HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 1 oktober 2019 is van

Holland Water B.V.
Nijendal 52
3972 KC DRIEBERGEN

een aanvraag tot verlenging van een toelating (overgangsrecht) ontvangen voor het middel

HW Bifipro

op basis van de werkzame stoffen koper en zilver.

HET COLLEGE BESLUIT tot verlenging van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage III bij dit besluit is voorgeschreven.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking en/of in de handleiding te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.

- Het toelatingsnummer.
- De etikettering zoals opgenomen in bijlage II bij dit besluit, deze moet volgens de voorschriften op de verpakking worden vermeld.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III, onder A.
- De gebruiksaanwijzing, hetzij letterlijk, hetzij naar zakelijke inhoud, zoals opgenomen in bijlage III, onder B. De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking en/of in de handleiding te worden aangebracht. De te hanteren aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 89, tweede lid van EU 528/2012 jo art 130a, vierde lid Wet gewasbeschermingsmiddelen en biociden (Wgb) jo art 4, tweede lid Wgb (oud) jo art 121 Wgb (oud) jo art 44 Wgb (oud) .
Classificatie en etikettering	artikel 89, tweede lid, Verordening 528/2012, jo. artikel 130a, vierde lid, WBB, jo. artikel 50 WGB oud
Gebruikt toetsingskader	RGB (Hoofdstuk 10)

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden.

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE of post@ctgb.nl.

Ede, 2 juni 2023

Het college voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Drs. R.J.T. van Lint

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20191725 TVB
Type aanvraag:	aanvraag tot verlenging van een toelating (overgangsrecht)
Middelnaam:	HW Bifipro
Formele registratiedatum: *	3 oktober 2019

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
koper	99,90 % w/w
zilver	99,99 % w/w

De werkzame stof zilver is opgenomen in het reviewprogramma maar nog niet geplaatst voor het aangevraagde PT05 op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012.

De werkzame stof koper is opgenomen in het reviewprogramma maar nog niet geplaatst voor het aangevraagde PT05 op de Unielijst van Goedgekeurde Werkzame stoffen volgens Verordening 528/2012. Voor koper is een besluit van kracht voor het op de markt brengen van koperhoudende biociden voor essentieel gebruik (2014/85/EU).

3 Toelatingsinformatie

Toelatingsnummer:	13293 N
Expiratiedatum:	1 juli 2033
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Biocide
Gebruikers:	Professioneel
Aflever- en opgebruiktermijnen:	
Aflevertermijn professioneel gebruik:	6 maanden
Opgebruiktermijn professioneel gebruik:	12 maanden

4 Verpakkingsinformatie

Aard van het preparaat:
Diversen

13293 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel HW Bifipro

Professioneel

Zilver elektrode / koper elektrode

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram	-
Signaalwoord	Geen
Gevarenaanduidingen	-
Voorzorgsmaatregelen	-
Aanvullende etiketelementen	-

13293 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG/GA van het middel HW Bifipro

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik van de HW Bifipro elektroden in apparatuur voor koper-/ zilverionisatie van het merk HW Bifipro, ter bestrijding van Legionella en biofilm in waterleidingsystemen voor drinkwater in een collectieve watervoorziening van prioritaire instellingen.

Voor toepassing in waterleidingsystemen voor drinkwater geldt:

- De HW Bifipro biocide mag uitsluitend curatief worden ingezet (conform het Drinkwaterbesluit);
- Indien nodig dient het waterleidingsysteem te worden gereinigd voorafgaand aan plaatsing van de HW Bifipro apparatuur;
- De HW Bifipro apparatuur mag uitsluitend geïnstalleerd, afgesteld en onderhouden worden door technische engineers die bekend zijn met deze apparatuur (engineers van de leverancier zelf of van een partij die door de leverancier is aangewezen);
- De inwerkingstelling van de HW Bifipro apparatuur dient bij de Inspectie Leefomgeving en Transport (IL&T) te worden gemeld met het online formulier 'Melding inwerkingstelling alternatieve beheertechniek voor legionellapreventie';
- Het beheersplan (conform het Drinkwaterbesluit) dient gericht te zijn op borging van de effectiviteit van de HW Bifipro biocide in de gehele achterliggende waterinstallatie alsmede het voorkomen van neveneffecten, waarbij in ieder geval moet worden voldaan aan de richtlijnen zoals beschreven in BRL K 14010-2/01 (Beoordelingsrichtlijn voor het KIWA-attest met productcertificaat voor legionellapreventie met alternatieve technieken, deel 2: elektrochemische technieken: koper- en zilverionisatie en anodische oxidatie);
- Van de uitvoering van het beheersplan dient verslag te worden gedaan in het logboek (conform het Drinkwaterbesluit).

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.

GEBRUIKSAANWIJZING

Toepassing:
De HW Bifipro apparatuur wordt direct na de watermeter geïnstalleerd, zodanig dat alle relevante tappunten van behandeld water worden voorzien.

Dosering:
Koper

- De effectieve dosering van koper per etmaal is 400 µg/l;
    - Variant 1: Koper wordt per etmaal aan 100% van het water gedoseerd. De koperdosering binnen een etmaal is maximaal 400 µg/l
    - Variant 2: Koper wordt per etmaal aan maximaal 80% van het water gedoseerd. De koperdosering binnen een etmaal varieert van 0 tot 500 µg/l.
    - Variant 3: Koper wordt per etmaal aan maximaal 50% van het water gedoseerd. De koperdosering binnen een etmaal varieert van 0 tot 800 µg/l.

  Waarbij voor koper op elk tappunt de wettelijke eis van 2000 µg/l niet wordt overschreden.

