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

Evaluation of active substance

Competent Authority Report

Dicopper oxide

Product type 21: antifouling products

Document III A2

Final CAR

March 2016

eCA: FRANCE

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	[redacted]	
2.2	**Chemical name (IIA2.2)**	[redacted]	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	[redacted]	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	1317-39-1	
2.4.2	**EC-No**	215-270-7	
2.4.3	**Other**	CIPAC 8084	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	[redacted]	
2.5.2	**Structural formula**	[redacted]	
2.5.3	**Molecular mass**	143.09	X
2.6	**Method of manufacture of the active substance (IIA2.1)**	In brief, the method involves the catalysed oxidation of [redacted] metal. Specific information relating to each applicant are confidential, and are detailed in the Confidential Section.	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	[redacted]	X
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	Specific information relating to each applicant are confidential, and are detailed in the Confidential Section.	
2.8.1	**Isomeric composition**	Not applicable	
2.9	**The origin of the natural active substance or the**	[redacted] used in the manufacture of [redacted] is obtained from reclaimed/recycled sources, e.g. scrap metal.	

precursor(s) of the active substance (IIA2.9)

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

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

Evaluation of active substance

Competent Authority Report

Dicopper oxide

Product type 21: antifouling products

Document III A3

Final CAR

March 2016

eCA: FRANCE

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	ASTM E537-86, Method A1 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	>673 ± 0.5K at 101.72 kPa		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	X1 X
3.1.2 Boiling point				Not required, as boiling point will occur at temperatures greater than 360°C, based on determination of melting point.			See Justification for non-submission of data A3.1.2	ok
3.1.3 Bulk density/ relative density								
Bulk density	Method A1 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2	5.87×10^3 kg m^{-3} at 20.0 ± 0.5°C		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted]	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		batch N°. 28.08.02 Manufacturer: Nordox					Determination of physico-chemical properties. SPL Project Number 1515/003	
Relative density	Method A1 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	5.87		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	X1
3.2 Vapour pressure (IIA3.2)				It is not possible to determine a vapour pressure due to the high melting point (and hence high boiling point) of [redacted]			See Justification for non-submission of data A3.2	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2.1 Henry´s Law Constant (Pt. I-A3.2)				Henry's Law Constant is not possible to calculate without a value for vapour pressure.			See Justification for non-submission of data A3.2.1	ok
3.3 Appearance (IIA3.3)								ok
3.3.1 Physical state	Conducted to satisfy the requirements of Council Directive 91/414/EEC, Annex II, as amended in Commission Directive 94/37/EC, Annex I.	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	Opaque solid in the form of a fine, easily compactable powder		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	**X1** X
3.3.2 Colour	Conducted to satisfy the requirements of Council Directive 91/414/EEC, Annex II, as amended in Commission Directive 94/37/EC, Annex I.	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	Orange		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	**X1**
3.3.3 Odour	Conducted to satisfy	**purity:** [redacted]	Odourless		Y	(1) valid	OConnor, B.,	**X1**

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	the requirements of Council Directive 91/414/EEC, Annex II, as amended in Commission Directive 94/37/EC, Annex I.	**specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox				without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	
3.4 Absorption spectra (IIA3.4)								
UV/VIS	A mixture was prepared by adding aqueous [redacted] solution to aqueous glucose and gelatine PEG. The mixture was sonicated and heated in a water bath. NaOH solution was added into the mixture. After purification, Cu_2O spheres were obtained.	Created *in situ*	[redacted]	The UV–visible absorption spectrum shows two broad absorption peaks at 465 and 495 nm	N	2	[redacted] 2006; Solution-phase synthesis of single-crystal hollow [redacted] spheres with nanoholes. Nanotechnology 17, 1501–1505	X
UV/VIS	OCDE 101	[redacted]	Maximal absorption at : 260 nm (marginal) for neutral solution 206 nm for alkaline solution	As the concentration of the saturated solutions was not known, no extinction	Y	1	[redacted] 2006; UV/VIS absorption spectrum of [redacted] study code	X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			225 nm for acidic solution	coefficient could be calculated.			20051363/01-PCSD	
IR	Test material was mixed thoroughly with potassium bromide and ground. An aliquot of this mixture was pressed into a disc and scanned over the range 4000 to 400 cm-1 using potassium bromide as the reference.	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	[redacted] Temp: 21.0 ± 0.5°C	With the exception of the single peak at 633 cm, all other absorption bands observed are attributable to either trace levels of moisture or atmospheric carbon dioxide. No evidence was found in the infrared spectrum that contradicts the proposed chemical structure of the test material	Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	X1 X
NMR				Determination of NMR spectra is not applicable to simple inorganic compounds which are practically insoluble in the			See Justification for non-submission of data A3.4(c)	X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				solvents required to carry out an NMR spectra.				
MS				Determination of MS spectra is not applicable to metals, as MS is the molecular fragmentation at certain energy levels. On this basis, MS analysis of [redacted] would provide no useful information.			See Justification for non-submission of data A3.4(d)	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5)								
Water solubility 1	Method A6 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	**28.6 g l^{-1}** Temp: 20.0 ± 0.5°C pH: 4.0 Not realistically measureable.	Test material neutralised acidic solutions – this solubility was achieved by continuous acidification	Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	**X1** **X**
Water solubility 2	Method A6 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	**6.39×10^{-4} g l^{-1}** Temp: 20.0 ± 0.5°C pH: 6.5 to 6.6		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	**X1** **X**
Water solubility 3	Method A6 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	**<5.39×10^{-4} g l^{-1}** Temp: 20.0 ± 0.5°C pH: 9.7 to 9.8		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number	**X1** **X**

