 8.0 Temp. 10°C</i>	0.301	<i>Conducted at RISE Research Institutes of Sweden to ISO 17025:2017 Not GLP</i>	<i>Pinori, E. (2020) IUCLID 10.3.3</i>
<i>AquaNet Boost_{old}</i>	<i>Leach Rate Determination of Tralopyril and Metabolites from AquaNet Boost ASTM D 6903-07 and ISO 15181-1</i>	<i>Artificial seawater (Coastal waters), Mean pH 8.1 Mean Temp. 9°C</i>	0.572	<i>Conducted at CASE Laboratories, Inc. in compliance with GLP</i>	<i>Andreyko II, M. (2020a) IUCLID 10.3.4</i>
<i>AquaNet Boost_{old}</i>	<i>Leach Rate Determination of Tralopyril and Metabolites from Net Coated with AquaNet Boost ASTM D 6903-07 and ISO 15181-1</i>	<i>Artificial seawater (Coastal waters), Mean pH 8.1 Mean Temp. 9°C</i>	0.0524	<i>Conducted at CASE Laboratories, Inc. in compliance with GLP</i>	<i>Andreyko II, M. (2020b) IUCLID 10.3.5</i>

Leaching behaviour for tralopyril

2017 Leaching Study - Painted Polycarbonate Cylinders

Pinori, E. (2017)

Reliability cannot be determined, mainly due to limited reporting. In general, the study report and study summary does not reflect the level of detail required in the test guideline. For example, no information is given on the pH, temperature and salinity in the holding tank each time the conditions were monitored, maximum holding tank biocide limit.

2020 Leaching studies

In order to determine the differences between a rotating painted cylinder leaching test and a cylinder with a coated fish net attached, two different types of studies have been conducted. One using a painted cylinder (2 studies), the other using a coated net fixed to a cylinder (1 study). This demonstrates a difference between the leaching rates derived from painted cylinders and coated fish nets. Previously it was speculated that the leaching of the paint would be identical at the

Leaching behaviour for tralopyril

interface of water and painted surface as the adhesion of the paint to the drum and likewise the adhesion of the paint to the net is not what this study determines. However, experimental results have shown that leaching from the nets is significantly lower than from the cylinders.

2020 Leaching studies – Coated Polycarbonate Cylinders

Both Premium and Boost_{old} contain similar concentrations of tralopyril (22.59 g/L (1.99% w/w) & 24.90 g/l (1.96% w/w) for Premium and Boost respectively). Therefore the leaching rates for Boost represent a worst-case for Premium. The paint is identical apart from the copper content (Cu₂O 9.99% premium & 24.8% Boost). Therefore, read across from one type of paint to another is possible for tralopyril.

The flow rate of the study was approximately 9 cm/s (19 rpm). This was based on the 90th percentile flow rate of all fish farms summarised in the NEA Scenario for nets used in fish farms. The study was conducted at a temperature relevant for Norwegian fish farms. This was agreed to be between 9 and 13°C.

Tralopyril concentration were determined using the direct method. This quantifies the active substances directly with fewer sample preparation steps (the in-direct method detailed in ISO 15181-6 will not be used).

A full sampling schedule in accordance with the procedure outlined in the ISO-15181-1 standard was used.

The use of polycarbonate cylinders have been used as specified in the ISO 15181-6 standard. An updated excel spreadsheet with guideline calculations for mean release rate (µg/cm²/day) have been provided.

It is believed that this is representative for Norwegian fish farm environmental conditions and will be used as a basis for refinement of risk assessments.

Pinori, E. (2020)

This study determined the release rate of tralopyril from polycarbonate cylinders painted with AquaNet Boost_{old}. The study was conducted in accordance with ISO 15181-1:2007 with a few modifications (detailed below) into substitute ocean water prepared according to ASTM D 1141-98. Modifications of the specific laboratory condition defined in ISO 15181-1 (2007) included the following:

- I. Temperature of the Artificial Sea Water in the holding tank to be 10°C (+/-1°C) instead of to 25°C (+/-1°C) as specified in the ISO 15181-1.
- II. Temperature for the release rate measuring tanks to be 10°C (+/-1°C) instead of to 25°C (+/-1°C) as specified in the ISO 15181-1.
- III. Rotational speed of the cylinders under extraction to be 20 (+/-1) r/min for 1h, instead of the 60(+/-1) r/min as specified in the ISO 15181-1.

The analysis for tralopyril concentration measurements in extraction water has not been performed as described in ISO 15181-6:2012, but according to Janssen/RISE AGR 5255, method for tralopyril and metabolites. This method is available to authorities in confidential form upon request.

AquaNet Boost_{old} was applied to polycarbonate cylinders in triplicate, dry film thickness was measured at study start and study end. Any deviations from ISO 1518-1 are noted in the study report. The test started on 9th March 2020 (Day 0) and finished on 23rd April 2020 (Day 45). The study report contains raw data for tralopyril concentration in the holding tanks, individual cylinder

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analyses with blanks, study temperature, pH, and salinity records. Sample calibration curves and chromatograms are included along with an ISO 17025 accreditation certificate.

According to the equations set out ISO 15181 the cumulative and mean tralopyril release rates were determined.

$$R_{0,14} = 6.637 \mu\text{g}/\text{cm}^2$$

$$R_{21,\text{end}} = 0.301 \mu\text{g}/\text{cm}^2/\text{day}$$

Andreyko II, M. (2020a)

This study determined the release rate of tralopyril from polycarbonate cylinders coated with AquaNet Boost_{old}. The study was conducted in accordance with ASTM 6903-07 (equivalent to ISO 15181-1:2007) with a few modifications (detailed below) into substitute ocean water prepared according to ASTM D 1141-98. Modifications of the specific laboratory conditions defined in ASTM 6903-07 included the following:

- I. Temperature of the Artificial Sea Water in the holding tank to be 9°C (+/-1°C) instead of to 25°C (+/-1°C) as specified in ASTM 6903-07.
- II. Temperature for the release rate measuring tanks to be 9°C (+/-1°C) instead of to 25°C (+/-1°C) as specified in ASTM 6903-07.
- III. Rotational speed of the cylinders under extraction to be 19 (+/-1) r/min for 1h, instead of the 60(+/-5) r/min as specified in ASTM 6903-07.

