ERMA New Zealand

Evaluation and Review Report

Application for Approval to Import or Manufacture Micron 77 for Release

Application Number: HSR09023

Executive Summary

Background information

- Akzo Nobel Coatings Ltd is seeking approval to import Micron 77 as an antifouling paint for use on boats.
- Micron 77 is proposed to be available in four different formulations: Red, Black, Blue and Navy Blue.
- Antifouling paints are applied to the hulls of vessels to prevent the build up of aquatic organisms on the hull surface by the slow release of biocides. Antifouling paints are currently used on docks, fishnets and buoys.
- As a result of the intended release of the biocide(s) from the antifouling paints, they have the potential to accumulate in the aquatic environment to levels that can be toxic to non-target aquatic organisms.
- Given the proposed use pattern of the Micron 77 formulations, no quantitative human or environmental modeling has been carried out.
- There are currently antifouling paints approved for use in New Zealand, containing either copper oxide or copper pyrithione as the primary biocide. The majority of these antifouling paints approved in New Zealand were transferred to the HSNO regime in 2004 under the transfer of Timber Preservatives, Antisapstains and Antifouling Paints to the full framework of the HSNO Act. However, a number have been approved via applications under Part 5 of the HSNO Act since 2001.
- Antifouling paints as a group are currently on the Chief Executive Initiated Reassessment List.

Overseas regulatory authority reviews

- The Agency notes that copper oxide belongs to the list of existing active substances to be examined under the review programme as an active ingredient in antifouling products by the European Union (EU, 2007). In the past, the Dutch Government had proposed to forbid the application of copper-based antifouling preparations on pleasure crafts in the Netherlands in 1999; however, the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) (European Commission, 2003) on the Dutch regulatory action was critical due to uncertainties associated to whether the scientific justification provided was sufficient.
- The Agency notes that copper pyrithione has been evaluated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The Office of Chemical Safety of the Department of Health and Ageing has considered the toxicological aspects of copper pyrithione, and advised that in respect to human health there are no toxicological objections to the approval of this chemical. The APVMA is satisfied that the proposed importation and use of copper pyrithione would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use (APVMA, 2005). To the Agency's knowledge, the use of copper pyrithione as an active biocide in antifouling paints has not been forbidden by any regulatory organisation overseas. In addition, it is the most used booster biocide in combination with copper oxide in antifouling products in Japan (Okamura and Mieno, 2006).

Classification

- The Agency has classified the Micron 77 formulations based on their composition and the effects of their components. All four formulations have the same hazard profile. The classifications for all Micron 77 formulations are summarised in the table below:

Hazardous Property	Applicant's Assessment	Agency's Assessment
Flammable Liquid	3.1C	3.1C
Acute Toxicity (Oral)	6.1D*	6.1D
Acute Toxicity (Dermal)		6.1E
Acute Toxicity (Inhalation)		6.1D
Skin Irritancy	6.3A	6.3A
Eye Irritation/Corrosion	6.4A	8.3A
Carcinogenicity	6.7B	6.7B
Reproductive/developmental toxicity	No	6.8B
Reproductive/developmental toxicity via lactation	6.8C	6.8C
Target Organ Toxicity	6.9B	6.9B
Aquatic Ecotoxicity	9.1A	9.1A
Ecotoxic to terrestrial vertebrates	9.3B	9.3B

*The applicant has provided an overall acute toxicity classification without determining whether it is oral, dermal or inhalation.

- The applicant classified the formulations of Micron 77 as eye irritants (6.4A) based on the preliminary advice provided from the Agency. However, the Agency has reviewed the formulations and considers that, in the absence of formulation data, the 8.3A classification should be assigned.
- Similarly, the applicant has not classified Micron 77 as a reproductive/developmental toxicant based on the preliminary advice provided. However, the Agency considers there was an error in this advice and the 6.8B classification should have been included.

Controls

- The Agency has proposed that the default controls for all Micron 77 formulations be modified, such that:
  - the control requiring Tolerable Exposure Limits (TELs) to be set is deleted (T1);
  - Workplace Exposure Standard (WES) values have been set for components of the Micron 77 formulations (T2);
  - no Environmental Exposure Limits (EELs) are set at the present time and any default values are deleted (E1);
  - the control requiring an application rate to be set is deleted (E2);

- further controls regarding stationary containment systems, secondary containment and unintended ignition of flammable substances are added; and
- the approved handler and tracking controls are deleted.

- The Agency notes that the risk assessment was completed based on the use of Micron 77 formulations as antifouling paints. Consequently, the Agency proposes the following additional control:
    - No person may use Micron 77 for any purpose other than as an antifouling paint to prevent, by the slow release of biocides, the build up of aquatic organisms on the hulls of vessels or other surfaces in contact with water.

- The Agency considers that it is appropriate for certain variations to be made to the default controls. These variations are discussed in Section 4 of this E&R Report and further in Appendix 3.

Risk Assessment

- The Agency considers that, with the default and additional controls in place, there are ***negligible*** risks to human health and to the environment and no potentially significant costs associated with the release of Micron 77. Therefore, the Agency considers that it is evident that the benefits of releasing Micron 77 outweigh the costs and the application may be approved in accordance with clause 26.

Table of Contents

1. The Application

1.1. The application details are summarised in Table 1.1.

Table 1.1 Details of the application HSR09023

Application Code	HSR09023
Application Type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application Sub-Type	Notified - Category A
Applicant	Akzo Nobel Coatings Ltd
Date Application Received	6 May 2009
Submission Period	19 May 2009 – 1 July 2009
Consideration Due	12 August 2009
Postponement of Consideration	Due to delays in completing this report the consideration was postponed
Consideration	1 October 2009
Purpose of the Application	To import Micron 77 as a single pack anti-fouling paint for use on boats.
Parties Notified	On 19 May 2009 the following were notified: • the Minister for the Environment, • interested parties listed in Appendix 5, • the public[1].
Submissions received	One submission was received from the Ministry of Agriculture and Fisheries. The submitter would like the substance approved for importation with the requirement of a specific label statement on all cans: "When carrying out hull maintenance, or preparation to replace the coatings, it is important this be carried out in an area or facility so that no residues including those in waste wash-water are released to the sea".
ERMA staff involved in the assessment	Jo Prankerd - Advisor (Hazardous Substances) Tonderai Kaitano – Advisor (Hazardous Substances) Apostolos Koutsaftis - Advisor (Hazardous Substances) Patrick Gemmell - Senior Advisor (Kaupapa Kura Taiao).
ERMA staff member responsible for review	Noel McCardle - Senior Advisor (Hazardous Substances).
Information assessed	• The application • A range of references supplied to ERMA NZ by the applicant • A confidential appendix.

[1] The application was advertised in the Dominion Post, the New Zealand Herald, The Christchurch Press and the Otago Daily times and placed on the ERMA New Zealand website.

1.2. This report should be read in conjunction with the attached Supplementary Information which contains information on:

- The legislative criteria.
- Approach to risk assessment.
- Decision pathway used in the decision process.

1.3. The Agency considers that it accessed sufficient information to undertake a full assessment of the substance from a scientific and technical perspective and that there are no other significant uncertainties that need to be considered by the Authority.

1.4. The Agency notes that the importation, transport, use and disposal of the substance will also be subject to other legislation such as the Health and Safety in Employment Act 1992, the Resource Management Act 1991 and the Land Transport Act 1998.

2. The substance, its lifecycle and its hazardous properties

The substance and its lifecycle

2.1. Micron 77 is a substance that will be imported into New Zealand as an antifouling paint. It is intended for use on boats and will be applied by brush and roller or by air/airless spray. Micron 77 will be available in four different colours; red, blue, black and navy.

2.2. The applicant has provided the following details about the lifecycle of the Micron 77 formulations.

2.2.1. **Importation**. Micron 77 will be imported into New Zealand in correctly labelled cans or paint pails. Micron 77 will be imported in typical shipping containers with other paint products.

2.2.2. **Storage/ transportation.** Micron 77 will be transported from the wharf by road to the company warehouse by accredited freight movers and will be stored in a suitably equipped warehouse. Micron 77 will be despatched to applicators or stores by accredited road transport operators. The substance will be stored on shelves or in a paint/dangerous goods store. The applicant notes that this substance will be transported in a similar way to the existing product Micron 66 and in accordance with the requirements of flammable substances.

2.2.3. **Use.** Micron 77 is intended for use as an antifouling paint on boats and will be applied by brush and roller, which the applicant indicates will produce the minimum loss of product to the environment, or by air/airless spray. The applicator or private customer will open cans of paint and apply it to the hull of the boat. The applicant indicates overspray will settle out either on spray booth filters or the surrounding covers of the tented vessel and will cure to a solid waste which can be disposed of via the normal landfill waste route. The applicant further states that contact with the product will mainly occur during the process of opening, mixing and applying the product but given all workers will be wearing appropriate safety gear, contact will be minimal.

2.2.4. **Disposal.** The applicant has stated the preferred disposal route is by way of use as antifouling paint is generally a higher cost than other types of paint. Any paint left in a can could be kept for either the next job or the next application to the same

boat. Alternatively, if the product is required to be disposed of it could be sent to a suitable disposal site. The applicant states empty cans will be allowed to dry out and placed in an approved waste bin for disposal. The equipment will be washed out and the used solvent collected for disposal as a hazardous waste. Where the boat is taken out of the water for maintenance work involving the antifouling paint being washed or the antifouling paint being high pressure washed down, all washings will be collected in both cases. In all cases of disposal, this will be done in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991.

Classification of the substance

2.3. The four Micron 77 formulations have been classified by the Agency based on their composition and the effects of their components. The Agency's classification of Micron 77 is different to that proposed by the applicant. Further details of the Agency's hazard classification are documented in Appendix 1 and Confidential Appendix 7.

2.4. The applicant classified the formulations of Micron 77 as eye irritants (6.4A) based on the preliminary advice provided from the Agency. However, the Agency has reviewed the formulation and considers in the absence of formulation data the 8.3A (eye corrosive) classification should be assigned.

