

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

15 June 2007

Purpose of the Application	To gain approval to amend the <i>Denatured Ethanol Group Standard 2006</i> to permit ethanol denatured with 0.25% tertiary butyl alcohol together with 10 ppm denatonium benzoate to be sold to the general public (and industry) under the existing conditions of this group standard.
Applicant	Damar Industries Ltd
Date Application Notified	2 March 2007
Consideration Date	13 June 2007
Considered by	A Committee of the Authority

1 Summary of decision

- 1.1 The amendment to the *Denatured Ethanol Group Standard 2006* to permit ethanol denatured with 0.25% tertiary butyl alcohol together with 10 ppm denatonium benzoate to be sold to the general public (and industry) under the existing conditions of this group standard is **approved** in accordance with the relevant provisions of the Act, the HSNO Regulations and the HSNO (Methodology) Order 1998 (the Methodology).
- 1.2 Clauses 4(4) and 4(5) of the *Denatured Ethanol Group Standard 2006* are omitted and substituted with the following clauses:
- (4) *Subject to subclause (5), a substance that is available for sale in New Zealand must only be denatured with one or more of the following:*
- (a) 0.5% by volume diethyl phthalate;
 - (b) 0.25% by volume of tertiary butyl alcohol;
 - (c) 1% by volume acetic acid;
 - (d) at least 1.5% and not more than 2% by volume methanol;
 - (e) 15.6 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (15.6 ppm);
 - (f) 10 grams of denatonium benzoate per 1000 litres of ethyl alcohol (10 ppm) together with the addition of at least 1.5% and not more than 2% by volume methanol;
 - (g) 0.25% by volume methyl isobutyl ketone together with 5 – 10 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (5 – 10 ppm);
 - (h) 1% by volume of petrol (unleaded);
 - (i) 0.25% by volume tertiary butyl alcohol together with 10 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (10 ppm).

- (5) *Notwithstanding subclause (4), a substance that is available for sale to the general public—*
- (a) *must only be denatured with the specific formulations described in subclauses 4(e), (g) and (i); and*
 - (b) *should, where practicable, also contain at least 1.56 ppm methyl violet.*

2 Legislative criteria for the application

- 2.1 This decision to amend the *Denatured Ethanol Group Standard 2006* was determined in accordance with section 96C, taking into account matters relevant to the purpose of the Act specified under Part II of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act. To the extent necessary, consideration of the amendment to the *Denatured Ethanol Group Standard 2006* followed the relevant provisions of the Methodology. Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.

3 Application process

- 3.1 The need for this amendment was initially identified through a submission from Damar Industries in November 2006 during consultation on the reassessment of methylated spirits (which proposed to remove formulations of denatured ethanol containing methanol from sale to the general public). In its submission, Damar Industries requested that tertiary butyl alcohol at 0.25% by volume with 15.6ppm of denatonium benzoate be permitted for sale to the general public.
- 3.2 The Agency responded to this submission in their report to the Authority as follows:
“The Agency concurs that the Denatured Ethanol Group Standard should be amended to approve the additional formulation of denatured ethanol for sale to the general public: tertiary butyl alcohol at 0.25% by volume with 10 ppm denatonium benzoate. However, this will be addressed at a future date under part 6A of the HSNO Act”.
- 3.3 On 21 December 2006, the Authority’s Decision on the methylated spirits reassessment was released. The Authority decided that formulations of denatured ethanol containing methanol should not be sold to the general public after 21 June 2007.
- 3.4 Consequently, there are currently only two formulations of methylated spirits that will be available for sale to the general public from 21 June 2007:
- (1) ethanol denatured with 15.6 ppm denatonium benzoate; and
 - (2) ethanol denatured with 0.25% by volume methyl isobutyl ketone and 5-10 ppm denatonium benzoate.
- 3.5 On 2 March 2007, Damar submitted a formal application for the amendment of the *Denatured Ethanol Group Standard 2006*. They proposed that a third formulation of methylated spirits be permitted for sale to the general public, namely ethanol denatured with 0.25% by volume tertiary butyl alcohol and 10 ppm denatonium benzoate.
- 3.6 In accordance with section 96C(1)(h), public notification of the proposed amendment was made on 30 April 2007.