The analysis for tralopyril concentration measurements in extraction water has not been performed as described in ISO 15181-6:2012, but according to Janssen AGR 5707, method for tralopyril and metabolites. This method is available to authorities in confidential form upon request.

AquaNet Boost_{old} was applied to polycarbonate cylinders in triplicate, dry film thickness was measured at study start and study end. Any deviations from ASTM 6903-07 are noted in the study report. The test started on 9th March 2020 (Day 0) and finished on 23rd April 2020 (Day 45). The study report contains raw data for tralopyril concentration in the holding tanks, individual cylinder analyses with blanks, study temperature, pH, and salinity records. Sample calibration curves and chromatograms are included along with an GLP accreditation certificate.

According to the equations set out ASTM 6903-07 (identical to ISO 15181) the cumulative and mean tralopyril release rates were determined.

$$R_{0,14} = 5.812 \mu\text{g}/\text{cm}^2 \text{ (calculated by Battelle)}$$

$$R_{21,\text{end}} = 0.572 \mu\text{g}/\text{cm}^2/\text{day}$$

Note: $R_{21,\text{end}}$ is the weighted mean release rate, taking into account any differences in time between test days after the test system has become equilibrated. It is a more valid treatment of the data than calculation of the simple arithmetic average of the data. The release rate is used in MAMPEC to derive an emission load in g/d.

Calculation of a mean endpoint derived from two leaching rate studies

The leaching rates from Pinori, E., (2020) where $R_{21,\text{end}} = 0.301 \mu\text{g}/\text{cm}^2/\text{day}$ and from

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Andreyko II, M., (2020a) where $R_{21,end} = 0.572 \mu\text{g}/\text{cm}^2/\text{day}$ were used to derive a mean leaching rate of $R_{21,end} = 0.438 \mu\text{g}/\text{cm}^2/\text{day}$.

2020 Leaching studies – Coated Net

The rationale for refining the risk assessment for tralopyril with a 'leaching rate' study using an aquaculture net fixed to a cylinder is:

- The same modifications to the study design detailed above have also been used for this study to better reflect environmental conditions so that the study can be used in environmental risk assessments.
- The rotating cylinder method, represented by ISO 15181-1 and ASTM D6903-7, is known to significantly 'overestimate' leaching rates when compared to direct in situ measurements of copper and organotin release rates from in-service ship hulls.
When used, it is strongly recommended that an appropriate 'correction factor' is applied to allow a more accurate approximation of the biocide release rate from biocidal coatings. The appropriate correction factor established by Finnie (2006) for antifouling paints used on ship hulls is $\times 5.4$. Using a net in place of a painted cylinder is considered to be more representative of how this biocidal product is used in the environment and therefore a better estimate of actual leaching rate.
- By using a net in a regulatory leaching study the issues regarding fixation of paints for nets vs. fixation of paints for ship hulls are taken into account.
Using a net will consider the difference in surface material such as how will a hard metal surface influence the leaching as compared to a fibrous surface.
To resolve this the applicant has conducted studies using a painted cylinder and a coated net attached to a cylinder to derive leaching rates. Note, that the use of a polymeric net instead of the flat polycarbonate cylinder has not been validated in the ISO standard. There is a risk that the inherent variability of the test will be exaggerated when using a net, although this was not borne out by the results of the studies. The applicant considers conducting the study with both a cylinder and a net is preferable in order to use the most relevant data for the risk assessment.
- Additionally the paint system is designed to adhere on net fibres of Nylon, not solid surfaces of polycarbonate. The curing time for high water content paint like this is very high, and it can take longer to achieve curing on thicker layers such as that used on the cylinders. The ISO protocol does not account for this. The net filaments usually adds strength to the paint system, acting similar to fibre glass. The paint is designed to penetrate between the fibres and not form a thick outer layer. Because self-adhesion and adhesion to the polycarbonate cylinder is poor there is a high risk of paint flakes or particles being released during the extraction process. This may explain the higher losses of tralopyril and greater inconsistency in data from cylinder trials.

Andreyko II, M. (2020b)

This study determined the release rate of tralopyril from an aquaculture net coated with AquaNet Boost_{old} fixed to polycarbonate cylinders. The study was conducted in accordance with ASTM 6903-07 (equivalent to ISO 15181-1:2007) with a few modifications (detailed below) into substitute ocean water prepared according to ASTM D 1141-98. Modifications of the specific laboratory conditions defined in ASTM 6903-07 included the following:

- I. Temperature of the Artificial Sea Water in the holding tank to be 9°C ($\pm 1^{\circ}\text{C}$) instead of to 25°C ($\pm 1^{\circ}\text{C}$) as specified in ASTM 6903-07.

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- II. Temperature for the release rate measuring tanks to be 9°C (+/-1°C) instead of to 25°C (+/-1°C) as specified in ASTM 6903-07.
- III. Rotational speed of the cylinders under extraction to be 19 (+/-1) r/min for 1h, instead of the 60(+/-5) r/min as specified in ASTM 6903-07.

The analysis for tralopyril concentration measurements in extraction water has not been performed as described in ISO 15181-6:2012, but according to Janssen AGR 5707, method for tralopyril and metabolites. This method is available to authorities in confidential form upon request.

Aquaculture nets were prepared by Steen-Hansen using the same batch of paint used in Andreyko II, M. (2020a). These were attached to the cylinders by lightly gluing each node on the net to fix it to the test cylinder. They were covered with wax paper, and secured in place for a minimum of 5 minutes. No dry film thickness was measured. Any deviations from ASTM 6903-07 are noted in the study report. The test started on 9th March 2020 (Day 0) and finished on 23rd April 2020 (Day 45). The study report contains raw data for tralopyril concentration in the holding tanks, individual cylinder analyses with blanks, study temperature, pH, and salinity records. Sample calibration curves and chromatograms are included along with an GLP accreditation certificate.

According to the equations set out ASTM 6903-07 (identical to ISO 15181) the cumulative and mean tralopyril release rates were determined.

