

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2014-5126
Application: Changes to TGAI Product Chemistry – New Source (site) same registrant and Specifications
Product: Copper Flake Technical
Registration Number: 27903
Active ingredients (a.i.): Copper, metallic
PMRA Document Number : 2630479

Purpose of Application

The purpose of this application was to add a new manufacturing site to the technical product, Copper Flake Technical, and to amend the specifications.

Chemistry Assessment

Common Name: Copper (metallic)
IUPAC* Chemical Name: Copper
CAS† Chemical Name: Copper

* International Union of Pure and Applied Chemistry
 † Chemical Abstracts Service

Copper Flake Technical has the following properties:

Property	Result
Colour and physical state	Reddish-brown solid
Nominal concentration	95.75%
Odour	None
Relative density	4
Vapour pressure	Negligible
pH	Not applicable; not soluble in water
Solubility in water	Negligible
n-Octanol/water partition coefficient	Not applicable; solid metal

The required chemistry data for Copper Flake Technical have been provided, reviewed, and

found to be acceptable.

Health Assessments

Occupational and dietary exposure assessments were not required for this application.

Since the technical grade active ingredient (TGAI) is to formulate antifouling paints, the precautionary measures required when handling the TGAI are sufficient to protect from users.

The exposure mitigation measures present on the label, such as signal words, pictogram, precautionary statements and personal protective equipment requirements are adequate to address any toxicological concerns. These mitigation measures are also required for any end-use product formulated with this active ingredient for use as antifouling paints.

There is no concern for dietary exposure as the active ingredient is for non-food use (to formulate antifouling paints).

Environmental Assessment

The addition of the new manufacturing site for Copper Flake Technical is not expected to increase environmental risk.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the addition of a new manufacturing site and changes to the specifications of Copper Flake Technical.

References

PMRA Document Number	References
2470849	2014, Chemistry-2.1-9,2.11, 2.13, 2.14-Eckart Copper, DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.2,2.3,2.3.1,2.4, 2.5,2.6,2.7,2.8,2.9 CBI
2470850	2012, Chemistry-2.11.3-Manufacturing of Copper Flake Technical_V2, DACO: 2.11.3 CBI
2470851	2012, Determination of Total Copper and [CBI REMOVED] in Five Batches of Coated Copper Flakes, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2470852	2014, final 20121030_5_Batch_2011_Formatierung_Windows 7_rev2_non EU-revised, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2491384	2012, Determination of Total Copper and [CBI REMOVED] in Five Batches of

2592470 Coated Copper Flakes - Final Report, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2015, [CBI REMOVED] analysis-copper-19nov2015-B022-15 copper atomized
Data incoming goods, DACO: 2.13.4 CBI
2592471 2015, [CBI REMOVED] -09dec2015-B022a-
15_Kupfergriess_100_Data_incoming_goods, DACO: 2.13.4 CBI
2592472 2015, [CBI REMOVED] -additional-19nov2015, DACO: 2.13.4 CBI

A. Additional Information Considered

i) Published Information

2.0 Human and Animal Health

2013,

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3D/Q3D_Step2b.pdf (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Elemental Impurities, Q3D).

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