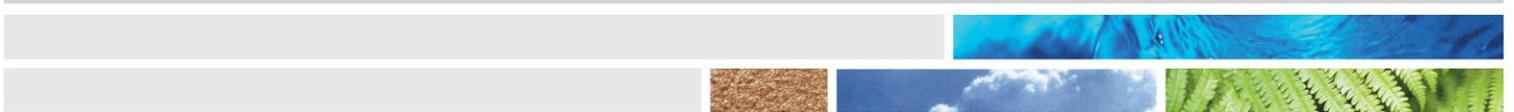




Environmental
Protection Authority
Te Mana Rauhi Taiao

New Zealand Inventory of Chemicals (NZIoC) Guide

AUGUST 2020





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Executive summary

Group Standards are approvals for a group of hazardous substances of a similar nature, type or use. Most domestic and workplace chemicals (except for pesticides, timber treatment chemicals and vertebrate toxic agents) are approved under group standards. The substances within a Group Standard are covered by one set of conditions, which state how they can be used and how to manage the related risks. Different types of products with different uses can be approved together under a single group standard. For example, the aerosol Group Standards include aerosol paints and aerosol cleaners. Each Group Standard contains a condition that requires notification to the EPA of any new chemical present in products approved under that standard.

This notified chemical is then added to the New Zealand of Chemicals (NZIoC) pending verification from the Chemical Abstracts Service (CAS). The NZIoC is able to be used by importers and manufacturers to determine if a product they are assigning to a Group Standard contains a new chemical.

This document acts as guidance to enable users of a Group Standard to comply with the obligations under the notification condition.

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) Notice 2017.

Hazardous chemical means any chemical: means, unless expressly provided otherwise by regulations, any chemical —

(a) With 1 or more of the following intrinsic properties:

- (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 1 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: means, unless expressly provided otherwise by regulations, any substance—

(a) With 1 or more of the following intrinsic properties:

(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 1 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...”

NZ 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 NZIoC is to provide a list of all the chemicals in New Zealand. It is not a list of approvals. The maintenance of an NZIoC 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.

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 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.

Operation and maintenance of the NZIoC

What will be on the NZIoC?

All chemicals known by the EPA to be present in New Zealand, including non-hazardous chemicals where these have been notified, will be listed on the NZIoC. Chemicals listed on the confidential section will not be publicly available.

Impurities and by-products will not be included on the NZIoC.

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 NZIoC will need to be notified.

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 NZIoC, 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, Labelling 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:

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

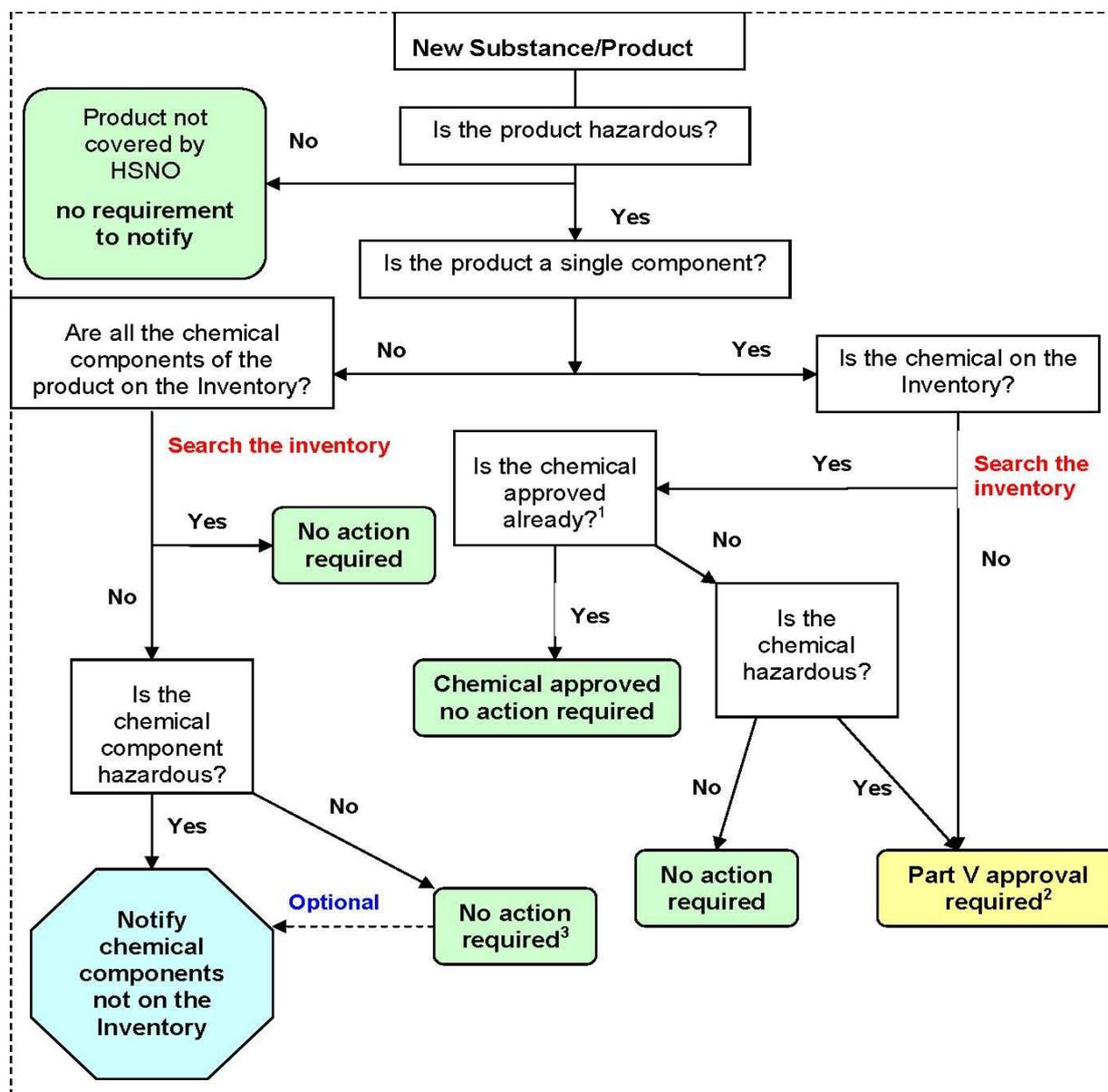
Exceptions to what needs to be notified include:

