

## Evaluation Report for Category B, Subcategory 4.1 Application

**Application Number:** 2005-2232  
**Application:** Application category B, subcategory: 4.1 (Conversion/ Extension of Temporary or Limited-Term Registration)  
**Product:** ADQ 2-J (bactericide)  
**Registration Number:** 26462  
**Active ingredients (a.i.):** Ethanol at 63.2 %  
**PMRA Document Number:** 1467291

### Background

This application was submitted to the PMRA to convert the temporary registration for ADQ 2-J (PCP # 26462) to a full registration. ADQ 2-J was originally given temporary registration in 2000, which has been renewed annually since then. ADQ 2-J was originally submitted for registration to replace paraformaldehyde for the control of bacteria in the tapholes of maple trees. Paraformaldehyde was discontinued in 1991 and illegal use of the product prompted legal action by the PMRA and CFIA against the manufacturer of paraformaldehyde pills for use in tapholes.

It should be noted that the applicant does not manufacture the end use product. ADQ 2-J is bought directly from Commercial Alcohols Inc and is used as is. Absolutely no adulteration to the end use product occurs. The denatured alcohol is not produced primarily as a pesticide, thus it is considered a commodity chemical.

For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

### Purpose of Application

ADQ 2-J is proposed for use as a bactericide on tapping bits and spouts. The application of the product involves immersing the parts directly into the end use product. This application for registration has been categorized as a USC # 3, empty food storage areas, with inhalation and dermal exposure being the primary routes of exposure of the end use product.

## **Chemistry Assessment**

A.D.Q.2-J, is a liquid solution containing ethyl alcohol at a nominal concentration of 63.2%. This end-use product has a density of 0.87 g/mL and pH of 7. The chemistry requirements for A.D.Q.2-J are complete.

## **Health Assessment**

The anticipated acute toxicity for the end use product, ADQ 2-J, is low, regardless of the route of exposure. The acute toxicity by the oral and dermal routes of exposure for ethanol, acetone, and ethyl acetate were all  $LD_{50} > 2000$  mg/kg. The  $LC_{50}$  values for all three components were  $> 2.0$  mg/L, thus the acute inhalation toxicity is also anticipated to be low.

The primary eye irritation of the end use product is not anticipated to be worse than its most irritating component. As such, ADQ 2-J is not expected to exceed severe irritation as a classification for ocular irritation. The primary skin irritation of the end use product is anticipated to be minimal and is not expected to be a dermal sensitizer.

The personal protective equipment (PPE) recommended on the proposed label for ADQ 2-J (goggles and/or face mask, long sleeved shirt, long pants, and footwear) and the restriction for outdoor handling and use is considered adequate to address any potential for occupational exposure. The precautionary statement on the proposed label for ADQ 2-J (unauthorized personnel should not be present during the application or handling of the product) is considered adequate to mitigate any risk due to exposure of bystanders.

As a result of the end use product's volatile nature (evaporation rate = 1.8) and its relatively low boiling point (81° C), we do not anticipate that any significant concentration of denatured ethanol residue will remain in the processed food. There is also a label recommendation to discard the first sap flow after the application of the product. Therefore, no significant dietary exposure to ethanol and/or any of its metabolites is anticipated.

## **Maximum Residue Limit**

Since no significant dietary exposure to ethanol and/or its metabolites is anticipated, promulgation of a Maximum Residue Limit (MRL) was considered unnecessary.

## **Environmental Assessment**

An environmental assessment of A.D.Q.2-J for use to prevent growth of microorganisms on tapping materials when maple trees are tapped was not required since the product will be used in a localized manner (i.e. on tapping material only), and minimal environmental exposure is expected through normal label use. Environmental concerns have been mitigated through adequate statements on the product label.

## Value Assessment

ESAD has no outstanding efficacy data requirements for the conversion of this product to full registration. However, revisions to the label were required, in the directions for use section, and in other sections to reflect the most recent label statement requirements.

## Conclusions

The PMRA has completed an evaluation of the subject application and has found the information sufficient to grant full registration for use as a bactericide on tapping bits and spouts when collecting sap from maple trees.

## Reference List

### A. List of Studies/Information Submitted by Registrant

#### Health Assessment

PMRA 1085374. Fédération des producteurs acéricoles du Québec (2005) *ADQ 2-J draft label dated 14-January-2005*.

### B. Additional Information Considered

#### i) Published Information

##### Health Assessment

PMRA 1466637. CHEMINFO (1995) *Ethyl acetate [CAS No 141-78-6]*.

PMRA 1464077. Commercial Alcohols Inc. (2005) *MSDS: DA-2J denatured ethyl alcohol grade no 2J (derived from 95 % ethyl alcohol)*. Chatham, Ontario.

PMRA 1464075. ECETOC (1998) *Technical Report No. 48(2): Eye irritation reference chemicals data bank (second edition)*. Brussels, Belgium.

PMRA 1464072. HSBBD (2005) *Ethyl acetate [CAS No 141-78-6]*.

PMRA 1464080. IUCLID Dataset (2000) *Ethyl acetate [CAS No 141-78-6]*.

PMRA 1464079. Nakamura, A. *et al.* (1994) *A new protocol and criteria for quantitative determination of sensitization potencies of chemicals by guinea pig maximization test*. *Contact Dermatitis*, **31**:72-85.

PMRA 1464073. OECD (1999) *SIDS: acetone [CAS No 67-64-1]*. Paris, France.

PMRA 1464085. OECD (2004) *SIDS: ethanol [CAS No 64-17-5]*. Berlin, Germany.

ii) Unpublished Information Considered

Health Assessment

None.

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