- 3.7 Submissions closed on 12 June 2007.
- 3.8 Various government departments (including the Ministry for the Environment, Ministry of Health, the Department of Labour, the New Zealand Food Safety Authority and the New Zealand Customs Service), Crown entities and interested parties, which in the opinion of the Agency would be likely to have an interest in the application, were notified of the receipt of the application (sections 53(4) and 58(1)(c), and clauses 2(2)(e) and 5) and provided with an opportunity to comment or make a public submission on the application.
- 3.9 No comments were received. However, it is noted that the Ministry of Health responded to the proposal as follows:
- “The Ministry has no objection to the proposed formulation of methylated spirits (ie, ethanol denatured with 0.25% by volume tertiary butyl alcohol and 10 ppm denatonium benzoate) intended for sale to the general public.”*
- 3.10 A public hearing was not required to be held.
- 3.11 The following members of the Authority considered the application (section 19(2)(b)): Professor George Clark (Chair), Dr Kieran Elborough and Ms Deborah Read.
- 3.12 The Agency prepared a consideration paper to aid the Committee in its decision making process. The consideration paper addressed the matters referred to in sections 96B and 96C and the sole submission received during the consultation period.
- 3.13 The information available to the Committee comprised:
- the consideration paper; and
 - the *Denatured Ethanol Group Standard 2006* with proposed changes tracked.

4 Consideration

Purpose of the application

- 4.1 The purpose of the application is to gain approval to amend the *Denatured Ethanol Group Standard 2006* to permit ethanol denatured with 0.25% tertiary butyl alcohol together with 10 ppm denatonium benzoate to be sold to the general public (and industry) under the existing conditions of this group standard.

Sequence of the consideration

- 4.2 In accordance with clause 24, the approach adopted by the Committee was to:
- identify the amendments to the *Denatured Ethanol Group Standard 2006* to be considered by the Authority;
 - consider the matters that the Authority needs to be satisfied with under Part 6A of the Act to amend this group standard;
 - confirm that the Agency’s internal quality assurance process has been undertaken; and

- confirm that the '28 day rule' should not apply to this amendment and it will instead come into force on the date of publication in the Gazette.
- reach a decision on the proposed amendment to the *Denatured Ethanol Group Standard 2006*.

Proposed amendments

4.3 The proposed amendment to the *Denatured Ethanol Group Standard 2006* is to omit clauses 4(4) and 4(5) of the *Denatured Ethanol Group Standard 2006* and substitute them with the following clauses:

- (4) *Subject to subclause (5), a substance that is available for sale in New Zealand must only be denatured with one or more of the following:*
- (a) *0.5% by volume diethyl phthalate;*
 - (b) *0.25% by volume of tertiary butyl alcohol;*
 - (c) *1% by volume acetic acid;*
 - (d) *at least 1.5% and not more than 2% by volume methanol;*
 - (e) *15.6 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (15.6 ppm);*
 - (f) *10 grams of denatonium benzoate per 1000 litres of ethyl alcohol (10 ppm) together with the addition of at least 1.5% and not more than 2% by volume methanol;*
 - (g) *0.25% by volume methyl isobutyl ketone together with 5 – 10 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (5 – 10 ppm);*
 - (h) *1% by volume of petrol (unleaded);*
 - (i) *0.25% by volume tertiary butyl alcohol together with 10 g denatonium benzoate per 1000 litres ethyl alcohol to be denatured (10 ppm).*
- (5) *Notwithstanding subclause (4), a substance that is available for sale to the general public—*
- (a) *must only be denatured with the specific formulations described in subclauses 4(e), (g) and (i); and*
 - (b) *should, where practicable, also contain at least 1.56 ppm methyl violet.*

Requirements of Part 6A of the Act

Public notification

4.4 Before amending a group standard, section 96C(1)(h) requires the Authority to publicly notify—

- (i) the proposal to amend the group standard; and
- (ii) its assessment of the matters required under subsections (1)(a), (b), (c), (d) and (e) in relation to the group standard as proposed to be amended¹.