Zilver

- De effectieve dosering van zilver per etmaal is 1,0 µg/l;
    - Variant 1: Zilver wordt per etmaal aan 100% van het water gedoseerd. De zilverdosering binnen een etmaal is maximaal 1 µg/l.
    - Variant 2: Zilver wordt per etmaal aan maximaal 20% van het water gedoseerd. De zilverdosering binnen een etmaal varieert van 0 tot 5 µg/l.
    - Variant 3: Zilver wordt per etmaal aan maximaal 10% van het water gedoseerd. De zilverdosering binnen een etmaal varieert van 0 tot 10 µg/l.

Beheer:
Om nauwkeurige dosering van de koper- en zilverionen zeker te stellen, vindt er geen ionisatie plaats bij een waterdoorstroming van 1% of minder van het maximale te meten debiet (bijvoorbeeld: bij een maximaal debiet van 200 l/min vindt er geen ionisatie plaats bij 2 l/min of minder). Bovendien wordt bij een heel hoog debiet ook geen koper en zilver gedoseerd, aangezien de verblijftijd van de koper- en zilverionen in het leidingstelsel (en daarmee het desinfecterende effect) bij een hoog debiet beperkt is.

Bovengenoemde effectieve koper- en zilverdoseringen gelden ook voor de toepassing van de HW Bifipro apparatuur bij waterinstallaties met een reinwaterkelder.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV RISKMANAGEMENT

Contents

1 Introduction....4
2 Identity....4
3 Physical and chemical properties....5
4 Analytical methods for detection and identification....5
5 Efficacy....6
6 Human toxicology....11
7 Environment....12
8 Conclusion....19
9 Classification and labelling....19
10 References....20
Appendix I. Input environmental parameters for modelling....21

1 Introduction

1.1 Applicant

Holland Water B.V.
Nijendal 52
3972 KC DRIEBERGEN
The Netherlands

1.2 Active substance

Copper and silver

1.3 Product

HW Bifipro, formerly called ICA-systeem

1.4 Function

HW Bifipro is used to control Legionella in drinking water (PT05).

1.5 Background to the application

This concerns an application for prolongation of an existing authorisation of a biocidal product.

1.6 Intended uses

The product is currently authorized in the NL under both registration number 13293 (currently trading under system name ICA-systeem) and registration number 13292 (currently trading under system name Bifipro) to control Legionella and biofilm in collective drinking water systems of priority institutional buildings (PT05).
Extension of the authorization for the product HW Bifipro, comprising new systems trading under system name HW Bifipro as well as systems currently trading under system names ICA and Bifipro, is requested for a reduction of the in-use active substance concentration.
The product is intended for professional use.

1.7 Packaging details

	Material	Size / content	Other information
Professional use	Cu Electrode	200mm x 30mm x 10mm	Plastic wrapping optional
	Cu Electrode	400mm x ø19mm	
	Cu Electrode	400mm x ø10mm	
	Cu Electrode	150mm x ø15mm	
	Ag Electrode	200mm x 30mm x 10mm	
	Ag Electrode	200mm x 30mm x 2mm	
	Ag Electrode	200mm x ø19mm	
	Ag Electrode	100mm x ø19mm	
	Ag Electrode	100mm x ø10mm	
	Ag Electrode	130mm x ø13mm	

2 Identity

2.1 Identity of the active substance

2.1.1 Copper

Common name	Copper
Name in Dutch	Koper
Chemical name	Copper
CAS no	744-50-8

EC no	231-159-6

The active substance copper is not yet included in the Union list of approved substances of EU Regulation 528/2012. A revised CAR is available (June 2017, eCA: France).
Sufficient information on copper is available in this dossier and in public literature.

2.1.2 Silver

Common name	Silver
Name in Dutch	Zilver
Chemical name	Silver
CAS no	7440-22-4
EC no	231-131-3

The active substance silver is not yet included in the Union list of approved substances of EU Regulation 528/2012. Initial application for approval is in progress (eCA: SE). A CAR is not available.
Sufficient information on silver is available in this dossier and in public literature.

Certificates of analysis were submitted for both precursors indicating that there is no risk of the release of heavy metals (such as lead) in unacceptable concentrations.

2.2 Identity of the biocidal product

Name	HW Bifipro
Formulation type	XX
Content active substance	Copper: 99,90% w/w
	Silver: 99,99% w/w

2.3 Overall conclusions identity

The identity of the active substances and the biocidal product is sufficiently described.

Data requirements
None.

3 Physical and chemical properties

3.1 Physical and chemical properties of the active substance

Sufficient information on the precursors copper and silver is available in this dossier and in public literature.

3.2 Physical and chemical properties of the biocidal product

This product is based on controlled electrolysis of copper and silver. The copper and silver electrodes are placed in separate ionisation chambers. The electrodes may have the following dimensions:

Cu Electrode	200mm x 30mm x 10mm
Cu Electrode	400mm x ø19mm
Cu Electrode	400mm x ø10mm
Cu Electrode	150mm x ø15mm
Ag Electrode	200mm x 30mm x 10mm
Ag Electode	200mm x 30mm x 2mm
Ag Electrode	200mm x ø19mm
Ag Electrode	100mm x ø19mm
Ag Electrode	100mm x ø10mm
Ag Electrode	130mm x ø13mm

The physical and chemical properties of the precursors copper and silver (metal in solid state) are not relevant for the risk assessment.

The electrodes do not degrade nor spoil in such way that it could influence the safety of the user or decrease the efficacy.

3.3 Overall conclusions physical and chemical properties

The physical and chemical properties of the active substances and the biocidal product are sufficiently described by the available information.

A shelf life of 30 years is assigned.

Data requirements
None.

4 Analytical methods for detection and identification

Sufficient information regarding analytical methods (e.g. AAS, ICP-AES, and ICP-MS) for copper, silver, copper-ions, and silver-ions are available in public literature.