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
							1515/003	
3.6 Dissociation constant (-)				No testing is possible by Method 112 of the OECD Guidelines for the Testing of Chemicals, due to the negligible solubility of the test material in water. Any addition of acid to solutions of the test material would result in reaction with the [redacted]			See Justification for non-submission of data A3.6	X
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	Method A6 of Commission Directive 92/69/EEC	**purity:** [redacted] **specification:** As given in section 2 batch N°. 28.08.02 Manufacturer: Nordox	Toluene <1.4×10^{-2} DCM <1.0×10^{-2} n-Hexane <1.2×10^{-2} Ethyl acetate <1.2×10^{-2} Methanol <9.8×10^{-3} Acetone <1.3×10^{-2}		Y	(1) valid without restriction	[redacted] 2003; Nordox [redacted] Determination of physico-chemical properties. SPL Project Number 1515/003	**X1** **X**
	CIPAC MT 181	**purity:** [redacted]	1,2 DCE <10 g l^{-1}		Y	(1) valid	[redacted]	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		specification: As given in section 2 batch N°. 250905 Manufacturer: Nordox	p-Xylene <10 g l^{-1} n-Heptane <10 g l^{-1} Ethyl acetate <10 g l^{-1} Methanol <10 g l^{-1} Acetone <10 g l^{-1}			without restriction	2006; Solubility of [redacted] in organic solvents; GAB Report No. 20051363/01-PSBO	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				Based upon the solubility in organic solvents, a determination of the stability in organic solvents is unnecessary.			See Justification for non-submission of data A3.8	X
3.9 Partition coefficient n-octanol/water (IIA3.6)				It is generally considered that the determination of octanol/water partition coefficients for [redacted] from sparingly soluble compounds is impractical for technical reasons.			See Justification for non-submission of data A3.9	X
3.10 Thermal stability, identity of relevant breakdown products				Based on the high melting point for [redacted]			See Justification for non-submission of data A3.10	ok

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
(IIA3.7)				[redacted] a determination of the thermal stability is unnecessary				
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)				Based on the high melting point for [redacted] a determination of the flammability, including auto-flammability is unnecessary			See Justification for non-submission of data A3.11	X
3.12 Flash-point (IIA3.9)				A Flash-point value was not determined, as this is not relevant to solid compounds, such as [redacted]			See Justification for non-submission of data A3.12	ok
3.13 Surface tension (IIA3.10)				Not required for substances with a water solubility of < 1 mg l^{-1}			See Justification for non-submission of data A3.13	
3.14 Viscosity (-)				A determination of viscosity is not			See Justification for non-submission	ok

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				applicable to a solid, such as [redacted]			of data A3.14	
3.15 Explosive properties (IIA3.11)				Based on the chemical composition and experience in use, it is considered that this test would give a negative result for [redacted]			See Justification for non-submission of data A3.15	X
3.16 Oxidizing properties (IIA3.12)				Based on the chemical composition and experience in use, it is considered that [redacted] would not have oxidising properties			See Justification for non-submission of data A3.16	
3.17 Reactivity towards container material (IIA3.13)				No reactivity towards commonly used materials, such as polyethylene			See Justification for non-submission of data A3.17	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				lining.				

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]

[redacted]

	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A3.1.2 **Annex Point A3.1.2** **IUCLID: 2.2**	**A3.1.2, Boiling point**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.2.1 **Annex Point A3.2.1** **IUCLID: 2.4**	**A3.2.1, Henry's law constant**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.2 **Annex Point A3.2** **IUCLID: 2.4**	**A3.2, Vapour pressure**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.4.3 **Annex Point A3.4.3** **IUCLID: 1.1.2**	**A3.4.3, NMR spectra**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section A3.4.3 **Annex Point A3.4.3** **IUCLID: 1.1.2**	**A3.4.3, NMR spectra**
Conclusion	[redacted]
Remarks	

Section A3.4.4 **Annex Point A3.4.4** **IUCLID: 1.1.2**	**A3.4.4, Mass Spectrometry**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.6 Annex Point A3.6	A3.6 Dissociation Constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.8 **Annex Point A3.8** **IUCLID: 2.14**	**A3.8, Stability in organic solvents used in b.p. and identity of relevant breakdown products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.9 **Annex Point A3.6** **IUCLID: 2.5**	**A3.9, Partition coefficient n-octanol/water**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section A3.9	A3.9, Partition coefficient n-octanol/water
Annex Point A3.6	
IUCLID: 2.5	
Remarks	

Section A3.10 **Annex Point A3.10** **IUCLID: 2.9**	**A3.10, Thermal stability and identity of breakdown products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.11 **Annex Point A3.11** **IUCLID: 2.9**	**A3.11, Flammability, including auto-flammability and identity of combustion products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.12 **Annex Point A3.12** **IUCLID: 2.7**	**A3.12, Flash-point**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.13 **Annex Point A3.13** **IUCLID: 2.6.2**	**A3.13, Surface tension**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.14 **Annex Point A3.14** **IUCLID: 2.13**	**A3.14, Viscosity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A3.15 **Annex Point A3.15** **IUCLID: 2.10**	**A3.15, Explosive properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section A3.15 **Annex Point A3.15** **IUCLID: 2.10**	**A3.15, Explosive properties**
Conclusion **Remarks**	[redacted]

Section A3.16 **Annex Point A3.15** **IUCLID: 2.11**	**A3.16, Oxidising properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

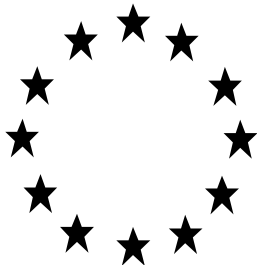
Section A3.17 **Annex Point A3.17** **IUCLID: 8.8**	**A3.17, Reactivity towards container material**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
[redacted]		
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

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

Evaluation of active substance

Competent Authority Report

Document IIIA 4



Dicopper oxide

Product type 21: antifouling products

Final CAR

March 2016

eCA: FRANCE

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1/4.2 & IIIA-IV.1 **4.2 a(soil), b(air), c(water)**

The following Reference(s) are provided under a letter of access from the [redacted] and may be found in the original documentation pertaining to that submission. Access is granted to both the original reference and all summary documents in the [redacted] dossiers on [redacted] by Letter of Access dated 1 April 2006 (Included in Appendix 5 of this submission).