4.5 A public notice was placed in the main metropolitan newspapers (New Zealand Herald, Dominion Post, Christchurch Press and the Otago Daily Times) indicating the release for consultation of an amendment to the *Denatured Ethanol Group Standard 2006*.

¹ These are the matters that relate to efficiency and effectiveness, nature, type or circumstance of use, international practices and standards, and controls under sections 77, 77A and 77B.

- 4.6 Release of this proposal was also notified on the ERMA New Zealand website on 30 April 2007. The consultation document was available from the consultation page of the website from that date.
- 4.7 As required under the Act, thirty working days were allowed from the release of the proposed amendment to the *Denatured Ethanol Group Standard 2006* on the website for the receipt of submissions. The submission period ran from 30 April 2007 to 12 June 2007.
- 4.8 The consultation document included a submission form and explained the process for making a submission. No submissions were received.

More efficient and effective

- 4.9 Before amending a group standard, sections 96C(1)(a), (b) and (c) require the Authority to be satisfied that amending the group standard is a more efficient and effective way of managing the risks of all the hazardous substances in the identified group.
- 4.10 The proposed amendment to the Denatured Ethanol Group Standard 2006 (permitting the use of 0.25% tertiary butyl alcohol together with 10ppm denatonium benzoate in methylated spirits formulations sold to the general public) is considered to be a more efficient way of managing the risks associated with denatured ethanol. This is because the proposal amounts to the most efficient use of resources and, in addition, the benefits outweigh any costs. Damar, the primary New Zealand supplier of methylated spirits to the general public², indicated that it is most efficient for them to buy only one type of denatured alcohol that is ready for sale to industrial users, and then further denature that which is sold to the general public with the addition of a small amount of denatonium benzoate. Thus, the only formulation that will be available for them to do this from 21 June 2007 is ethanol denatured with 0.25% by volume methyl isobutyl ketone together with 5-10 ppm denatonium benzoate. However, methyl isobutyl ketone is not compatible with many of the industrial uses of methylated spirits, such as Damar's waterborne roadmarking formulations (which use substantial quantities of denatured alcohol). Furthermore, ethanol denatured with tertiary butyl alcohol is readily available in New Zealand whereas the alternative denatured with methyl isobutyl ketone is available only in very limited supply.
- 4.11 The proposed amendment to the Denatured Ethanol Group Standard 2006 (permitting the use of 0.25% tertiary butyl alcohol together with 10ppm denatonium benzoate in methylated spirits formulations sold to the general public) is also a more effective way of managing the risks than existing formulations having regard to the overriding purpose of the HSNO Act (the protection of the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances³). The hazard classification of tertiary butyl alcohol is 3.1B, 6.1E, 6.3B and 6.4A. Thus, tertiary butyl alcohol has only irritancy classifications (6.3B, 6.4A) in addition to ethanol (3.1B, 6.1E, 9.1D). These irritancy classifications do not impart themselves onto the denatured

² Damar supplies approximately 80% of the methylated spirits sold to the general public under the following trade names: Andrew, Caltex, BP, Budget, Butlers, Carters, Placemakers and Resenes. This equates to approximately 325,000 kg or 400,000 litres annually.

³ Section 4 HSNO Act

ethanol at 0.25%. Thus, this additional combination of denaturants permitted for sale to the general public, 0.25% tertitary butyl alcohol together 10 ppm denatonium benzoate, will render the ethanol un-potable while not conferring any additional hazardous properties to the ethanol. This amendment, therefore, is considered to meet the purpose of the Act.