2.5. Similarly, the applicant has not classified Micron 77 as a reproductive/developmental toxicant based on the preliminary advice provided. However, the Agency considers there was an error in this advice and the 6.8B classification should have been included.

Table 2.1 The applicant's and Agency's classifications of Micron 77 Red, Black, Blue and Navy

Hazardous Property	Applicant's Assessment	Agency's Assessment
Flammable Liquid	3.1C	3.1C
Acute Toxicity (Oral)	6.1D*	6.1D
Acute Toxicity (Dermal)		6.1E
Acute Toxicity (Inhalation)		6.1D
Skin Irritation/Corrosion	6.3A	6.3A
Eye Irritation/Corrosion	6.4A	8.3A
Carcinogenicity	6.7B	6.7B
Reproductive/developmental toxicity	No	6.8B
Reproductive/developmental toxicity via lactation	6.8C	6.8C
Target Organ Toxicity	6.9B	6.9B
Aquatic Ecotoxicity	9.1A	9.1A
Ecotoxic to terrestrial vertebrates	9.3B	9.3B

*The applicant has provided an overall acute toxicity classification without determining whether it is oral, dermal or inhalation.

Default controls

2.6. The HSNO Regulations specify a number of controls based on the classification of the substance. These default controls are designed to mitigate the potential risks associated with each of the hazardous properties and are listed in Appendix 3. The Authority is able to vary the default controls and impose controls under sections 77 and 77A to produce a set of controls relevant to Micron 77. Variations and additional controls are considered in Section 4 of this report.

2.7. The analysis of risk takes into account the controls that derive from the HSNO Regulations (in particular the default controls identified in Appendix 3) and from other legislation. The identification and assessment of effects assumes the controls are in place.

3. Identification and assessment of risks, costs and benefits

3.1. The Agency's identification and assessment of risks and costs (adverse effects) and benefits (positive effects) is set out in Appendix 2 and supported by information in the Supplementary Information (sections 3 and 4).

Risks and costs

Human health

3.2. The Micron 77 formulations have been classified as acute oral, dermal and inhalation toxicants (6.1D, 6.1E, 6.1D), a skin irritant (6.3A), an eye corrosive (8.3A), carcinogenic (6.7B), a reproductive/developmental toxicant (6.8B), a reproductive/developmental toxicant via lactation (6.8C) and a target organ toxicant (6.9B). Given the use pattern of the Micron 77 formulations, the Agency has not carried out quantitative human exposure modelling.

3.3. The classification of Micron 77 indicates that this substance may cause chronic effects (6.7B, 6.8B, 6.8C, 6.9B). The Agency notes that chronic hazards normally require repeated exposure for the adverse effects to occur.

3.4. In addition to the toxic properties above, Micron 77 is classified as presenting a medium flammability hazard (3.1C) and thus has the potential to cause ***minimal*** to ***major*** adverse health effects (ranging from smoke inhalation to burns, for example). However, the Agency considers that adherence to the HSNO controls on flammable substances will ensure that the level of risk to human health associated with its flammable properties is ***negligible.***

3.5. The results of the qualitative assessment of the human health risks associated with the Micron 77 formulations are documented in Table 3.1.

Table 3.1 Qualitative assessment of human health risks

Description		Magnitude	Likelihood	Comment	Effect level
Manufacture* and packaging	Acute	Minimal to moderate	Highly improbable	Should the Micron 77 formulations be manufactured in New Zealand in the future, the Agency considers the HSNO requirements for PPE,	Negligible
	Chronic	Major	Highly		

Description		Magnitude	Likelihood	Comment	Effect level
			improbable	equipment, emergency management and provision of information will apply and reduce the level of risk of chronic effects to negligible. The Agency considers the workers involved in the manufacture of these substances will be familiar with the processes and associated risks and further notes the general public are typically excluded from manufacturing facilities.	
Importation, transport, storage	Acute	Minimal to moderate	Highly improbable	Workers and bystanders will only be exposed to the substance during this part of the lifecycle in isolated incidents where spillage occurs. HSNO controls and adherence to the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 (as applicable) will apply.	Negligible
	Chronic	The risk of chronic effects is sufficiently remote that it is not necessary to address given that spillage will only occur in isolated incidents.			
Use – operator exposure	Acute	Minimal to moderate	Highly improbable	Micron 77 will be labelled to identify its potential risks minimising the opportunity for it to cause toxicity. Adherence to HSNO requirements for PPE and storage requirements as well as the ANZECC Code of Practice is considered to adequately manage occupational risks arising from the use of the Micron 77 formulations and reduce the level of risk to negligible.	Negligible
	Chronic	Major	Highly improbable		
Use – public exposure	Acute	Minimal to moderate	Highly improbable	There is a potential risk to members of the public if painting operations are carried out in public areas. The Agency considers such exposures are likely to be either single or of very short duration resulting in a negligible level of effect.	Negligible
	Chronic	The risk of chronic effects is sufficiently remote that it is not necessary to address.			
Use – operator exposure during boat maintenance activities	Acute	Minimal to moderate	Highly improbable	There is the potential for operators to be exposed to Micron 77 during boat maintenance activities, (e.g. sanding down or cleaning of hulls). It is considered that controls under the HS&E Act will mitigate the effect of such exposures.	Negligible
	Chronic	Major	Highly improbable		
Use – exposure to	Acute	Minimal to moderate	Highly improbable	The level of effect of the risk to members of the public suffering	Negligible

Description		Magnitude	Likelihood	Comment	Effect level
members of the public during boat maintenance activities	Chronic	The risk of chronic effects is sufficiently remote that it is not necessary to address.		adverse effects from the cleaning and sanding of hulls is considered to be negligible as members of the public would need to be very close to the work area, and any exposure is likely to be either single or episodic, of very short duration and at low levels.	
Disposal	Acute	Minimal	Highly improbable	Disposal of the excess substance is considered unlikely and risk will be minimised with detailed instructions for disposing of both excess substance as well as packaging. The applicant indicates it is possible for any excess paint to be stored for the next job.	Negligible
	Chronic	The risk of chronic effects is sufficiently remote that it is not necessary to address.			

*The applicant has indicated that the manufacture of Micron 77 formulations in New Zealand is unlikely. However, it is possible that these substances could be manufactured in New Zealand in the future. Consequently, the risks associated with the manufacture of Micron 77 formulations have been evaluated so that approval of these substances will be applicable to both the import and manufacture of Micron 77.

Environmental

3.6. Micron 77 has been classified as being very toxic in the aquatic environment (9.1A) and toxic to terrestrial vertebrates (9.3B). No quantitative modeling has been performed.

3.7. In addition to its ecotoxic properties, Micron 77 has been classified by the Agency as being flammable (3.1C – medium hazard). The Agency considers that there is potential for damage to the environment to occur if Micron 77 were to be ignited at any stage of its lifecycle. However, the Agency considers that adherence to the HSNO controls on flammable substances will ensure that the level of risk to the environment associated with its flammable properties is ***negligible.***

3.8. Table 3.2 documents the results of the qualitative assessment undertaken and identifies the impact of potential risks at each stage in the substance's lifecycle. In conclusion, the Agency considers the risk to the environment is negligible.

Table 3.2 Qualitative assessment of potential environmental risks

Description	Magnitude	Likelihood	Comment	Effect level
Manufacture* and packaging	Minor	Highly improbable	Should the Micron 77 formulations be manufactured in New Zealand, the Agency considers workers involved in the manufacture of these substances will be familiar with the manufacturing processes and risks. In addition, with the controls in place, the Agency considers the opportunity for the substances to be released in to the environment is limited.	Negligible
Importation, transport, storage	Minor	Highly improbable	Given adherence to the HSNO controls (e.g. packaging, identification and emergency management) and the Land Transport Rule 45001, Civil Aviations Act 1990 and	Negligible

Description	Magnitude	Likelihood	Comment	Effect level
			Maritime Transport Act 1994 (as applicable) the Agency considers a spill to be highly improbable. Furthermore, a spill is likely to lead to localised effects only involving small quantities of the substance.	
Use – application of paints to vessels	Minor	Highly improbable	Environmental contamination could potentially arise from paint over spray or direct spillage of the paint. However, this is likely to lead to localised effects only. Detailed guidance on the application and use of antifouling paints is detailed in the ANZECC Code of Practice for Antifouling and In-water Hull Cleaning and Maintenance; however, it is noted that not all boat owners will be aware of this code. It is considered that the Micron 77 formulations will pose a negligible increase in risk than currently approved antifouling paints, all of which contain copper.	Negligible
Leaching into the aquatic environment from vessels hulls	Minor	Very unlikely	Cumulative leaching from vessels whilst moored, particularly around impacted areas such as marinas, could potentially result in adverse effects to aquatic organisms. The Agency considers the level of effect of this risk to be negligible as the effect is likely to be localised and furthermore noting there are other factors to take into consideration when assessing such risks (refer Appendix 2).	Negligible
Environmental contamination from maintenance activities	Minor	Highly improbable	Environmental contamination may result from exposure to paint debris and/or dust from cleaning and sanding of hulls. As previously mentioned the ANZECC Code of Practice for Antifouling and In-water Hull Cleaning and Maintenance provides guidance on the use, removal and disposal of antifouling paints. The Agency considers the use of this guidance as well as controls set under the RMA will mitigate the effect of such exposures and the Micron 77 formulations, as a replacement for Micron 66, are unlikely to pose a greater risk than the currently approved antifouling paints.	Negligible
Disposal	Minor	Highly improbable	Users will in most cases use all of the substance by its normal use as an antifouling paint due to the typical purchase price of these kinds of paints, as well as taking into account the possibility for it to be stored for a later use. It is considered likely that small quantities of the substance will be involved. If Micron 77 is disposed of by means other than use, this will be in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991.	Negligible

*The applicant has indicated that the manufacture of Micron 77 formulations in New Zealand is unlikely. However, it is possible that these substances could be manufactured in New Zealand in the future. Consequently, the risks associated with the manufacture of Micron 77 formulations have been evaluated so that approval of these substances will be applicable to both the import and manufacture of Micron 77.