4.1 Overall conclusions methods of analysis

The submitted analytical methods meet the requirements.

Data requirements
None.

5 Efficacy

5.1 Function

HW Bifipro is a water disinfectant based on copper and silver electrodes (copper (99.90% w/w), silver (99.99% w/w) which are used for copper and silver ionisation.

5.2 Field of use envisaged

The product is currently authorized in the NL under both registration number 13293 (trading under system name ICA) and registration number 13292 (trading under system name Bifipro) to control Legionella and biofilm in collective drinking water systems of prioritary institutional buildings (PT05).

Extension of the authorization for the product HW Bifipro, comprising new systems trading under system name HW Bifipro as well as systems currently trading under system names ICA and Bifipro, is requested for a reduction of the in-use active substance concentration.
The product is intended for professional use.

5.3 Effects on target organisms and efficacy

5.3.1 Efficacy data submitted and evaluation of data

Four studies were provided of which all were used in this assessment. These are summarised in Table 1. Data from one field study could not be used to demonstrate efficacy of the product due to lack of data on the in-use concentration of the product or too short test periods. Data from one other field test was disregarded for the efficacy assessment as the test period was too short to conclude on the efficacy of the product.

Table 1. Summary of studies assessed

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Legionella			
Field test	*Legionella pneumophila*	**Concentration (%):** 0-10 µg/l Ag, 110-860 µg/l Cu **Water quality:** drinking water **Test period**: 11 months (27/08/2013 – 08/08/2014) **Test site:** 1 location with >100 draw points, 32 of which were sampled 1-13 times over an 11-month period.	Of the 32 draw points sampled, data for 28 draw points could not be used to assess the efficacy of the proposed in-use Ag concentration as the initial presence of Legionella was either not determined or too low (< 1000 CFU/l) in line with the BPR Efficacy Guidance part B+C to conclude that the draw point was contaminated with Legionella. Data for four draw points could be used to assess efficacy. Apartment 106: Legionella contamination was brought down from 1100 CFU/l to <100 CFU/l, as only 2 samplings are available it could not be determined whether control was realized for a longer time period. No information on the initial dose of silver is available. It was not demonstrated that the dose of <1 µg/L Ag resulted in control of Legionella. Apartment 124: Legionella contamination was brought down from 19000 CFU/l to <100 CFU/l. Due to the limited time period where control was achieved it could not be determined whether the infection was systematically under control or not. It was not demonstrated that a dose of 1 µg/L Ag resulted in control of Legionella. Hotel room 101: Legionella contamination was brought down from 11000 CFU/l to <100 CFU/l. No information on the in-use silver concentration is available for the second sampling point. It was not demonstrated that the dose of <1 µg/L Ag resulted in control of Legionella as samplings took place over a 2-month period only. Hotel room 201: Legionella contamination was brought down from 18000 CFU/l to <100 CFU/l. No information on the in-use silver concentration is available for the second sampling point. It was not demonstrated that the dose of <1 µg/L Ag resulted in control of Legionella as samplings took place over a 2-month period only.

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Field test	*Legionella pneumophila*	**Concentration (%):** 110-860 µg/l Cu **Water quality:** drinking water **Test period**: sites were sampled twice over a 2-month period **Test sites:** 10 locations with at least 4 draw points sampled in total. For 3 sites two samplings are available, for 7 sites 1 sampling (after 1 month) is available. Drinking water in all locations was treated with a combined Cu/Ag treatment prior to the start of dosing Cu only. Initial measurements of Legionella were performed at all locations, except for locations 1 and 10. Legionella presence at all draw points sampled was <100 CFU/L.	Due to the test period of 2 months this data is not taken into account as no conclusion can be drawn over this short time period. Location 1: One month after treatment with 420-490 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 2: One month after treatment with 29-350 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 3: One month after treatment with 400-550 µg/L Cu Legionella presence is <100 CFU/l at all draw points, but one (300 CFU/L). Two months after treatment with 420-560 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 4: One month after treatment with 140-440 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Two months after treatment with 170-380 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 5: One month after treatment with 140-410 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 6: One month after treatment with 240-980 µg/L Cu Legionella presence is <100 CFU/l at all draw points, but one (300 CFU/L). Location 7: One month after treatment with 120-680 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 8: One month after treatment with 200-290 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Two months after treatment with 250-300 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 9: One month after treatment with 230-930 µg/L Cu Legionella presence is <100 CFU/l at all draw points. Location 10: One month after treatment with 170-450 µg/L Cu Legionella presence is <100 CFU/l at all draw points.

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Field test	*Legionella pneumophila*	**Concentration (%):** average of 1 µg/l Ag, 400 µg/l Cu **Water quality:** drinking water **Test period**: 6 months **Test site:** 4 locations with >200 draw points, 8-10 sampling points were used per location For location 2, 3 and 4 Legionella has been treated with electrochemical technique for multiple years	Location 1: Started with an infestation of Legionella (>1000 CFU/l), after 6 months of treatment the Legionella infestation was at the last three sampling time points on average for all sampling points <100 CFU/l. Dosing was pulsed with an average of <0.5 µg/l Ag and 187-264 µg/l Cu. Location 2: Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Pulse dosing was used with an average of 1 µg/l Ag and 195-398 µg/l Cu. Location 3: Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Dosing was continuous with on average of 1 µg/l Ag and 281-388 µg/l Cu. Location 4: Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Dosing was continuous with on average of 1 µg/l Ag and 170-335 µg/l Cu. In total all sampling points tested show that for 90% of the sampling points Legionella is controlled.

