



**Transfer of
Substances**

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Summary of Submissions: Group Standards for Embalming Products

April 2006

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1. Introduction

1.1 Background to the Consultation

This document reports on the submissions that were received on proposals to establish group standards for embalming products. Group standards are a form of hazardous substances approval under Part 6A of the Hazardous Substance and New Organisms (HSNO) Act 1996.

ERMA New Zealand released for public consultation eight group standards for embalming products on 1 February 2006. Consultation closed on 17 March 2006. Notification of this consultation was via public notice in the four main metropolitan newspapers and the ERMA New Zealand web site.

The consultation document and draft group standards,¹ or a letter advising of the availability of these documents, were provided to approximately 12 parties who were considered likely to have an interest in this consultation. This included companies who notified embalming products under the Toxic Substances Act 1979, other industry sectors and associations, government departments, enforcement agencies and territorial authorities. The documentation was also available on the 'consultation page' of the ERMA New Zealand website.²

Three submissions were received, with one submitter requesting a hearing. Following further consultation with this submitter, their points of concern were addressed, and no hearing was required.

The comments made by submitters are summarised in Section 2, along with the Agency's response. Where a submitter's comment resulted in a change to the group standard proposal, this is indicated in the table. Each submitter is identified numerically, and the name of the submitter given at the beginning of the table.

The main points made in the submissions were:

- That labelling, safety data sheet and packaging requirements should be fully aligned with the GHS and UN;
- A request that persons holding NZ Embalming Certificates be deemed approved handlers;

This summary of submissions has been provided to all parties who made a submission on the embalming product group standards, major notifiers of embalming products³ and to the Hearings Committee of the Authority.⁴ It is also available from the ERMA New Zealand web site:

<http://www.ermanz.govt.nz/hs/groupstandards/standards/embalming.html>. A copy will be provided to any other interested party on request.

¹ Provided electronically on CD. No paper copies were distributed unless specifically requested.

² These documents remain available on the ERMA New Zealand web site:
<http://www.ermanz.govt.nz/consultations/gs/anp.asp>.

³ Notifiers with only a few NOTS have been advised by letter of the availability of this summary of submissions.

⁴ The Authority is the decision making body of ERMA New Zealand. It is made up of up to eight members appointed by the Minister for the Environment. The Hearings Committee is made up of selected members of the Authority with relevant experience in the subject area being considered for approval under the HSNO Act.

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Email NOTS@ermanız.govt.nz and enter “Embalming Products Summary of Submissions” in the subject line.

1.2 Moving NOTS

When group standards were released for consultation, notifiers were given a list of their products notified under the Toxic Substances Act 1979 (NOTS) associated with each standard. If a NOTS had been incorrectly assigned by ERMA New Zealand to a specific group standard, the notifier is able to reassign it to the appropriate group standard. If a notifier moves a NOTS from one group standard to another (or removes the NOTS from a group standard because they determine it to be non-hazardous) we asked in the consultation document for the notifier to advise us.

To assist notifiers reassign their NOTS, ERMA New Zealand has developed an excel template that can be accessed by emailing us at: NOTS@ermanız.govt.nz.⁵ Once the notifier has recorded on the template the NOTS that need to be moved, they must email the completed template back to us for processing. This template will be available up until 30 June 2006.

Where a submitter requested that a NOTS be moved from one group standard to another, this information is not provided in Section 2, because it is specific to that notifier and in some cases could result in the disclosure of confidential information. This moving of NOTS is independent of the scope and conditions of a group standard, and consequently has not resulted in any change to any of the group standard proposals. Where notifiers requested as part of their submission that NOTS be reassigned, we will move them to the group standard(s) they indicated, and they do not need to use the template unless they have further changes to make.

As a result of the consultation, and notifiers reviewing the placement of their NOTS in group standards, it has been necessary to develop an additional group standard to capture NOTS that did not fit within the original group standard proposals.⁶ In addition, a small number of NOTS will be transferred individually because of their hazard properties.⁷

1.3 Overlap of Consultation with Chemicals of Concern

The group standard proposals included a condition requiring notification to the Authority if a substance contains a Chemical of Concern. A separate consultation on the concept of developing a list of chemicals of concern was undertaken concurrently with the group standards consultation. Submissions received on the chemicals of concern provision of group standards are included in the summary of submissions from the Chemicals of Concern

⁵ The template and process operate in such a way that requires notifiers to contact ERMA New Zealand. This is to safeguard data confidentiality.