AUTHOR(S)	YEAR	TITLE SOURCE (WHERE DIFFERENT FOR COMPANY) COMPANY, REPORT NO.	TNG SECTION	TNG #
[redacted]	1993	AOAC Official Method 990.08, 1993. Metals in Solid Wastes; Inductively Coupled Plasma Atomic Emission Method. AOAC Official Methods of Analysis; Metals and Other Elements, Chapter 9, page 31; Not GLP; Published	4,2a	1
[redacted]	1983	EPA/600/4-79/020, March 1983, Methods for Chemical Analysis of water and Wastes; Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2a	2
[redacted]	1986	Methods for Chemical Analysis of Water and Wastes. Method 220.1 ([redacted] Atomic Absorption, direct aspiration). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2a	2
[redacted]	1986	Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846). Method 3050B (Acid digestion of sediments, sludges and soils). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2a	2
[redacted]	1986	Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846). Method 7210 ([redacted] Atomic Absorption, direct aspiration). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2a	2
[redacted]	1992	Atomic Absorption Methods. Method 7000A Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2a	2
[redacted]	1994	Method 7029. NIOSH Manual of Analytical Methods, Fourth Edition, 8/15/94; Not GLP; Published	4,2b	1
[redacted]	2003	Method 7300. Elements by ICP (Nitric/ Perchloric Acid Ashing) NIOSH Method of Analytical Methods, Fourth Edition, 3/15/2003; Not GLP; Published	4,2b	2
[redacted]	1983	EPA/600/4-79/020, March 1983, Methods for Chemical Analysis of water and Wastes; Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	1
[redacted]	1986	Methods for Chemical Analysis of Water and Wastes. Method 220.1 ([redacted] Atomic Absorption, direct aspiration). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	1
[redacted]	1986	Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846). Method 7210 ([redacted] Atomic Absorption, direct aspiration). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	1
[redacted]	1992	Atomic Absorption Methods. Method 7000A Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	1

AUTHOR(S)	YEAR	TITLE SOURCE (WHERE DIFFERENT FOR COMPANY) COMPANY, REPORT NO.	TNG SECTION	TNG #
[redacted]	1983	EPA/600/4-79/020, March 1983, Methods for Chemical Analysis of water and Wastes; Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	2
[redacted]	1983	Methods for Chemical Analysis of Water and Wastes. Method 220.2 ([redacted] Atomic Absorption, furnace technique). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	2
[redacted]	1992	Method 7211 ([redacted] Atomic Absorption, furnace technique). Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	2
[redacted]	1983	EPA/600/4-79/020, March 1983, Methods for Chemical Analysis of water and Wastes; Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	3
[redacted]	1983	Inductively Coupled Plasma – Atomic Emission Spectrometric Method for Trace Element Analysis of Water and Wastes – Method 200.7. Washington, DC; U.S. Environmental Protection Agency; Not GLP; Published	4,2c	3

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A4.2(c)	Analytical Methods for Detection and Identification	
Annex Point IIA4.1/4.2 & IIIA-IV.1	**A4.2c(04) Analytical method for the determination of [redacted] in seawater by Differential Pulse Anodic Stripping Voltammetry (DPASV)**	

1 REFERENCE

			Official use only
1.1	**Reference**	**Reference 1** [redacted] 2004; Total Dissolved [redacted] in Seawater by Differential Pulse Anodic Stripping Voltammetry at a Hanging Mercury Drop Electrode DPASV HMDE; CEFAS Burnham Laboratory Standard Operating Procedure: TCu-2, (Issue 1); Not GLP; Unpublished **Reference 2** [redacted] 2004; [redacted] Speciation in Seawater by Differential Pulse Anodic Stripping Voltammetry on a Thin Mercury Film at a Rotating Glassy Carbon Disk Electrode DPASV TMF RGCDE; CEFAS Burnham Laboratory Standard Operating Procedure: LCu-2, (Issue 1); Not GLP; Unpublished **Reference 3 (Filtration method – appended to TCu-2)** [redacted] 2001; Filtration and analysis of suspended particulate matter in seawater; CEFAS Burnham Laboratory Standard Operating Procedure: Cu-FIL-1; Not GLP; Unpublished **Reference 4 (Validation data – appended to TCu-2)** [redacted] 2005; The Speciation of [redacted] in samples collected from the Marine Environment; Cefas contract report C1385; Not GLP; Unpublished	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with a letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**		X
2.2	**GLP**		
2.3	**Deviations**		

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**		
3.1.1	Enrichment	None required	
3.1.2	Cleanup	SOP [redacted] describes the procedure for filtering seawater samples for analysis of [redacted] species and analysis of suspended particulate matter. Samples are filtered through a pre-weighed acid washed Nuclepore 0.2 µm polycarbonate filter. The filtrate is collected and analysed for total dissolved and labile [redacted] After air-drying the membrane in laminar flow hood, it is reweighed to constant weight and the level of SPM (in mg/L) determined using the following formulae.	

