

Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2014-1182
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: High Purity Grade 70% H₂O₂
Registration Number: 31776
Active ingredients (a.i.): hydrogen peroxide
PMRA Document Number: 2512534

Background

The source of hydrogen peroxide used to determine chemical equivalency was Registration Number 27431.

Purpose of Application

The purpose of this application was to register a new source of the technical grade active ingredient, hydrogen peroxide, by a different Registrant.

Chemistry Assessment

Accepted Name: Hydrogen peroxide
IUPAC Chemical Name: Hydrogen peroxide
CAS Chemical Name: Hydrogen peroxide

High Purity Grade 70% H₂O₂ has the following properties:

Property	Result
Colour and physical state	Colourless liquid
Nominal concentration	70.5%
Odour	Slightly sharp or pungent acidic, irritating odour
Density	1.29 g/mL
Vapour pressure	0.1 kPa (20°C)
pH	4.4
Solubility in water	Completely soluble

Property	Result
n-Octanol/water partition coefficient (K_{ow})	$\log K_{ow} = -1.57$ (estimated)

The chemistry requirements for High Purity Grade 70% H₂O₂ have been fulfilled.

Health and Environmental Assessments

As the new source of hydrogen peroxide is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of High Purity Grade 70% H₂O₂.

References

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- 2410624 2014, Starting Material MSDSs, DACO: 2.11.2 CBI
- 2410625 2014, CHEMINFO Chemical Profiles Created by CCOHS (Hydrogen Peroxide greater than 35%), DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9
- 2443234 2014, Manufacturing process, DACO: 2.11,2.11.2 CBI
- 2443238 2001, HYDROGEN PEROXIDE: CORRELATION BETWEEN CONCENTRATION AND DENSITY FOR H₂O₂ SOLUTIONS, DACO: 2.13.1 CBI
- 2443241 2014, Impurities, DACO: 2.13.4 CBI
- 2495417 2015, Batch Data, DACO: 2.13.3 CBI
- 2495418 2015, Detailed Information on Starting Materials, DACO: 2.11.2 CBI
- 2500533 2015, Revised Manufacturing Summary, DACO: 2.11.1 CBI

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