⁶ Hazardous Substances (Embalming Products, Corrosive [8.2C]) Group Standard Notice 2006.

⁷ Refer: <http://www.ermanız.govt.nz/hs/groupstandards/individual.html>.

consultation. This summary of submissions will shortly be available from: <http://www.ermanz.govt.nz/hs/groupstandards/coc.asp>. As a result of this consultation, group standards for embalming products will no longer contain a Chemicals of Concern notification condition.

1.4 Combining Group Standards

As group standards have been finalised following consultation, we have found it advantageous to combine or “roll-up” certain group standards by:

1. application type, and/or
2. hazard.

For embalming products, the Class 3.1B and 3.1C flammable group standards have been combined, and renamed *Embalming Products (Flammable) Group Standard*.

From the consultation on other sets of group standards, submissions were received requesting that group standards be combined to reduce the number industry would otherwise have to deal with. A preference for fewer group standards was confirmed in separate discussions with a number of industry sectors. We also recognised the advantages of rolling up group standards from a management and administrative perspective, provided that, in so doing, the combined group standards were no less user-friendly or the conditions any more or less onerous to comply with.

The rolling-up of group standards has been possible because of the template format on which they are based. Importantly, combining group standards has not meant that there are further requirements on a substance approved under that combined group standard than would have applied if the individual group standards were kept separate. It does, however, mean that, for some conditions, various options are presented, and the relevant option has to be chosen depending on the hazard of the substance concerned.

Parties who read the original group standard proposals will also notice that the group standards have been reformatted to simplify the numbering scheme and to improve their readability and presentation. In addition, some editing and word-smithing has been carried out. Again, this reformatting and editing has not changed the requirements of any aspect of the group standard.

1.5 Approval of Group Standards

The Hearings Committee of the Authority is responsible for considering and approving group standards. Copies of amended group standards will be provided to the Committee for consideration.⁸

As noted earlier, a copy of this summary of submissions has been provided to the Hearings Committee. Although Section 2 of this summary may indicate that an amendment has been made to the group standards as consulted on, it is the Hearings Committee that is the decision maker. That is, the Agency’s recommendation that a group standard be changed as indicated in Section 2 requires final approval by the Authority.

The Hearings Committee is scheduled to consider the group standards for *Embalming Products* on 4 May 2006. A notice of their decision will be placed on the ERMA New Zealand web site as soon as practicable after the consideration.

⁸ Group standards that were consulted on will be amended as indicated in Section 2.

Because we have identified a need to undertake further consultation on key matters concerning group standard proposals, any decision of the Hearings Committee will only be an interim (provisional) decision at this time (see following section).

1.6 Further Consultation Required

Since the release of the original group standard proposals, there is a need for further consultation to:

1. address matters inadvertently omitted from some group standards, particularly with respect to tracking of the most toxic (Class 6.1B) substances and the labelling of hazardous ingredients; and
2. seek further feedback on certain points raised by submitters from the initial consultation.

A copy of this consultation document is available from the ERMA New Zealand web site: <http://www.ermanz.govt.nz/consultations/gs/addgs.asp>.

As a consequence of undertaking further consultation, there will be a further consideration by the Hearings Committee to address these additional matters and give final approval to the group standards proposed. This consideration is scheduled for June 2006.

1.7 Gazetting of Group Standards and Staged Implementation

Following final approval by the Authority, group standards will be established by publication of a notice in the *New Zealand Gazette*, and will come into force on 1 July 2006. All NOTS that fit the scope of a group standard will become deemed approved hazardous substances at this time.

A full list of group standard proposals, for embalming products and other product types, is available from: <http://www.ermanz.govt.nz/hs/groupstandards/list.html>.

Coinciding with the transfer of NOTS will be the commencement of a period of staged implementation. The details of staged implementation are given in Annex 1.

After 1 July 2006, ERMA New Zealand will write to all notifiers with a list of their NOTS that are deemed approved under group standards and the HSNO approval number for each group standard.

