

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.12 and Category C, Subcategory 8.2 Application

Application Number:	2009-1808
Application:	New/changes to product chemistry guarantee, identity of
	formulants, proportion of formulants and new/changes to the
	product labels – application rate increase and new site or host
Product:	Pathene 500
Registration Number:	30694
Active ingredients (a.i.):	3-(Trimethoxysilyl)-propyldimethyloctadecyl Ammonium
Chloride [TAC]	
PMRA Document Number : 2195927	

Purpose of Application

The purpose of this application was to register a new material preservative for various fibres and fabrics, building materials and components, roofing materials, and walls and flooring based on the labels of the precedent products from Aegis Environmental Management Inc, AEM 5700 Antimicrobial (Registration Number 15133) and AEM 5772-EP Antimicrobial (Registration Number 28541).

Chemistry Assessment

Pathene 500 is a solution containing the active ingredient 3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride at a nominal concentration of 5.0%. This product has a density of 1.0 g/mL and pH of 5. The chemistry requirements for Pathene 500 have been completed.

Health Assessments

The Pathene 500 is based upon two precedent products. As such, the acute toxicity profile of the Pathene 500 is not expected to change for the current application.

Compared to the registered end-use products, Pathene 500 has a lower guarantee of TAC and no methanol. In addition, no systemic toxicological hazard concerns are identified for TAC and acute health risk mitigation measures are required on the label. Thus, considering the overall weight of evidence, exposures for workers during mixing, loading, application and clean-up, and post-application for workers and homeowners (including children) coming in contact with residues on Pathene 500 treated articles are not expected to be of concern.

A food residue assessment was not required for this application.

Environmental Assessment

The use expansion of 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride and the change in product formulation for Pathene 500 are not expected to lead to an increase in environmental risk. Label mitigating measures are required to reduce exposure of sensitive aquatic environments.



Value Assessment

Eleven laboratory/small-scale efficacy trials were considered to support the use of Pathene 500 as a preservative for various materials (brick, concrete, mat, wallpaper, styrofoam and natural and synthetic textiles). The environmental/humidity chamber test demonstrated that the rate of 1% active ingredient was effective without being excessive. Some of the proposed label uses could not be supported, either because there was no clear pest problem or value for the use, or due to the lack of supporting data and rationales. The use of Pathene 500 as a material preservative is acceptable for the materials tested.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Pathene 500, and has found the information sufficient to register it as a new material preservative for various fibres and fabrics, building materials and components, roofing materials, and walls and flooring.

References

PMRA	Reference
Document	
Number	
2013294	EP- Corrosion Characteristics, DACO: 3.5.14
2116843	2011, File #27AM3651P Determination of Storage Stability, DACO:
	3.5.10
1878380	TGAI- Pathene 500-full document, 14 pp., 2010, DACO: 2.0
2013288	EP- Pathene MB- file #23. AMS 1860 - Product Chemistry Testing for an
	End-use Product Following Product Properties Test Guidelines, Series
	830, 47 pp., 1999, DACO: 2.12.1
1878367	EP and TGAI- Pathene 500- file #6, 6 pp., 2010, DACO: 2.11.2, 3.2.1
1878366	EP and TGAI- Pathene 500- file #5, 20 pp., 2010, DACO: 2.11.3, 3.2.2
1878368	EP and TGAI- Pathene 500- file #1, 4 pp., 2010, DACO: 4.2.1, 4.6.1,
	5.11, 5.8
1878385	EP and TGAI- Pathene 500- file #4, 9 pp, 2010, DACO: 8.2.3.6
2116858	File #34 Antimicrobial Efficacy Testing of Pathene 500, DACO: 10.2.2,
	10.2.3.1, 10.2.3.3
2116859	File #35 ASTM G160- Standard Practice for Evaluating Microbial
	Susceptibility, DACO: 10.2.3.1, 10.2.3.3
2116860	File #36 ASTM D3272 Standard Test Method for Persistance to Growth
	of Mold, DACO: 10.2.3.1, 10.2.3.3
2116861	File #37 Antimicrobial Finishes on textile Materials, DACO: 10.2.3.1,
	10.2.3.3
2116865	File #38 Standard Test Method for Determining Fungi Resistance, DACO:
	10.2.3.1, 10.2.3.3
2116828	Pathene 500- EP- full document, DACO: 10.1
2128047	Pathene 500 efficacy clarification, DACO: 10.2
2134168	Clarifax email message PDF, DACO: 10

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