

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, & 3.13 Application

**Application Number:** 2008-0890  
**Application:** New EP Product Chemistry-Guarantee, Identity of Formulants and Proportion of Formulants  
New to Product Labels-Precautions  
**Product:** AMA 424-C Antimicrobial Agent  
**Registration Number:** 29739  
**Active ingredients (a.i.):** Dazomet (DAZ)  
**PMRA Document Number :** 1905832

### Purpose of Application

The purpose of this application was to register AMA 424-C Antimicrobial Agent, a new material preservative, containing dazomet for use as a material preservative for clay slurries, adhesives, coatings and high viscosity suspensions.

### Chemistry Assessment

AMA 424-C Antimicrobial Agent is formulated as a solution containing dazomet at a nominal concentration of 24 %. This end-use product has a density of 1.14 – 1.15 g/cm<sup>3</sup> and a pH of 13.16. With the exception of the storage stability study that was due to commence July 2009, the chemistry requirements for AMA 424-C Antimicrobial Agent are complete.

### Health Assessments

AMA 424-C Antimicrobial Agent is considered to be of slight toxicity to rats via the oral route (LD<sub>50</sub> = 1650 mg/kg), moderate toxicity to rabbits via the dermal route (LD<sub>50</sub> = 900 mg/kg), and corrosive via inhalation. It is corrosive to the eye and severely irritating to the skin of rabbits. It is considered to be a potential dermal sensitizer.

The proposed uses of dazomet should not result in an increase in potential occupational exposure over registered uses of the active ingredient since the material being treated, the maximum application rate and the application methods fall within the currently registered products. Based on the acute toxicology of the proposed product, personal protective equipment is required and is reflected on the label.

## **Environmental Assessment**

An environmental assessment was not conducted as no additional environmental data were required to support the registration of AMA 424-C Antimicrobial Agent. The proposed rate of application is equivalent or lower than current registered rates for the dazomet and the active is already registered for the same use pattern.

## **Value Assessment**

Efficacy data were submitted to register AMA 424-C Antimicrobial Agent as a new material preservative. Dazomet will be used for the preservation of clay slurries, adhesives, coatings and high viscosity suspensions. The provided data supports these uses.

## **Conclusion**

The PMRA has conducted a review of the available information for this application and has determined that full registration for AMA 424-C Antimicrobial Agent can be supported.

## **References**

### **Studies/Information Provided by Applicant/Registrant**

| <b>PMRA #</b> | <b>Reference</b>  |
|---------------|---|
| 1624042       | 2008, Requested Chemistry Data, DACO: 3.0 CBI                           |
| 1624043       | 2008, AMA-424C Starting Materials, DACO: 3.2.1 CBI                      |
| 1624045       | 1997, AMA-424-C Analytical Methodology, DACO: 3.4.1 CBI                 |
| 1631330       | 1985, Storage Stability Study, DACO: 3.5.10 CBI                         |
| 1631331       | 2008, Waiver Request Dielectric Breakdown Voltage, DACO: 3.5.15 CBI     |
| 1759358       | 2000, Study relative to manufacturing methods for AMA-24, DACO: 3.2 CBI |
| 1759359       | 2009, Storage Stability Study Commitment, DACO: 3.5.10 CBI              |
| 1759361       | 1984, Acute Oral LD50, DACO: 4.6.1                                      |
| 1759362       | 1984, Acute Dermal LD50, DACO: 4.6.2                                    |
| 1759363       | 2009, DACO 4.6.3 Waiver Request, DACO: 4.6.3                            |
| 1759364       | 1984, Primary Eye Irritation, DACO: 4.6.4                               |
| 1759365       | 1984, Primary Dermal Irritation, DACO: 4.6.5                            |
| 1759366       | 2009, Dermal Sensitization Waiver Request, DACO: 4.6.6                  |
| 1624038       | 2008, Overview of Efficacy Studies submitted, DACO: 10.2                |
| 1624039       | 2003, Efficacy Studies using Dazomet Technical, DACO: 10.2.3.2(E)       |

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