

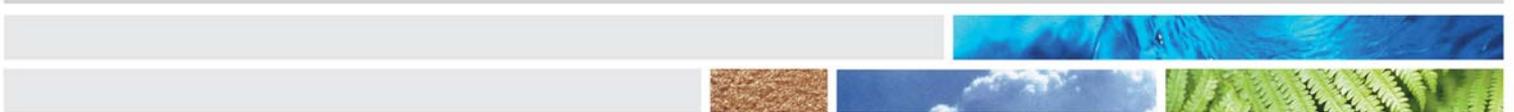


Environmental
Protection Authority
Te Mana Rauhi Taiao

Operational Policies and Procedures

New Zealand Inventory of Chemicals (NZIoC)

NOVEMBER 2011 (CONTENT AS ORIGINALLY WRITTEN MARCH 2007)



POLICIES AND PROCEDURES

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Executive Summary

Group Standards were issued by the Authority on 1 July 2006 to effect the transfer of notified toxic substances. Each Group Standard contains a condition that requires notification to the Authority of any new chemical present in products approved under that standard.

This 'notification condition' requires the development of an Inventory of Chemicals present in New Zealand. This New Zealand Inventory of Chemicals will be used by importers and manufacturers to determine if a product they are assigning to a Group Standard contains a new chemical.

The Inventory currently on the EPA website has limited functionality. Development of a searchable web based database is currently underway. The search function will be based on CAS number with limited searching available on chemical names. The design includes the ability to then directly make an application for listing a new chemical component by emailing in the completed form. Note that notifications also require the submission of hazard data on the new chemical component.

This document sets out the policy and procedures to enable users of a Group Standard to comply with the obligations under the notification condition.

The chemicals on the Inventory will be updated regularly. Amendments to the Inventory will be made by a formal process briefly outlined in this document .

Definitions

Chemical means the same as the definition of chemical in the group standards: "chemical" means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical, but excluding any solvent which may be separated without affecting the stability of the chemical or change its composition.

CMR means a substance that is a carcinogen, mutagen or reproductive toxicant when assessed against the criteria for carcinogenicity, mutagenicity and reproductive toxicity set out in the Hazardous Substances (Classification) Regulations 2001

Hazardous chemical means any chemical:

- a. With one or more of the following intrinsic properties (which meet the criteria prescribed in the Hazardous Substances [Minimum Degrees of Hazard] Regulations 2001):
 - (i) *Explosiveness:*
 - (ii) *Flammability:*
 - (iii) *A capacity to oxidise:*
 - (iv) *Corrosiveness:*
 - (v) *Toxicity (including chronic toxicity):*
 - (vi) *Ecotoxicity, with or without bioaccumulation; or*



- b. Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition:

Hazardous chemical component means the same as hazardous chemical but where the chemical is a component of a product.

Hazardous substance means any substance:

- a. With one or more of the following intrinsic properties (which meet the criteria prescribed in the Hazardous Substances [Minimum Degrees of Hazard] Regulations 2001):
- (i) *Explosiveness:*
 - (ii) *Flammability:*
 - (iii) *A capacity to oxidise:*
 - (iv) *Corrosiveness:*
 - (v) *Toxicity (including chronic toxicity):*
 - (vi) *Ecotoxicity, with or without bioaccumulation; or*
- b. Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition:

Non hazardous chemical means a chemical which does not meet the property criteria of a hazardous chemical

Non hazardous chemical component means a chemical component which does not meet the property criteria of a hazardous chemical component

Non hazardous substance means a substance which does not meet the property criteria of a hazardous substance

Product means a mixture or a solution composed of two or more chemical components in which they do not react

Single component product means the same as the definition of chemical in the group standards.

“chemical” means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical, but excluding any solvent which may be separated without affecting the stability of the chemical or change its composition.

Substance means the same as the definition of substance in the HSNO Act:

“Substance means—

(a) Any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof:

(b) Any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound:

(c) *Any mixtures or combinations of any of the above...*

Inventory of Chemicals

Why Have an Inventory of Chemicals?

The purpose of the HSNO Act is to protect the environment, and the health and safety of people and communities, by preventing or managing adverse effects of hazardous substances and new organisms. If we don't know what the hazardous substances are how can we prevent or manage any of the associated risks? To assist in achieving this purpose it is important to know what chemicals are present in New Zealand whether as individual chemicals or as components of products. The identification of these chemicals may also facilitate future actions to improve risk management (where such actions can be demonstrably justified), and is consistent with the EPA's risk reduction strategy.