3.9. Risks to the environment during manufacturing, importation, transport, storage, use and disposal are assessed as negligible.

Benefits

3.10. The applicant considers that the availability of the Micron 77 antifouling paints will provide the following benefits:

- The maintenance of New Zealand's marine industry as being at the forefront of boat building technology;
- The ability to offer industry with proven new technology products, that are available to overseas users, to maintain the local industries ability to compete in the worldwide market place;
- A step wise improvement and replacement to the existing Micron 66 product. Micron 77 has improved recoatability and performance in fresh/brackish waters and areas where there is a large run off of rain water from the land; and
- As the Micron 77 formulations are being released globally, their introduction will ensure foreign boats entering New Zealand for repairs and maintenance can be maintained with the same antifouling.

3.11. The Agency notes that benefits may be derived from the availability of the Micron 77 formulations as antifouling paints in New Zealand.

Likely effects of the substance being unavailable

3.12. The Agency notes that there are currently other antifouling paints approved for use in New Zealand. The likely effects of Micron 77 being unavailable would thus be a reduction in consumer choice for end-users as well as a reduction in sales for Akzo Nobel Coatings Ltd and employment opportunities in the company. In addition, the potentially significant benefits discussed above would not be realised.

4. Setting controls

Variations to Default Controls

4.1. As a result of the risk assessment, the Agency considers that the following variations should be made to the default controls. These variations are summarised in Table 4.1 below. A full description of the rationale for these variations is documented in Appendix 3.

4.2. The Agency notes that similar variations were made to antifouling paints on their transfer to the HSNO regime.

Table 4.1 Variations to the default controls for Micron 77 formulations.

Control Code	Subject matter	Variation	Comment
T1	Limiting exposure to toxic substances through	The Agency proposes this control be deleted.	The Agency considers Micron 77 does not contain any components that meet the requirement of

	the setting of TELs		Regulation 11(1)(a).
T2	Controlling exposure to in places of work through the setting of WESs	WES values are proposed to be adopted as HSNO WES values.	Department of Labour WES values have been set for the components of the Micron 77 formulations. These values are identified in Appendix 3. These DOL WES values are considered relevant to Micron 77.
E1	Limiting exposure to ecotoxic substances though the setting of EELs	No EEL values are set at this time and the default EELs are deleted.	Until the Agency has developed formal policy on the implementation of section 77B, it proposes that the default EEL water and soil values be deleted.
E2	Restrictions on use of substances in application areas	The Agency proposes this control be deleted.	As these products are intended to be applied to a boat (or marine structure), the Agency considers this control is not relevant to the Micron 77 formulations.
AH1/E7	Approved handler/security requirements for certain ecotoxic substances	The Agency proposes this control be deleted.	The Agency considers the intended release of antifouling biocides into the environment from vessel hulls (or marine structures) is beyond the control of the approved handler. With respect to the potential for environmental contamination around marinas as a result of boat maintenance operations, the Agency notes that this is a matter that may be more appropriately managed on a site-specific basis under the RMA.
TR1	General tracking requirements	The Agency proposes this control be deleted.	The Agency considers that tracking the substance would be unduly onerous, as the key risks can be managed through other controls such as packaging, labelling and emergency management requirements.
F2/T7	Restrictions on the carriage of hazardous substances on passenger service vehicles	These controls may be combined.	These controls may be combined as they relate to the same regulations.
T4/E6	Requirements for equipment used to handle substances	These controls may be combined.	These controls may be combined as they relate to the same regulations.
D2/D4/ D5	Disposal requirements for hazardous substances	These controls may be combined.	These controls may be combined as they relate to the same regulations.
P5/P13/ P14/P15	Packaging requirements for hazardous substances	These controls may be combined.	These controls may be combined as they relate to the same regulations.

Proposed additional controls

4.3. As the Agency has only considered the risks of the four Micron 77 substances in terms of their use as antifouling paints, the Agency considers that the substances

should be restricted to such use. Accordingly the Agency considers that the following control should be applied to Micron 77:

4.3.1. No person may use Micron 77 for any purpose other than as an antifouling paint to prevent, by the slow release of biocides, the build up of aquatic organisms on the hulls of vessels or other surfaces in contact with water.

4.4. The Agency notes that the specified controls do not address the risks associated with stationary container systems, nor do they allow for dispensation where it is unnecessary for any associated pipework to have secondary containment. They also do not address all the risks associated with the unintended ignition of flammable substances. Accordingly, the Agency considers that the application of controls addressing these risks will be more effective than the specified (default) controls in terms of their effect on the management, use and risks of the substance. Such controls were applied to antifouling paints on transfer to the HSNO regime. The Agency considers that these controls are similarly appropriate for the management of the risks associated with Micron 77 and proposes that the additional controls shown in Table A4.1 of Appendix 4 should apply.

4.5. Control **EM12** relates to the requirements for secondary containment of pooling substances[2]. The Agency considers that the additional subclauses should be added after subclause (3) of regulation 36 of the Hazardous Substances (Emergency Management) Regulations 2001[3]. These subclauses are shown Table A4.1 of Appendix 4.

4.6. The Agency notes the submitter's proposal of a label statement regarding the potential for adverse effects to occur in the aquatic environment during boat maintenance activities. The Agency has considered this potential risk to the aquatic environment and considers that the proposed controls, as well as adherence to the guidance provided in the ANZECC Code of Practice, are considered sufficient to mitigate the risks and the introduction of Micron 77 will not result in a greater risk to the environment than that posed by currently approved antifouling paints. Additionally, to remain consistent with previous decisions the Agency is not proposing to set a label statement as an additional control. The Agency will review the current controls on all antifouling paints upon a reassessment of all antifouling paints.

5. Overall Evaluation and Recommendations

5.1. The Agency considers that there are negligible risks to human health and to the environment and no potentially significant costs associated with the release of Micron 77. Therefore, the Agency considers that it is evident that the benefits of releasing Micron 77 outweigh the costs.

5.2. Consequently**,** the Agency recommends that the Authority approve Micron 77, in accordance with clause 26, for import or manufacture with the controls documented in Appendix 4.

[2] Regulations 35 – 41 of the Hazardous Substances (Emergency Management) Regulations 2001

[3] These sub-clauses were applied to pesticides on transfer to the Act.

Appendix 1: Hazard classification of Micron 77 Red, Black, Blue and Navy Blue

Data from effects testing of the formulation were not provided for any hazard endpoint for Micron 77 Red, Black, Blue and Navy Blue so classification was estimated using information on the effects of the components and mixture rules. A summary of the physical, toxicity and ecotoxicity hazard classifications associated with Micron 77 Red, Black, Blue and Navy Blue and their components are provided in Confidential Appendix 7 in Tables A7.1 to A7.12. The relevant sections of the User Guide to Thresholds and Classifications under the HSNO Act (ERMA 2008a) that describe the mixture rules are listed in Table A1.1.

Data quality – overall evaluation

The Agency has adopted the Klimisch et al (1997) data reliability scoring system for evaluating data used in the hazard classification and risk assessment of chemicals (section 1.2.4 in ERMA 2008a). The data used by the Agency to classify Micron 77 Red, Black, Blue and Navy Blue are predominantly the classifications which have been officially gazetted during the transfer process and are publicly available through the HSNO Chemical Classification Information Database (CCID) (ERMA 2008b). With regard to ecotoxicity and environmental fate, generally these data are low quality by current international standards.

The Agency acknowledges that there are frequently data gaps in the hazard classification for chemicals which have been in use internationally for a long time. International programmes such as the OECD High Production Volume programme (OECD 1990) and REACH (EU 2006) are progressively working towards filling these data gaps. As new information becomes available, and resources permit, the Agency will endeavour to update the HSNO classifications for those substances.

The effect of the lower quality data on the overall evaluation of the effects of Micron 77 Red, Black, Blue and Navy Blue was not significant because no quantitative exposure modelling was performed.

Table A1.1: Location of mixture rules within the User Guide to the Thresholds and Classifications in the HSNO Act (V2.0. March 2008) (ERMA 2008a).

Hazard	User Guide to HSNO Thresholds and Classifications Reference
Subclass 6.1 Acute Toxicity	Part V, Chapter 10, Page 12
Subclass 6.3/8.2 Skin Irritancy/Corrosivity	Part V, Chapter 11, Page 7
Subclass 6.4/8.3 Eye Irritancy/Corrosivity	Part V, Chapter 12, Page 9
Subclass 6.5 Contact and Respiratory Sensitisation	Part V, Chapter 13, Page 8
Subclass 6.6 Mutagenicity	Part V, Chapter 14, Page 5
Subclass 6.7 Carcinogenicity	Part V, Chapter 15, Page 8
Subclass 6.8 Reproductive Developmental Toxicity	Part V, Chapter 16, Page 11
Subclass 6.9 Target Organ Systemic Toxicity	Part V, Chapter 17, Page 10
Subclass 9.1 Aquatic Ecotoxicity	Part VI, Chapter 19, Page 18
Subclass 9.2 Soil Ecotoxicity	Part VI, Chapter 20, Page 8
Subclass 9.3 Terrestrial Vertebrate Ecotoxicity	Part VI, Chapter 21, Page 7
Subclass 9.4 Terrestrial Invertebrate Ecotoxicity	Part VI, Chapter 22, Page 5

References

ERMA New Zealand (2008a) *User Guide to HSNO Thresholds and Classifications.* ERMA New Zealand, Wellington.

