

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number:	2010-4023
Application:	Changes to TGAI Product Chemistry-
	Specifications
Product:	Repak Calcium Hypochlorite
Registration Number:	18123
Active ingredients (a.i.):	Calcium Hypochlorite
PMRA Document Number English PDF: 2018381	

Purpose of Application

The purpose of this application was to update the specifications of an existing technical grade active ingredient, Repack Calcium Hypochlorite (Registration Number 18123).

Chemistry Assessment

Common Name:	calcium hypochlorite
Chemical Name:	hypochlorous acid, calcium salt (2:1)

Repak Calcium Hypochlorite has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	Available chlorine 68.63% present as calcium hypochlorite
Odour	slight chlorine odour
Specific gravity	0.99-1.07
Vapour pressure	N/A as the product is a solid
рН	7.7 (1% solution)
Solubility in water	217 g/L (27°C)
n-Octanol/water partition coefficient	N/A as the product is practically insoluble in octanol and not required for an inorganic salt

The chemistry requirements for Repak Calcium Hypochlorite have been completed.

Health Assessments

The proposed changes in the specifications of Repak Calcium Hypochlorite are not expected to impact the toxicological profile. No toxicology data are required.



Environmental and Value Assessment

Environmental or value assessments were required for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the changes in the product specifications are acceptable.

References

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1950752	2010, Manufacturers Name and Office Address, DACO: 2.2
1950753	2010, Manufacturing Summary, DACO: 2.11.1
1950754	2010, Manufacturing Summary, DACO: 2.11.1 CBI
1950755	2010, Description of Starting Materials, DACO: 2.11.2
1950756	2010, Description of Starting Materials, DACO: 2.11.2 CBI
1950758	2010, Detailed Production Process Description, DACO: 2.11.3
1950759	2010, Detailed Production Process Description, DACO: 2.11.3 CBI
1950761	2010, Discussion of Formation of Impurities, DACO: 2.11.4
1950762	2010, Discussion of Formation of Impurities - Confidential Test Data, DACO: 2.11.4 CBI
1950763	2010, Establishing Certified Limits, DACO: 2.12.1
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1950765	2010, Methodology/Validation, DACO: 2.13.1
1950766	2010, Methodology/Validation - Confidential Business Information, DACO: 2.13.1 CBI
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1950769	2010, Batch Data, DACO: 2.13.3 CBI
1950772	2010, Impurities of Toxicological Concern, DACO: 2.13.4

- 1950776 2010, Impurities of Toxicological Concern Confidential Business Information, DACO: 2.13.4 CBI
- 2007846 The Determination of Available Chlorine and impurity [CBI REMOVED], in Cal/Hypo, DACO: 2.13.1 CBI
- 2007848 The Determination of impurities [CBI REMOVED], in Calcium Hypochlorite {Ca(OCl)2}, DACO: 2.13.1 CBI
- 2007850 The Determination of impurities[CBI REMOVED], in Cal/Hypo [CBI REMOVED], DACO: 2.13.1 CBI
- 2007852 The Determination of impurities in Cal/Hypo, DACO: 2.13.1 CBI
- 2007854 The Determination of Total Chlorine Species in Calcium Hypochlorite, DACO: 2.13.1 CBI
- 2007856 The Determination of impurity [CBI REMOVED], in Cal/Hypo, DACO: 2.13.1 CBI
- 2007858 2011, Batch data, DACO: 2.13.3 CBI

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