The aim of the Inventory is to provide a list of all the chemicals in New Zealand. It is not a list of approvals. See the section on restrictions on the inventory.

The maintenance of an Inventory is consistent with the approach taken in many other developed countries, including Australia, USA and Europe and forms an integral part of the risk management framework for Group Standards.

Requirement to Notify Chemicals for the Inventory

The transfer of over 100,000 notified substances (NOTS) from the transitional provisions to the main part of the HSNO Act was completed on 1 July 2006. This transfer was effected with the Authority issuing 200 Group Standards in the Hazardous Substances (Group Standards) Notice 2006. This notice was published as a supplement to the New Zealand Gazette.

Group Standards are not "closed" approvals but allow for the introduction of new products if they meet the scope and conditions of the Group Standard. One condition that specifically applies to new products is the following condition set out in Schedule 1 Part 9 of the Group Standards which requires Notification to the Authority.

Inventory of Chemicals

Where a substance is imported into, or manufactured in, New Zealand after 30 June 2006, if that substance contains a hazardous chemical that is not listed on the Inventory of Chemicals, then the importer or manufacturer of the substance must at the time they first import or manufacture the substance, notify the Authority in writing of:

- a. the name of the substance; and*
- b. the HSNO approval number and/or title of the Group Standard under which the substance has a deemed approval; and*

- c. *the name and CAS number of the chemical not listed on the Inventory of Chemicals that is present in the substance; and*
- d. *the concentration of that chemical in the substance; and*
- e. *the hazardous properties of the chemical, including the provision of the relevant hazard data used to assign the substance to the Group Standard; and*
- f. *the proposed use of the substance.*

The notification process is not designed to provide enough information for a new chemical component to be fully assessed, classified and given an approval. The Group Standards are designed to manage the risks of the substances approved under them not to determine the hazards of the individual components of each product. Hazard information of the component is required for notification to show that the hazards associated with the new chemical component have been assessed by the notifier and have been taken into account when the product has been classified. There are no criteria for acceptability of hazard data provided through the notification process.

The Inventory

Where did these CAS numbers come from?

The majority of the listed CAS numbers were compiled using the lists of individual chemical substances that were transferred to HSNO under the transitional provisions of the Act. This includes the substances from the *Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004*, the *Hazardous Substances (Chemicals) Transfer Notice 2006*, all the components of NOTS, whether they were single chemicals or formulated products where CAS numbers were provided, components of various applications that have been approved under HSNO and any notifications to the Inventory received since 1 July 2006. In theory this would cover all the chemicals currently present in New Zealand except where products have been self deemed to be similar to existing substances. Note that this includes non hazardous chemicals. All the CAS numbers on the Inventory have been verified.

As many notifications (NOTS) did not include full compositional data we are aware that our current list may be incomplete. We are asking that you check that the components of your products that have been approved under Group Standards, including any products that you have self deemed, are on the current Inventory (see the section the notification process). The EPA will be accepting notification for components of NOTS without hazard data till 1 July 2008. Only the following information needs to be supplied when notifying components of NOTS.

- NOTS number
- Substance/Product name
- New chemical component name
- CAS number

The current form of the Inventory has limited functionality. The EPA is developing a searchable database which will be more user friendly (see the [section on accessing the inventory](#)).

Operation and Maintenance of the Inventory

What will be on the Inventory

All chemicals known by the EPA to be present in New Zealand, including non hazardous chemicals, will be listed on the Inventory. Chemicals listed on the confidential section will not be publicly available (see Section on confidentiality). This includes the known components of transferred substances and components of Part V applications.

The definition of chemical with respect to the inventory is the definition given in the group standards.

“chemical” means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical, but excluding any solvent which may be separated without affecting the stability of the chemical or change its composition.

By this definition impurities and by-products will not be included on the Inventory

Manufactured articles that contain a hazardous substance (other than an explosive substance) are not considered hazardous substances under the HSNO Act and are, therefore, not required to be notified. Refer to the EPA Information Sheet on Manufactured Articles, which can be found on our [website](#).

What needs to be Notified

Any hazardous component of a new formulated product using a Group Standard approval that is not on the Inventory will need to be notified. A new formulated product is one that is imported into, or manufactured in, New Zealand after 30 June 2006.