ERMA New Zealand (2008b) HSNO Chemical Classification Information Database (CCID) http://www.ermanz.govt.nz/hs/compliance/chemicals.html

European Union (2006) *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC*. http://reach.jrc.it/

Klimisch, HJ, Andreae, E, Tillman, U (1997). A systematic approach for evaluating the quality of experimental and ecotoxicological data. *Regulatory Toxicology and Pharmacology* 25: 1–5.

OECD (1990) Manual for Investigation of HPV Chemicals. http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html Retrieved 23 January 2008.

Appendix 2: Risk Assessment

The methodology involved in assessing risk is outlined in the Supplementary Information section.

Qualitative risk assessments have been carried out to evaluate the level of risk to operators, bystanders and the environment for all stages of the lifecycle. The level of risk has been evaluated on the basis of the magnitude and likelihood of adverse effects occurring to people or the environment.

The Agency did not identify any risks associated with society and the community, the market economy or New Zealand's international obligations.

Relationship of Māori to the environment

The Agency notes that the substance triggers a number of hazardous properties giving rise to the potential for cultural risk. However, based on the information provided, the Agency considers that the risks will be *negligible*. The rationale for this approach is outlined in the Supplementary Information (section 3).

Human health risk assessment

Operator exposure assessment

All four formulations contain the two actives copper oxide and copper pyrithione. The general public may be exposed to, these and other components in the formulations via food and or drinking water.

Given that antifouling paints are designed to leach biocides from painted surfaces as a function of their use, environmental contamination may occur, especially in areas where several vessels are moored together. The risk of environmental contamination and bioaccumulation of the active ingredients is discussed in detail in the Environmental Exposure and Risk Assessment section of this report.

The 19th Australian Total Diet Survey (http://turin/sites/felix/apps/1/HSR09023/e/The%2019th%20Australian%20Total%20Diet%20Survey.pdf) examined a number of metal contaminants, including copper, in all foods. The survey concluded that overall estimated mean intakes (from *all* food sources) were below the tolerable limit of 0.2 mg/kg bw/day.

Given that copper is widely distributed in nature and its compounds have many industrial and agricultural uses, the Agency considers that Micron 77 antifouling paint formulations should not pose an unacceptable risk to the public when used as directed and in compliance with relevant codes of practice. For example, the Australian and New Zealand Environment Conservation Council (ANZECC) Code of Practice for Antifouling and In-water Hull Cleaning and Maintenance provides guidance on the application, use, removal and disposal of antifouling paints.

Occupational Exposure

The Agency notes that personnel may be exposed to components of Micron 77 during application of the paints or whilst undertaking maintenance of painted surfaces. Because the Agency does not have a suitable model for this type of application and exposure, no operator exposure modeling has been undertaken for Micron 77. Nevertheless, the Agency considers that occupational risks arising from Micron 77 will be adequately mitigated by setting appropriate controls e.g. PPE requirements, storage conditions as well as the ANZECC Code of Practice referred to above.

Environmental exposure and risk assessment

All four antifouling paints contain the two active ingredients, copper oxide and copper pyrithione at very similar concentrations. With respect to ecotoxicity, Micron 77 Red, Black, Blue and Navy Blue trigger 9.1A and 9.3B hazard classifications. No quantitative environmental exposure modelling has been performed. A qualitative assessment of the risks to the environment over the entire lifecycle of the substance will be carried out in the main body of the E&R Report and is briefly addressed below.

Generic risks from copper-based antifoulants

The potential areas of risk to the environment from the use of copper-based antifouling paints include:

- Environmental contamination from leached biocides, especially in areas where several vessels are moored together, e.g. inland bays and marinas (given that these substances are designed to deliberately leach biocides from painted surfaces as a function of use).
- Environmental contamination could occur during painting activities, as a result of over-spray, run-off or direct spillage of the paint into the water. Contamination is also possible during boat maintenance activities from paint debris/dust resulting from the sanding or water-blasting of hulls in preparation for repainting, or the washing/cleaning of hulls. It is noted that ANZECC have developed a Code of Practice for Antifouling and In-water Hull Cleaning and Maintenance which contains detailed guidance on the application, use, removal and disposal of antifouling paints, e.g. it specifies that preparation areas should be bounded to ensure accidental spillage cannot escape to water, spillage should be treated with a suitable adsorbent and disposed of as controlled waste, and with respect to vessels of less than 25m, surfaces should be protected from drift of spray through the use of tarpaulins and sheeting. However, it is recognised that not all boat owners will be aware of the code, or will always follow the correct procedures. In addition, it is noted that not all marinas/hardstands/slipways etc have appropriate facilities or procedures in place for the disposal of wastes from boat maintenance activities.

The Agency acknowledges there is a risk of environmental contamination as a result of the use of antifouling paints, particularly around impacted areas such as marinas, inland bays as a result of boat maintenance activities (including application of paint) and cumulative leaching from vessels whilst moored.

However, the Agency notes there are a number of factors to take into consideration when attempting to assess such risks. One such consideration is the fact that there are many sources

of input of contaminants into the environment, especially for ubiquitous metallic species such as copper. Also of relevance is the degree to which contaminants partition from the aqueous phase and adsorb onto sediment which impacts on the bioavailability of contaminants.

The bioavailability (and therefore toxicity) of metals in aquatic sediments depends on the speciation of the metal, the type of sediment, and the physiology and food selection of the organisms. For example, sequestration of copper results in the occurrence of various copper species with various levels of bioavailability.

Harbour sediments are typically anoxic with a high content of sulphides which will bind to metal ions. Therefore, metals such as copper will be expected to be relatively strongly sequestered in harbour sediments.

Organisms are exposed to (sediment-bound) contaminants via interstitial (pore) water and sediment ingestion, with toxicity being affected by the relative bioavailability of the toxicants, as well as exposure to multiple toxicants. Thus even if measurable levels of contaminants were detected in sediment, there may not be a toxic effect seen in marine organisms if the chemical were sediment-bound and not bio-available.

Bioaccumulation:
The bioaccumulation of metals and inorganic metal compounds is a complex process and bioaccumulation data should be used with care. The ability of aquatic organisms to bioaccumulate metals is very species dependent, e.g. bio-monitoring programmes world-wide have reported differences between mussels, oysters, cockles and pipi. There is conflicting information in the literature with respect to the degree that metals bioconcentrate through the aquatic food chain. The ANZECC Water Quality Guidelines 2000 (Chapter 8.3) note that copper is readily accumulated by plants and animals and that toxic effects occur when the rate of uptake exceeds the rate of physiological or biochemical detoxification and excretion. However, other studies have shown that copper is not highly mobile in aquatic food webs and there appears to be little evidence to support the general occurrence of significant biomagnification of this metal within marine or freshwater food chains ("Bioaccumulation Testing and Interpretation for the Purpose of Sediment Quality Assessment, Status and Needs". USEPA, Feb 2000).

It is recognised that most aquatic organisms have the ability to regulate the level of metals in their tissues through a variety of mechanisms. As such, it is noted that although the levels of metals accumulated in aquatic organisms does increase in impacted environments, the levels do not increase to the same extent as they do in the water and sediment in the surrounding environment ("Bioaccumulation Testing and Interpretation for the Purpose of Sediment Quality Assessment, Status and Needs". USEPA, Feb 2000).

Specific risks from copper pyrithione

Copper pyrithione is classified as a 9.1A (fish), 9.1A (crustacean) and 9.1A (algae), as are the majority of the other 12 organic co-biocides currently used in antifouling paints in New Zealand.

Copper pyrithione affects bacteria, algae and zooplankton, both through direct effects, but also through indirect effects due to initial changes in community function and structure.

These changes lead to changes in system functions such as primary and secondary production as well as changes in nutrient turnover.

Indirect estimations of degradation gave half-lives for copper pyrithione of 7-8 minutes when sterile seawater solutions were exposed to sunlight. However, when the compound was kept in the dark, a half-life could not be determined during the 48-hours of the experiment. When seawater containing bacteria and algae was used, no increase in degradation time was observed suggesting no biological degradation. Moreover, when exposed to the light in the laboratory, no degradation was observed. When a degradation experiment was performed at different depths in sea water column, the half-life was between 120 and 210 min at 0.5 meters, and with no significant degradation below 2m. Copper pyrithione is quickly broken down at high light intensities, but persist for days in light conditions typical for estuarine and coastal areas (Dahllöf et al., 2005).

Despite its apparent persistence in the aquatic environment and its high ecotoxicity, copper pyrithione is a commonly used booster biocide in antifouling paints worldwide, it has already been approved in New Zealand and it is not raising any specific concerns compared with other commonly used booster biocides.

Overall Assessment of Risks from Micron 77 Red, Black, Blue and Navy Blue

In conclusion, the Agency considers that the environmental risks from the copper oxide and copper pyrithione present in Micron 77 Red, Black, Blue and Navy Blue will be similar to those posed by the majority of antifouling paints currently on the market, all of which contain copper and some of which contain copper pyrithione.

The applicant did not provide any information on the leaching rates of the specific biocides present in Micron 77 Red, Black, Blue or Navy Blue so an accurate assessment of environmental exposure was not able to be carried out. On a generic level, the Agency notes that biocide leaching rates can vary considerably as they are dependent on a number of factors including the nature of the applied paint film, how recently the vessel was painted, the nature of the biocides themselves, water pH, water temperature, water flow rates etc. Average leaching rates for copper of approximately 10 - 40 µg / cm^2 / day have been reported, whilst for a range of selected organic co-biocides (not including copper pyrithione but zinc pyrithione), leaching rates of approximately 1 - 5µg / cm^2 / day have been reported (Assessment of Antifouling Agents in Coastal Environments (ACE) Final Scientific and Technical Report, June 2002).

From these data, it is theoretically possible to calculate a predicted environmental concentration of biocides in a given area such as a marina. However, such calculations assume static conditions (worse case) with no account taken of tidal effects which would cause considerable dilution.