2. Submitter's Comments and Agency Response and Recommendations

Code to Submitters

No.	Submitter
1	G S Shapland Ltd
2	NZ Embalmers Association
3	Regal Manufacturers Limited

Submitter	Submission	Agency response and recommendation	Group standards amended
Conditions for labelling			
1	The labelling requirement to have the name, full address and telephone number for the NZ manufacturer, importer or supplier; and a 24 hour emergency telephone number is unreasonable. We request you remove this requirement.	This condition is based on the HSNO regulations, but had been made more stringent in a number of aspects. The condition will be amended to align exactly with the current regulatory requirements. Note the need for a 24 hr emergency phone number is a requirement of the Emergency Management Regulations for certain hazard classifications.	Yes – amend to align with HSNO regulations
1	We also suggest that you allow compliance with the HSNO identification regulations.	Group standards have been amended to allow for compliance with the labelling requirements of the group standard via compliance with the HSNO Identification, Emergency Management and Disposal regulations.	Yes – new condition included to provide for an alternative means of compliance.
1	A condition of using a Group Standard should be the requirement to notify ERMNZ of the trade name of the product and provide the name, full address and telephone number for the NZ manufacturer, importer or supplier; and a 24 hour emergency telephone number. This information could be available to emergency services without imposing additional costs on industry. We suggest a register to be held by ERMNZ of the emergency contact details. This information could then be made available to emergency services.	The concept of developing and maintaining a register of all substances approved under a group standard is contrary to the philosophy of group standards, which was based on industry being able to manufacture and import substances under a group standard without the requirement to advise ERMA New Zealand. Other industries have indicated they would be opposed to such a requirement, as it will impose significant cost on their business. The requirement for emergency information has been adopted from the Emergency Management Regulations. As noted above, these regulations can be used as an alternative means of compliance.	No
1	The group standards permit compliance with overseas	The 2010 date has been set based on current expectations of when	No

Submitter	Submission	Agency response and recommendation	Group standards amended
	labelling requirements as adequate until 31 December 2010. This date is premature as it is unlikely other countries such as Australia and Canada will have implemented GHS by then.	the GHS will be adopted internationally. Any review of this date based on any delay in implementation of GHS globally would only be contemplated in response to that circumstance occurring. To review and amend the date now would be premature given the current expectation of GHS adoption globally.	
Conditions for safety data sheets			
1	The information in the group standards for safety data sheets is not the same as the GHS. The NZ requirements should be aligned fully with the GHS. Having to produce NZ specific SDSs will impose additional unreasonable costs.	Aside from the requirement for local regulatory information (e.g. the name of the group standard and/or HSNO approval number and the HSNO classification), the SDS provisions of the group standard are consistent with the GHS. The GHS guidance on the preparation of SDS do require relevant national information on the regulatory status of a substance (refer Annex 4, Section A4.3.15.1 of the <i>GHS System of Classification and Labelling of Chemicals</i> (2005)). The group standard provisions for SDS are also fully consistent with the NZCIC Code of Practice for SDS. As set out in Annex 1, the staged implementation provisions provide 2 years before SDS must to be compliant with the conditions of the group standard.	No
1	We request that compliance with the HSNO identification, emergency management and disposal regulations be allowed for safety data sheets.	The group standards set out the requirements for SDS that are consistent with the GHS, which are based on the 16 header format. This format is now recognised as international best practice. The HSNO regulations, in contrast, do not stipulate the 16 header format. For this reason, we will not provide an alternative means of compliance by way of the HSNO regulations. ERMA New Zealand wishes to encourage compliance for all SDS on the 16 header format.	No
Conditions for packaging			
1	The requirement to have a group standard compliant label on the outer package of a multiple package is unreasonable and contrary to international transport requirements.	This was not the intent of this condition, although it is acknowledged that the condition as written in the group standard was poorly drafted. This has been amended, and now reads: <i>Where a substance is labelled in compliance with subclauses (1) to (9), but some or all of the required information is obscured by outer packaging, the outer packaging of the substance must bear: the labelling or marking required by:</i> a) subclauses (4)(a) and (b); or	Yes – amend to align with HSNO regulations