Cut-off levels for notification will be based on the respective hazard cut-off concentrations. The simple rule will be that if a component contributes to the hazard of a product, then if the component is not on the Inventory, it is required to be notified. Regulations require much of this information on the safety data sheet (SDS) at the same concentration as the hazard cut-offs for class 6 classifications.

Table 1 Comparison of Classification, Labeling and SDS cut-offs for class 6 substances

	Classification Cut-off (%)	Label Identification Cut-off (%) ^c	Safety Data Sheet Cut-off (%) ^c
6.5A	0.1	0.1 ^a	0.1
6.5B	0.1	0.1 ^a	0.1
6.6A	0.1	0.1	0.1
6.6B	1.0	1.0	1.0
6.7A	0.1	0.1	0.1
6.7B	0.1	1.0	0.1
6.8A	0.1	0.3	0.1
6.8B	0.1	3.0	0.1
6.9A ^b	1.0	10.0	1.0
6.9B ^b	1.0	10.0	1.0

Notes:

- The label warning for sensitizers between 0.1% and 1.0% (0.2% for gaseous respiratory sensitizers) may differ from the label warning for sensitizers $\geq 1.0\%$ (0.2%). In special case, identification may be required below the 0.1% level if a lower value has been used for classification.
- Applies to both single exposure and repeat exposure target organ systemic toxicants.
- The use of these concentration cut-offs can be subject to variation depending on the outcome of a substance specific risk assessment.

Exceptions to what needs to be notified include:

- Concentration/s of component/s less than the mixture cut off values unless there are hazardous property reasons to notify the component/s. For example, the substance CAS 2634-33-5, 1,2-Benzisothiazol-3(2H)-one (BIT), which is a sensitiser at concentrations as low as 0.05% compared to the standard cut off of 0.1%.
- New fragrance materials for inclusion under a Food Additives and Fragrance Materials Group Standard
- Components of cosmetic products covered under the Cosmetics Group Standard
- Chemicals held under exempt laboratory status

While notification of new chemicals which fall under these exceptions is not a requirement any chemicals that are notified to the Agency will be added to the Inventory. We would like the Inventory to be complete as possible.

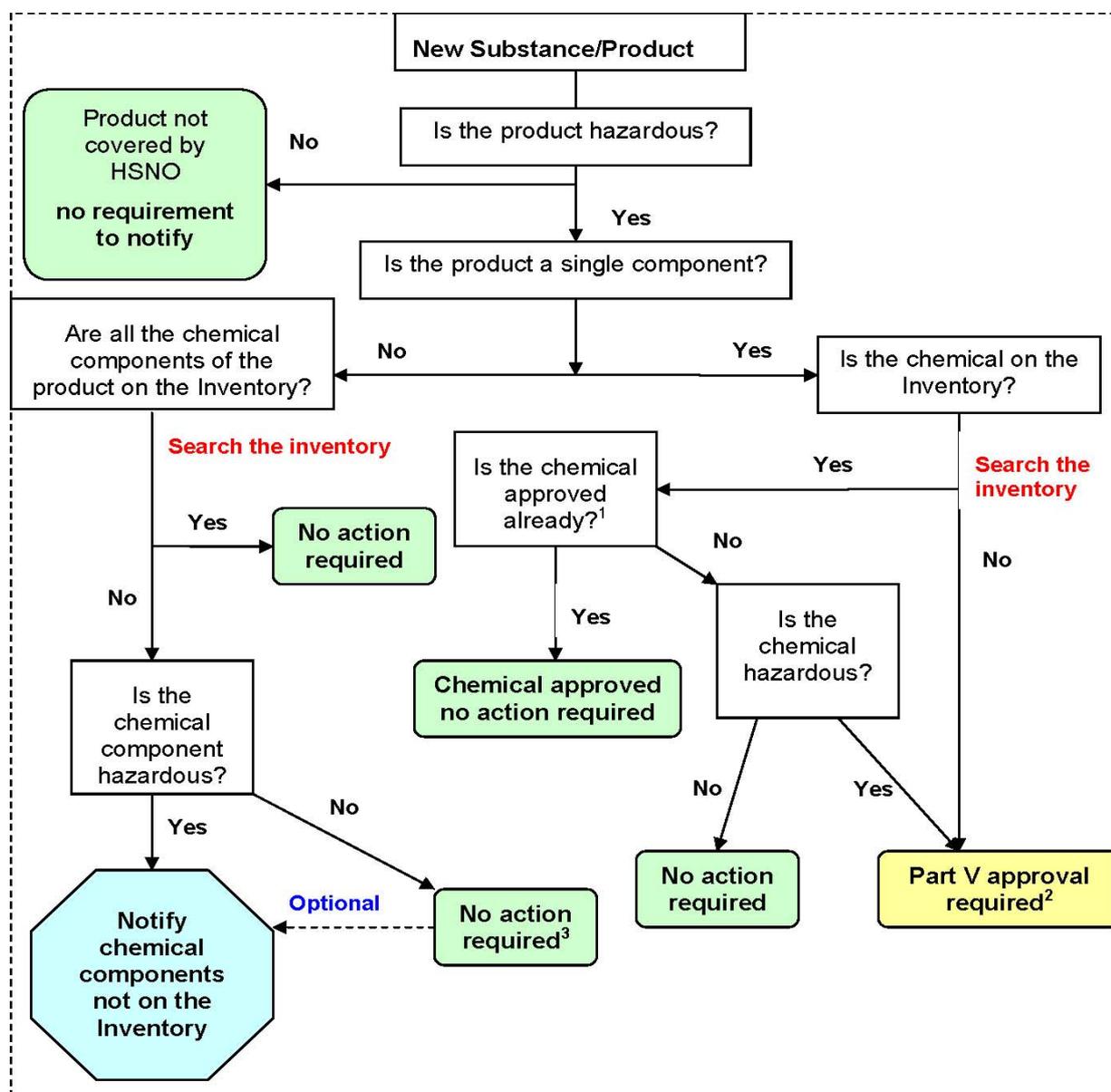
Note that notification of single component chemical products is not allowed for most Group Standards under clause 4 (Scope of Group Standard). The definition of single component chemical product has the same meaning as the definition of chemical in the group standards.