One set of conditions for similar nature, type, or circumstance of use

- 4.12 Before amending a group standard, section 96C(1)(e) requires that the Authority be satisfied that if the group standard applies to more than 1 hazardous substance or product, all the hazardous substances or products have a similar nature, or are of a similar type, or have similar circumstances of use, such that the risks of the group of hazardous substances or products can be effectively managed by 1 set of conditions.
- 4.13 The proposed amendment would have little effect on the similar nature characteristic of substances that are currently by this group standard. The *Denatured Ethanol Group Standard 2006* will continue to only cover denatured ethanol; that is solutions of more than 90% ethanol that have been denatured to render unsuitable for human consumption. Thus, all of the substances covered by this group standard will continue to have similar chemical and physical properties, as well as continuing to share the key property of being denatured (i.e. rendered unfit for human consumption). The proposed amendment will merely allow a further combination of denaturants to be used in formulations of methylated spirits to be sold to the general public (and industry).
- 4.14 In summary, the proposed amendment merely adds one more formulation of denatured ethanol to those approved for sale to the general public (and industry) under the Group Standard:
- 0.25% tertiary butyl alcohol by volume together with 10 ppm denatonium benzoate.

International practices and standards

- 4.15 Before issuing or amending a group standard, section 96C(1)(f) requires that the Authority consider the best international practices and standards for the safe management of hazardous substances and products.
- 4.16 The Agency has no reason to believe that the use of 0.25% tertiary butyl alcohol together with 10 ppm denatonium benzoate as a permitted combination of denaturants for denatured ethanol sold to the general public reflects anything other than best international practice.

Controls under sections 77, 77A and 77B

- 4.17 Before issuing or amending a group standard, section 96C(1)(g) requires that the Authority consider the types of controls appropriate for the group in accordance with sections 77, 77A and 77B.
- 4.18 The Agency does not consider it is necessary to consider the variation of controls under sections 77, 77A and 77B as the conditions within this group standard will remain unchanged from those previously decided upon.

‘28 Day Rule’

- 4.19 It is proposed that the ‘28 day rule’ will not apply to this amendment and, instead, it should come into force on the date of publication in the *Gazette*. This proposal has been notified to the Minister. Waiving the ‘28 day rule’ is considered to be reasonable in this case by the Agency, as it would allow the amendment to come into force on or before 21 June 2007, where the presently prevalent formulation of denatured ethanol will no longer be permitted for sale to the general public (i.e. ethanol denatured with 1.5-2% methanol together with 10 ppm denatonium benzoate).

Quality Assurance Process

- 4.20 As required by the Internal Quality Assurance System for the amending of deemed regulations, approved by the Authority in August 2006, this amendment was formally ‘certified’ by Manager, Legal & Risk stating compliance with the following matters:
- 4.20.1 The amendment (and the deemed regulation) is within the empowering provisions of the Act (namely, section 96B).
 - 4.20.2 The amendment has no effect on the principles of the Treaty of Waitangi.
 - 4.20.3 The amendment has no effect on the rights and freedoms guaranteed by the New Zealand Bill of Rights Act 1990 and Human Rights Act 1993.
 - 4.20.4 The amendment complies with the privacy principles in the Privacy Act 1993.
 - 4.20.5 The amendment has no effect on New Zealand’s international obligations.
 - 4.20.6 The amendment will come into force on the date of publication in the *Gazette*.
 - 4.20.7 The wording of the amendment and the associated *Gazette* notice have been drafted by Manager, Legal & Risk and raises no issues which need to be drawn to the attention of the House by the Regulations Review Committee pursuant to Standing Order 378.

5 Decision

- 5.1 The Committee, having considered the application to amend the Denatured Ethanol Group Standard 2006 made under section 96B of the Act, approves the proposed amendment to the Denatured Ethanol Group Standard 2006 and to its publication in the New Zealand *Gazette*. Furthermore, the Committee considers it appropriate that the ‘28 day rule’ is waived and that this amendment come into force on the date of publication in the *Gazette*.

Professor George Clark

Date: 15 June 2007

Chair