Test (version) Phase, step	Test organism(s)	Test parameters	Test results*
Field test	*Legionella pneumophila*	**Concentration (%):** average of ~400 µg/l Cu **Interfering substances:** drinking water **Contact time**: 4-5 months **Test site:** 4 locations with >100 draw points, 6-10 sampling points were used per location For location 2, 3 and 4 Legionella has been treated with electrochemical technique since ~2013. Location 2, 3, and 4 were treated with Cu and Ag until April 2022, the field trial started in October 2022.	Location 1 : Started with an infestation of Legionella (>1000 CFU/l), after 5 months of treatment the Legionella infestation at the final sampling time was on average (for all sampling points) <100 CFU/l. Measured concentration of Cu was 350-427 µg/l Cu. Measured concentration of Ag was on average 0 µg/l. In total all sampling points tested show that less than 90% of the sampling points Legionella is controlled. The data for the following locations are not taken into account as it could not be determined that the efficacy is only due to the presence of Cu due to the amount of Ag measured during the test period. Location 2 : Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Measured concentration of Cu was 209-309 µg/l. Measured concentration of Ag was on average 0.8-2,4 (average 1.4) µg/l. Location 3 : Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Measured concentration of Cu was 319-413 µg/l. Measured concentration of Ag was on average 2.3-4.9 (average 3.3) µg/l. Location 4 : Legionella presence was < 100 CFU/l at the start of the trial and no Legionella was detected during the trial. Measured concentration of Cu was 319-419 µg/l. Measured concentration of Ag was on average 0.6-1.8 (average 1.3) µg/l.

* The most challenging test conditions resulting in the required lg reduction should be given.

Copper and silver dosing

The available information was sufficient to evaluate the efficacy of HW Bifipro for control of biofilm and Legionella, considering evaluation is done under article 121 of the WGB. The studies show that HW Bifipro complies with the criteria for drinking water disinfectants for the key species of the target organisms, when used in accordance with the instructions described on the WG/GA for the combined dosing of silver and copper. The field trial with 4 locations was performed with the claimed concentrations according to the WG/GA. Location 1 showed that the treatment is effective in reducing the Legionella infection to acceptable limits (<100 CFU/l). Location 2, 3 and 4 demonstrated that at locations with a history of Legionella infection the situation can be controlled (<100 CFU/l) by the performed treatment.

Copper only dosing

The available information was sufficient to evaluate the efficacy of HW Bifipro for control of biofilm and Legionella, considering evaluation is done under article 121 of the WGB. The studies show that HW Bifipro does not comply with the criteria for drinking water disinfectants for the key species of the target organisms, when used in accordance with the instructions described on the WG/GA for the

dosing of copper only. The field trial with 4 locations was performed with the claimed concentrations according to the WG/GA. Location 1 showed that the treatment is able to reduce the Legionella infection after 5 months of treatment, but does not meet the requirement that at 90% of all sampling points Legionella should be controlled. At the remaining three locations the average silver concentration exceeded 1 µg/L during the test period. At this concentration level silver contributes towards efficacy and the data from these three locations can therefore not be used to demonstrate copper by itself is sufficiently efficacious. Therefore dosing of copper only cannot be authorized.

5.3.2 Evaluation of the label (WG/GA)

The applicant has provided a WG/GA in Dutch. This has been adapted to our standards.

5.4 Mode of action

Positively charged copper ions form electrostatic compounds with negatively charged cell walls of microorganisms. These compounds disturb cell wall permeability. Copper ions penetrate the cell wall and as a result they will create an entrance for silver ions (Ag+). These penetrate the core of the microorganism. Silver ions bind to various parts of the cell, such as the DNA and RNA, cellular proteins and respiratory enzymes, causing all life support systems in the cell to be immobilized resulting in cell death.

5.5 Limitations on efficacy including resistance

5.5.1 General limitations

The following limitations are mentioned: De HW Bifipro electrodes and equipment should comply to the conditions prescribed in BRL K 14010-2/01 (Beoordelingsrichtlijn voor het Kiwa-attest met productcertificaat voor legionellapreventie met alternatieve technieken, deel 2: elektrochemische technieken: koper-/zilverionisatie en anodische oxidatie). This information is included in the WG/GA.

5.5.2 Resistance

Copper and silver ions have an unspecific mode of action and therefore resistance development is not expected.

5.5.3 Resistance management strategies

No management strategy is necessary.

5.6 Overall conclusions of efficacy

Based on the data submitted and considering that the evaluation is done under article 121 of the WGB,

- it can be concluded that HW Bifipro, when used in accordance with the proposed label (WG/GA) is effective in controlling Legionella and biofilm in collective drinking water systems when dosing copper and silver;
- it **cannot** be concluded that HW Bifipro, when used in accordance with the proposed label (WG/GA) is effective in controlling Legionella and biofilm in collective drinking water systems when dosing only copper.

6 Human toxicology

6.1 Human health effects assessment active substance

Copper and silver are existing active substances, not yet included in Union list of approved active substances for PT05.

6.2 Check previous evaluation

Authorisation was granted 26/02/2010. The WGGA is amended to include only the PT05 use as well as amendments to the copper and silver concentration due to risk for the environment.
The reference value in drinking water for copper is 2 mg/l according to table II of Appendix A of the Drinking Water Decree (Drinkwaterbesluit) and RIVM advice (RIVM project M/703719/06/BD).
(These quality standards are based on the European Drinking Water Directive (EU Directive 2020/2184 (replaces 98/83/EC). It is not allowed to fill up the full reference value for copper with this technique in connection with the contribution of copper from other sources. There is no reference value for silver in the Drinking Water Decree or the European Drinking Water Directive. A reference value of 50 µg/l is used for silver. This reference value is based on a recommendation from the RIVM (RIVM project M/703719/06/BD), where a limit value of 100 µg/l was recommended for the use of silver to combat legionella. Since a silver concentration of 50 µg/l is considered more than sufficient for the control of Legionella and also taken into account the environmental impact and long-term exposure, the Committee of Experts Water Supply Decree (of VROM, secretary of KIWA) has opted for a standard value of 50 µg/l as 90% percentile with a maximum of the recommended 100 µg/l. The value is also indicated in Table IIId of the Drinking Water Rules (Drinkwaterregeling) with regard to the monitoring programme that is stipulated when copper-silver ionisation is used.

