



Application for Registration or Variation to a Chemical Product

1. This application is for (please tick the appropriate box):

Registration of a **NEW PRODUCT**: OR a **VARIATION** to an existing registered product:

PRODUCT, FEE & CATEGORY DETAILS (MUST BE COMPLETED)

2. Full Name of Product: ECOsmarte CopperPlus

3. APVMA Product Number: (59599, application number 36163)
[Existing registered products only]

4. Fee enclosed: \$ _____

5. Proposed category/item number: 12, 24, 26

Refer to Ag or Vet Manual on the APVMA website for a list of category/item numbers and descriptions.

6. Purpose of Application and Description of Use: Registration of a 1000 gr/kg pair of copper bars (electrodes) for use in ECOsmarte ionisation equipment for the control of algae in swimming pools

APPLICANT/REGISTRANT CONTACT DETAILS (MUST BE COMPLETED)

7. Name of Applicant/Registrant (can be a company): ECOsmarte-AustralAsia Pty Ltd

8.

ACN/ARBN/OVERSEAS EQUIVALENT No: 113 053 651

Street Address: Shop 6 / 19 Coondoo Street, Kuranda, QLD 4881

Postal Address: PO Box 874, Kuranda, QLD 4881

Name of Contact Person in the company: Nicolaas J. Wouterse (Nico) / Peter Tamas Keller (Sarva)

Position/Title: CEO

Email address: nico@ecosmarte.com.au

Telephone Number: (_07_) 4093 8288

Facsimile Number: (_07_) 4093 8299

APPROVED PERSON DECLARATION (MUST BE COMPLETED)

9. *I hereby declare that the information provided with this application is complete and correct.*

Name of Approved Person (can be a company): Nicolaas J. Wouterse

Position/Title: CEO

Address (postal): PO Box 874, Kuranda, QLD 4881

Name of Contact Person in the Company: Nicolaas J. Wouterse

Position/Title: CEO

Signature: _____ (Signature MUST be in ink) Date: ____/____/____

False declaration may lead to prosecution under application section(s) of the Agricultural and Veterinary Chemicals Code Act 1994.

PLEASE NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to *Guidelines for Letters of Authority for Approved Persons* for additional information.

9. NEW DATA

Has data been provided with this application?

Yes No

If Yes, ensure the Data List is included as both an electronic & a hard copy and tick the option you've used;

Option 1 - hard copy with the application and electronic copy sent to DataList@apvma.gov.au

Option 2 - hard copy with the application and electronic copy saved to Disk/CD and included with application

10. PROTECTED DATA

Refer to http://www.apvma.gov.au/registration/data_protection.shtml for further information.

Reference Product Number	Reference Product Name

Access to Protected Data

Is access to Protected Data required?¹

Yes No

Does the Protected Data relate to:

Chemical Review?:

Yes No

TRIPS?:

Yes No

Application Protected Data?:

Yes No

11. AUTHORISING PARTIES²

Name	Consent Required?*	Provided with Application	To be provided separately
1. N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Not required when applicant is Authorising Party.

12. DISTINCT USES

Refer to http://www.apvma.gov.au/registration/data_protection.shtml for further information.

List all proposed **distinct** uses (eg Crop / Crop Group / Animal / Situation)

Algaecontrol in swimming pools

- Applicants are required to check the Data Protection page on the APVMA website (http://www.apvma.gov.au/registration/data_protection.shtml) for the existence of any Protected Data in relation to the application being made. Applicants must be aware of protected data in connection with Chemical Reviews, TRIPS and application related protected data.
- List all Authorising Parties from the APVMA's list of Protected Data in relation to the nominated reference product.