$R_{0,14} = 1.467 \mu\text{g}/\text{cm}^2$ (calculated by Battelle)

$R_{21,\text{end}} = 0.0525 \mu\text{g}/\text{cm}^2/\text{day}$

Conclusions

The results from the coated net (Andreyko II, M., 2020b) is more representative of the intended use pattern of the product. $R_{21,\text{end}} = 0.0525 \mu\text{g}/\text{cm}^2/\text{day}$ is applicable for use for both Premium and Boost_{old} products.

Parameters for refined emission (E_{local}) and PEC calculations

Parameter	EU fish farm scenario ¹ (tier 1)	Norwegian fish farm scenario ² (tier 2)
Refined fraction of released copper per deployment time of nets, $F_{a.i.}$ *	0.44 0.28	0.44 0.28
Release Rates from Leaching Studies – used in refined assessment to calculate 'Load' in MAMPEC **	0.301 $\mu\text{g}/\text{cm}^2/\text{day}$ 0.572 $\mu\text{g}/\text{cm}^2/\text{day}$ 0.437 $\mu\text{g}/\text{cm}^2/\text{day}$ (n=2) 0.0525 $\mu\text{g}/\text{cm}^2/\text{day}$	0.301 $\mu\text{g}/\text{cm}^2/\text{day}$ 0.572 $\mu\text{g}/\text{cm}^2/\text{day}$ 0.437 $\mu\text{g}/\text{cm}^2/\text{day}$ (n=2) 0.0525 $\mu\text{g}/\text{cm}^2/\text{day}$

* $F_{a.i.}$ of 0.44 from calculated from Ulriksen, U. (2020) including both cleaned and not in-situ cleaned nets, average of wall and bottom samples from all nets that were deployed at sea during summer months. $F_{a.i.}$ of 0.28 from Ulriksen, U. (2020). Document ID: DOKID-794567110-370, Steen-Hansen.

**Release rates from Pinori, E. (2020), Andreyko II, M. (2020a), Calculated Average (0.437, n=2) from the two previous studies, and Andreyko II, M. (2020b). The use of leaching rates in MAMPEC is discussed after 'Daily emission outputs using leaching rates from laboratory studies' below.

Daily emission outputs (E_{local})

Product	F _{a.i.} for Copper	EU fish farm scenario (tier 1)		Norwegian fish farm scenario (tier 2)	
		Copper	Tralopyril	Copper	Tralopyril
AquaNet Premium	0.8	8184 g/d	1844 g/d	12462 g/d	2808 g/d
AquaNet Premium	0.44	4501 g/d	See below	6854 g/d	See below
AquaNet Premium	0.28	2865 g/d	See below	4362 g/d	See below
AquaNet Boost _{old}	0.8	22867 g/d	2033 g/d	34818 g/d	3096 g/d
AquaNet Boost _{old}	0.44	12575 g/d	See below	19150 g/d	See below
AquaNet Boost _{old}	0.28	8002 g/d	See below	12186 g/d	See below

Note: F_{a.i.} of 0.44 and 0.28 used to refine daily emission inputs for Copper

Daily emission outputs using leaching rates from laboratory studies

Product	Study	EU fish farm scenario (tier 1)		Norwegian fish farm scenario (tier 2)	
		Leaching rate (µg/cm ² /day)	Tralopyril (g/d)*	Leaching rate (µg/cm ² /day)	Tralopyril (g/d)*
AquaNet Premium [#]	Pinori, E. (2020)	0.301	153.6003	0.301	233.877
	Andreyko II, M. (2020a)	0.572	291.892	0.572	444.444
	Mean	0.437	223.0011	0.437	339.549
	Andreyko II, M. (2020b)	0.0525	26.7908	0.0525	40.793
AquaNet Boost _{old}	Pinori, E. (2020)	0.301	153.6003	0.301	233.877
	Andreyko II, M. (2020a)	0.572	291.892	0.572	444.444
	Mean	0.437	223.0011	0.437	339.549
	Andreyko II, M. (2020b)	0.0525	26.7908	0.0525	40.793

Note: [#]AquaNet Boost_{old} has been used as a surrogate for AquaNet Premium as both products have the same paint formulation and equivalent amount of tralopyril

*Calculated by MAMPEC 3.1

Use of Leaching Rates in MAMPEC

MAMPEC is able to calculate the 'Total Emission Load' in g/d when a leaching rate is provided. The screenshots below show where the leaching rate is inputted. In the 'Emission Screen' input the leaching rate into 'Leaching rate (at birth)' (see Figure 6). The values in the 'Service Life' tab are set to match the values for N_{net} (10) and AREA_{net} (7770 m²) in the Norwegian Scenario Document. The model then calculates the 'Total Emission Load'. For example, when the leaching rate 0.0525 µg/cm²/day is entered into 'Leaching Rate (at birth)', MAMPEC calculates a Total Emission Load of 40.7925 g/d (see Figure 7). This value is used in place of the E_{local} calculation for a daily emission load from a fish farm.

MAMPEC 3.1 interface showing input fields for leaching rate and emission calculations. The 'Leaching rate (at berth)' is set to 0.0525 $\mu\text{g}/\text{cm}^2/\text{d}$. The 'Total emission' is calculated as 4.08E+001 g/d.

Length class (m)	Surface area (m ²)	# Ships at berth (/d)	# Ships moving (/d)	Application factor (%)
0-10	7770	10	10	100
10-50	120	0	0	100
50-100	450	0	0	100
100-150	3061	0	0	100
150-200	5999	0	0	100
200-250	9917	0	0	100
250-300	14814	0	0	100
300-350	22645	0	0	100
300-350	27547	0	0	100

Leaching rate (at berth): 0.0525 $\mu\text{g}/\text{cm}^2/\text{d}$
 Leaching rate (moving): 0 $\mu\text{g}/\text{cm}^2/\text{d}$

Service life Application / removal

Ships at berth: 4.08E+001 g/d
 Ships moving: 0.00E+000 g/d

Application professional

New building: 0.00E+000 g/d
 Maintenance: 0.00E+000 g/d
 Removal: 0.00E+000 g/d

Application non professional

Maintenance: 0.00E+000 g/d
 Removal: 0.00E+000 g/d

Totals

Total service life: 4.08E+001 g/d
 Total new building: 0.00E+000 g/d
 Total maintenance: 0.00E+000 g/d
 Total removal: 0.00E+000 g/d
 Total: 4.08E+001 g/d

Figure 6: MAMPEC screenshot showing where to input a laboratory derived leaching rate: e.g. 0.0525 $\mu\text{g}/\text{cm}^2/\text{day}$ is inputted into 'Leaching Rate (at birth)'.