Assuming a leach rate of 5 µg biocide / cm^2 / day, a 20 m^2 wetted hull area gives a leach rate of 1g / vessel / day as described below:

5 µg / cm^2 per day
= 5 µg / 0.0001 m^2 per day
= 1,000,000µg / 20 m^2 per day
= 1 g / vessel per day

Assuming 150 vessels in the marina, each leaching 1 g biocide / day gives a leach rate of 150 g of biocide per day for the whole marina (assumes worst case scenario of a static environment, i.e. excludes any dilution effects from tidal flows etc).

Assuming a marina size of 300 m x 200 m x 3 m = 180,000m^3 (180,000,000 L) gives:

150 g biocide / 180,000,000 L per day
= 0.0008 mg/L per day
= 0.8 µg/L per day

As mentioned, this value of 0.8 µg/L has been calculated assuming a static environment, with no account taken of influencing factors such as degradation or the considerable dilution effect caused by tidal flow. The actual water concentration of copper pyrithione in the marina will be a function of the leaching, biodegradation (which is expected to be slow), sorption, the specific local conditions of the marina, particularly tidal flow. It is noted that the estimated daily leaching rate of 0.8 µg/L is five times less than the lowest acute toxicity value reported for copper pyrithione (96 hour LC_{50} = 4.3 µg/L for fathead minnow). Nevertheless, it is noted that marinas are highly impacted environments, both physically and due to the variety of chemicals present. The contribution of copper pyrithione to this impact is not expected to exceed that of other biocides.

Appendix 3: Default controls for Micron 77 Red, Black, Blue and Navy Blue and their variations.

Based on the hazard classification as shown in Table 3.1, the set of associated controls has been identified. These default controls, expressed as control codes[4], are listed in Table A3.1.

Table A3.1: List of default controls for Micron 77

HSNO Classification	HSNO Controls
3.1C 6.1D 6.1E 6.3A 6.7B 6.8B 6.8C 6.9B 8.3A 9.1A 9.3B	**Class 1 to 5 substances** F1, F2, F3, F5, F6, F11, F12, F14, F16, GN35A **Toxic** T1, T2, T4, T5, T7 **Ecotoxic** E1, E2, E5, E6, E7 **Identification** I1, I2, I3, I5, I8, I9, I10, I11, I13, I16, I17, I18, I19, I20, I21, I22, I23, I25, I28, I29, I30 **Packaging** P1, P3, P5, P13, P14, P15, PG3, PS4 **Disposal** D2, D4, D5, D6, D7, D8 **Emergency Management** EM1, EM2, EM6, EM7, EM8, EM9, EM10, EM11, EM12, EM13 **Personnel Qualifications** AH1 **Tracking** TR1

The Authority is able to vary the default controls and impose controls under sections 77 and 77A to produce a set of controls relevant to substance under assessment. The following discussion reviews the default controls and rationalises their use for these substances.

Toxicity Controls

Setting of TELs (Control Code T1)

Tolerable Exposure Limits (TELs) are designed to limit the extent to which the general public is exposed to hazardous (toxic) substances. A TEL represents the maximum concentration of a substance legally allowable in a particular medium, and can be set as either a guideline value or an action level that should not be exceeded. For the purposes of setting TELs, an environmental medium is defined as air, water, soil or a surface that a hazardous substance may be deposited onto.

TELs are established from PDE (Potential Daily Exposure) values, which are themselves established from ADE (Acceptable Daily Exposure) values or reference doses (RfD) which are similar to ADE but are used to protect against a specific toxic effect of concern.

Human exposure may also occur through food or drinking water. Exposure through food is normally managed via the establishment of Maximum Residue Limits (MRLs) as set by the Minister of Food

[4] Control codes are those assigned by ERMA NZ to enable easy cross reference with the regulations. A detailed list of these codes is contained in the Supplementary Information (section 2).

Safety on the advice of the New Zealand Food Safety Authority (NZFSA), whilst exposure through drinking water is managed via the establishment of Maximum Acceptable Values (MAVs) as set by the Ministry of Health. From the Australian Total Diet Survey, it is apparent that the actives do not accumulate in the marine food chain. The only component of Micron 77 with potential to bioaccumulate is component C (present at 3.92%). However, the Agency notes that this component is present at a low concentration and that antifouling paints are designed to release the actives slowly over a long period of time. Therefore, it is considered that the risk of this component actually accumulating in the marine food chain is low.

Setting of PDEs

If an ADE or RfD value is set for a substance, or component of a substance, a PDE value for each relevant exposure route must also be set. A PDE is an amount of substance (mg/kg bodyweight/day), calculated in accordance with Regulation 23, that estimates the relative likelihood of particular exposures. A PDE for any single exposure route is a fraction of the ADE or RfD, and the sum of all PDE values from all possible exposures must be less than or equal to the ADE or RfD.

The main routes of exposure considered are ingestion (food, water, air, soil), inhalation (air) and skin contact (surface deposition, water, soil).

Setting of ADEs

An ADE is an amount of a hazardous substance (mg/kg bodyweight/day), that, given a lifetime of daily exposure, would be unlikely to result in adverse human health effects. An RfD (reference dose) is a similar measure that can be used to protect against a specific toxic effect of concern.

Regulation 11(1) of the Hazardous Substances (Classes 6, 8 and 9) Controls Regulations 2001 determines when an ADE/RfD is required to be set:

> *(1) This regulation applies to a class 6 substance if-*
>
> *(a) it is likely to be present in-*
>
> *(i) 1 or more environmental media; or*
>
> *(ii) food; or*
>
> *(iii) other matter that might be ingested; AND*
>
> *(b) it is a substance to which a person is likely to be exposed on 1 or more occasions during the lifetime of the person; AND*
>
> *(c) exposure to the substance is likely to result in an appreciable toxic effect.*

If all three requirements of regulation 11(1) are met, then an ADE/RfD should be set for the relevant component(s), and PDE and TEL values subsequently established for each relevant exposure route.

The toxicity classifications of Micron 77 that trigger the need to consider setting a TEL are 6.1D, 6.3A, 8.3A, 6.7B, 6.8B, 6.8C, 6.9B.

The Agency notes that antifouling paints are designed to release copper ions and that this element is ubiquitous in the environment. Therefore, the Agency considers that Micron 77 does not contain any

components that meet the requirement of Regulation 11(1)(a). Therefore, ADEs are not set for any components of this substance, and subsequently no TELS are set.

Setting of WES (Control Code T2)

Workplace Exposure Standards (WES) are designed to protect persons in the workplace from the adverse effects of toxic substances. A WES is an airborne concentration of a substance (expressed as mg substance/m3 of air, or ppm in air), which must not be exceeded in a workplace and only applies to places of work (Regulation 29(2), Hazardous substances (Classes 6, 8 and 9 Controls) Regulations 2001).

Regulation 29(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when a WES is required to be set. If all three of the requirements of this regulation are met then a WES is required to be set.

Regulation 29 states:

(1) This regulation and regulation 30 apply to a class 6 substance if,-

(a) under the temperature and pressure the substance is to be used in, it can become airborne and disperse in air in the form of inspirable or respirable dust, mists, fumes, gases or vapours; AND

(b) human exposure to the substance is primarily through the inhalation or dermal exposure routes; AND

(c) the toxicological and industrial hygiene data available for the substance is sufficient to enable a standard to be set.

When setting WES, the Authority must either adopt a value already proposed by the Department of Labour or already set under HSNO or derive a value by taking into account the matters described in Regulation 30(2) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations.

ERMA New Zealand typically adopts WES values listed in the Workplace Exposure Standards (Effective from 2002) document (refer to the link below).

http://www.osh.govt.nz/order/catalogue/pdf/wes2002.pdf

The Agency notes that at this time Department of Labour WES values have been set for components of the Micron 77 formulations as shown in the following table.

Table A3.1 – Components of Micron 77 formulations with or without set WES values

Formulation	DoL WES set
Micron 77 Red	A1, A2, A3, A4, D1, D2, D3, D4, F, G, H, K
Micron 77 Blue	A1, A2, A3, A4, D1, D2, D3, D4, F, G, H, J, K
Micron 77 Black	A1, A2, A3, A4, D1, D2, D3, D4, E, F, G, H, K, L
Micron 77 Navy	A1, A2, A3, A4, D1, D2, D3, D4, F, G, H, L

No values have been found to have been set for the remaining components of the Micron 77 formulations, whether by DoL or any relevant overseas body that the Agency monitors. The DoL WES values detailed above are considered relevant to Micron 77 and it is proposed that these are adopted as HSNO WES.

Ecotoxicity Controls

Setting of EELs (Control code E1)

Regulation 33 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 specify that an environmental exposure limit (EEL) may be set for a class 9 substance for one or more environmental media if organisms that live in that environment may be exposed to the substance. An EEL is the (maximum) concentration of a substance in an environmental medium that will present a negligible risk of adverse environmental effects to organisms (excluding humans) in non-target areas.

As specified by regulation 32, a default EEL of 0.1 µg/L water is set for any class 9.1 substance, and 1 µg/kg soil (dry weight) for any class 9.2 substance.

For the purposes of setting EELs, an environmental medium is defined as water, soil or sediment where these are in the natural environment, or a surface onto which a hazardous substance may be deposited.

An EEL can be established by one of three means:

- Applying the default EELs specified in regulation 32
- Adopting an established EEL as provided by regulation 35(a)
- Calculating an EEL from an assessment of available ecotoxicological data as provided by regulation 35(b).

The Hazardous Substances and New Organisms (Approvals and Enforcement) Act 2005 added a new section (s77B) to the HSNO Act, which, amongst other things provided the Authority with the ability to set EELs as guideline values, rather than the previous pass/fail values.

However, until the Agency has developed formal policy on the implementation of s77B, it proposes not to set EELs for any components of Micron 77 at this time. It is also proposed that the default EEL water value be deleted until the policy has been established.

Setting of Application Rate (Control Code E2)

These regulations relate to the requirement to set an application rate for a class 9 substance that is to be sprayed or applied to an area of land (or air or water) and for which an EEL has been set. These products are intended to be applied to a boat (or marine structure) and as such, the Agency considers this control is not relevant to Micron 77 Red, Black, Blue or Navy Blue.

