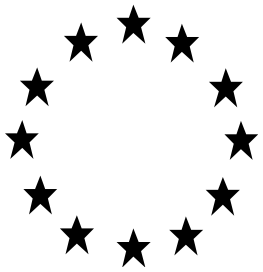
Competent Authority Report



COPPER PYRITHIONE (PT 21)

DOCUMENT III A5
Effectiveness against target organisms and intended uses

Applicant: API Corporation
Rapporteur Member State: Sweden

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KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Antifouling agent (product type 21), via a wide spectrum against both prokaryotic and eukaryotic cells	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled**	General sessile marine organisms such as, Algae, barnacles, encrusting bryozoans, hydroids, slime, tunicates, coelenterates, filamentous bryozoans, molluscs, polychaetes.	x
5.2.2	**Products, organisms or objects to be protected**	Deep sea ship's hulls and to a less extent coastal ship's hulls. For new building and maintenance and repair of commercial sea-going vessels.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms**	For the description of the effects on target organisms see below tables, taken from Document IIIB, section 5.	x

Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of dilutant(s)	Other substance(s) added	Application technique	Remarks
all	PT21	Solvent-based thinner	max. 5% (v/v)	no	spraying	Klijnstra et al, 2006 Kawahara, 2006

Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
all	PT21	spraying	1	n.a.	No variations of the application depending on the different parts of the Community due to geographical or climatic conditions have to be made.	Klijnstra et al., 2006 Kawahara, 2006

Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1480 Vessel speed (knot): 15 Dock interval (months): 27	Fouling resistance rating: 100 Antifouling rating: 100	Kawahara, 2006[1)] test no. 1
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1240 Vessel speed (knot): 14 Dock interval (months): 25	Fouling resistance rating: 95 Antifouling rating: 50	Kawahara, 2006[1)] test no. 2

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1300 Vessel speed (knot): 15 Dock interval (months): 31	Fouling resistance rating: 100 Antifouling rating: 80	Kawahara, 2006[1)] test no. 3
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1360 Vessel speed (knot): 18 Dock interval (months): 27	Fouling resistance rating: 94 Antifouling rating: 94	Kawahara, 2006[1)] test no. 4
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1480 Vessel speed (knot): 22 Dock interval (months): 39	Fouling resistance rating: 100 Antifouling rating: 95	Kawahara, 2006[1)] test no. 5
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1110 Vessel speed (knot): 16-17 Dock interval (months): 24	Fouling resistance rating: 100 Antifouling rating: 95	Kawahara, 2006[1)] test no. 6
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1480 Vessel speed (knot): 19 Dock interval (months): 23	Fouling resistance rating: 100 Antifouling rating: 95	Kawahara, 2006[1)] test no. 7
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1720 Vessel speed (knot): 15 Dock interval (months): 32	Fouling resistance rating: 85 Antifouling rating: 40	Kawahara, 2006[1)] test no. 8
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms	ASTM D 3623-78a	Application rate (g/m^2): 1540 Vessel speed (knot): 15 Dock interval (months): 30	Fouling resistance rating: 85 Antifouling rating: 70	Kawahara, 2006[1)] test no. 9

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
PT 21 Anti-fouling paint	marine vessels and structures, ship hulls	Sea Grandprix 1000 (see specification section 2)	natural mixed population of fouling organisms native to the North Sea.	Static raft exposure test with panels coated with paints with and without the test substance	Natural fouling conditions in a harbour at the North Sea.	Paints with the test substance show good antifouling efficacy during at least 18 months	Klijnstra et al., 2006[2)]

1) Kawahara (2006) Efficacy of Sea Grandprix 1000H, Chugoku Marine Paints Ltd., Study no. AP-0013, Non-GLP, Unpublished

2) Klijnstra et al. (2006) Efficacy determination of antifouling paints containing copper pyrithione, TNO Industrial Technology, Report no. CA05.8040, GLP, Unpublished

5.3.2	**Likely concentrations at which the A.S. will be used**	Based on the outcome of the efficacy studies 1.5% a.s. is used in anti-fouling paint.	X

Data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations

Product type	Application type	Number and timing of application	Concen-tration (%)	Information on recommended variations of the application rate in different locations	Remarks
PT21	spraying	1	1.5%	No variations of the application depending on the different parts of the Community due to geographical or climatic conditions have to be made.	Klijnstra et al., 2006 Kawahara, 2006

5.4	**Mode of action (including time delay) (IIA5.4)**	See document IIIB, Section 5.7.	
5.4.1	**Mode of action**	Copper pyrithione has a wide spectrum against both prokaryotic and eukaryotic cells and there has been rare occurrence of resistance observed. This suggests that the pyrithione molecule has more than one mode of action against micro-organisms. (Nelson and Hyde, 1981)	x
5.4.2	**Time delay**	Lott and Shaw (1949) present the hypothesis that activity of the structurally similar 1-hydroxy-2-pyridone would be its chelating effect (1st mode). More recently, it is shown that the corresponding cyclic hydroxamic acid structure is contributing to the activity of 1-hydroxy-pyridinethion (Chandler and Segel, 1978), and its dipole structure might yield para-quaternary ammonium groups showing efficacy (2nd mode). The 3rd mode is suggested from observations that growth of mold (Pencillium) is inhibited by pyrithione (1-hydroxy-pyridinethione) 's preventing intake of various nutrients (Chandler and Segel, 1978). As such inhibition is increased when the pH decreases, pyrithione might break proton concentration gradient via cell membrane like other organic acids and inhibit transport of solute through cell barrier. There is indirect proof that pyrithione is antagonistic with pyridoxal (pyritine derivative and one component of vit. B6 complex) for further metabolism. If those are correct, activity of pyrithione must be similar of that of sulfur drug which prohibits production of folic acid of micro-organisms. Albert et al. (1956) reports that pyrithione must make 2:1 complex with Fe in order to pass through the cell membrane, but once in a cell, this complex must be broken to show activity.	x
5.5	**Field of use envisaged (IIA5.5)**		
	MG04: Other biocidal products	Product type 21	
	Further specification	Field of use: To control growth and settlement of fouling organisms on marine vessels; Subfields of use: Shipping lane and commercial harbour. Overall use pattern: Sprayed airless.	x
5.6	**User (IIA5.6)**		
	Industrial	Not intended for industrial use.	
	Professional	For professional use only. Application method: spraying (airless).	
	General public	Not intended for general public use.	
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**	In 1981 (Nelson and Hyde) it was reported that only a low incidence of resistance occurred with pyrithione compounds. Since then no literature is found on development of resistance.	x
5.7.2	**Management strategies**	Since the occurrence of resistance is not relevant, no resistance management strategies have to be applied.	
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	20	x

For the summary of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged see document IIIB, Section 5.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

Materials and methods

[redacted]

Conclusion

Reliability

Acceptability

[redacted]

Remarks