

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Application Form (HSC14) for Notification of New Chemical Components approved under Group Standards

(if your substance is a single chemical it is not eligible for inclusion on a Group Standard by the notification process)

Send by post to: ERMA New Zealand, PO Box 131, Wellington 6140 OR

email to: inventory@ermanz.govt.nz

Company name:		
Company address:		
Postal address [if different to company address]		
Contact name:		
Job title		
Contact person phone / e-mail:	(0)	

New Chemical Information

Name of new chemical	
CAS number of new chemical	

Note: CAS numbers and names will be added to the Inventory subject to verification that the CAS number is current and that the name is commonly associated with this CAS number. If the chemical does not have a CAS number please give a reason.

Product Information

Substance Name/Product Name	
HSNO Approval number and/or title of Group standard	
Use of substance	
Concentration of New Chemical in product	

Confidentiality

Is a confidential listing requested for all or part of the information supplied? **Yes/No**

If Yes please provide written evidence to support a case for confidentiality (see Notes on Confidentiality)

Hazardous properties of New Chemical

If a SDS is provided for the **new chemical** only information on toxic properties 6.6, 6.7 and 6.8 need be completed below.

Include HSNO classifications where possible. Alternative information could include; R Phrases, hazard and precautionary statements, LD₅₀'s etc.

SDS of new chemical attached: Yes / No

Is the new Chemical Hazardous: Yes/No

UN number (if any)		Physical State	Solid/Liquid/Gas
Flammable properties	Flashpoint=	Boiling point=	
Oxidising properties			
Corrosive properties	pH=		
Toxic properties	Acute Toxicity 6.1		
	Skin irritation 6.3		
	Eye irritation 6.4		
	Sensitisation 6.5	Is the new chemical a sensitizer Yes/No/Unknown Respiratory or Skin	
	Mutagen 6.6¹	Is the new chemical a mutagen Yes/No/Unknown If yes provide information on the mutagen this chemical is replacing and why the new chemical is of lower hazard.	
	Carcinogen 6.7¹	Is the new chemical a carcinogen Yes/No/Unknown If yes provide information on the carcinogen this chemical is replacing and why the new chemical is of lower hazard.	
	Reproductive/ developmental 6.8¹	Is the new chemical a reproductive toxicant Yes/No/Unknown If yes provide information on the reproductive toxicant this chemical is replacing and why the new chemical is of lower hazard.	
	Target organ 6.9		
Ecotoxic properties			

¹Note: Under Section 4 Scope of Group Standard sub clause 5 of the Group Standards have conditions restricting the inclusion of carcinogens, mutagens and reproductive toxicants

Subclause 5 for a Toxic [6.7] Group Standard

No substance shall be permitted under this Group Standard if it contains a chemical that is a CMR that is not listed on the Inventory of Chemicals, unless—

- (a) the new CMR is used to completely replace an existing CMR in the substance; and
- (b) the new CMR has a lower hazard classification than the existing CMR.

Subclause 5 for all other Group Standards

No substance shall be permitted under this Group Standard if it contains a chemical that is a mutagen or reproductive toxicant that is not listed on the Inventory of Chemicals, unless—

- (a) the new mutagen or reproductive toxicant is used to completely replace an existing mutagen or reproductive toxicant in the substance; and
- (b) the new mutagen or reproductive toxicant has a lower hazard classification than the existing mutagen or reproductive toxicant.

Instructions to complete form

You need to ensure that all relevant information is provided in full before you send in the form. If the form is incomplete, we will be unable to process your notification and will need to contact you to fill in the missing information.

New Chemical – the component in the product which is not on the Inventory.

Substance name – this is the trade name of the product which contains the new chemical.

HSNO Approval number and/or title of Group Standard– this is the approval number or name of the Group Standard under which the substance has a deemed approval.

Name of new chemical – include the name that the chemical is known to you by. The name given to the CAS number on the Inventory will be the CAS name. The name you provide here will be added to the synonyms field if it matches the CAS number. If you have any other names or relevant registry numbers you would like added to the synonyms on the Inventory include these also but please provide justification for their inclusion.

CAS number – Chemical abstracts service registry number.

Please check that the CAS number matches the name of the new chemical. A useful website for checking these details is ChemID Plus <http://chem.sis.nlm.nih.gov/chemidplus/>. If these details don't match, we will need to ask you for more information i.e. to confirm whether the name or the CAS number is correct. If the chemical does not have a CAS registry number please explain why not.

Concentration of Chemical – the concentration of the new chemical in the formulated product.

Use of substance – this is the use of the formulated product, please be as specific as possible

SDS - please attach a Safety Data Sheet for the new chemical if you have one. The SDS should provide all the required hazard data.

UN number – Include the UN number, class and packing group where applicable.

Hazard Properties

The appropriate information listed is not an exhaustive list and is meant as a guide only.

Flammable properties - Appropriate information includes;

HSNO classes	3.1A-D, 3.2A-C, 4.1.1A-B, 4.1.2A-G, 4.1.3A-C, 4.2A-C, 4.3A-C
R Phrases	R5, R6, R7, R10, R11, R12, R14, R15, R17
Hazard phrases	Flammable, Highly flammable, Extremely flammable, Contact with water liberates extremely flammable gas, Spontaneously flammable in air
UN class	3, 4.1, 4.2, 4.3, PG I, II or III,

Oxidising properties – Appropriate information includes;

HSNO classes	5.1.1A-C, 5.1.2A, 5.2A-G
R Phrases	R5, R6, R7, R8, R9
Hazard phrases	Oxidising, Contact with combustible materials may cause fire, Explosive when mixed with combustible material
UN class	5.1, PG I, II or III, 5.2,

Corrosive properties – Appropriate information includes;

HSNO classes	8.2A, 8.2B, 8.2C, 8.3A
R Phrases	R34, R35, R41
Hazard phrases	Causes burns, Risk of serious damage to eyes
UN class	8, PG I, II or III

Acute Toxicity 6.1 – Appropriate information includes;

HSNO classes	6.1A, 6.1B, 6.1C, 6.1D, 6.1E (including exposure route)
R Phrases	R20-R29
Hazard phrases	Harmful/toxic/very toxic by inhalation in contact with skin/ if swallowed
UN class	6.1, PG I, II or III

Other appropriate information includes LD₅₀'s for oral, dermal or inhalation exposure routes.