The above drinking water standards have been included in the WGGA for both copper and silver:
- copper 400 - 800 µg/l and
- silver 0- 10 µg/l

(Use concentrations are as measured directly behind the ionisation system)
And for copper no exceedance of the legal reference value of 2000 µg/l at every tapping point.

Conclusions of current authorization can be taken over for prolongation.

7 Environment

7.1 Introduction

Authorisation is requested for HW Bifipro containing copper (Cu) and silver (Ag) as active substances. The biocidal product is intended for use as drinking water disinfectant (PT05) and for professional use only. The intended uses are described in Table E.1.

Table E.1 Intended uses, dose, and use concentrations of the active substances.

Area of use envisaged	Concentration active substance in product - electrodes (%)	Use concentration active substance (µg/L averaged over 24 hours)[1, 2]	
Drinking water disinfection (PT05)	99.9% (copper), 99.99% (silver)	Coper Silver	400 µg/L 1.0 µg/L

[1] Coper is dosed 400 µg/L continuously, 500 µg/L for 19 hours, or 800 µg/L for 10 hours;
[2] Silver is dosed 1 µg/L continuously, 5 µg/L for 4.8 hrs, or 10 µg/L for 2.4 hrs.

HW Bifipro concerns a drinking water treatment system that automatically releases copper and silver from electrodes to control Legionella in drinking water systems. It is installed in the piping preferably directly after the meter. Depending on the properties of the piping and the intensity of the infestation, copper and silver are dosed continuously at low concentrations or periodically at higher concentrations, but the amount released daily is limited to its maximum. Therefore, the concentrations listed in Table E.1. are the average daily concentrations. To avoid accumulation of copper and silver, the ions are not released when the water consumption is low. Release also stops at very high consumption rates as the retention time of water in the circuit is insufficient to be efficacious. Moreover, copper and silver are dosed independently due to their different modes of action.

7.2 Product related studies

The exposure assessment is based on data for the active substances. There are no fate or ecotoxicity data available for the product.

7.3 List of endpoints

Various specification of copper has been approved as biocidal active substance in accordance to EU regulation 528/2012. Elementary copper has been approved as a wood preservative (PT08) and antifouling paint (PT21), but is under review for the product types PT02, 05 and 11. Nevertheless, all dossiers share the same list of endpoints with respect to the environmental risk assessment, which was applied in the current environmental risk assessment.

The active substance silver in different specifications is under review for the product types PT01-07, 09, and 11 according to the regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. A silver core dossier has been prepared by Sweden and has been agreed by the biocidal product committee (BPC) working groups, and forwarded to the BPC. However, awaiting for the commission's decision, no silver-based active substances are currently approved. The endpoints for the current risk assessment were taken from the silver core dossier.

The data for the active substances applied in the current risk assessment are presented in appendix I and section 7.5.

7.4 Environmental exposure assessment

7.4.1 Chemistry and/or metabolism

As discussed in the CAR for copper, metals are natural elements and are therefore, by definition, not degradable. However, copper and its inorganic metal compounds are subject to chemical transformation processes once released to the environment. When Cu(II) is introduced into the environment, the cupric ion typically binds to organic and inorganic ligands contained within water, sediment and soil. In water Cu(II) binds to dissolved organic matter, and in sediment and soil Cu(II) will also bind with varying affinities to organic and inorganic components. In all these environmental compartments, the binding affinities of Cu(II) with organic and inorganic matter is dependent on pH, the oxidation-reduction potential in the local environment, and the presence of competing metal ions and inorganic anions. Although copper will not degrade in waste water, waste water treatment is expected to reduce the amount of copper in the effluent to 13% due do adsorption on organic carbon.

The Ag+ ion is an elemental inorganic charged species that cannot be transformed into related degradation products or metabolites and, consequently, chemical and biodegradation processes in water, sediment or soil will have no effect. Therefore, the fate of silver in terms of its speciation in the different environmental compartments is more relevant. In the aquatic environment, colloidal or adsorbed Ag2S is the major stable residual form of silver. Silver has a very strong affinity for suspended particulate matter in water and is readily bound to iron or sulphides or manganese oxyhydroxides via reaction with surface sulfhydryl groups. In sediment, silver may be associated with manganese and iron oxides, clay particles or precipitated as insoluble chloride. In soil, silver is strongly bound to soil organic matter (humic and fulvic acids) or is present as insoluble oxides and other insoluble or weakly soluble salts. Therefore, although degradation of the silver+ ion does not occur, it is able to interact with a wide array of natural materials so that the vast majority of silver in the environment is rapidly bound to mineral particles or organic matter, or is precipitated as insoluble salts. Waste water treatment is expected to reduce the amount of silver to 9% due to adsorption on sewage sludge.

7.4.2 Distribution in the environment

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will therefore occur during the application of products holding the biocide. Table E. 2 summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Emissions from active substance production and product formulation are not part of the risk assessment. The routes of entry into the environment are explained in more detail in the next sections.

Table E. 2 Foreseeable routes of entry into the environment on the basis of the intended use.