PRODUCT NAME: ECOsmarte – CopperPlus		APVMA PRODUCT NUMBER: 59599		
13. FORMULATION DETAILS (MUST BE COMPLETED)				
FULL formulation details - every constituent must be listed.				
Please indicate how the formulation details are supplied:				
<input checked="" type="checkbox"/> I have provided the full details below; OR <input type="checkbox"/> I have arranged for the formulator/s (identified in Question 10) to provide details to the APVMA using a copy of this page.				
For every constituent, provide the following information in Column One :-				
<ul style="list-style-type: none"> The common chemical name of the constituent, including purity details were applicable (eg. 93% purity, sufficient to give 100 g/L) (Australian approved names to be used where they exist, trademarked names not to be used on their own) 				
For every constituent, provide the following information in Column Two :-				
<ul style="list-style-type: none"> The Chemical Abstract Service Registry Number (CAS Number) where available 				
For every constituent, provide the following information in Column Three :-				
<ul style="list-style-type: none"> Where a constituent is manufactured to an APVMA active constituent Standard, quote the relevant active constituent approval number (eg. 50001); AND/OR Where a constituent is manufactured to an acceptable compendial Standard, quote the standard and the year (eg. BP2003); AND/OR Where a constituent is manufactured to a manufacturer's specification, mark 'MS' and ensure that a copy of the specification issued by the manufacturer is included. 				
For every constituent, provide the following information in Column Four :-				
<ul style="list-style-type: none"> The nominal concentration of the constituent, including overages and allowing for constituent purities (eg. g/kg, g/L, mg/tablet). 				
For every constituent, provide the following information in Column Five :-				
<ul style="list-style-type: none"> The purpose or purposes of the constituent (eg. active, binder, solvent, preservative). 				
Column One	Column Two	Column Three	Column Four	Column Five
CONSTITUENT NAME	CAS NUMBER	CONSTITUENT STANDARD	CONCENTRATION	PURPOSE IN FORMULATION
(a) Active constituent/s				
100 % pure copper			1000 gr/kg	Algaecide
(b) Other constituent/s				
Total Weight/Weight (solids, semi-solids) or Weight/Volume (liquids)			1000 gr/kg	
Specific gravity (SG) (liquids only)				
Formulation type: (eg. Pour-On, Tablet, Powder, Paste, Aerosol, Wetable Powder, Emulsifiable Concentrate etc.)			Pair of bars (electrodes)	
Does the product contain any ingredients with a risk of transmitting agents of animal spongiform encephalopathies?				
Yes _____ <input type="checkbox"/> No _____ <input checked="" type="checkbox"/>				
NOTE: For imported ingredients of biological origin, copies of relevant AQIS Permits to Import Quarantine Material (PI 985) or a copy of the completed application form must be attached.				<input type="checkbox"/>

PRODUCT NAME: ECOsmarte-CopperPlus

APVMA PRODUCT NUMBER: 59599

14. FORMULATORS DETAILS (MUST BE COMPLETED)

Note: For Veterinary Products: -The formulator/s nominated in should be the manufacturer licensed to manufacture the product for which registration is being sought. The name and address of the formulator should correspond with that on the evidence of GMP compliance under section 15.

Formulator(s) name(s)

ECOsmarte Planet Friendly Inc

Street address(es) of formulation site(s).

1600 East 78th Str
Minneapolis, MN 55423
USA

15. GOOD MANUFACTURING PRACTICE (MUST BE COMPLETED FOR VETERINARY PRODUCTS ONLY)

Good Manufacturing Practice

Tick as appropriate and provide the appropriate appendix reference number where relevant.

Copy of the APVMA Manufacturers Licence
OR proof of application for one (Australian manufacturers only)

Not required: _____
Attached: _____

OR
In the case of overseas manufacturers: APVMA recognised
Overseas Certificate of GMP Compliance.

Attached: _____

OR
Audit report from an APVMA recognised Australian or
overseas GMP auditor

Attached: _____

OR
Submission of Plant Master File that has been certified
by an APVMA recognised overseas regulatory authority

Attached: _____

AND
Names and addresses of all other facilities involved
such as-packaging & labelling, contractors, analytical
labs involved in manufacturing (where applicable)

Attached: _____

16. MANUFACTURERS OF ACTIVE CONSTITUENTS (MUST BE COMPLETED)

Details of the manufacturing source(s) of the active constituent(s) used in both agricultural and veterinary chemical products must be provided. The quality of each active constituent and each source listed below must be demonstrated by the provision of analysis results that comply with the relevant APVMA active constituent Standard, compendial standard or manufacturers specification.