MAMPEC 3.1 interface showing calculated load in g/d. The 'Load' is calculated as 40.7925 g/d.

Run name: [] Generate name

Environment: 1. Norway Fish Farm 2019 Change

Compound: 2. Tralopyril (2019) Change

Emission: 1. Norway Scenario with leaching Rate (Checked) Change

Load: 40.7925 g/d

Background concentrations

Background conc. [] Add constant to simulation results [] Add initial sediment concentration

ug/l (total conc. whole area) [] [] []

ug/l (dissolved water conc. whole area) [] [] []

Run date: [] Run model

Figure 7: MAMPEC screenshot showing 'Load in g/d' calculated from 'Leaching Rate (at birth)' input: e.g. a Load of 40.7925 g/d is calculated when 0.0525 $\mu\text{g}/\text{cm}^2/\text{day}$ is used.

Calculated PEC values and risk characterisation –: The EU fish farm scenario

AquaNet Premium

AquaNet Premium					
Average PEC values with Cu background concentrations					
Copper	Study	PEC _{dissolved} [$\mu\text{g}/\text{L}$]	PEC _{dissolved} /	PEC _{suspended} matter	PEC _{suspended} matter /

PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw			PNEC_{water}₁	[µg/g dw]	PNEC_{sediment}₁
EU fish farm scenario F _{a.i.} 0.8 (8184 g/d)	-	1.21	1.05	30.31	0.31
F _{a.i.} 0.44 (4501 g/d)	Ulriksen, U. (2020)	1.16	1.01	23.91	0.24
F _{a.i.} 0.28 (2865 g/d)	Ulriksen, U. (2020)	1.14	0.99	21.07	0.21
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	-	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water}₁	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment}₁
EU fish farm scenario F _{a.i.} 0.8 (1844 g/d)	-	0.04	26.00	0.01	15.33
R _{21,end} 153.6 g/d	Pinori, E. (2020)	0.0033	1.96	0.0009	1.16
R _{21,end} 291.8 g/d	Andreyko II, M. (2020a)	0.0063	3.73	0.0017	2.20
R _{21,end} 223.0 g/d	Mean	0.0048	2.85	0.0013	1.68
R _{21,end} 26.7 g/d	Andreyko II, M. (2020b)	0.0006	0.34	0.0002	0.20

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risks for the environment without further refinement.

Premium – EU Scenario

For active ingredient copper with copper background concentrations added in: using a refined F_{a.i.} reduces the PEC/PNEC ratio to below the trigger value of 1 and therefore indicates an acceptable risk for the environment.

For tralopyril: using a leaching rate from a leaching rate study with a 'net' was found to reduce the PEC/PNEC ratio to below the trigger value of 1 and therefore indicates an acceptable risk for the environment.

Premium product: an acceptable risk to the environment was indicated when the PECs were refined.

AquaNet Boost_{old}

AquaNet Boost_{old}					
Average PEC values with Cu background concentrations					
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	Study	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water}₁	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment}₁
EU fish farm scenario F _{a.i.} 0.8 (22867 g/d)	-	1.40	1.22	55.80	0.56
F _{a.i.} 0.44 (12575 g/d)	Ulriksen, U. (2020)	1.27	1.10	37.90	0.38

F _{a.i.} 0.28 (8002 g/d)	Ulriksen, U. (2020)	1.21	1.05	30.00	0.30
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	-	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
EU fish farm scenario F _{a.i.} 0.8 (2033 g/d)	-	0.04	25.97	0.01	15.33
R _{21,end} 153.6 g/d	Pinori, E. (2020)	0.0033	1.96	0.0009	1.16
R _{21,end} 291.8 g/d	Andreyko II, M. (2020a)	0.0063	3.73	0.0017	2.20
R _{21,end} 223.0 g/d	Mean	0.0048	2.85	0.0013	1.68
R _{21,end} 26.7 g/d	Andreyko II, M. (2020b)	0.0006	0.34	0.0002	0.20

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risks for the environment without further refinement.

Boost_{old} Conclusions – EU Scenario

For active ingredient copper with copper background concentrations added in: even when using a refined F_{a.i.} the PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risk for the environment.

For tralopyril: the risk to the environment was refined using leaching rate studies. An acceptable risk for the environment was indicated when using a leaching rate from a study conducted using 'net' as the sample matrix.

Boost_{old} product: an unacceptable risk to the environment was indicated.

Calculated PEC values and risk characterisation – The Norwegian fish farm scenario

AquaNet Premium

AquaNet Premium					
Average PEC values with Cu background concentrations					
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	Study	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario F _{a.i.} 0.8 (12462 g/d)	-	1.14	0.99	21.35	0.22
F _{a.i.} 0.44 (6854 g/d)	Ulriksen, U. (2020)	1.12	0.98	18.99	0.19

F _{a.i.} 0.28 (4362 g/d)	Ulriksen, U. (2020)	1.11	0.97	17.94	0.18
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	-	PEC _{dissolved} [µg/L]	PEC _{dissolved} / PNEC _{water} ¹	PEC _{suspended matter} [µg/g dw]	PEC _{suspended matter} / PNEC _{sediment} ¹
Norwegian fish farm scenario F _{a.i.} 0.8 (3096 g/d)	-	0.011	6.75	0.007	8.86
R _{21,end} 233.8 g/d	Pinori, E. (2020)	0.0009	0.51	0.0005	0.67
R _{21,end} 444.4 g/d	Andreyko II, M. (2020a)	0.0017	0.97	0.0010	1.28
R _{21,end} 339.5 g/d	Mean	0.0013	0.74	0.0008	0.97
R _{21,end} 40.7 g/d	Andreyko II, M. (2020b)	0.00015	0.09	0.00009	0.12

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risks for the environment without further refinement.