Main scenario	Environmental compartments exposed				
	STP[1]	Freshwater[2]	Saltwater[2]	Soil[3]	Air
Drinking water disinfection (PT05)	++	+	-	++	+

++ Compartment directly exposed, + Compartment indirectly exposed, - Compartment not exposed, [1] Sewage Treatment Plant, [2] Including sediment, [3] Including groundwater.

When the product is used to disinfect drinking water, the main route of entry into the environment is via STP, to surface water and sediment. Direct exposure of soil is also possible, when the water is for example used to spray gardens, sport fields etc. Emission to air during application is not expected as the product is poured to water and preserved products are not applied by spraying etc. However, the active substance may be indirectly released to air due to evaporation during sewage treatment.

Application of sewage sludge as a soil fertiliser is highly unlikely in The Netherlands as its chemical composition does not fulfil the environmental standards regarding organic pollutants and heavy metals. In order to avoid unnecessary contamination of the receiving soils, sewage sludge is treated as hazardous waste instead.

7.4.3 Predicted environment concentration calculations

7.4.3.1 General

Predicted Environmental Concentrations (PECs) were calculated according to relevant exposure scenario documents (ESDs, release to the environment), the guidance on biocide legislation, Part B+C, volume IV (distribution in the environment), the Technical Agreement on Biocides (TAB). Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated. Possible pH effects on the environment were not considered, because the STP and receiving compartments are expected to have sufficient buffering. As the intended application rates are provided as target concentration ranges, the assessment was made for the highest concentrations only. The applied methods are explained below. The risk assessment is based on the active substance's physical-chemical properties as listed in appendix I and the concentrations as listed in **Table E.1**.

In accordance to the assessment reports for copper, background concentrations in surface water and sediment were taken into account. The calculated PEC values for the intended uses were added to the background concentrations to obtain the final PEC values for copper to be used in the risk assessment. The background concentrations are presented in the table below.

Table E.3 Background concentrations for copper in freshwater and sediment

	Freshwater (µg/L)	Sediment (mg/kg wwt)	Soil (mg/kg wwt)	Groundwater (µg/L)
Regional Background Concentration	2.9	14.7	21.6	2.9

Drinking water disinfection (PT05)

Emission to the sewer was calculated according to TAB agreement 228. The TAB agreement concerns a refinement of the ESD for PT05 in which the amount of active substance discharged to the sewer system was corrected for the volume of drinking water (1400 m³).

The product is not intended to be used by drinking water companies supplying a whole network of customers, but restricted to water systems in selective buildings that require the control of Legionella. Therefore, the total volume as prescribed in the TAB (1400 m³) is adapted accordingly In line with the original authorisation, it is assumed that 270 inhabitants per STP (2.7%; one priority institutional building) use drinking water from collective systems disinfected with the product. Hence, E_{local} (calculated in line with the formula above) is multiplied by 0.027 to obtain the final E_{local} for 270 users for one STP. The applicant suggested (in their background information on emission scenario) to use a lower value, based on assumptions of the number of priority institutional buildings in The Netherlands using drinking water from collective systems disinfected with the product. This assumption would result in one priority institutional building per 30 190 inhabitants, hence one priority institutional building divided over three STPs. However, CTGB regards it more realistic to expect that (at least) one priority institutional building emits to one STP.

Finally, daily emission is corrected for the fraction of the incoming water that is treated with copper and silver. In summary, emission to the sewer was estimated as follows:

$$E_{local} = 0.001 \cdot C_{drinking\ water} \cdot f_{treated} \cdot V_{drinking\ water} \cdot f_{institutional} \cdot e^{-kT}$$

Where:

E_{local}	Emission to the STP (kg/d)
$C_{drinking\ water}$	efficacious concentration in preserved drinking water (mg/L, see footnote table E.1.)
$f_{treated}$	fraction of the total water volume treated (see footnote table E.1.)
$V_{drinkling\ water}$	volume drinking water discharged daily (1400 m³)
$F_{institutional}$	fraction of the total water volume supplied to institutional buildings (0.027)
k	degradation rate constant of active substance in the sewer (/h)
T	residence time in the sewer (1 h)
0.001	correction factor from mg to kg ($1E^{-6}$) combined with m³ to L (1000)

Emission was calculated from the average daily concentrations as presented in Table E.1, i.e. $C_{drinking\ water}$ is 400 µg Cu/L or 1.0 µg Ag/L dosed continuously ($f_{treated}$ is one). Note that the daily release to the sewer is independent for all combinations of dose ($C_{drinking\ water}$) and time ($f_{treated}$) as proposed by the applicant. Degradation in the sewer system was not considered for both active substances as metals are persistent.

Direct emission to soil is possible when the water is used outdoors, for example to water gardens and sport fields. However, no emission scenario is available to assess the risks for emission to soils use.

7.5 Environmental effect assessment

Risk assessment is based on Predicted No-Effect Concentrations (PNECs) for the different compartments which are derived from ecotoxicity data and applying assessment factors. The assessment factor depends on the type of test performed (acute or chronic), the toxicological endpoint (effect concentrations (ECs), no-observed effect concentrations (NOECs), etc), and the number of data and is determined according to the guidance on biocide legislation, Part B+C, volume IV. The PNECs based on the ecotoxicological data applied for the current risk assessment are presented in the table below.

