

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2015-1500
Application: New technical grade active ingredient product chemistry –
 New source (site), new registrant
Product: Prohexadione Calcium Technical
Registration Number: 32682
Active ingredients (a.i.): Prohexadione-calcium
PMRA Document Number: 2692258

Purpose of Application

The purpose of this application was to register a new source, Prohexadione Calcium Technical (guarantee 94.44% prohexadione calcium), by a new registrant.

Chemistry Assessment

Common Name: Prohexadione Calcium Technical
IUPAC* Chemical Name: calcium 3-oxido-5-oxo-4-propanoylecyclohex-3-ene-1-carboxylate
CAS† Chemical Name: Cyclohexanecarboxylic acid, 3,5-dioxo-4-(1-oxopropyl)-, ion(1-), calcium, calcium salt (2:1:1)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Prohexadione Calcium Technical has the following properties:

Property	Result
Colour and physical state	Yellow solid
Nominal concentration	94.44%
Odour	Sweet smell
Density	1.453 g/mL
Vapour pressure	1.335×10^{-5} at 25°C
pH	6.72
Solubility in water	174 mg/L
n-Octanol/water partition coefficient	Log K_{ow} = -2.90

The required chemistry data for Prohexadione Calcium Technical have been provided, reviewed, and found to be acceptable.

Health Assessments

Product manufactured at the new site, for the new registrant, is considered toxicologically equivalent to a currently registered technical product. New toxicological data were neither submitted nor required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed a review of all information in support of Prohexadione Calcium Technical and found it sufficient to grant full registration.

References

PMRA Document Number	Reference
2524763	2015, Applicants name and office address, DACO: 2.1
2524764	2015, Manufacturers name and office address, DACO: 2.2
2524765	2015, Product trade name, DACO: 2.3
2524766	2015, Other names, DACO: 2.3.1 CBI
2524767	2015, Common name, DACO: 2.4
2524768	2015, Chemical name, DACO: 2.5
2524769	2015, Chemical Abstracts Services Registry Number, DACO: 2.6
2524770	2015, Structural Formula, DACO: 2.7
2524771	2015, Molecular formula, DACO: 2.8
2524772	2015, Molecular weight, DACO: 2.9
2524773	2015, Manufacturing summary, DACO: 2.11.1 CBI
2524774	2015, Description of Starting Materials, DACO: 2.11.2 CBI
2524775	2015, Detailed Production process description, DACO: 2.11.3 CBI
2524776	2015, Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2524777	2015, Establishing Certified Limits, DACO: 2.12.1 CBI
2524778	2015, Methodology/Validation, DACO: 2.13.1 CBI
2524779	2011, Analytical Method Validation and Five Batch Characterisation for Prohexadione-Ca, DACO: 2.13.1 CBI
2524780	2015, Confirmation of Identity, DACO: 2.13.2 CBI
2524781	2013, Five Batch Characterisation of Prohexadione-Calcium, DACO: 2.13.2, 2.13.3 CBI
2524782	2015, Batch Data, DACO: 2.13.3 CBI
2524783	2015, Impurities of Toxicological Concern, DACO: 2.13.4 CBI
2524784	2015, Colour, DACO: 2.14.1
2524785	2015, Physical State, DACO: 2.14.2
2524786	2015, Odour, DACO: 2.14.3
2524787	2015, Melting Point / Melting Range, DACO: 2.14.4
2524788	2015, Boiling Point / Boiling Range, DACO: 2.14.5
2524789	2015, Density or Specific Gravity, DACO: 2.14.6
2524790	2015, Water Solubility (mg/L), DACO: 2.14.7
2524791	2015, Solvent Solubility (mg/L), DACO: 2.14.8
2524792	2015, Vapour Pressure, DACO: 2.14.9
2524793	2015, Dissociation Constant, DACO: 2.14.10
2524794	2015, Octanol / Water Partition Coefficient, DACO: 2.14.11
2524795	2015, UV / Visible Absorption Spectra, DACO: 2.14.12
2524796	2015, Stability (Temperature, Metals), DACO: 2.14.13
2524797	2015, Storage Stability Data, DACO: 2.14.14
2524798	2015, pH, DACO: 2.14.15, 830.7000
2524799	2015, Sample of Analytical Standards and Residues of Concern, DACO: 2.15
2524800	2000, Review report for the active substance prohexadione-calcium, DACO: 2.14.12, 2.14.15, 2.14.8, 830.7000

2524801 U.S. EPA, 2000, Pesticide Fact Sheet: Prohexadione Calcium, DACO: 2.14.10

2544218 2013, Specifications – [CBI Removed], DACO: 2.11.2 CBI

2544219 2013, Specifications -[CBI Removed], DACO: 2.11.2 CBI

2544220 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544221 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544222 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544223 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544224 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544225 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544226 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544227 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544228 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544229 2013, Specifications - [CBI Removed], DACO: 2.11.2 CBI

2544230 2013, Specifications - [CBI Removed], solid, DACO: 2.11.2 CBI

2544231 2011, Analytical Method Validation and Five Batch Characterisation for Prohexadione-Ca, DACO: 2.13.1 CBI

2544232 2013, Five Batch Characterisation of Prohexadione-Calcium, DACO: 2.13.1 CBI

2604066 2016, Detailed production process description, DACO: 2.11.3 CBI

2655684 2016, Starting Materials, DACO: 2.11.2, 2.11.3 CBI

2655687 2011, Assay and Validation of Prohexadione-Ca Five Batch Analysis, DACO: 2.13.1 CBI

2655688 2016, Analytical Limited Method Validation for the Determination of Toluene in Prohexadione-Calcium by Headspace Gas Chromatography - Mass Spectrometry (GC-MS), DACO: 2.13.1, 2.13.4 CBI

2655689 2016, Prohexadione-Calcium - Five Batch Characterisation, Toluene by Headspace GCMS, DACO: 2.13.4 CBI

2656723 2016, Submission 1322812 Standard and Blank Chromatograms, DACO: 2.13.1 CBI

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