SPM = [Wt membrane +sample - Wt membrane] (mg) / Total volume of seawater filtered (L)

3.2	**Detection**		
3.2.1	Separation method	There is no separation method in the conventional meaning of chromatographic separation. Instead, the electrode response for [redacted] are distinguished by firstly measuring the amount of labile [redacted] in the solution [redacted], ie. that [redacted] which is electrolytically active enough to elicit a potentiometric response at the electrode. [redacted] bound to dissolved organic matter is not regarded as having this property. After determining the labile fraction, the sample is acidified and UV-digested, essentially releasing all the organic [redacted] and the total signal measured (TCu-2).	
3.2.2	Detector	Potentiometer	X
3.2.3	Standard(s)	Determined by standard addition	
3.2.4	Interfering substance(s)	Potential interferences can come from the following effects; Overlapping stripping peaks caused by similarity in oxidation potential Presence of surface-active organic compounds that adsorb on the Hg surface and inhibit metal deposition Formation of intermetallic compounds (e.g., [redacted] which affect peak size and position However, appropriate laboratory procedures minimise these interferences.	
3.3	**Linearity**		
3.3.1	Calibration range	Method is linear over a wide range, typically 0 – 50 µg l^{-1}. It is possible by varying the deposition time of the sample on the electrode, to bring samples into this range.	
		[redacted]	
3.3.2	Number of measurements	Six standard solutions (0, 0.5, 5, 10, 20 and 50 ug/L) were run to perform the linearity test.	
3.3.3	Linearity	$r^2 = 0.996$	

3.4	**Specifity: interfering substances**	Limited scope for interferences if appropriate laboratory procedures are employed	
3.5	**Recovery rates at different levels**	The method was tested for accuracy by reference to certified reference materials and by spike recovery from a standard. Ref BCR505 (1.87 ± 0.10 µg l^{-1}) – Measured 1.89 µg l^{-1} Ref SLEW-3 (1.55 ± 0.10 µg l^{-1}) – Measured 1.50 µg l^{-1} Spiked recovery at 2 µg l^{-1} gave a recovery of 93%	
3.5.1	Relative standard deviation	Not reported	
3.6	**Limit of determination**	The detection limit is dependable on the deposition time. For a typical 300 second deposition time 1.0 µg l^{-1} is achievable. (found by 3 times the standard deviation of six replicate results read at a low concentration). Deposition times of up to 900 seconds can be used to give possible detection limits of 0.4 µg l^{-1}	X
3.7	**Precision**		
3.7.1	Repeatability	**Standard Error -Within Batch** 7 readings taken concurrently on the same sample;	

Date	**Peak height**
01/05/01	72.2
	74.2
	76.4
	79.0
	80.2
	82.5
	85.3
Mean	**78.5**
SD	**4.61**
RSD %	**5.9**

Standard Error Between Batch

The same sample read on Four different days;

Date	**Concentration (µg l^{-1})**
01/05/01	2.085
01/05/01	2.231
01105/01	1.968
10/05/01	1.936
02/05/01	2.013
02/05/01	1.921
02/05/01	2.089
08/05/01	1.924
08/05/01	2.043
08/05/01	1.957
Mean	**2.023**
SD	**0.102**
RSD%	**5.0**

X

3.7.2	Independent laboratory validation	None performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Votammetry refers to a class of electroanalytical techniques in which the current at a working (polarized) electrode is measured as a function of a potential waveform applied to the electrode. Anodic stripping voltammetry is used for the determination of trace metal ions.

Principle:

1) Accumulation/Preconcentration step: Analytes are first deposited on the electrode cathodically (reduced) for a fixed period of time;

$M^{n+} + n^{e-} \rightarrow M$

2) Stripping step: The analytes are then selectively oxidized (stripped) during a potential scan in the anodic direction

$M \rightarrow M^{n+} + n^{e-}$

n^{e-} is measured as peak current.

Because of the differential pulse of the stripping, with the Peak potentials identifying the metal ions in the sample, there is limited scope for interferences if appropriate laboratory procedures are employed;

[redacted]

4.2 Conclusion

Validity criteria can be considered as fulfilled for analysis in seawater

4.2.1 Reliability

The methodology was not validated to the standards of GLP. X

However, the analytical procedure is widely employed, and a wealth of literature supports its use for the application discussed. Therefore, based on the assessment of materials and methods, it is appropriate to assign a reliability indicator of 1

4.2.2 Deficiencies

No

Section A4.2(c)	Analytical Methods for Detection and Identification
Annex Point IIA4.1/4.2 & IIIA-IV.1	**A4.2c(04) Analytical method for the determination of [redacted] in seawater by Differential Pulse Anodic Stripping Voltammetry (DPASV)**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]

Section A4.2(c)	Analytical Methods for Detection and Identification
Annex Point IIA4.1/4.2 & IIIA-IV.1	A4.2c(04) Analytical method for the determination of [redacted] in seawater by Differential Pulse Anodic Stripping Voltammetry (DPASV)

Materials and methods

[redacted]

Section A4.2(c)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.1/4.2 & IIIA-IV.1	**A4.2c(04) Analytical method for the determination of [redacted] in seawater by Differential Pulse Anodic Stripping Voltammetry (DPASV)**

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1/4.2 & IIIA-IV.1 **4.2 d(body fluids and tissues)**

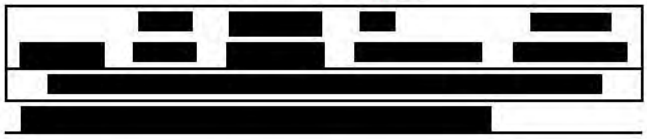
The following Reference(s) are provided under a letter of access from the [redacted] and may be found in the original documentation pertaining to that submission. Access is granted to both the original reference and all summary documents in the [redacted] dossiers on [redacted] by Letter of Access dated 1 April 2006 (Included in Appendix 5 of this submission).