Approved Handler Controls - Highly ecotoxic substances (AH1, E7)

Approved handler requirements have been triggered for Micron 77 Red, Black, Blue and Navy Blue as a result of their 9.1A classification. Consistent with the approach taken for other antifouling paints, the Agency considers that the approved handler controls can be **deleted** as provided by section **77 (4)(b)** as it is recognised that the intended release of antifouling biocides into the environment from vessel hulls (or marine structures) is beyond the point of control of the approved handler. With respect to the potential for environmental contamination around marinas etc., as a result of boat maintenance operations, the Agency notes that this is a matter that may be more appropriately managed on a site-specific basis under the RMA.

This approach is consistent with the Authority's policy on approved handler and tracking controls for class 9 substances (November 2003).

Tracking control - Highly ecotoxic substances (TR1)

Tracking requirements have been triggered for Micron 77 as a result of its 9.1A classification. However, for substances where the tracking control has been triggered solely as a result of ecotoxicity, it is considered that any risk that may arise during its life-cycle are adequately managed by other controls such as packaging, labeling and emergency management requirements. The Agency therefore considers the tracking control can be deleted as provided by section 77(4)(b).

This approach is consistent with the Authority's policy on approved handler and tracking controls for class 9 substances (November 2003).

Identification controls

Identification of Toxic and/or Corrosive Components on Labels/Documentation (SDS)

The Hazardous Substances (Identification) Regulations 2001 specify that certain toxic and/or corrosive components are required to be specified on the product label and on SDS documentation.

Identification of toxic components on labels

Regulations 25(e) and 25(f) require that certain toxic components are required to be specified on the product label.

Regulation 25(e) states:

...a toxic substance must be identified by...

'information identifying, by its common or chemical name, every ingredient, that would, independently of any other ingredient, give the substance a hazard classification of 6.1A, 6.1B, 6.1C, 6.5, 6.6, 6.7, 6.8 or 6.9, and the concentration of that ingredient in the substance."

Regulation 25(f) states:

...a toxic substance must be identified by...

"information identifying (other than an ingredient referred to in paragraph (E)) that would, independently of any other ingredient, give the substance a hazard classification of 6.1D, and the concentration of the ingredient that would contribute the most to that classification."

Identification of corrosive components on labels

Regulation 19(f) requires that certain corrosive components are required to be specified on the product label.

Regulation 19(f) states:

...a corrosive substance must be identified by...

"If the substance contains any ingredient in such a concentration that the ingredient would, independently of any other ingredient, cause the substance to be classified as class 8.2 or class 8.3, in respect of each such ingredient,-
(i) its common or chemical name; and

(ii) a statement of its concentration in the substance

Identification of toxic and/or corrosive components on SDS

Regulation 39(5) of the Hazardous Substances (Identification) Regulations 2001, states that certain corrosive and toxic components are required to be specified on documentation.

Regulations 39(5) states:

"The requirements of regulation 19(f) or (as the case requires) regulation 25(e) apply to all documentation; but any ingredient required by that provision to be identified (other than an ingredient to which regulation 26 applies) must also be identified by any Chemical Abstract Services number allocated to it."

Concentration cut-offs for component identification

Consistent with the guidance provided by GHS, the Hazardous Substances Standing Committee (HSSC) agreed that the concentration cut-offs triggering the requirement for identification of components on labels and documentation are:

HSNO Classification	Cut-off for label (% w/w)	Cut-off for SDS (% w/w)
6.5A, 6.5B, 6.6A, 6.7A	0.1	0.1
6.6B	1	1
6.7B	1	0.1
6.8A, 6.8C	0.3	0.1
6.8B	3	0.1
6.9A, 6.9B	10	1

Micron 77 - Components requiring identification

Under these regulations, as determined by the HSSC (March 2006), the name and concentration of the following components need to be specified on the label and documentation of all the Micron 77 formulations:

Components to be identified on Micron 77 formulations

Label	Documentation
Copper oxide, copper pyrithione, A^2, F, A^3, D^1, D^2, H, C	Copper oxide, copper pyrithione, A^2, F, A^3, D^1, D^2, H, C

Appendix 4: Proposed controls for Micron 77

Table A4.1: Proposed controls for Micron 77 – codes, regulations and variations.

Control Code[5]	Regulation[6]	Topic	Variations
Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001			
F1	7	General test certification requirements for hazardous substance locations	
F2, T7 (class 6, 8 and 9 controls)	8, 10	Restrictions on the carriage of toxic, corrosive or flammable substances on passenger service vehicles	Controls F2 and T7 are combined
F3	55	General limits on flammable substances	
F5	58, 59	Requirements regarding hazardous atmosphere zones for class 2.1.1, 2.1.2 and 3.1 substances	
F6	60-70	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances	
F11	76	Segregation of incompatible substances	
F12	77	Requirement to establish a hazardous substance location if flammable substances are present	
F14	81	Test certification requirements for facilities where class 2.1.1, 2.1.2 or 3.1 substances are present	
F16	83	Controls on transit depots where flammable substances are present	
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001			
T2	29, 30	Controlling exposure in places of work	The DOL WES values are adopted for the following components of the formulations of Micron 77. Micron 77 Red: A^1, A^2, A^3, A^4, D^1, D^2, D^3, D^4, F, G, H, K. Micron 77 Blue: A^1, A^2, A^3, A^4, D^1, D^2, D^3, D^4, F, G, H, J, K. Micron 77 Black: A^1, A^2, A^3, A^4, D^1, D^2, D^3, D^4, E, F, G, H, K, L. Micron 77 Navy: A^1, A^2, A^3, A^4, D^1, D^2, D^3, D^4, F, G, H, L.

[5] Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand User Guide to the HSNO Control Regulations.

[6] These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

Control Code[5]	Regulation[6]	Topic	Variations
			Refer to confidential Appendix 7 for the identity of the components.
T4, E6	7	Requirements for equipment used to handle hazardous substances	Controls T4 and E6 are combined.
T5	8	Requirements for protective clothing and equipment	
E1	32-45	Limiting exposure to ecotoxic substances through the setting of EELs	No EEL values are set at this time and the default EELs are deleted.
E5	5(2), 6	Requirements for keeping records of use	
Hazardous Substances (Identification) Regulations 2001			
I1	6, 7, 32-35, 36 (1)-(7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1)-(7) – Comprehensibility, Clarity and Durability of information	
I2	8	Priority identifiers for corrosive substances	
I3	9	Priority identifiers for ecotoxic substances	
I5	11	Priority identifiers for flammable substances	
I8	14	Priority identifiers for toxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I10	19	Secondary identifiers for corrosive substances	
I11	20	Secondary identifiers for ecotoxic substances	
I13	22	Secondary identifiers for flammable substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of Generic Names	
I18	27	Use of Concentration Ranges	
I19	29-31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported	
I20	36(8)	Durability of information for class 6.1 substances	
I21	37-39, 47-50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 47 – Information not included in	

Control Code[5]	Regulation[6]	Topic	Variations
		approval Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request	
I22	40	Specific documentation requirements for corrosive substances	
I23	41	Specific documentation requirements for ecotoxic substances	
I25	43	Specific documentation requirements for flammable substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	
I30	53	Advertising corrosive and toxic substances	
Hazardous Substances (Packaging) Regulations 2001			
P1	5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility Regulation 9A and 9B – Large Packaging	
P3	9	Packaging requirements for substances packed in limited quantities	
P5, P13, P14, P15	11, 19, 20, 21	Packaging requirements for hazardous substances	Controls P5, P13, P14 and P15 are combined
PG3	Schedule 3	The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).	
PS4	Schedule 4	This schedule describes the minimum packaging requirements that must be complied with when a substance is packaged in limited quantities	
Hazardous Substances (Disposal) Regulations 2001			
D2, D4, D5	6, 8, 9	Disposal requirements for flammable, toxic, corrosive and ecotoxic substances	Controls D2, D4 and D5 are combined
D6	10	Disposal requirements for packages	
D7	11, 12	Disposal information requirements	
D8	13, 14	Disposal documentation requirements	
Hazardous Substances (Emergency Management) Regulations 2001			
EM1	6, 7, 9-11	Level 1 emergency management information: General requirements	
EM2	8(a)	Information requirements for corrosive substances	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12-16, 18-20	Level 2 emergency management documentation requirements	

Control Code[5]	Regulation[6]	Topic	Variations
EM9	17	Additional information requirements for flammable and oxidising substances and organic peroxides	
EM10	21-24	Fire extinguisher requirements	
EM11	25-34	Level 3 emergency management requirements – emergency response plans	
EM12	35-41	Level 3 emergency management requirements: secondary containment	*The following subclauses shall be added after subclause (3) of regulation 36:* *(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—* *(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and* *(b) is not required to be located in a secondary containment system.* *(5) In this clause, pipework—* *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a*

Control Code[5]	Regulation[6]	Topic	Variations
			transfer line.
EM13	42	Level 3 emergency management requirements: signage	
Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004			
Regulations 4 to 43 where applicable		The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers and must be complied with as relevant	
Additional controls set under s77A			
The controls relating to stationary container systems, secondary containment and unintended ignition of flammable substances, as set out in Schedules 8, 9 and 10 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the *New Zealand Gazette*, 26 March 2004, No. 35, page 767), as amended, shall apply to this substance, notwithstanding clause 1(1) of Schedules 8 and 9 and clause 1 of Schedule 10.			
Micron 77 may not be used for any purpose other than as an antifouling paint to prevent, by the slow release of biocides, the build up of aquatic organisms on the hulls of vessels or other surfaces in contact with water.			