Table E. 4 Predicted no-effect concentrations for copper and silver

Compartment	Lowest endpoint	AF	PNEC	Test/species
Copper				
STP	NOEC: 0.23 mg/L	1	0.23 mg/L	Nitrification test

freshwater	HC5-50: 0.0156 mg/L	2	0.0078 mg/L	HC5-50 from SSD (chronic data)
Sediment	-	-	18.9 mg/kg wwt	Calculated based on equilibrium partitioning
Soil	HC5-50: 40.35 mg/kg wwt	1	40.35 mg/kg wwt	HC5-50 from SSD (chronic data)
Silver				
STP	EC_{50}: 0.9 mg/L	100	0.009 mg/L	respiration inhibition test
freshwater	NOEC: 0.08 µg/L	10	0.008 µg/L	Acute and chronic toxicological data available for fish, daphnids, and algae, Fish *(Oncorhynchus mykiss)* are the most sensitive.
Sediment	NOEC: 0.0958 mg/kg wwt	10	0.00958 mg/kg wwt	Acute and chronic toxicological data available for Chironomids, *Hyalella Azteca* and *Lumbriculus variegatus*. *Lumbriculus variegatus* is the most sensitive sediment-dwelling organisms.
Soil	NOEC: 0.28 mg/kg wwt	50	0.0056 mg/kg wwt	NOEC inhibition of carbon respiration test
Birds	LC_{50}: > 76mg/kg diet	3000	25.3 µg/kg	Acute and short-term data available for mallard duck and northern bobwhite quail. Northern bobwhite quail is most sensitive.
Mammals	NOEC: 3 mg/kg diet	30	100 µg/kg	Rats

wwt wet weight
bw body weight

7.6 Risk characterisation for the environment

For each relevant compartment, PECs are divided by PNECs. Risks are considered unacceptable when PEC/PNEC >1.

7.6.1 Aquatic compartment (incl. sediment) and STP

7.6.1.1 Water and sediment organisms and micro-organisms in the STP

For both intended uses, emission via STP to the aquatic compartment is expected. The risk characterisation for the aquatic compartment (freshwater and sediment) indirectly exposed via an STP is presented in **Fout! Verwijzingsbron niet gevonden.**.

Table E. 5 PEC values and PEC/PNEC ratios for micro-organisms in the STP, freshwater and sediment indirectly exposed due to disinfection of drinking water and preservation of liquid in cooling systems (small open recirculating systems (continuous dose)).

Main scenario	STP		Freshwater		Sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)[1]	PEC/PNEC	PEC (mg/kg ww)	PEC/PNEC
Drinking water disinfection (PT05)						
Copper	9.83E-04	0.004	2.97E-03	0.380	15.2	0.801
Silver	1.70E-06	<0.001	5.05E-08	0.006	1.73E-03	0.181
Total	-	<0.005	-	0.386	-	0.982

[1] removal of the active substance(s) by sorption onto suspended matter is included.

PEC:PNEC values are below the trigger of one for all compartments. The application of the product in drinking water results in acceptable risks for emission via the STP when the product is dosed in accordance to the WG/GA. The standards for the aquatic environment are therefore met and no risk mitigation measures are required.

7.6.1.2 Monitoring data (surface water)

Dutch water boards have a well-established programme for monitoring pesticide contamination of surface waters for which the results are publicly available on-line (www. bestrijdingsmiddelenatlas.nl). Here, monitoring data are processed in a graphic format aiming to provide an insight into measured pesticide contamination of Dutch surface waters against environmental standards. The Pesticide Atlas was used to evaluate measured concentrations of pesticides in Dutch surface water, but no data are available regarding the presence of copper and silver in Dutch surface water.

7.6.1.3 Surface water intended for the abstraction of drinking water

Biocidal products with the active substances copper and silver have been on the market for more than three years. The existing active substances are not included in the list of substances of concern due to its presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb (2019). In addition, the active substances are not included in the recommended list of biocides to be monitored for drinking water from surface water (RIVM, 2010). Considering this the Ctgb concludes that there are in this case insufficient indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Thus the standards for surface water destined for the production of drinking water are met.

7.6.2 Terrestrial compartment

7.6.2.1 Soil organisms

For the intended use of the product for disinfection of drinking water, indirect emission of the active substance to soil via the STP is not expected. The standards for the soil environment are therefore met.

7.6.2.2 Non-target arthropods (including bees)

The risk assessment for arthropods is considered to be similar to the assessment for (other) soil organisms (above) due to their direct contact with soils. The standards for soil arthropods are therefore met. Because the active substances are not expected to have a systemic mode of action, secondary exposure of bees through pollen is considered negligible. Hence, the risk for non-target arthropods (including bees) is considered acceptable for intended uses of the product.

7.6.2.3 Groundwater

As no emission to soils is foreseen, emission to groundwater is negligible. The standard groundwater criterion of 0.1 µg silver /L and the threshold value for copper of 2 mg/L (as set in RIVM report on drinking water) are met. Hence, the intended uses of the product result in acceptable concentrations in groundwater.

7.6.2.4 Persistence in soil

As the active substances are inorganic compounds, the criteria for persistence in soils (180 days) do not apply. Therefore, the accompanied risks are considered acceptable.

7.6.3 Non compartment specific effects relevant to the food chain

7.6.3.1 Bioconcentration

In line with the Guidance on biocide legislation (Part B+C, volume IV) generally the log K_{ow} with trigger of 3 is used to establish the screening for potential for bioconcentration of substances. However, for metals the standard concept of assessing the potential for bioaccumulation is not applicable and a K_{ow} value is not a relevant property of such substances. As discussed in the assessment reports for silver, for many organic chemicals available data indicate that whole-body burdens can serve as useful

measurements of toxicological dose and these relationships appear to be independent of whether exposure occurred via water or diet. For metals, however, the situation is far more complex. Unlike organic compounds, uptake, distribution, and disposition of metals are typically governed by highly specific biochemical processes that alter the metal form and involve facilitated and/or active transport. Please refer to the section below for further discussion on the potential for bioaccumulation.

7.6.3.2 Primary and secondary poisoning of birds and mammals

The intended use is indoors and the product is not provided in the form of bait or granules. Hence, primary poisoning is not expected.