AUTHOR(S)	YEAR	TITLE SOURCE (WHERE DIFFERENT FOR COMPANY) COMPANY, REPORT NO.	TNG SECTION	TNG #
NIOSH	1994	Method 8005. NIOSH Manual of Analytical Methods, Fourth Edition, 8/15/94; Not GLP; Published	4,2d	1
NIOSH	1994	Method 8310. NIOSH Manual of Analytical Methods, Fourth Edition, 8/15/94; Not GLP; Published	4,2d	2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A4 (4.1-4.3)	Analytical Methods for Detection and Identification	
Annex Point IIA4.1/4.2 & IIIA-IV.1	**A4.3 Analytical method for the determination of [redacted] in fresh fish tissue (Inductively Coupled Plasma-Atomic Emission Spectrometry)**	

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1991; US EPA Method 200.11, Revision 2.1. Determination of Metals in Fish Tissue by Inductively Coupled Plasma-Atomic Emission Spectrometry. EPA/600/4-91-010, pp 177-209; Not GLP; Published	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with a letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
			X
		2	
2.1			
2.2			
2.3			
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	A 1 to 2 g sample of fish tissue is taken from a fresh (not previously frozen) fish and transferred to a preweighed, labeled polysulfone Oak Ridge type centrifuge tube. The tissue is dissociated using [redacted] low heat and vortex mixing.	
3.1.2	Cleanup	The following day, the metals in the resulting colloidal suspension are acid solubilized with nitric acid and heat, and then diluted with deionized, distilled water to a weight volume ratio equal to 1 g fish tissue per 10 mL of solution.	
3.2	**Detection**		
3.2.1	Separation method	The diluted sample is vortex mixed, centrifuged and finally the acidified aqueous solution is analyzed.	
3.2.2	Detector	Analysis is by direct aspiration background corrected ICP atomic emission spectrometry.	
3.2.3	Standard(s)	Characteristic atomic-line emission spectra are produced by a radio-frequency ICP. The spectra are dispersed by a grating spectrometer and the intensities of the lines are monitored by photomultiplier tubes. The photocurrents from the photomultiplier tubes are processed and controlled by a computer system.	X
3.2.4	Interfering substance(s)	Background correction is required to compensate for the variable background contribution of fish matrix (precipitate, floatable solids, dissolved solids) and reagents [redacted] to the analyte determination.	X

3.3	**Linearity**		X
3.3.1	Calibration range	1-25 µg/mL	
3.3.2	Number of measurements	Periodical	
3.3.3	Linearity	Analysed values should be within an interval of 95% to 105% of the expected value or the instrument should be recalibrated.	
3.4	**Specificity: interfering substances**	Specific for [redacted] at 324.754 nm Location for Background Correction: - 0.061 nm Background correction is required to compensate for the variable background contribution of fish matrix (precipitate, floatable solids, dissolved solids) and reagents ([redacted] to the analyte determination.	
3.5	**Recovery rates at different levels**	Mean recovery from salmon fillet at a concentration of 3.2 µg [redacted] wet tissue sample was 100%.	X
3.5.1	Relative standard deviation	3.8% (n = 4)	
3.6	**Limit of determination**	Method Detection Limit: 0.05 µg [redacted] wet tissue (determined in Laboratory Reagent Blank matrix because of background concentrations in fish tissue)	X
3.7	**Precision**		
3.7.1	Repeatability	Precision and Recovery of Data Laboratory Fortified Blank Concentration, µg/g 	
3.7.2	Independent laboratory validation	The precision and recovery data presented in this method are single independent laboratory verification data.	

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Give a short description and discussion of the method (all analytical methods should be summarized in tabular form in the hazard and effects assessment document (see sample table there)

This US EPA method is an inductively coupled plasma (ICP)-atomic emission spectrometric procedure for use in determination of naturally occurring and accumulated metals in the edible tissue portion (fillet) of fish.

A 1 to 2 g sample of fish tissue is taken from a fresh (not previously frozen) fish and transferred to a preweighed, labeled polysulfone Oak Ridge type centrifuge tube. The tissue is dissociated using [redacted], low heat and vortex mixing. The following day, the metals in the resulting colloidal suspension are acid solubilized with nitric acid and heat, and then diluted with deionized, distilled water to a weight volume ratio equal to 1 g fish tissue per 10 mL of solution. The diluted sample is vortex mixed, centrifuged and finally the acidified aqueous solution is analyzed. Analysis is by direct aspiration background corrected ICP atomic emission spectrometry.

Background correction is required to compensate for the variable background contribution of fish matrix (precipitate, floatable solids, dissolved solids) and reagents ([redacted] to the analyte determination. Mean recovery from salmon fillet at a concentration of 3.2 µg Cu/g wet tissue sample was 100% (RSD 3.8%, n = 4). Method Detection Limit: 0.05 µg Cu/g wet tissue (determined in Laboratory Reagent Blank matrix because of background concentrations in fish tissue).

4.2 Conclusion

This US EPA standard analytical method is fit for purpose (determination of [redacted] in edible fish tissue).

4.2.1	Reliability	[redacted]	X
4.2.2	Deficiencies	None in the context of the method's requirement for specific laboratory and instrument validation associated with a formal quality control program consisting of an initial demonstration of laboratory capability and the analysis of reagent blanks, fortified blanks and samples as a continuing check on performance.	X

Section A4 (4.1-4.3)	Analytical Methods for Detection and Identification
Annex Point IIA4.1/4.2 & IIIA-IV.1	**A4.3 Analytical method for the determination of [redacted] in fresh fish tissue (Inductively Coupled Plasma-Atomic Emission Spectrometry)**

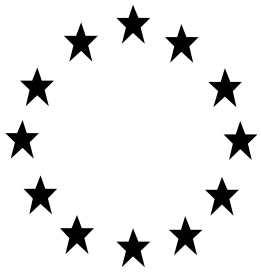
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