The relevant clause from the Group Standards is as follows:

Despite clause 19 of Schedule 1, no substance shall be permitted under this Group Standard if it is a hazardous chemical that is not listed on the Inventory of Chemicals.

For the purposes of the preceding subclause “chemical” means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical, but excluding any solvent which may be separated without affecting the stability of the chemical or change its composition.

Flow Chart: How do you know if you are required to notify?



¹ Not all Chemicals listed on the Inventory have approvals under the HSNO Act to be imported or manufactured in their own right. A small number (6-8000) have been assessed for their hazards and risks and do have approvals by virtue of having been transferred individually in the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004, or the Hazardous Substances (Chemicals) Transfer Notice 2006. A number of other chemicals by virtue of being transferred under Group Standards approvals are also approved under HSNO. These chemicals can use either the individual approval number or a Group Standard approval if they fit the scope of the Group Standard. The remainder can only be imported as components of approved products.

² A hazardous chemical which does not have an EPA approval cannot be imported or manufactured before a Part V approval is obtained.

Part V approval routes include:

- Full Release
- Rapid/Low hazard
- Rapid/Similar
- Rapid/Reduced Hazard.

For more information on these approval routes visit the EPA website

³ While there is no legal obligation to notify non hazardous chemicals, any such chemical notified will be added to the Inventory.

Restrictions on the Inventory

Under either individual or Group Standard approvals some chemicals have controls or conditions placing restrictions on their use. These restrictions will be noted on the Inventory.

Examples of restrictions include:

- the Fire Fighting Chemicals Group Standard excludes perfluoroalkyl sulfonate, and perfluorooctanoic acid.
- lindane may not be used for any purpose other than (a) for research and development; or (b) as an ingredient in the manufacture of a medicated product for use on humans.

New CMRs

The 'Scope' of each Group Standard contains a condition restricting components which are carcinogens, mutagens and reproductive toxicants (CMRs).

Under a Group Standard approval a new CMR can only be added to the Inventory if (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.

Accessing the Inventory

Development of a searchable web based database is currently underway. The search function will be based on CAS number with limited searching available on chemical names. The design includes the ability to then directly make an application for listing a new chemical component by emailing in the completed form. Note that notifications also require the submission of hazard data on the new chemical component.