As stated in the draft CAR, copper is an essential trace element and well-regulated in living organisms. Differences in copper uptake rates are related to essential needs, which vary with characteristics and processes, such as the species, size, life stage and seasons. Copper homeostatic mechanisms are applicable across species with specific processes being active depending on characteristics and processes such as the species and life stages. Simple estimations on secondary poisoning are therefore not applicable. There is overwhelming evidence to show the absence of copper biomagnification across aquatic and terrestrial food chains. Differences in sensitivity among species are not related to the level in the trophic chain, but rather to the capability of internal homeostasis and detoxification. Field data have further provided evidence on the mechanisms of action of copper in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning.

As discussed in the core dossier for silver, the standard concept of assessing potential for bioaccumulation with BCF factor is not applicable for this inorganic metal compound. Since silver binds strongly to sediments and particulate matter, the most likely risk for secondary poisoning arises from the transfer from sediment via sediment-living organisms to a predator. In line with the core dossier for silver, an assessment can be performed based on the risk for sediment-living organisms. If the risk for sediment-living organisms is acceptable, the risk for predating birds and mammals will also be acceptable, which is the case for the concerning product.

Regarding the soil compartment, no biota (soil) accumulation factor is available. Hence, an assessment for birds and mammals feeding on terrestrial organisms cannot be performed.

Therefore, the standards for secondary poisoning of birds and mammals are met.

7.6.4 Atmosphere

Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that copper and silver contribute to depletion of the ozone layer as the compounds are not listed as ‘controlled substance’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. AOPwin does not calculate a half-life in air for these active substances and the CARs for copper and silver do not contain half-life values in air either. Hence, it is not possible to perform the standard assessment by comparing calculated half-life to the trigger of 2 days, which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. However, the assessments reports for both substances state that copper and silver are not volatile (see Appendix I). Emission to air during application and during waste water treatment is not expected. Hence, concentrations of copper and silver are expected to be negligible in the atmosphere, and the environmental risk to air is therefore considered acceptable.

7.7 Measures to protect the environment (risk mitigation measures)

No risk mitigations were proposed by the applicant. Considering that emission to the environment results in concentrations below any threshold, risk mitigations measures were not deemed necessary.

7.8 Overall conclusion for the aspect Environment

An authorisation of a biocide in the Netherlands is only possible when the risks related to the product application are acceptable. Unacceptable risks for the aquatic environment as well as predating birds and mammals are not expected. Hence, authorisation of HW Bifipro as a product for drinking water disinfection is acceptable from an environmental point of view.

8 Conclusion

Due to perceived environmental risks, the doses of copper and silver ions have been adjusted, with copper increased and silver reduced. After subsequent efficacy testing, it was found to sufficiently control Legionella and biofilm in water supply systems for drinking water in a collective water supply of priority establishments.

The applicant has proven that HW Bifipro (formerly called ICA-systeem) under the proposed Legal Conditions for Use and the Directions for Use (WG/GA), is sufficiently effective and that no unacceptable risk is expected to human health, the person who uses the product and the environment.

9 Classification and labelling

This concerns a prolongation of an existing authorisation. Classification and labelling have not been changed.

10 References

Guidance
Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.
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Emission scenario documents
Emission Scenario Document on Drinking water disinfectants (PT05), European Commission DG ENV / RIVM, EUBEES, 2003
List of Endpoints
Silver core dossier. eCA Sweden, 2019
Assessment Report for copper flakes (coated with aliphatic acid) for PT21. eCA France, 2016. Draft CAR for Copper, PT2, 5, 11. eCA France. 2017
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Bakker, J. Biociden in oppervlaktewater voor drinkwaterproductie, National Institute of Public Health and the Environment, RIVM report 601712007, 2010, Bilthoven, The Netherlands.
Database with monitoring data from pesticides in surface water obtained from regional water boards. http://www.bestrijdingsmiddelenatlas.nl
Lijst met probleemstoffen voor de bereiding van drinkwater uit oppervlaktewater, VEWIN, 2019 http://www.vewin.nl/probleemstoffen
Other
Regulation (EC) No 1005/2009 of the European Parliament and the Council of 16 September 2009 on substances that deplete the ozone layer.

Appendix I. Input environmental parameters for modelling

	Value		Remarks
	Copper*	**Silver****	
molecular weight (g/mol)	63.5	107.87	
vapour pressure at test temperature (Pa)	$7.5x10^{-9}$	$1x10^{-6}$	
test temperature vapour pressure (°C)	20	20	
solubility at test temperature (mg/L)	0.27	$1x10^{-3}$	
test temperature solubility (°C)	20	20	
octanol-water partition coefficient (L/kg)	-	-	Since metals do not have the hydrophobic or lipophilic characteristics of organic compounds, the concept of Kow is not applicable
half-life for biodegradation in freshwater at 12°C (days)	$1x10^{6}$	$1x10^{6}$	Default for substances which are considered to be non-biodegradable
half-life for biodegradation in sediment at 12°C (days)	$1x10^{6}$	$1x10^{6}$	Default for substances which are considered to be non-biodegradable
Solid-water partition coefficient in soils ($K_{p\ soil}$; L/kg)	2120	398.11	
Solid-water partition coefficient in suspended matter ($K_{p\ susp}$; L/kg)	30246	$1.58x10^{5}$	
Biodegradability	Not biodegradable	Not biodegradable	

* CAR for copper (2016 / 2017)
**CAR for silver (2019)

Fate and distribution in the STP		
Compartment	Percentage [%]	
	Copper*	Silver**
Air	0	0
Water	13	9
Sludge	87	91
Degraded in STP	0	0

* CAR for copper, values as discussed for the Netherlands specifically (2017)
**CAR for silver (2019)