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

Evaluation of active substance

Competent Authority Report

Document IIIA 5



Dicopper oxide

Product type 21: antifouling products

Final CAR

March 2016

eCA: FRANCE

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	[redacted] is used in the control of fouling organisms in marine and freshwater environments.	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**	[redacted] is used on vessels which potentially cover large geographical ranges, therefore they are potentially exposed to multiple marine biotypes. The number of fouling organisms to which a vessel may be exposed is therefore large; there are over 4000 fouling species. Typical organisms are presented in Section 5.2.1, but this list is indicative, not restrictive.	
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Biofouling organisms as either "micro-organisms" or "macro-organisms". Micro-organisms are bacterial slimes/films consisting of organisms invisible to the naked eye. Macro-organisms are visible to the naked eye, and include hard-bodied organisms such as polychaete worms, barnacles, mussels, oysters and bryozoans (moss-like animals), and soft-bodied organisms such as hydroids (e.g., sea anemones), sponges and sea squirts.	X1
		Typical species of fouling organism include:	

Species	Common name
Molluscs-bivalves	
Hiatella artica	
Perna canaliculus	Green shelled mussel
Chlamys gemmulata	Fan scallop
Modiolarca impacta	Nestling mussel
Xenostrobus pulex	Small black mussel
Myutilus edulis	(Common) Blue mussel
Molluscs-gastropods	
Maoricyrpta costata	Rubber slipper shell
Ascideans	
Clona intestinalis	White sea squirt
Cnemidocarpa bicornuata	Orange Sea Squirt
Microcosmus kura	Brown sea squirt
Compound ascidean	Colonial sea squirts
Polychaete worms	
Galeolaria hystrix	Orange tube worm
Large Sabellid	Soft tube worm
Sorolid	
Coelenterate-hydroid	
Amphishetia bispinosa	
Bryozoa	
Hard encrusting	
Bugula type	
Porifera-sponges	

5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	[redacted] is used for the protection against fouling of both mobile (including but not limited to marine and freshwater vessels) and stationary (including but not limited to buoys, aquaculture nets, immersed structures) objects.	
5.3	**Effects on target organisms, and**	When [redacted] from [redacted] leaches into marine water with oxygen present the predominant	

likely concentration at which the active substance will be used (IIA5.3)

form of the [redacted] is the [redacted] This ion acts to retard biofouling via two mechanisms; (1) the ion retards organism's vital processes by inactivating enzymes, and (2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates. At the hull of the vessel the [redacted] is concentrated and is bioavailable overwhelming the natural biological processes of the organisms that under normal conditions can utilize the [redacted] as a micronutrient or expel excess [redacted] The cupric ion quickly complexes to inorganic and organic matter and becomes more dilute as it passes away from the vessel hull and therefore organisms can exist in close proximity to the ship such as on pilings of piers and docks (see diagram below). Therefore, independent from the source of the [redacted] (whether it is [redacted], it is the [redacted] that is the actual active substance in antifouling paint products.

[redacted]

The kinetics of [redacted] complexation with dissolved organic matter has been studies by [redacted] 1994 [A7.1.4(2)]. They observed the reaction kinetics of [redacted] and dissolved organic matter (DOM) using a stopped-flow flourescence techinique. Reference fulvic acid and water soluble soil organic matter was used as model DOM. Experimental conditions of pH 6, 5×10^{-5} M [redacted] and 5 mg C/L of DOM were used. Both organic ligands reacted rapidly with [redacted] with reaction half-lives in the millisecond range. This indicates that the [redacted] produced at the microlayer will rapidly be complexed to organic matter present in natural waters and its toxic potential reduced significantly. X2 X3

5.3.1 Effects on target organisms (IIA5.3)

Document IIIA Section 7 presents a significant amount of data which shows that [redacted] has the capability of controlling fouling organisms at achievable concentrations. These organisms include macroalgae (*Fucus vesiculosis*), microalgae (*Skeletonema costatum*), hard-shelled clams (*Mytilus edulis*), Sea urchins (*Paracentrotus lividus*). Tabulated information are provided in Table A5.3.

5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)

PT21

The concentration of [redacted] in antifouling paints is dictated by several factors, such as:

- Geographical range of the vessel

- Intended frequency of renewal
- Leaching rate of [redacted] from the paint in use
- Co-biocides included in the paint
- Salt form of the [redacted]

Therefore it is considered inappropriate to provide limiting information on concentrations in paint. Typical concentrations range from 10 to 70% as [redacted] X4

5.4 Mode of action (including time delay) (IIA5.4)

5.4.1 Mode of action

General

Non-specific binding of metals to an organism results in toxicity due to

1) blocking of the essential biological functional groups of biomolecules,

2) displacing essential metal ions in biomolecules, and

3) modifying the active conformation of biomolecules ([redacted] 1977).

For [redacted] there is also the possibility that this element undergoes redox cycling within the cell, resulting in the production of reactive oxygen radicals and leading to tissue damage and molecule dysfunction ([redacted] 1995).

The gill (waterborne exposure) and the gut tissue (dietary exposure) are commonly considered to be the primary target for metal uptake and/or toxicity ([redacted] 2002a). The gill is the tissue that is responsible for oxygen uptake and regulation of major ion balances ([redacted]), and is also the main route of waterborne metal uptake and toxicity. This multi-functional organ serves many purposes such as respiration, nitrogenous waste excretion, acid-base balance and osmoregulation. It has also been demonstrated that the gill serves a role in trace element absorption ([redacted] 1988; [redacted] 2002). Gill-like structures also occur in freshwater invertebrates and there is growing evidence that these structures have similar functions ([redacted] 1983; [redacted] 1997; [redacted] 2002a). [redacted] interacts with the gill cells at three different levels:

1) the metal reacts with biomolecules on the apical membrane of epithelial tissue, causing tissue damage and/or inhibition of transport channels,

2) the metal enters the epithelial tissue and reacts with transport channels on the basolateral membrane, and

3) the metal enters the extracellular fluids (blood or haemolymfe) from where it is distributed into other tissues.