Appendix 5: Parties notified

ARPPA
Chancery Green
Chemsafety Limited
Consumer Affairs
Far North District Council
Green Party of Aotearoa New Zealand
IMCD New Zealand Limited
Kaipara District Council
Lowndes Associates
Ministry of Agriculture and Forestry - Head Office
Napier Health Centre - Public Health Unit
New Zealand Chemical Industry Council Inc
New Zealand Customs Service
New Zealand Press Association
New Zealand Society of Gunsmiths Inc
Ngati Kahungunu Iwi Incorporated
Northland Health
Northland Regional Council
Pesticide Action Network Aotearoa New Zealand
Selleys Pty Ltd (ORICA)
South Taranaki District Council
Wellington City Council
1 Private Individual

Appendix 6: References

ACE (2002) Assessment of antifouling agents in coastal environments (MAS3-CT98-0178) Final Scientific and Technical Report
http://web.pml.ac.uk/ace/ACE%20Final%20Scientific%20&%20Technical%20Report.doc

Dahllöf, I., Grunnet, K., Haller, R., Hjorth, M., Maraldo, K., Petersen, DG. (2005) Analysis, fate and toxicity of zinc- and copper pyrithione in the marine environment. Copenhagen: Nordic Council of Ministers.

ERMA New Zealand (2008a) *User Guide to HSNO Thresholds and Classifications.* ERMA New Zealand, Wellington.

USEPA (2000) Bioaccumulation testing and interpretation for the purpose of sediment quality assessment. Status and needs. U.S. Environmental Protection Agency Bioaccumulation Analysis Workgroup Washington, DC 20460

Appendix 7: Confidential material

Supplementary Information

This document has been prepared to support the Agency's Hazardous Substances Evaluation and Review reports. It contains background information on five areas and has been divided into the following sections:

1) The regulatory basis for assessing the application.

2) Legislation that will affect the use of hazardous substances within New Zealand. This section covers the range of default controls available for use by the Agency and lists other legislation that will affect the use of hazardous substances.

3) Risk Assessment - The steps and methodology involved in assessment of effects.

4) Qualitative Descriptors for Risk/Benefit Assessment - the descriptors used to assess the level of each risk or benefit to determine their level of significance.

5) Decision Pathway - to be used when assessing an application for the release of hazardous substances.

1. Regulatory basis for assessing the application

1.1. The application was lodged pursuant to section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act").

1.2. The Evaluation and Review report ("the E&R report") takes into account matters to be considered in section 29; matters specified under Part 2 of the Act; and the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology"). Unless otherwise stated, references to section numbers in the report refer to sections of the Act and clauses to clauses of the Methodology.

1.3. The Minister for the Environment was advised of the application under section 53(4)(a) and given the opportunity to "call-in" the application under section 68. This action was not initiated.

1.4. The Authority is able to vary the default controls and impose controls under sections 77 and 77A to produce a set of controls relevant to the substance. Variations and additional controls for the substance are considered in Section 5 of the E&R report.

1.5. In undertaking this assessment the Agency has considered the Authority's approvals given to substances under Part 5 of the Act as well as those transferred to the Act under the *Hazardous Substances (Timber Preservatives, Antisapstains, and Antifouling Paints) Transfer Notice 2004*.

1.6. Section 96 provides that the Authority may identify and report to the Minister where it considers that a reduction in the likely occurrence of adverse effects similar to that achieved by the controls attached to any substance could be achieved by any environmental user charge, or a combination of an environmental user charge and controls.

1.7. The Agency considers that use of controls is the most effective means of managing the risks throughout the lifecycle of the substance being assessed. The imposition of an environmental user charge instead of, or in combination with controls, is therefore not recommended under this approval.

2. Legislation that will affect the use of hazardous substances within New Zealand

2.1. The HSNO legislation and other legislation, such as the Resource Management Act 1992 ("the RMA") and the Health and Safety in Employment Act ("the HSE Act") provide for a number of controls that are aimed at preventing exposure to hazardous substances, and/or mitigating any adverse effects caused by such substances in the event of an accident, or a breach of controls. The key controls that relate to the protection of human health and the environment during the various stages of the lifecycle of hazardous substances are outlined in the sections below.

HSNO Legislation

2.2. The controls available to control a substances use under the HSNO legislation are determined by the substances hazard classification and are comprehensively described in ERMA New Zealand's User Guide to the Threshold and Classifications under the Hazardous Substances and New Organisms Act 1996. The following paragraphs describe the sorts of controls available and list those that are available for use.

2.3. The *Hazardous Substances (Identification) Regulations 2001* require that the hazardous properties of substances be clearly identified on the label, as well as described in any documentation (Safety Data Sheet) supplied with the substance. While the substance is being transported (including importation), the regulations provide for bulk transport containers and/or any outer packaging to be labelled or marked in compliance with either the Land Transport Rule 45001, Civil Aviation Act 1990 or the Maritime Safety Act 1994 as relevant (control code I19).

Identification Controls	
I1	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I2	Priority identifiers for corrosive substances
I3	Priority identifiers for ecotoxic substances
I4	Priority identifiers for explosive substances
I5	Priority identifiers for flammable substances
I6	Priority identifiers for organic peroxides
I7	Priority identifiers for oxidising substances
I8	Priority identifiers for toxic substances
I9	Secondary identifiers for all hazardous substances
I10	Secondary identifiers for corrosive substances
I11	Secondary identifiers for ecotoxic substances
I12	Secondary identifiers for explosive substances
I13	Secondary identifiers for flammable substances

I14	Secondary identifiers for organic peroxides
I15	Secondary identifiers for oxidising substances
I16	Secondary identifiers for toxic substances
I17	Use of generic names
I18	Requirements for using concentration ranges
I19	Additional information requirements, including situations where substances are in multiple packaging
I20	Durability of information for class 6.1 substances
I21	General documentation requirements
I22	Specific documentation requirements for corrosive substances
I23	Specific documentation requirements for ecotoxic substances
I24	Specific documentation requirements for explosive substances
I25	Specific documentation requirements for flammable substances
I26	Specific documentation requirements for organic peroxides
I27	Specific documentation requirements for oxidising substances
I28	Specific documentation requirements for toxic substances
I29	Signage requirements
I30	Advertising corrosive and toxic substances

2.4. The *Hazardous Substances (Emergency Management) Regulations 2001* prescribe controls that must be complied with if the levels of substance held are above the trigger quantities specified. These controls are aimed at mitigating adverse effects in the event of a spill and prescribe specific requirements with respect to emergency management information, emergency response plans, secondary containment facilities and signage.

Emergency Management Controls	
EM1	Level 1 information requirements for suppliers and persons in charge
EM2	Information requirements for corrosive substances
EM3	Information requirements for explosive substances
EM4	Information requirements for flammable substances
EM5	Information requirements for oxidising substances and organic peroxides
EM6	Information requirements for toxic substances
EM7	Information requirements for ecotoxic substances
EM8	Level 2 information requirements for suppliers and persons in charge
EM9	Additional information requirements for flammable and oxidising substances and organic peroxides
EM10	Fire extinguisher requirements
EM11	Level 3 emergency management requirements: duties of person in charge, emergency response plans
EM12	Level 3 emergency management requirements: secondary containment
EM13	Level 3 emergency management requirements: signage

2.5. The *Hazardous Substances (Packaging) Regulations 2001* prescribe a number of controls aimed at ensuring hazardous substances are adequately and appropriately packaged.

Packaging Controls	
P1	General packaging requirements
P2	Specific criteria for class 4.1.2 and 5.2 substances
P3	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
P4	Packaging requirements for explosive substances
P5	Packaging requirements for flammable liquids
P6	Packaging requirements for liquid desensitised explosives
P7	Packaging requirements for flammable solids
P8	Packaging requirements for self-reactive flammable substances
P9	Packaging requirements for substances liable to spontaneous combustion
P10	Packaging requirements for substances that emit flammable gases when in contact with water
P11	Packaging requirements for oxidising substances
P12	Packaging requirements for organic peroxides
P13	Packaging requirements for toxic substances
P14	Packaging requirements for corrosive substances
P15	Packaging requirements for ecotoxic substances
PG1	Packaging requirements equivalent to UN Packing Group I
PG2	Packaging requirements equivalent to UN Packing Group II
PG3	Packaging requirements equivalent to UN Packing Group III
PS4	Packaging requirements as specified in Schedule 4

2.6. The *Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001* prescribe a number of controls aimed at ensuring hazardous substances handled in a manner appropriate to their toxicity.

Toxicity Controls	
T1	Limiting exposure to toxic substances through the setting of TELs
T2	Controlling exposure in places of work through the setting of WESs.
T3	Requirements for keeping records of use
T4	Requirements for equipment used to handle substances
T5	Requirements for protective clothing and equipment
T6	Approved handler/security requirements for certain toxic substances
T7	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
T8	Controls for vertebrate poisons

2.7. The *Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001* specify a number of controls primarily aimed at limiting the extent to which the environment are exposed to hazardous substances with ecotoxic properties.

Ecotoxicity Controls	
E1	Limiting exposure to ecotoxic substances through the setting of EELs
E2	Restrictions on use of substances in application areas
E3	Controls relating to protection of terrestrial invertebrates eg beneficial insects
E4	Controls relating to protection of terrestrial vertebrates
E5	Requirements for keeping records of use
E6	Requirements for equipment used to handle substances
E7	Approved handler/security requirements for certain ecotoxic substances

2.8. The *Hazardous Substances (Disposal) Regulations 2001* specify controls on the disposal of substances and their containers.

Disposal Controls	
D1	Disposal requirements for explosive substances
D2	Disposal requirements for flammable substances
D3	Disposal requirements for oxidising substances and organic peroxides
D4	Disposal requirements for toxic and corrosive substances
D5	Disposal requirements for ecotoxic substances
D6	Disposal requirements for packages
D7	Information requirements for manufacturers, importers and suppliers, and persons in charge
D8	Documentation requirements for manufacturers, importers and suppliers, and persons in charge

2.9. The *Hazardous Substances (Tracking) Regulations 2001* specify controls for the tracking of substances.

Tracking Controls	
TR1	General tracking requirements

2.10. The *Hazardous Substances (Personnel Qualifications) Regulations 2001* specify the qualifications required of an approved handler.