Skin irritation 6.3 – Appropriate information includes;

HSNO classes	6.3A, 6.3B
R Phrases	R38
Hazard phrases	Irritating to skin

Eye irritation 6.4 – Appropriate information includes;

HSNO classes 6.4A
 R Phrases R36
 Irritating to eyes

Sensitisation 6.5 – Appropriate information includes;

HSNO classes 6.5A, 6.5B
 R Phrases R42, R43
 Sensitisation by inhalation/skin contact

Mutagen 6.6 – Appropriate information includes;

HSNO classes 6.6A, 6.6B
 R Phrases R46, R68
 May cause heritable genetic damage

Carcinogen 6.7 – Appropriate information includes;

HSNO classes 6.7A, 6.7B
 R Phrases R40, R45
 Limited evidence of carcinogenic effect, May cause cancer

Reproductive/ developmental 6.8 – Appropriate information includes;

HSNO classes 6.8A, 6.8B, 6.8C
 R Phrases R60, R61, R62, R63, R64
 May/possible risk of impaired fertility, May/possible risk to the unborn child, May cause harm to breast-fed babies

Target organ 6.9 – Appropriate information includes;

HSNO classes 6.9
 R Phrases R39, R48 and in any combination with R20-R28
 Danger of serious damage to health by prolonged exposure

Ecotoxic properties – Appropriate information includes;

HSNO classes 9 .1, 9.2, 9.3 and 9.4

R Phrases R50, R50/53, R51/53, R52/53, R53

Toxic to aquatic organisms, May cause long-term effects in the aquatic environment

UN class 9

Other appropriate data includes; EC₅₀'s or LC₅₀'s for aquatic organisms

Information on environmental persistence

Notes on Confidentiality

Under the Official Information Act 1982 (OIA) ERMA New Zealand may be required to release information in response to a request for information under the Act.

Section 9(2)(b) of the OIA provides good reason for withholding information where it is necessary to protect information where making available of the information –

- (i) would disclose a trade secret; or
- (ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information..."

The following guidance is provided in order to assist notifiers to understand the sort of information which will need to be provided to ERMA New Zealand in order to justify withholding information about chemicals in accordance with the OIA Further information on when and how confidential information can be withheld from public release can be obtained from the website of the Office of the Ombudsmen www.ombudsmen.govt.nz

A. Trade Secrets

In order to establish that the information is in the nature of a trade secret, please provide the following information:

1. State to what extent is the information is known:
 - (a) outside the business; or
 - (b) by employees and others involved in the business.

[Note - it may be appropriate here to provide names of those persons who are subject to confidentiality agreements and to provide copies of such agreements or relevant clauses]

2. State the extent of the measures taken to guard the secrecy of the information.

[Note - include here information on how is the information stored/kept. How else is it protected – what physical measures and IT measures; who may access building, offices, IT system; what other security measures (swipe card access, passwords?) does the business have in place?]

3. State the amount of effort and money expended in developing the information (can you give ballpark figures?).

[Note - this is not about the value of the business but about how much money it has spent in developing its 'trade secret']

4. State the value of the information to the applicant.
5. State the ease or difficulty with which the information could be properly acquired or duplicated by others.

B. Commercial Prejudice

In order to establish that the disclosure of the information would be likely unreasonably to prejudice the applicant's 'commercial position' please provide the following information:

1. Please confirm (with supporting evidence) that the notifier is a profit making organisation and has a 'commercial position' to protect (ie is in business with a profit making motive and provide information on its competitors in that market).
2. Identify the prejudice likely to result to notifiers commercial position if the information is made available.

[Note – you must be able to explain “precisely” how the predicted harm or damage would be likely to result if the information is released. This can include the possibility of future harm which is not, at present, quantified. Ombudsmen guidance states that a mere assertion that prejudice will arise is not enough – applicant needs to identify the prejudice]

3. How likely is it that this prejudice would result from disclosure?

[Note - again, an assertion is not sufficient, try and show that there will be a "serious or substantial risk to a protected interest, a risk that might well eventuate"]

4. Explain why this prejudice would be "unreasonable".

[Note - you should not focus solely on quantum of harm that is likely to result but consider whether in all the circumstances the likely prejudice is “unreasonable” by reference to such things as the nature of the information and its current relevance and the likelihood that it is of a type that a holder would not want disclosed without their consent]

5. Explain why disclosure would be so likely to cause the predicted prejudice that it is necessary to withhold it.

[Note - it must be demonstrated that prejudice is so likely to occur that it is necessary to withhold the information in order to prevent that prejudice. A mere possibility of the prejudice occurring is not sufficient]

NOTES –

1. **depending on the quality of the information provided under the above headings, ERMA New Zealand may request further information from notifiers by way of clarification;**
2. **even if either of the section 9(2)(b) grounds are met, the OIA requires ERMA New Zealand to decide whether there are any overriding ‘public interest considerations’ which make it desirable to make the information available anyway;**
3. **decisions made by ERMA New Zealand on confidentiality may be subject to review by the Office of the Ombudsmen.**