Acute toxicity in fish and invertebrates

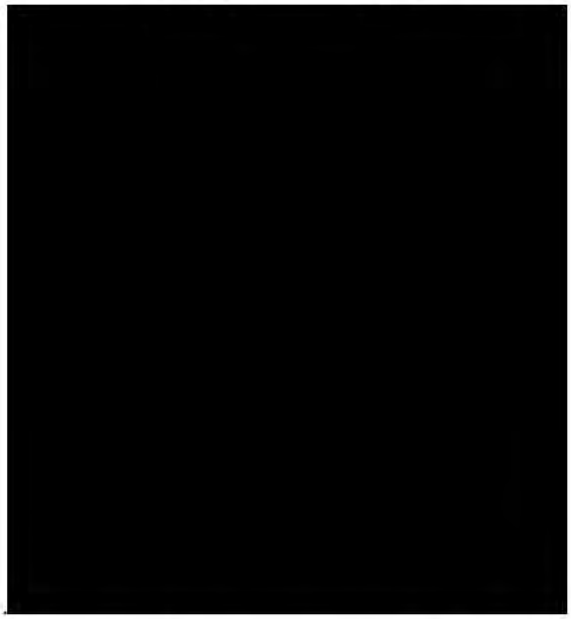
The main target of acute (short-term) metal toxicity appears to be the ion-regulation mechanisms, with the key target the disturbance of the sodium homeostasis and, to a lesser extent, the chloride absorption and nitrogenous waste excretion [redacted] 2002). [redacted] induced disturbance of sodium balance was first demonstrated in

Daphnia magna, (1948). Later findings of reduced plasma osmolarity, concentrations in various freshwater fish exposed to confirmed that this metal is an osmoregulatory toxicant 1970; 1982).

The disturbance of the sodium homeostasis at low concentrations is related to a reduction of branchial sodium uptake, whereas an increased sodium efflux is observed at higher levels. This efflux is related to an increased permeability of the branchial epithelium due to the displacement of calcium by in the tight junctions 1985).

First, appears to inhibit the basolateral Na^+/K^+ ATPase (e.g. 1987), related to increased concentration in the gill tissue (1998; 2000) and invoked by interference of Mg binding to this enzyme (1998). Secondly, inhibition of sodium channels and sodium-proton exchangers at the apical side has been reported to be targets for toxicity (2002). In addition, it has been suggested that may inhibit carbonic anhydrase and as such deplete the proton substrate for the sodium-proton exchanger (1999; 2002a). Finally, although the exact mechanisms of chloride uptake inhibition are not as well understood, decreases of sodium levels upon exposure are often accompanied with a decrease in chloride levels (1985; 1993). According to . (2002a), given the fact that sodium and chloride uptake are linked by carbonic anhydrase, this may point to this enzyme also being a likely target for toxicity.

The net loss of sodium (and chloride) creates an osmotic imbalance between plasma and tissues. Via a complex cascade of events, this eventually leads to cardiovascular collapse resulting in death (1998; 2002a).



The above figure is a schematic representation of a general model of acid-base, sodium, chloride and ammonia transport across the gill epithelium of freshwater organisms and the transport channels involved (after 2002a).

Chronic toxicity to fish and invertebrates

It is still unclear how ionoregulatory disturbance affects organisms in long-term exposures. [redacted] (2002b) indicate that in chronic exposures, one should also take into account that organisms may exhibit acclimation effects. To our knowledge, no studies have been performed investigating the possible effect of ionoregulatory malfunctioning on reproductive success. It has been suggested that a decrease of whole body Na^+ concentrations in D. magna chronically exposed to silver may have been responsible for the observed decreased reproduction ([redacted] 2002). Although high sodium losses may indeed result in an overall decreased fitness of the organism and in an enhanced energy requirement for maintenance purposes, there is no evidence that this is the only mechanism causing reduced reproductive success in chronic exposures.

Finally, the effects of long term exposures are always the combination of uptake via the water and via the food. The mechanisms related to dietary metal exposure, however, are currently insufficiently been studied ([redacted] 2003).

[redacted] toxicity to unicellular algae

It is commonly accepted that mechanisms of metal toxicity in algae are very different from those observed in fish and invertebrates. This seems logical, as the border between the intra- and extra-cellular environment in algae is not a gill but is generally composed of a polymeric cell wall and a plasma-membrane. A number of [redacted] toxicity mechanisms to algae have been reviewed by [redacted] (2000). At the cell-membrane, [redacted] may cause changes in membrane potential and permeability or may compete with essential metals for binding and uptake ([redacted] 1983; [redacted] 1996; [redacted] 2001). Interactions between [redacted] have been reported ([redacted] 1983; [redacted] 1981). Following transport into the cytoplasm, [redacted] can inhibit enzymes such as esterase and β-galactosidase ([redacted] 1996; [redacted] 2001) and cause changes in intracellular pH ([redacted] 1996). [redacted] is also reported to affect organelles such as chloroplasts and mitochondria. [redacted] (1994) reported structural alterations to thylakoid membranes of Chlorella species and inhibition of photosynthesis. [redacted] (1996) reported a disrupted mitochondrial electron transport upon [redacted] exposure. Finally, [redacted] inhibits algal growth due to the disruption of the glutathione metabolism: [redacted]related oxidation of oxidize thiol groups on enzymes or free thiols such as glutathione, results in a decrease of the reduced/oxidized glutathione ratio and subsequent inhibition of cell division ([redacted] 1987).

5.4.2 Time delay

The system of delivery of [redacted] as described in Section 5.3 indicates that effects are essentially instantaneous at the point of release, and no time delay is expected.