Premium Conclusions – Norwegian fish farm Scenario

For active ingredient copper with copper background concentrations added in: using a refined F_{a.i.} reduces the PEC/PNEC ratio to below the trigger value of 1 and therefore indicates an acceptable risk for the environment.

For tralopyril: using a leaching rate from a leaching rate study with a 'net' was found to reduce the PEC/PNEC ratio to below the trigger value of 1 and therefore indicates an acceptable risk for the environment.

Premium product: an acceptable risk to the environment was indicated when the PECs were refined.

AquaNet Boost_{old}

AquaNet Boost _{old}					
Average PEC values with Cu background concentrations					
Copper PNEC _{surrounding waters} = 1.15 µg/L PNEC _{sed} = 98.8 µg/g dw	Study	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water}¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment}¹
Norwegian fish farm scenario F _{a.i.} 0.8 (34818 g/d)	-	1.21	1.05	30.78	0.31
F _{a.i.} 0.44 (19150 g/d)	Ulriksen, U. (2020)	1.161	1.01	24.14	0.24
F _{a.i.} 0.28 (12186 g/d)	Ulriksen, U. (2020)	1.14	0.99	21.23	0.22
Tralopyril PNEC _{water} = 0.0017 µg/L PNEC _{sed} = 0.00079 µg/g dw	-	PEC_{dissolved} [µg/L]	PEC_{dissolved} / PNEC_{water}¹	PEC_{suspended matter} [µg/g dw]	PEC_{suspended matter} / PNEC_{sediment}¹
Norwegian fish farm scenario F _{a.i.} 0.8 (3096 g/d)	-	0.01	6.75	0.007	8.86
R _{21,end} 233.8 g/d	Pinori, E. (2020)	0.0009	0.51	0.0005	0.67
R _{21,end} 444.4 g/d	Andreyko II, M. (2020a)	0.0017	0.97	0.0010	1.28
R _{21,end} 339.5 g/d	Mean	0.0013	0.74	0.0008	0.97
R _{21,end} 40.7 g/d	Andreyko II, M. (2020b)	0.00015	0.09	0.00009	0.12

¹ PEC/PNEC ratios above 1 (values in **bold**) indicate unacceptable environmental risks.

Several PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risk for the environment without further refinement.

Boost_{old} Conclusions – Norwegian fish farm Scenario

For active ingredient copper with copper background concentrations added in: even when using a refined F_{a.i.} the PEC/PNEC ratios were found to be above the trigger value of 1 and therefore indicate unacceptable risk for the environment.

For tralopyril: the risk to the environment was refined using leaching rate studies. An acceptable risk for the environment was indicated when using a leaching rate from a study conducted using 'net' as the sample matrix.

Boost_{old} product: an unacceptable risk to the environment is indicated.

Risk characterisation for the EU scenario

The PEC/PNEC ratios based on PEC values calculated with the EU fish farm scenario are summarised in the following table.

AquaNet Premium

Summary table for the risk characterisation of AquaNet Premium in the EU fish farm scenario:

AquaNet Premium		PEC_{dissolved} /PNEC_{water}	PEC_{suspended matter} /PNEC_{sed}
AquaNet Premium with Cu background (Fa.i. & leaching rate refined)			
Copper	(F _{a.i.} 0.44, E _{local} 4501 g/d)	1.01*	0.24
Copper	(F _{a.i.} 0.28, E _{local} 2865 g/d)	0.99*	0.21
Tralopyril	(Andreyko II, M. (2020b) 26.7 g/d)	0.34	0.20

*with background concentrations of copper

Following refinement of the PECs using the F_{a.i.} for copper using field and farm study data and using leaching rate studies to refine tralopyril, the PEC/PNEC ratios fell below the trigger for both substances indicating an acceptable risk to the aquatic and sediment environments for both substances.

The RQ_{Product} calculated in the mixtures risk assessment tier 1 and 2 are discussed below in the Mixtures Toxicity Section.

AquaNet Boost_{old}

Summary table for the risk characterisation of AquaNet Boost_{old} in the EU fish farm scenario:

AquaNet Boost_{old}		PEC_{dissolved} /PNEC_{water}	PEC_{suspended matter} /PNEC_{sed}
AquaNet Boost_{old} with Cu background (Fa.i. & leaching rate refined)			
Copper	(F _{a.i.} 0.44, 12575 g/d)	1.10*	0.38
Copper	(F _{a.i.} 0.28, 8002 g/d)	1.05*	0.30
Tralopyril	(Andreyko II, M. (2020b) 26.7 g/d)	0.34	0.20

*with background concentrations of copper

Following refinement of the PECs using the F_{a.i.} for copper using field and farm study data and using a laboratory leaching rate to refine tralopyril, the PEC/PNEC for copper in the aquatic compartment was still above the trigger of 1 indicating an unacceptable risk.

The RQ_{Product} calculated in the mixtures risk assessment tier 1 and 2 are discussed below in the Mixtures Toxicity Section.

Risk characterisation for the Norwegian fish farm scenario

AquaNet Premium

The PEC/PNEC ratios based on PEC values calculated with the Norwegian fish farm scenario are summarised in the following table.

Summary table for the risk characterisation of AquaNet Premium in the Norwegian scenario:

AquaNet Premium		PEC_{dissolved} /PNEC_{water}*	PEC_{suspended matter} /PNEC_{sed}
------------------------	--	---	---

AquaNet Premium with Cu background (Fa.i. & leaching rate refined)			
Copper	(F _{a.i.} 0.44, 6854 g/d)	0.98	0.19
Copper	(F _{a.i.} 0.28, 4362 g/d)	0.97	0.18
Tralopyril	(Andreyko II, M. (2020b) 40.79 g/d)	0.09	0.12

*with background concentrations of copper

Following refinement of the PECs using the F_{a.i.} for copper using farm study data and using leaching rate studies to refine tralopyril, the PEC/PNEC ratios fell below the trigger for both substances in both the water and sediment compartments indicating an acceptable risk to the aquatic environment.

The RQ_{Product} calculated in the mixtures risk assessment tier 1 and 2 are discussed below in the Mixtures Toxicity Section.

