

Evaluation Report for Category B, Subcategory 1.3Application

Application Number:	2012-1253
Application:	B.1.3 – New Chemistry Specifications
Product:	Cambrex SDD Tabs
Registration Number:	30839
Active ingredients (a.i.):	available chlorine present as sodium dichloro-s-
	triazinetrione dihydrate
PMRA Document Number	: 2277849

Purpose of Application

The purpose of this application was to register the new product, Cambrex SDD Tabs, based on the precedent, Cambrex RF-SDD (Reg. No. 28727) which is owned by the same registrant.

Chemistry Assessment

Cambrex SDD Tabs is a solid containing the active ingredient available chlorine present as sodium dichloro-s-triazinetrione dihydrate at a nominal concentration of 56%. This product has a density of 1.0 g/cm^3 and pH of 5.5-7.0. The chemistry requirements for Cambrex SDD Tabs have been completed.

Health Assessment

Toxicological data were not required for this application. The toxicological profile of this technical grade active ingredient is considered equivalent to that of the precedent registered product.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of this product and has determined that Cambrex SDD Tabs is acceptable for full registration.

References

1343436 2006, Manufacturing Method, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI	
1343437	2006, Specifications, DACO: 2.12,2.12.1 CBI
1343438	2006, Analysis, DACO: 2.13,2.13.1,2.13.2 CBI



1343441	2006, Colour, DACO:
	2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.1 4.7,2.14.8,2.14.9
	,2.1.1.5,2.1.1.5
2174389	2012, Chemistry requirements, DACO: 2.0,2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2174391	2012, Preliminary Analysis, Batch data, DACO: 2.13,2.13.3,2.13.4 CBI
2174392	2012, Stotage stability data, DACO: 2.14.14 CBI
2225751	Batch data clarification, DACO: 2.13.3

ISSN: 1911-8082

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