5.5 Field of use envisaged (IIA5.5)

MG04: Other biocidal products	Product type PT21
Further specification	None

5.6 User (IIA5.6)

Section A5		Effectiveness against target organisms and intended uses	
	Industrial	Industrial exposure is not applicable for anti-fouling paints (TNsG, Human Exposure to Biocidal Products – worked example for antifouling use, part 3, p59)	
	Professional	Exposure can occur to professional users during application of paints in professional shipyards. Typically, exposure is restricted through the use of PPE as required, and the exposure has been modelled in relevant Document IIBs according to the models laid out in the Technical Notes for Guidance on the Human Exposure to Biocidal Products.	
	Non-Professional	Exposure can occur to non-professional users during application of paints. Typically, exposure is restricted through the use of PPE as required, and the exposure has been modelled in relevant Document IIBs according to the models laid out in the Technical Notes for Guidance on the Human Exposure to Biocidal Products.	
	General public	Indirect exposure to [redacted] in paint is unlikely to occur. However, there is the potential for limited exposure to a passer-by in an amateur shipyard touching wet paint on the surface of a vessel. This exposure has been modelled in relevant Document IIBs according to the models laid out in the Technical Notes for Guidance on the Human Exposure to Biocidal Products.	
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		
5.7.1	**Development of resistance**	There are no data to indicate organisms are developing resistance to the use of [redacted] in anti-fouling use. Historically, [redacted] has been used for in excess of three centuries, and still exhibits efficacy, indicating resistance is not likely to be of concern.	X5
5.7.2	**Management strategies**	None required	
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	Tonnage data are considered to be company confidential information, and are specified in the Confidential Section.	

Section A5 **Effectiveness against target organisms and intended uses**

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Section A5	Effectiveness against target organisms and intended uses
	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Table A5.3: [redacted]
[redacted]licable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Anti-foulant	PT21	[redacted] was used as a precursor to [redacted]	Macroalgae (*Fucus vesiculosis*)	The study investigated the effects of different levels of dissolved organic carbon (DOC) on [redacted] speciation and its bioavailability and subsequent toxicity to the germling life stages of the macroalgae, Fucus vesiculosis, following a 14 d exposure. The exposure media was measured for [redacted] concentrations.	This study was run with a culture medium control together with nominal [redacted] concentrations of 20, 40, 80, 160, 320 µg l^{-1}. Fucus cultures were incubated at 20 ± 2°C, under flowthrough conditions. After 14 days, growth was determined using an inverted microscope with camera	Comparison of the EC50 for both [redacted] with increasing corrected DOC concentration can be seen clearly below. For [redacted] an EC50 of approximately 40 µg l^{-1} was found at background DOC concentrations. A DOC concentration of 1.65 mg l^{-1} was required to significantly increase the [redacted] EC50 value (73.8µg l^{-1}) above that measured at background DOC levels ($p<0.05$). A further significant increase in the [redacted] EC50 was found at the highest DOC concentration, almost 3 times that recorded when DOC (as HA Humic acid) was absent from the test media (117.3 µg l^{-1}, $p<0.05$).	[redacted] 2006d
Anti-foulant	PT21	[redacted] was used as a precursor to [redacted]	Microalgae (*Skeletonema costatum*),	OECD guideline 201, Alga, Growth Inhibition Test, also satisfies requirements of the relevant EU guideline	This study was run with a culture medium control together with nominal [redacted] concentrations of 1, 2, 4, 8, 16, 32, 64 and 128 µg l^{-1}. Algal cultures were incubated at 20 ± 2°C, under	Data From Smytha Draft to be replaced by data from From Smyth b Based on areas under the growth curve the results obtained at 72 hours were: NOEC = 8.0 µg l^{-1} LOEC = 16 µg l^{-1} EbC50 = 26.3 µg l^{-1}	[redacted] 2006b

					continuous illumination of "cool white" light, with orbital shaking at 100 rpm, in a Gallenkamp type INR-401 orbital incubator. After 24, 48 and 72 hours samples were taken from the exposure vessels to obtain the particle density	Based on logarithmic growth rate over the test period, the results obtained were: NOEC = 7.54 µg l^{-1} LOEC = 13.6 µg l^{-1} ErC50 = 23.8 µg l^{-1}	
Anti-foulant	PT21	[redacted] was used as a precursor to [redacted]	Hard-shelled clams (*Mytilus edulis*)	Wild-caught organisms were exposed to different levels of [redacted] in a flowthrough system. Growth was measured by laser diffraction, and [redacted] levels in the water were measured by potentiometric stripping analysis.	*Mytilus* were acclimated to laboratory conditions, then exposed for 10 or 20 days to nominal concentrations of 5, 10 and 15 µg l^{-1} added [redacted] (experiment 1) and 1.6, 3.2, 6.4 µg l^{-1} added [redacted] (experiment 2) for short term experiments. They were exposed for 20 and 24 days to nominal concentrations of 2, 4, 8 µg l^{-1} added [redacted] for long term experiments.	Significant growth inhibition occurred at concentrations greater than 2 µg l^{-1} added [redacted]; at 15 µg l^{-1} added metal growth almost ceased.	[redacted] 1985

Anti-foulant	PT21	Not reported	Sea urchins (*Paracentrotus lividus*)	Fertilised eggs were exposed to different levels of [redacted] and fulvic acids (FA) and allowed the complete development of embryos into pluteus larvae while minimizing background mortality. After the incubation period, larvae were fixed with a few drops of 40% formalin. The length of 25 individuals was recorded under inverted microscope as the endpoint of the bioassay.	The vials were incubated at 20 ± 0.1°C for 48 h. Total [redacted] concentrations were assayed (10 to 180 µg/l),, and increasing amounts of FAs were added to each to reduce labile [redacted] concentrations from toxic to nearly nontoxic levels.	From the test system not incorporating the protective effect of the FA, the EC10 value is 16.5 µg l^{-1} From the test system not incorporating the protective effect of the FA, the EC50 value is 32.9 µg l^{-1}	[redacted] 2006;

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