AquaNet Boost_{old}

Summary table for the risk characterisation of AquaNet Boost_{old} in the Norwegian scenario:

AquaNet Boost_{old}		PEC_{dissolved} /PNEC_{water}*	PEC_{suspended matter} /PNEC_{sed}
AquaNet Boost_{old} with Cu background (Fa.i. & leaching rate refined)			
Copper	(F _{a.i.} 0.44, 19150 g/d)	1.01	0.24
Copper	(F _{a.i.} 0.28, 12186 g/d)	0.99	0.22
Tralopyril	(Andreyko II, M. (2020b) 40.79 g/d)	0.09	0.12

*with background concentrations of copper

Following refinement of the PECs using the F_{a.i.} for copper using farm study data and using leaching rate studies to refine tralopyril, the PEC/PNEC ratios fell below the trigger for both substances in both aquatic and sediment compartments indicating an acceptable risk in each environment.

The RQ_{Product} calculated in the mixtures risk assessment tier 1 and 2 are discussed below in the Mixtures Toxicity Section.

Terrestrial compartment

The proposed uses of the Premium products as antifouling coatings for nets used in aquaculture would not result in any direct or indirect exposure of the terrestrial environment. Hence the risks to the terrestrial compartment are considered acceptable.

Groundwater

The proposed uses of the Premium products as antifouling coatings for nets used in aquaculture would not result in any exposure to groundwater. Hence the risks to groundwater are considered acceptable.

Primary and secondary poisoning

Dicopper oxide

The CAR of the active substance dicopper oxide (PT21, 2016) states that because of the homeostasis of metals, BCF values are not indicative of the potential bioaccumulation. There

is therefore limited evidence of accumulation and secondary poisoning of inorganic forms of metals, and biomagnification in food webs.

Tralopyril

A substance is considered to have the potential to fulfill the criterion of bioaccumulation if the log K_{ow} exceeds 4.5. The CAR of the active substance states that for tralopyril the log K_{ow} is pH dependant with values of 4.4, 3.5 and 2.4 reported for pH 4, 7 and 9 respectively. Therefore, under fresh and marine water conditions tralopyril does not meet the B criterion set by the TGD.

However, the risk to fish-eating birds was assessed, in accordance with the assessment methodology described in the CAR for tralopyril (PT 21, UK, 2014).

Equation 95 from the Guidance on the BPR, Vol. IV Part B was used to calculate the PECs for fish.

$$PEC_{\text{Coral, predator}} = BCF_{\text{fish}} \cdot BMF \cdot PEC_{\text{seawater}}$$

As a first tier, the highest calculated PEC_{seawater} (dissolved), i.e. 0.04 µg/L from the EU fish farm scenario was used for the secondary poisoning assessment. According to the CAR for tralopyril (ref), a BCF_{fish} of 3.2 L/kg is used, as a worst case estimate. The BMF is set to 1, in accordance with the Guidance on BPR, Vol. IV Part B.

$$PEC_{\text{Coral, predator}} = 1.28\text{E-}04 \text{ mg/kg} = 0.13 \text{ µg/kg}$$

The $PNEC_{\text{Coral}}$ presented in the CAR for tralopyril is as follows:

$$PNEC_{\text{Coral}} = 3.6\text{E-}03 \text{ mg/kg} = 3.6 \text{ µg/kg}$$

No unacceptable risks are hence identified for secondary poisoning via the aquatic food chain since the $PEC/PNEC$ ratio is below 1, as shown below:

$$PEC_{\text{Coral, predator}} / PNEC_{\text{Coral}} = 0.04$$

As stated in the CAR for tralopyril, it should additionally be mentioned that the fate of tralopyril has shown that it will be rapidly degraded to the primary and secondary metabolites CL322,250 and CL322,248 that have lower log K_{ow} s than the parent compound. No further assessment is considered necessary.

Mixture toxicity

According to the PT 21 Product Authorisation manual, products that contain relevant mixtures of substances (e.g. multiple active substances) an assessment of mixture toxicity is triggered. At tier 1 this requires simple summation of individual $PEC/PNEC$ ratios. This approach has been followed, see the chapter on risk characterisation above.

At tier 2 of the mixtures risk assessment (see ECHA, 2014³), the RQ_{product} is determined by use of a modified toxic unit approach. This approach allows for the summation of toxic units across different active substances (or substances of concern) that have differing amounts of experimental data and therefore differing assessment factors used in the determination of

³ ECHA, (2014). Transitional Guidance on mixture toxicity assessment for biocidal products for the environment.

the PNECs for each substance. In this tier, the three trophic levels are assessed independently, using the same assessment factor used for calculating the PNEC of the respective substance at tier 1 and according to the following equation:

$$RQ_{Product} = \max \sum_{i=1}^n \left(\frac{PEC}{ECx/AF} \right)_i$$

where:

- PEC = predicted environmental concentration
- ECx = the lowest effect concentration affecting x% (may also be a NOEC) for the trophic level and substance
- AF = Assessment factor used in the determination of the PNEC for the substance assessed individually

The $RQ_{Product}$ is the highest RQ of all the trophic levels.

Lowest endpoints used in PNEC calculations

The lowest endpoints and associated assessment factors used in the individual risk assessment for copper and tralopyril are summarised in the following table:

Substance	Taxa	Species	Chronic Endpoints	Value (µg/L)	Assessment factor
Copper	Fish	<i>Atherinops affinis</i>	NOEC	55	2
	Invertebrate	<i>Ceriodaphnia dubia</i>	NOEC	4	2
	Algae	<i>Phaeodactylum tricornutum</i>	NOEC	2.9	2
Tralopyril	Fish	<i>Danio rerio</i>	NOEC	0.17	100
	Invertebrate	<i>Daphnia magna</i>	NOEC	0.2	100
	Algae	<i>Navicula pelliculosa</i>	NOEC	0.73	100

The RQ_{Product} calculated in the mixtures risk assessment (tier 1) are above the trigger value of 1 in both the aquatic and sediment compartments. Refining the $F_{a.i.}$ for copper and using the leaching rate studies to refine tralopyril resulted in the reduction of RQ_{Product} which was below the trigger value for sediment but still above the trigger value for the aquatic environment. Thus, it is necessary to refine the mixtures assessment further according to tier 2 for the aquatic environment.

