

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2008-4048
Application: B.1.3 New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: Repak Calcium Hypochlorite
Registration Number: 18123
Active ingredients (a.i.): Calcium Hypochlorite
PMRA Document Number : 1861929

Purpose of Application

The purpose of this application is to change the specifications of the technical grade active ingredient Repack Calcium Hypochlorite (Registration No. 18123). The change is to address a discrepancy in the product guarantee identified during product renewal.

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 71.2% present as calcium hypochlorite
Odour	slight chlorine odour
Specific gravity	0.99-1.07
Vapour pressure	N/A as the product is a solid
pH	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 change in the specifications of Repak Calcium Hypochlorite is not expected to impact the toxicological profile. No toxicology data are required.

Environmental and Value Assessment

No environmental or value assessments were required for this application.

Conclusion

Following the assessment of all available data, the PMRA is able to support change to the specifications for Repak Calcium Hypochlorite.

References

PMRA Document Number	Reference
1669457	2008, Applicants Name and Office Address, DACO: 2.1
1669458	2008, Manufacturers Name and Office Address, DACO: 2.2
1669459	2008, Manufacturing Summary, DACO: 2.11.1
1669460	2008, Manufacturing Summary, DACO: 2.11.1 CBI
1669464	2008, Description of Starting Materials, DACO: 2.11.2
1669465	2008, Description of Starting Materials, DACO: 2.11.2 CBI
1669466	2008, Detailed Production Process Description, DACO: 2.11.3
1669467	2008, Detailed Production Process Description, DACO: 2.11.3 CBI
1669468	2008, Discussion of Formation of Impurities, DACO: 2.11.4
1669469	2008, Discussion of Formation of Impurities - Confidential Test Data, DACO: 2.11.4 CBI
1669470	2008, Establishing Certified Limits, DACO: 2.12.1
1669471	2008, Establishing Certified Limits - Confidential Test Data, DACO: 2.12.1 CBI
1669472	2008, Methodology/Validation, DACO: 2.13.1
1669473	2008, Methodology/Validation - Confidential Business Information, DACO: 2.13.1 CBI
1669474	2008, Confirmation of Identity, DACO: 2.13.2
1669475	2008, Batch Data, DACO: 2.13.3
1669476	2008, Batch Data, DACO: 2.13.3 CBI
1669477	2008, Impurities of Toxicological Concern, DACO: 2.13.4
1669478	2008, Impurities of Toxicological Concern - Confidential Business Information, DACO: 2.13.4 CBI
1830263	2009, The Determination of Available Chlorine and Chlorate in Cal/Hypo [CBI REMOVED], DACO: 2.13.1 CBI
1830264	2009, The Determination of Calcium in Cal/Hypo, DACO: 2.13.1 CBI
1830265	2009, The Determination of [CBI REMOVED], DACO: 2.13.1 CBI
1830266	2009, The Determination of [CBI REMOVED] in Cal/Hypo, DACO: 2.13.1 CBI
1830267	2009, The Determination of [CBI REMOVED], DACO: 2.13.1 CBI
1830268	2009, The Determination of [CBI REMOVED] in Calcium Hypochlorite, DACO: 2.13.1 CBI
1830269	2009, ANALYTICAL REPORT, DACO: 2.13.4 CBI
1832282	2009, CALCIUM HYPOCHLORITE SAMPLE PREPARATION, DACO: 2.13.1 CBI

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