Submitter	Submission	Agency response and recommendation	Group standards amended
		<p>b) <i>the Land Transport Rule; or</i> c) <i>the Civil Aviation Rule; or</i> d) <i>the Maritime Rule.</i></p> <p>This is identical to the current provisions of the HSNO (Identification) Regulations. Again, as noted above, the identification regulations can be used as an alternative means of compliance.</p>	
1	The requirement for substances with classifications of 8.3A, 6.5A, 6.6A, 6.8A, or 6.9A to be PG III is unreasonable and contrary to international packaging requirements. We request that the group standard be amended so that it does not require a higher standard of packaging than the UN.	The packaging requirements of the group standards have been amended so that they align with the UN Model Regulations for the transportation of dangerous goods. 6.5A, 6.6A, 6.7A, 6.8A or 6.9A will no longer trigger PGIII. Refer to http://www.ermanz.govt.nz/consultations/gs/addgs.asp . We will also remove the requirement for 8.3A to be packaged to PGIII.	Yes – amend to align with UN Model Regulations
1	We have concerns over schedule 4 packaging being applied to inner packages (i.e. bottles). The HSNO regulations permit a statement on the package that it does not comply. We request that this exemption is included in the group standards.	Whilst the packaging regulations allows for small quantities of substances of certain hazard classes not to have to comply with schedule 4 of the regulations, we have not applied this to the embalming products group standards. This is because this clause in the packaging regulations was specifically included to cater for small packages of consumer products available from retail outlets. Embalming products are not of this nature.	No
Approved handler			
2	We request that those holding NZ Embalmer Practising Certificates be exempted from the approved handler requirements. To be a full practicing member embalmers are required to complete a training course and also complete 5 embalming cases per year. Practising certificates are reissued every two years.	<p>The staged implementation provisions of group standards allow a person with the necessary experience to deem themselves as an approved handler for a period of two years (refer Annex 1).</p> <p>We agree that there is considerable benefit in putting in place a system whereby a person holding a current NZ Embalmer Practising Certificate is automatically deemed to be an approved handler. We wish to progress this initiative with the NZ Embalmers Association during the two year staged implementation period, acknowledging that, and pending a positive outcome, this would require a future amendment to the group standards.</p> <p>Alternatively, a test certifier could assess the course and training that is involved in obtaining a Practising Certificate as fulfilling the test certification requirements to be an approved handler. Under this option, no amendment to the group standard would be necessary.</p>	No, not at this time. A future amendment may be possible following further discussion with the industry.

Submitter	Submission	Agency response and recommendation	Group standards amended
3	Those holding NZ Certificate in Embalming should be deemed to have an approved handlers certificate as per the vet practising certificates. The Weltech course has already been approved by a test certifier as meeting the personnel qualification regulations. They must do 10 hours of training every two years and have a witnessed declaration that they complete 5 embalmings a year.	See response above.	No
Other conditions			
1	Protective equipment The requirement that a person does not come into contact with a substance is impractical and unreasonable. Should be amended to; "Is exposed to the lowest practicable concentration of the substance. This concentration shall not cause any adverse health effects and at no time exceed the WES."	The condition as written is adopted directly from the <i>Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations</i> . This condition is non prescriptive, thereby allowing for a variety of means of compliance.	No
1	Passenger service vehicle restrictions These appear to be unreasonable low for low hazard substances, especially as up to 10L of flammable liquids are allowed.	The passenger service vehicle limits are adopted from the HSNO regulations. In the case of a 6.1C substance, the restrictions are driven by the toxicity of the substance, not its flammability. The restrictions only apply when a substance is carried in the main (public) carriage of a vehicle, such that, in the event of a spillage, there may be public in the immediate vicinity who might be exposed. The limits do not apply to a substance that is carried in the principle luggage compartment of a passenger service vehicle.	No
1	For fragrance materials it is unreasonable to impose compliance with the IFRA standard without providing a copy of it for viewing. We suspect it will be restrictive and impose additional costs.	The fragrance industry supports compliance with the International Fragrance Association (IFRA) Code, which is generally considered to be best international practice. This requirement is a condition of the Food Additives and Fragrance Materials Group Standard (see http://www.ermanz.govt.nz/hs/groupstandards/standards/fafm.html , not of the Embalming Products Group Standard. A copy of the IFRA Code of Practice is available from http://www.ifraorg.org/GuideLines.asp .	No amendment required
3	We are happy with the tracking provisions provided they apply to all equivalent competitors products.	Tracking is required of every product that has an acute toxicity hazard (HSNO 6.1B). This condition is included in the three Embalming Products Group Standards that cover 6.1B substances. The condition will apply regardless of the supplier or distributor of the	No