Tier 2: modified Toxic Unit Summation (TUS)

Mixtures assessment tier 2: Modified Toxic Unit Summation (TUS) separated for trophic levels

Tier 2 calculations for AquaNet Premium - $PEC_{\text{dissolved}} / PNEC_{\text{water}}$

Cu PEC	Tralopyril PEC	Trophic level	Substance	NOEC (µg/L)	Assessment factor (AF)	NOEC/AF	PEC (µg/L)	PEC/(NOEC/AF)	RQ_{Product}
$F_{a.i.} 0.8, 12462 \text{ g/d}$	$(F_{a.i.} 0.8, 2808 \text{ g/d})$	Fish	Copper	55	2	27.5	1.14	0.04	6.79
			Tralopyril	0.17	100	0.0017	0.011	6.8	
		Invertebrate	Copper	4	2	2	1.14	0.57	6.31
			Tralopyril	0.2	100	0.002	0.011	5.7	

		Algae	Copper	2.9	2	1.45	1.14	0.79	2.36
			Tralopyril	0.73	100	0.0073	0.011	1.57	

F _{a.i.} 0.8, 12462 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.14	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.14	0.57	0.65
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.14	0.79	0.81
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

F _{a.i.} 0.44, 6854 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.12	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.12	0.56	0.64
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.12	0.77	0.79
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

F _{a.i.} 0.28, 4362 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.11	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.11	0.56	0.63
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.11	0.77	0.79
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

Tier 2 calculations for AquaNet Boost^{old} - PEC_{dissolved} / PNEC_{water}

Cu PEC	Tralopyril PEC	Trophic level	Substance	NOEC (µg/L)	Assessment factor (AF)	NOEC/AF	PEC (µg/L)	PEC/(NOEC/AF)	RQ _{Product}
F _{a.i.} 0.8, 34818 g/d	(F _{a.i.} 0.8, 2808 g/d)	Fish	Copper	55	2	27.5	1.21	0.04	6.79
			Tralopyril	0.17	100	0.0017	0.011	6.8	
		Invertebrate	Copper	4	2	2	1.21	0.61	6.34
			Tralopyril	0.2	100	0.002	0.011	5.7	

		Algae	Copper	2.9	2	1.45	1.21	0.84	2.41
			Tralopyril	0.73	100	0.0073	0.011	1.57	

F _{a.i.} 0.8, 34818 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.21	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.21	0.61	0.68
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.21	0.84	0.86
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

F _{a.i.} 0.44, 19150 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.16	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.16	0.58	0.66
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.16	0.80	0.82
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

F _{a.i.} 0.28, 12186 g/d	Andreyko II, M. (2020b) 40.79 g/d	Fish	Copper	55	2	27.5	1.14	0.04	0.13
			Tralopyril	0.17	100	0.0017	0.00015	0.09	
		Invertebrate	Copper	4	2	2	1.14	0.57	0.65
			Tralopyril	0.2	100	0.002	0.00015	0.08	
		Algae	Copper	2.9	2	1.45	1.14	0.79	0.81
			Tralopyril	0.73	100	0.0073	0.00015	0.02	

Summary:**Tier 2 mixture toxicity summary - $PEC_{dissolved} / PNEC_{water}$**

Tier 2 (using average PEC values with Cu background concentrations)								
Product	Cu PEC based upon	Tralopyril PEC based on	Sensitive trophic level	Copper PEC/ (NOEC/AF)	Tralopyril PEC/ (NOEC/AF)	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
AquaNet premium	$F_{a.i.} 0.8, 12462 \text{ g/d}$	$(F_{a.i.} 0.8, 2808 \text{ g/d})$	Fish	0.04	6.8	6.79	N	
	$F_{a.i.} 0.8, 12462 \text{ g/d}$	Andreiko II, M. (2020b) 40.79 g/d	Algae	0.79	0.02	0.81	Y	
	$F_{a.i.} 0.44, 6854 \text{ g/d}$	Andreiko II, M. (2020b) 40.79 g/d	Algae	0.77	0.02	0.79	Y	
	$F_{a.i.} 0.28, 4362 \text{ g/d}$	Andreiko II, M. (2020b) 40.79 g/d	Algae	0.77	0.02	0.79	Y	
AquaNet Boost _{old}	$F_{a.i.} 0.8, 34818 \text{ g/d}$	$(F_{a.i.} 0.8, 2808 \text{ g/d})$	Fish	0.04	6.8	6.79	N	
	$F_{a.i.} 0.8, 34818 \text{ g/d}$	Andreiko II, M. (2020b) 40.79 g/d	Algae	0.84	0.02	0.86	Y	
	$F_{a.i.} 0.44, 19150 \text{ g/d}$	Andreiko II, M. (2020b) 40.79 g/d	Algae	0.80	0.02	0.82	Y	

	Fa.i. 0.28, 12186 g/d	Andreyko II, M. (2020b) 40.79 g/d	Algae	0.79	0.02	0.81	Y	
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AquaNet Premium in the Norwegian fish farm scenario

RQ_{Product} calculated in the mixtures risk assessment (tier 2) is above the trigger value of 1 before refinement of the PECs. Using the leaching rate from Andreyko II, M. (2020b) to refine tralopyril resulted in the reduction of RQ_{Product} which was below the trigger value for the aquatic environment (0.81). Therefore AquaNet Premium shows acceptable risk to the aquatic environment following tier 2 mixtures risk assessment.

AquaNet Boost_{old} in the Norwegian fish farm scenario

The RQ_{Product} calculated in the mixtures risk assessment (tier 2) is above the trigger value of 1 before refinement of the PECs. Using the leaching rate from Andreyko II, M. (2020b) to refine tralopyril resulted in the reduction of RQ_{Product} which was below the trigger value for the aquatic environment (0.86). AquaNet Boost_{old} therefore shows an acceptable risk to the aquatic environment following tier 2 mixtures risk assessment

Conclusion:

The mixtures risk assessment indicated unacceptable risks to the aquatic environment at tier 1 in both products for both scenarios.