The database will include the following information:

- Chemical name – this will be the CAS name
- CAS number

- Synonyms or Associated names – this will include the gazetted name where relevant, any known common name and the name supplied by the notification process (if it is a legitimate name). Other registry numbers and names may be included where this is appropriate to the class of chemical. Trade names will not be included.
- Approval Status
- Restrictions/Exclusions
- Date added to Inventory

A txt file with all the CAS numbers on the Inventory will also be maintained on the EPA website. This will enable industry to incorporate the New Zealand Inventory of Chemicals in any database they might have in order to facilitate compliance.

Information will not be able to be lodged directly into the Inventory. Verification of the CAS number and names is required before a new listing is made.

The database containing the Inventory information will be publicly available via the EPA website. The only information made available will be as listed above. All other information supplied on the notification form will be stored in a confidential file. Only EPA staff will have access to the confidential information. In addition, a confidential section will be maintained on the Inventory (see Section on confidentiality). Requests for information under the Official Information Act may require the EPA to release information to other parties.

Updating the Inventory

Once you have notified a new chemical it does not need to appear on the Inventory before you can legally import a substance containing this chemical. The Inventory will only be updated quarterly.

When updates are made to the Inventory the searchable database and the txt file of CAS numbers will be updated on the EPA website. To receive notification of any updates to the Inventory you will be able to register on the Website Update Notifications web page to receive an email notification that an update has occurred.

Confidentiality

It should be noted that the Inventory consists solely of a list of chemicals and there is no linkage to commercial or proprietary products which contain these chemicals and components.

The EPA acknowledges that, in some circumstances, notifiers may wish to keep some information confidential for reasons of commercial sensitivity. There can be a conflict between a notifier's need for confidentiality and the objective of providing for full and informed public participation in the operation of HSNO Act. However, to the extent that it is legally able to do so, the EPA will treat as confidential, for as long a period as is specified by the notifier, all information provided by that notifier which is classified as commercially confidential. Confidential listings on the Inventory will be reviewed after five years.

Where supporting data is provided the EPA will recognise confidential listings on other international inventories.

In other cases the EPA will, however, rely on the person providing proposed confidential information, to identify it as such and to justify this position. 'Confidential information' for these purposes is primarily information which may be withheld under the Official Information Act, in particular, section 9(2)(b) which provides a 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...”

These are potentially tough tests to satisfy especially given that there will be no identification of products containing the notified chemicals on the Inventory and the Agency will not be prepared (or able) to accept mere assertions, for example, as to commercial prejudice, but instead will require an explanation of exactly how prejudice might occur and why that is unreasonable.

In addition to the Official Information Act, information may be protected by virtue of the interaction of HSNO with other Acts. For example, in applications for an innovative agricultural compound under Part 6 of the ACVM Act 1997 or for an innovative medicine under the Medicines Act 1981, the relevant confidentiality provisions of those Acts will apply to the EPA as provided for in section 55 of the HSNO Act.

If you believe that information you may notify should be kept confidential, you will be required to justify your grounds for this. Question 2 on the submission form asks you to give reasons why confidentiality may be required and an indication of the length of time that confidentiality should apply for.

Fees

There will generally be no fees associated with notification of new chemicals for the Inventory. However, where the importer/manufacturer notifying the new chemical does not have any hazard data they will be required to make a Status of Substance Request for informal advice on the hazards of the substance. The fee for this service is \$100 + GST.

Notification process

Notification of a new chemical component in accordance with Schedule 1, Part 9 of a Group Standard will be required at the time the substance containing the new chemical is first imported or manufactured in New Zealand.

Notification will be by means of an Application Form for Notification of New Chemical Components Approved under Group Standards with a requirement to provide the information specified under the conditions of the Group Standard. This will include substance name (product name), the HSNO approval number and/or title

of the Group Standard under which the substance has an approval, the name and CAS of the “new chemical component”, the concentration of the “new chemical component” in the substance, information on the hazardous properties of the “new chemical component”, the proposed use of the substance, whether or not the chemical component is a carcinogen, mutagen or reproductive toxicant.

Information on the hazardous properties of the “new chemical component” can be supplied in the form of an SDS. As indicated in section 2.8 above, if the notifier does not have any hazard data for the new chemical component, they will need to submit a Status of Substance request (HS6A) to the Agency for informal advice on the hazards of the substance and a fee of \$100 +GST will be charged.