Submitter	Submission	Agency response and recommendation	Group standards amended
		product.	
3	Disposal: For clarification it should be spelt out this section does not apply to waste products which have the appropriate permissions form the local authority to enter the drainage system.	<p>The Embalming Products Group Standards do not include conditions for the management of <i>hazardous waste</i>. However, the disposal conditions do apply to any residual waste substance that is intended for disposal. To clarify the distinction, once an embalming fluid is mixed with bodily fluids and diluted it is no longer a <i>hazardous substance</i> but is a waste material, which may or may not be hazardous depending on the extent of dilution.</p> <p>The management of hazardous waste is being addressed at a policy level by the Ministry for the Environment (refer http://www.mfe.govt.nz/issues/waste/hazardous/index.html). For the disposal of waste to sewer, this is often managed by local government via compliance with the model trade waste bylaw.</p>	No
Product allocation to group standards			
3	We have a number of products we think are non hazardous that should be removed from the subsidiary hazard group standard.	<p>We have reviewed the products concerned, and have communicated directly with this submitter on their hazard status.</p> <p>Note that under the group standards framework, a manufacturer or importer is responsible for self-classifying their substance and placing it in the appropriate group standard. A corollary to this is that a manufacturer or importer can also conclude that their product is non-hazardous under HSNO.</p> <p>For manufacturers and importers who prefer not to self-classify or who wish to get confirmation from ERMA New Zealand of their self-classification, we will be offering a product classification service. This will be similar to the Status of Substance (SOS) process currently provided by ERMA New Zealand.</p>	No amendment required

Annex 1: Staged Implementation for NOTS

All group standards will contain provisions for staged implementation. These provisions will apply to notified toxic substances (NOTS) that are transferred from the transitional provisions to the main framework of the HSNO Act. The purpose of staged implementation is to allow importers, manufacturers and users of embalming products a period of time to become familiar with the new group standard conditions, and to progressively implement these conditions.

The key dates for staged implementation are set out in the table below.

1 July 2006	NOTS transferred to HSNO. Six month period commences before any group standard conditions apply. Persons continue to comply with current regulatory requirements
1 January 2007	Approved handler test certificates required (either deemed ¹ or full five year certificate) ² Compliance required with all group standard conditions, with the exception of conditions for: <ul style="list-style-type: none"> ➤ Test certificates for hazardous substance locations² ➤ Stationary bulk container systems ➤ Emergency management² ➤ Signage² ➤ Labelling, safety data sheets and packaging
1 July 2007	Compliance required with emergency management conditions ² (fire extinguishers, response plans and secondary containment)
1 January 2008	Test certificates required for hazardous substance location ²
1 July 2008	Report required from test certifier for existing stationary bulk container systems Compliance required with conditions for: <ul style="list-style-type: none"> ➤ Labelling^{3,4} ➤ Safety data sheets ➤ Signage² ➤ Packaging
1 January 2009	Full 5 year approved handler test certificate required
1 July 2009	Test certificate required for existing stationary bulk container systems
31 December 2010	Product labels are compliant to this date if they comply with the labelling requirements of Europe, Australia, USA or Canada ⁴

1. A person with two years experience in handling hazardous substances can deem themselves as an approved handler to 31 December 2008.
2. Staged implementation provisions may not apply for approved handler test certificates, location test certificates, emergency management and signage if compliance is already required for a similar class of hazardous substance (see section 'If existing HSNO Provisions Apply').
3. Other than for substances that comply with the labelling requirements of Europe, Australia, USA or Canada.
4. A group standard condition proposes that a 4 year period be allowed for compliance with labelling, provided that the product labels comply with the regulatory requirements for labelling that apply in these countries. This provision will apply to new products as well as NOTS.

If Existing HSNO Provisions Apply

Where existing HSNO provisions apply for approved substances (e.g. dangerous goods transferred on 1 April 2004), then there will be no staged implementation for an approved handler test certificate, location test certificate, emergency management or signage if persons are already required to hold test certificates or have emergency management provisions and signage in place for the same class of substance. In this situation, compliance should have already been achieved. Therefore, full compliance for the NOTS is required by 1 January 2007. All other provisions for staged implementation (e.g. labelling, packaging etc) will apply as set out above. Full staged implementation (including for test certificates, emergency management and signage) will apply if **new classes** of substances are transferred as NOTS.

For example, a person who imports or manufacturers a class 3.1 flammable NOTS will not receive staged implementation for test certificates, emergency management or signage if they also store class 3.1 flammables that are already HSNO approved substances and for which they require test certificates, emergency management and signage. If, however, they are manufacturing or storing NOTS that are of a different class (e.g. class 5 oxidising substances), then staged implementation will apply as set out above, but only for that new class.

Further Information

Further details on staged implementation and general compliance requirements will be provided to notifiers in the lead-up to transfer. For other compliance information, you can contact the ERMA New Zealand Hazardous Substance Compliance Line, by:

Phone: 0800 376 234, or

Email: dginfo@ermanz.govt.nz.