Approved handler Controls	
AH1	Approved Handler requirements (including test certificate and qualification requirements)

2.11. The *Hazardous Substances (Tank Wagon and Transportable Container) Regulations 2001* prescribe a number of controls relating to tank wagons and transportable containers.

Tank Wagon and Transportable Containers Controls
The Hazardous Substance (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers.

Other legislation

2.12. For internal land transport within New Zealand, the Land Transport Rule: Dangerous Goods 2005 will govern the type of transport, the qualifications of the driver and carrier, and the information requirements for transportation including packaging. Drivers are required to carry emergency management instructions for the substance they are carrying. For internal sea transport within New Zealand (e.g. across the Cook Strait), packages will have to meet the labelling requirements of the IMDG Code for the transport of dangerous goods by sea.

2.13. Under the HSE Act, employers and workers are required to be aware of all hazards.

2.14. The RMA prohibits discharge of contaminants into the environment unless it has been expressly allowed for in a Regional Plan, resource consent or by regulation. This is relevant to all stages of the substance's lifecycle, with specific relevance to the substance during its manufacturing, storage, use and disposal.

3. Risk assessment

3.1. The process by which the risk assessment of substances should be undertaken is specified in the Methodology. The process requires that the risks and benefits of a substance be identified and then assessed for their level of significance.

3.2. Potentially non-negligible risks must first be identified for evaluation following clauses 9 and 11, (which incorporate sections 5, 6 and 8) of the Methodology. These risks must then be assessed in accordance with sections 5 and 6 and clauses 9 and 12. The assessment must be undertaken with regard to:

- the environment,
- human health and safety,
- the relationship of Māori to the environment,
- society and the community,
- the market economy, and
- New Zealand's international obligations.

3.3. For the purposes of the assessment the following definitions are made in Regulation 2 of the Methodology.

- A "cost" is "the value of a particular adverse effect expressed in monetary or non-monetary terms". Thus, these should be assessed in an integrated fashion together with the risks of the adverse effects in the following assessment.
- A "benefit" is "the value of a particular positive effect expressed in monetary or non-monetary terms". Benefits that may arise from any of the matters set out in clauses 9 and 11 were considered in terms of clause 13.

3.4. To facilitate the assessment of risks the applicant and the Agency have identified the most common potential sources of risk to the environment and to human health and safety through release, spillage or exposure throughout the lifecycle of the substance. These are tabulated in Table S3.1 and are used as the basis for the risk assessment in the "Identification and Assessment of effects" section of the E&R report.

Table S3.1: Potential sources of risks associated with hazardous substances

Lifecycle Activity	Associated Source of Risk
Manufacture / Import	An incident during the manufacture or importation of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Transport or storage	An incident during the transport or storage of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Use – application to vessels	Application of the substance resulting in exposure of users or bystanders or the environment; or an incident during use resulting in spillage and subsequent exposure of users or the environment to the substance.
Use – on vessels	Leaching into the aquatic environment from vessel hulls/marine surfaces
Maintenance of vessels or equipment	Removal of old (dried) antifouling paint from a vessel or equipment, with subsequent exposure of users or the environment to the dust.
Disposal	Disposal of the substance or packaging resulting in exposure of people or the environment to the substance.
Spillage or use near an ignition source	Ignition or explosion resulting in physical injury to people or damage to the environment.

3.5. In undertaking the assessment the Agency notes that the evidence provided by the applicant and additional evidence found by the Agency, relating to the hazardous properties of the substances is largely scientific in nature (clause 25(1)). However, as the evaluation of risks, costs and benefits has been carried out on a qualitative basis, it is recognised that there is a degree of uncertainty in the risk analysis.

3.6. The level of risk has been evaluated on the basis of the magnitude and likelihood of adverse effects occurring to people or the environment.

3.7. In accordance with section 29, consideration is given to the likely effects of the substances being unavailable.

3.8. As in 3.2 above outlining the aspects in which the risk assessment is undertaken in relation with, the Agency assesses each application for any effects associated with the relationship of Māori to the environment. In most cases the substance will trigger a number of hazardous properties giving rise to the potential for cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

3.9. In addition, the introduction and use of hazardous substances have the potential to inhibit the ability of iwi/Māori to fulfil their role as kaitiaki, particularly in relation to the guardianship of waterways given the highly ecotoxic nature of the substance to aquatic species, and potential risks to the mauri ora of human health under prolonged exposure to this substance.

3.10. Where significant effects on the relationship of Māori to the environment are identified during the Agency's risk assessment these will be fully discussed in the body of the E&R report. Where effects are identified which will have a negligible

impact the following process will be undertaken to ensure that significant effects are not overlooked.

3.11. The Agency will consider the information outlined in the report, to determine that there is a minimal impact from the substance on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga to ensure that any impacts are highly improbable.

3.12. If this is determined the overall level of risk will therefore be considered to be negligible assuming that the substance will be handled, stored, transported, used, and disposed of, in accordance with the explicitly stated default and additional controls proposed in the report, and any other controls required by other legislation.

3.13. However, the Agency will propose that should inappropriate use, or accident, result in the contamination of waterways or the environment generally, that users will be required to notify the appropriate authorities including the relevant iwi authorities in that region. This action should include advising them of the contamination and the measures taken to contain and remediate.

4. Qualitative descriptors for risk/benefit assessment

4.1. This section describes how the Agency staff and the Authority address the qualitative assessment of risks, costs and benefits. Risks and benefits are assessed by estimating the magnitude and nature of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the level of the risk associated with that effect, which is a two dimensional concept. Because of lack of data, risks are often presented as singular results. In reality, they are better represented by 'families' of data which link probability with different levels of outcome (magnitude).

4.2. The magnitude of effect is described in terms of the element that might be affected. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the 'what if' element. Tables S4.1 and S4.2 contain generic descriptors for magnitude of adverse and beneficial effect. These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here to illustrate how qualitative tables may be used to represent levels of adverse and beneficial effect.

Table S4.1 Magnitude of adverse effect (risks and costs)

Descriptor	Examples of descriptions - Adverse
Minimal	Mild reversible short term adverse health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term adverse economic effects on small organisations (businesses, individuals), temporary job losses No social disruption
Minor	Mild reversible short term adverse health effects to identified and isolated groups Localised and contained reversible environmental impact, some local plant or animal

	communities temporarily damaged, no discernible ecosystem impact or species damage Regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses Potential social disruption (community placed on alert)
Moderate	Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation) Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage Medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses Some social disruption (e.g. people delayed)
Major	Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community Long term/irreversible damage to localised ecosystem but no species loss Measurable adverse effect on GDP, some long term (more than five years) job losses Social disruption to surrounding community, including some evacuations
Massive	Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths Extensive irreversible ecosystem damage, including species loss Significant on-going adverse effect on GDP, long term job losses on a national basis Major social disruption with entire surrounding area evacuated and impacts on wider community

Table S4.2 Magnitude of beneficial effect (benefits)

Descriptor	Examples of descriptions - Beneficial
Minimal	Mild short term positive health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term beneficial economic effects on small organisations (businesses, individuals), temporary job creation No social effect
Minor	Mild short term beneficial health effects to identified and isolated groups Localised and contained beneficial environmental impact, no discernible ecosystem impact Regional beneficial economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job creation Minor localised community benefit
Moderate	Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups Measurable benefit to localised plant and animal communities expected to pertain to medium term Medium term (one to five years) regional beneficial economic effects with some national implications, medium term job creation Local community and some individuals beyond immediate community receive social benefit.

Major	Significant beneficial health effects to localised community and specific groups in wider community Long term benefit to localised ecosystem(s) Measurable beneficial effect on GDP, some long term (more than five years) job creation Substantial social benefit to surrounding community, and individuals in wider community.
Massive	Significant long term beneficial health effects to the wider community Long term, wide spread benefits to species and/or ecosystems Significant on-going effect beneficial on GDP, long term job creation on a national basis Major social benefit affecting wider community

4.3. The likelihood applies to the composite likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and
- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

4.4. Thus, the likelihood is not the likelihood of an organism escaping, or the frequency of accidents for trucks containing hazardous substances, but the likelihood of the specified adverse effect[7] resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods[8]. The best way to determine the likelihood is to specify and analyse the complete pathway from source to impact.

4.5. Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability, the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table S4.3 Likelihood

Descriptor	Description
Highly improbable	Almost certainly not occurring but cannot be totally ruled out
Very unlikely	Considered only to occur in very unusual circumstances
Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions
Likely	A good chance that it may occur under normal operating conditions
Highly likely	Almost certain, or expected to occur if all conditions met

4.6. Using the magnitude and likelihood tables a matrix representing a level of risk/benefit can be constructed.

[7] The specified effect refers to scenarios established in order to establish the representative risk, and may be as specific as x people suffering adverse health effects, or y% of a bird population being adversely affected. The risks included in the analysis may be those related to a single scenario, or may be defined as a combination of several scenarios.

[8] Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

4.7. In the example shown in Table S4.4, four levels of risk/benefit are allocated: A (negligible), B (low), C (medium), and D (high). These terms have been used to avoid confusion with the descriptions used for likelihood and magnitude, and to emphasise that the matrix is a tool to help decide which risks/benefits require further analysis to determine their significance in the decision making process.

4.8. For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach. The purpose of developing the tables for both risk and benefit is so that the risks and benefits can be compared.

Table S4.4 Level of risk

	Magnitude of effect				
Likelihood	**Minimal**	**Minor**	**Moderate**	**Major**	**Massive**
Highly improbable	A	A	A	B	B
Very unlikely	A	A	B	B	C
Unlikely	A	B	B	C	C
Likely	B	B	C	C	D
Highly likely	B	C	C	D	D

5. Decision Path