The notifier will receive a letter confirming receipt of their notification within 15 working days of the EPA receiving the notification. There are no acceptance criteria for data submitted for notification for the Inventory. Notifications will be added to the Inventory subject to verification of the CAS number. The new chemical component name supplied with the notification will also be added to the synonyms subject to verification that it is commonly associated with the notified CAS number. If there are any issues with the verification the notifier will be contacted and a resolution agreed upon. The group standard condition is fulfilled upon notification and verification is not required before the product can be assigned and approved under the appropriate group standard. Neither does the new chemical component need to appear on the “official” Inventory before the new substance can be imported or manufactured.

Where the importer/manufacture does not have access to the full compositional information for a product, provisions for third party notification can be provided.

Letting us know if chemicals are not on the Inventory

The requirement to notify in accordance with Schedule 1 Part 9 of the Group Standards only applies to substances imported into, or manufactured in, New Zealand after 30 June 2006. This means that transferred substances do not need to meet this condition.

When the chemical is a component of a product transferred under a Group Standard approval it should theoretically already be on the Inventory. However, full compositional information on many of the substances transferred was not provided at the time products were notified under the transitional provisions of HSNO. This means that some components of transferred products are not currently on the Inventory.

Although it is not a requirement of using a Group Standard approval we would encourage industry to tell us which components of their transferred substances are not currently on the Inventory. The reasons you might want to do this include:

- If you have a new product which you know is the same as an existing substance you will not need to check the Inventory if you are confident all the components of your products are on the Inventory.
- Your customers can be confident products that you supply are compliant.
- Provides a more complete Inventory of the chemicals in New Zealand.

For notification of components of transferred substances you will not need to fill in the standard notification form. All you need to do is show that the product was notified (provide NOTS number or notification form) and provide the compositional data, with CAS number, showing that the chemical is a component of that notified product and we will add it to the Inventory.

The EPA will also be comparing the Inventory with the Australian Inventory of Chemicals (AICS) with the possibility of adding some chemicals from AICS that are not currently on the Inventory.

Notification of Non Hazardous Chemicals

The notification of non hazardous substances is not mandatory. The HSNO Act states; The purpose of this Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

While it is not mandatory to notify non hazardous chemicals you are encouraged to do so if you wish to. The notification process will be the same as for hazardous chemicals and you will be required to provide evidence that the chemical is non hazardous.

Non hazardous chemicals will be included on the Inventory where notified.

Not all chemicals on the Inventory have been assessed by the EPA, therefore, there will be no indication on the Inventory whether or not a chemical is hazardous or non hazardous.

Chemical Components with No CAS Number

For confidentiality reasons it is possible that a chemical may not have a CAS number.

When notifying a chemical with no CAS number you will need to provide a proper chemical name and where this information is required to be kept confidential you will need to demonstrate good grounds for this as described in the section on confidentiality.

These chemicals will be verified as not currently having a CAS number before they are added to the confidential or non confidential section of the Inventory as unique chemicals.

Third Party Notification

Where third party notification is required a reference number will be supplied to the notifier to pass on to the third party to allow notification of confidential information.

Where the third party has all the relevant information they can notify on behalf of a New Zealand supplier.



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

under the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, PO Box 131, Wellington 6140 OR email to: inventory@epa.govt.nz
Please allow 10 working days for processing.

If your substance is a single chemical it is not eligible for inclusion on a Group Standard by the notification process.

Date

Organisation's Name

Organisation's Postal Address

Contact Name

Job Title

Contact's Phone

Contact's Email



Important

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.

The Official Information Act requires the EPA to decide whether there are any overriding 'public interest considerations' which make it desirable to make the information below available, even if section 9(2)(b) grounds are met.