Following the tier 2 calculations both products showed acceptable risks to the aquatic environment following the refinement of the PECs using refined leaching rates determined) for tralopyril and copper.

Aggregated exposure (combined with relevant emission sources)

Article 19(2) and Annex VI of the Biocidal Products Regulation (EC) 528/2012 (BPR) state that the evaluation shall take into account cumulative and synergistic effects associated with the relevant individual components of the biocidal product. According to the provisions given in the BPR, aggregated risk assessments shall not be carried out routinely in the Review Programme but only where relevant.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

Not relevant.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (FAMILY)

Author	Year	Title Report No. Laboratory GLP Published	Owner
Andreyko II, M	2020a	Leach Rate Determination of Tralopyril and Metabolites from Aquanet Boost Report No. 3990-04 Case Laboratories, Inc. Yes No	Janssen PMP
Andreyko II, M	2020b	Leach Rate Determination of Tralopyril and Metabolites from Net Coated with Aquanet Boost Report No. 3990-05 Case Laboratories, Inc. Yes No	Janssen PMP
Bernal, J.	2018a	In-vitro human skin penetration of total copper in AquaNet premium PT21 Biocide product Report no. S17-08528 Eurofins agrosience services Chem SAS Yes No	Steen-Hansen
Bernal, J.	2018b	In-vitro human skin penetration of ¹⁴ C-tralopyril in AquaNet premium PT21 Biocide product Report no. S17-08526 Eurofins agrosience services Chem SAS Yes No	Steen-Hansen
Bjarnemark,	2016a	Method Development for Tralopyril in Fish and	Steen-Hansen

Author	Year	Title Report No. Laboratory GLP Published	Owner
F.		Shell Fish Tissue" from Janssen PMP implemented at SP, Report 6P05760-01. SP Technical Research Institute of Sweden No No	
Bjarnemark, F.	2016b	Analysis of Tralopyril in Fish Tissue Report: 6P05760-02 Report: 6P05760-03 SP Technical Research Institute of Sweden No No (Results included in Ulriksen, 2021)	Steen-Hansen
Bjarnemark, F.	2017	Analysis of Tralopyril in Fish Tissue: Report: 7P02775-04 RISE Research Institutes of Sweden AB No No (Results included in Ulriksen, 2021)	Steen-Hansen
Bjarnemark, F	2019	Analysis of Tralopyril in Fish Tissue Report no. 7P02775-20	Steen-Hansen
Bloecher, N, Floerl, O	2018	Guidelines for efficacy testing of antifouling coatings for nets in field tests. Technical paper, Norwegian Environment Agency, Oslo.	
Fagerlid, S	2017	AquaNet Boost Norway 2017 DOKID-1294561088-216 Steen-Hansen No No	Steen-Hansen
Fagerlid, S	2017	AquaNet Boost Greece 2017 DOKID-1294561088-211 Steen-Hansen No No	Steen-Hansen
Fagerlid, S	2017	AquaNet Premium Greece 2017 DOKID-1294561088-220 Steen-Hansen No No	Steen-Hansen

Author	Year	Title Report No. Laboratory GLP Published	Owner
Fischer, A	2017	Interim report 3 months AquaNet Premium Boost 7PO4987-04 RISE, Sweden No No	Steen-Hansen
Hope, B	2017	AquaNet Boost Norway Trial 2 2017 DOKID-1294561088-97 Steen-Hansen No No	Steen-Hansen
Hope, B	2017	AquaNet Premium Norway Trial 2 2017 DOKID-1294561088-97 Steen-Hansen No No	Steen-Hansen
Hope, B	2018	AquaNet Premium Norway 2018 DOKID-1294561088-97 Steen Hansen No No	Steen-Hansen
Hope, B	2018	AquaNet Boost Norway 2018 DOKID-1294561088-97 Steen Hansen No No	Steen-Hansen
Hope, B	2021	Fish accumulation study_MH_Trommo, DOKID-794567110-510 (Revision 3.0) RISE laboratory No No	Steen Hansen
Le Page, G	2020	Screen on synergistic interactions RH/17/005/A BattelleUK No No	Steen-Hansen
Pinori, E	2017	Measurement of the release rate of biocide from AF paints 2017-05-15 RISE Research Institute of Sweden AB No No	Steen-Hansen
Pinori, E	2020	Determination of release rate of Tralopyril from antifouling paint according to ISO 15181-1 and -6 62P01843-2 RISE Research Institute of Sweden AB No No	Steen-Hansen

Author	Year	Title Report No. Laboratory GLP Published	Owner
Ulriksen, U	2017	AquaNet Boost Norway 2017 DOKID-1294561088-113 Steen-Hansen No No	Steen-Hansen
Ulriksen, U	2020	Biocide release from Aquaculture nets DOKID-794567110-370 Steen-Hansen No No	Steen-Hansen
Ulriksen, U	2021a	Fish tissue residue study, Econeas DOKID-1294561088-215 Report revision: 2.0 Steen Hansen No No	Steen Hansen
Ulriksen, U	2021b	Fish tissue residue study, Econeas Related to DOKID-1294561088-215 (Reference: 2.2.6.3) Steen Hansen No No	Steen Hansen
Younis, S	2017	Hazardous properties testing on a sample of Aquanet Premium Boost GLP301001671AR1V1/2017 Dekra Insight, UK Yes No	Steen-Hansen
Wallace, J.	2020	The <i>In Vitro</i> Percutaneous Absorption of Dicopper Oxide in AquaNet Premium Paint Formulation through Human Split-Thickness Skin Report number 786208 (Report amendment 1) Charles River Yes No	Steen Hansen

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

3.2.1 *Output tables from the environmental exposure assessments*

Available upon request.

3.2.2 *Output tables from the human health exposure assessments*

The following excel-file has been uploaded to RBP3 separately:
HH_Exposure_Premium BPF.xlsx

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCES

None.

3.4 RESIDUE BEHAVIOUR

Premium BPF is only to be used as antifouling paints applied to aquaculture nets and it is not expectable residues of the actives substances or its degradation products. Therefore, it is not required complying with the obligations under the Biocides Regulation (BPR).

3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1)

Please see section 2.2.5.5.

3.6 OTHER

REFERENCES

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