Complete the following details for each of the active constituent(s) manufacturing source(s)

Active Constituent Name (Australian approved name where applicable)	AC Approval Number (if applicable)	Name and street address of the manufacturing site
Copper (Cu)	Exempt	N/a

For all active constituents listed above address the following:

- If an active constituent listed above is NOT an approved agricultural or veterinary active constituent include a completed Approval of an Active Constituent (KP21_F8) form for the approval of a new active constituent and provide the necessary data detailed in the Part 2 Chemistry and Manufacture Requirements Series with the approval application;
- If an active constituent listed above is an approved agricultural active constituent but the manufacturing site given does not appear on the APVMAs Record of Approved Active Constituents then include a completed Approval of an Active Constituent (KP21_F8) form for the approval of a new source of an approved active constituent and provide the necessary data detailed in the Part 2 Chemistry and Manufacture Requirements Series with the approval application and one (1) recent (analysed within the last two years) analysis result of a batch of the active constituent(s) to be used in the product demonstrating conformance with the relevant APVMA Standard(s);
- If an active constituent listed above is an approved agricultural active constituent and the manufacturing site given appears on the APVMAs Record of Approved Active Constituents then specify the active constituent approval number and provide one (1) recent (analysed within the last two years) analysis result of a batch of the active constituent(s) to be used in the product demonstrating conformance with the relevant APVMA Standard(s);
- If the active constituent listed above is an approved veterinary active constituent then specify the active constituent approval number(s) (if known), nominate and provide the relevant Standard(s) or specification(s) (compendial, manufacturers etc) and provide one (1) recent (analysed within the last two years) analysis result of a batch of the active constituent(s) to be used in the product demonstrating conformance with the specified Standard(s)/specification(s).

PRODUCT NAME: ECOsmarte-CopperPlus		APVMA PRODUCT NUMBER: 59599
17. CONTAINER AND PACK SIZE DETAILS (MUST BE COMPLETED)		
Please provide details regarding the product container and product pack size details.		
Pack size(s)	Brief description of the packaging material, including that which is in direct contact with the product	Method of label attachment
Currently approved pack size(s)		
Proposed Pack Size(s)		
Standard 1.5” Turbo 2”	10 * 3.3 * 2 cm 10 * 4.5 * 2 cm	Wrap & Glue Wrap & Glue
18. STORAGE STABILITY DETAILS (MUST BE COMPLETED)		
Please provide the following details:		
For veterinary chemical products and date controlled agricultural chemical products only: The proposed shelf life expiry period from the date of manufacture: (e.g. 2 years; 18 months).		
Non-date controlled agricultural chemical products are expected to demonstrate acceptable storage stability of at least 2 years under normal conditions.		
For all chemical products: The proposed storage conditions: (e.g. below 30 °C, room temperature; normal conditions).		Normal storage conditions.
For all chemical products: Has data to support the storage stability of the product been provided with this application?		Yes _____ <input type="checkbox"/> No _____ <input checked="" type="checkbox"/>
If no to previous, has data to support the storage stability of the product been provided with a previous application for this product?		Yes _____ <input type="checkbox"/> specify: _____ No _____ <input checked="" type="checkbox"/>
If no stability data has been provided ensure that a suitable scientific argument has been provided to address this requirement.		

19. LABEL DETAILS (MUST BE COMPLETED)

Please complete the following label details:

(a) Requested label number & dimension of labels for all pack sizes (Give dimensions in centimetres).

Pack size (eg 10 L)	Label size (eg 20 x 10 cms)	Proposed packsize identifier (eg 10 L, 1 kg)
Standard	10 * 10 cm	Copper-Plus, Standard / Turbo

(b) Indicate which labels are to be approved.

{Tick at least one of the following}

- Marketed Product Label (MPL) [APVMA preferred]
- Printer's Proof Label (identical in size to MPL)
- Printer's Proof Label (different size to MPL)
- Text label

Other: (Please Specify) See label attached.....

Note: Type 2 Marketed Product Labels are not accepted. Can be approved as Printer's Proof Labels (PPLs)

(c) Method of attachment of label to container

Details:.... Wrap&Glue.....

20. APPROVED PERSONS CHECKLIST (MUST BE COMPLETED)

Tick appropriate boxes to verify that required documentation is attached:

(Note: To help achieve efficient processing refer to full checklist and ensure all relevant information has been provided)

- Cover letter, addressed to Client Services Officer, outlining exact purpose of application. √
- Copy of the current label with all additions and deletions clearly identified. X
- Copy of the proposed new label without changes identified. √
- Appropriate fee included OR covering letter states why no fee applicable. √
- Documentation attached authorising an approved person to act on company's behalf. X
- Have you signed the application form in ink and completed all relevant sections? √
- Have you included Consent for Use Letters for any referenced Protected Data? X
- Have you included a complete Data List in the correct format? √

Please return the fully completed application to:
 Client Services Officer
 Registration Client Services
 Australian Pesticides & Veterinary Medicines Authority
 PO Box E240
 Kingston ACT 2604