Definitions

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	<p>Appropriate information includes;</p> <p>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</p> <p>GHS Category Flammable liquids, Flammable solids, Self-reactive substances and mixtures, Solid desensitized explosives, Self-heating substances and mixtures, Pyrophoric liquids or solids, Substances and mixtures, which in contact with water, emit flammable gases</p> <p>R Phrases R5, R6, R7, R10, R11, R12, R14, R15, R17</p> <p>Hazard phrases Flammable, Highly flammable, Extremely flammable, Contact with water liberates extremely flammable gas, Spontaneously flammable in air</p> <p>UN class 3, 4.1, 4.2, 4.3, PG I, II or III,</p>
Oxidising properties	<p>Appropriate information includes;</p> <p>HSNO classes 5.1.1A-C, 5.1.2A, 5.2A-G</p> <p>GHS Category Oxidising liquids or solids, Organic peroxides</p> <p>R Phrases R5, R6, R7, R8, R9</p> <p>Hazard phrases Oxidising, Contact with combustible materials may cause fire, Explosive when mixed with combustible material</p> <p>UN class 5.1, PG I, II or III, 5.2,</p>
Corrosive properties	<p>Appropriate information includes;</p> <p>HSNO classes 8.1A, 8.2A, 8.2B, 8.2C, 8.3A</p> <p>GHS Category Corrosive to metals, Skin corrosion/irritation Category 1A, 1B, or 1C, Serious eye damage/eye irritation Category 1</p> <p>R Phrases R34, R35, R41</p> <p>Hazard phrases Causes burns, Risk of serious damage to eyes</p> <p>UN class 8, PG I, II or III</p>
Acute Toxicity 6.1	<p>Appropriate information includes;</p> <p>HSNO classes 6.1A, 6.1B, 6.1C, 6.1D, 6.1E (including exposure route)</p> <p>GHS Category Acute toxicity: Oral/Dermal/Inhalation Category 1, 2, 3, 4 or 5</p> <p>R Phrases R20-R29</p> <p>Hazard phrases Harmful/toxic/very toxic by inhalation in contact with skin/ if swallowed</p> <p>UN class 6.1, PG I, II or III</p> <p>Other appropriate information includes LD50's for oral, dermal or inhalation exposure routes.</p>
Skin irritation 6.3	<p>Appropriate information includes;</p> <p>HSNO classes 6.3A, 6.3B</p> <p>GHS Category Corrosive to metals, Skin corrosion/irritation Category 2</p>

	<p>or 3</p> <p>R Phrases R38</p> <p>Hazard phrases Irritating to skin</p>
Eye irritation 6.4	<p>Appropriate information includes;</p> <p>HSNO classes 6.4A</p> <p>GHS Category Serious eye damage/eye irritation Category 2</p> <p>R Phrases R36</p> <p>Hazard phrases Irritating to eyes</p>
Sensitisation 6.5	<p>Appropriate information includes;</p> <p>HSNO classes 6.5A, 6.5B</p> <p>GHS Category Respiratory sensitization Category 1 or Skin sensitization Category 1</p> <p>R Phrases R42, R43</p> <p>Hazard phrases Sensitisation by inhalation/skin contact</p>
Mutagen 6.6	<p>Appropriate information includes;</p> <p>HSNO classes 6.6A, 6.6B</p> <p>GHS Category Germ cell mutagenicity Category 1 or 2</p> <p>R Phrases R46, R68</p> <p>Hazard phrases May cause heritable genetic damage</p>
Carcinogen 6.7	<p>Appropriate information includes;</p> <p>HSNO classes 6.7A, 6.7B</p> <p>GHS Category Carcinogenicity Category 1 or 2</p> <p>R Phrases R40, R45</p> <p>Hazard phrases Limited evidence of carcinogenic effect, May cause cancer</p>
Reproductive/ developmental 6.8	<p>Appropriate information includes;</p> <p>HSNO classes 6.8A, 6.8B, 6.8C</p> <p>GHS Category Toxic to reproduction Category 1 or 2 and effects on lactation</p> <p>R Phrases R60, R61, R62, R63, R64</p> <p>Hazard phrases May/possible risk of impaired fertility, May/possible risk to the unborn child, May cause harm to breast-fed babies</p>
Target organ 6.9	<p>Appropriate information includes;</p> <p>HSNO classes 6.9</p> <p>GHS Category Specific Target Organ Systemic Toxicity (single or repeat exposure)</p> <p>R Phrases R39, R48 and in any combination with R20-R28</p>

	Hazard phrases	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
	GHS Category	Aquatic toxicity acute Category 1, 2, or 3, Aquatic toxicity chronic Category 1, 2, 3 or 4
	R Phrases	R50, R50/53, R51/53, R52/53, R53
	Hazard phrases	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) the EPA 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 the EPA 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

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 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Respiratory <input type="checkbox"/> Skin
	Mutagen 6.6¹	Is the new chemical a mutagen <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes provide information on the carcinogen this chemical is replacing and why the new chemical is of lower hazard:
	Reproductive/developmental 6.8¹¹	Is the new chemical a reproductive toxicant <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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			

¹ Note: 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.

Confidential Listing Justification

To be completed only for notifications for confidential listing.

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:

- **outside the business; or**
- **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 notifier's 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 demonstrate 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.



Environmental
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Te Mana Rauhi Taiao

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