- 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 sensitizer 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 EPA will be added to the NZIoC.

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.

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



¹ Not all Chemicals listed on the NZIoC have approvals under the HSNO Act to be imported or manufactured in their own right. A small number have been assessed for their hazards and risks and do have approvals. 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 an approval is obtained.

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

Notification process

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

The new chemical can be notified to the EPA using the *HSC14 Application Form for Notification of New Chemical Components Approved under Group Standards*. Information on the hazardous properties of the “new chemical component” can be supplied in the form of an SDS. The EPA will review if the hazardous properties of the new chemical meet the conditions specified under the Group Standard selected. To close out notification obligations, we aim to provide notification confirmation within 40 working days of the EPA formally receiving the notification. The new chemical is considered to be notified upon receipt of a confirmation letter from the EPA. The new chemical information will be sent to CAS for verification of the CAS number. Subject to verification it will be added to the NZIoC and made publicly accessible on the website (if non-confidential). If there are any issues with CAS verification, the notifier will be contacted.

Updating the NZIoC

Once you have notified a new chemical it does not need to appear on the website before you can legally import or manufacture a substance containing this chemical, but you do require confirmation that the notification has been added before importing or manufacturing. To receive notification of any updates to the NZIoC on the website contact inventory@epa.govt.nz

Confidentiality

It should be noted that the NZIoC 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, information provided by that notifier which is classified as commercially confidential.

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

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...”

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. Refer Confidentiality section on the application form.

Restrictions on the NZIoC

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 NZIoC.

Examples of restrictions include:

- Veterinary medicine may not be used for any purpose other than as a component in a formulated veterinary medicine.
- POPS - 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 NZIoC 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.

Letting us know if chemicals are not on the NZIoC

The requirement to notify in accordance with Schedule 1 of the Group Standards only applies to substances imported into, or manufactured in, New Zealand after 30 June 2006. This means that substances transferred from the former Toxic Substances database 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 NZIoC. 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 NZIoC.

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 NZIoC. 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 NZIoC if you are confident all the components of your products are on the NZIoC.
- Your customers can be confident products that you supply are compliant
- Provides a more complete NZIoC of the chemicals in New Zealand.

Notification of non-hazardous chemicals

The notification of non-hazardous substances is not mandatory but you can notify these if you wish to do so. 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 NZIoC where notified.

Not all chemicals on the NZIoC have been assessed by the EPA, therefore, there will be no indication on the NZIoC 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 NZIoC as unique chemicals.

Accessing the NZIoC

The NZIoC database can be accessed via the EPA website. The listed chemicals are also available to download in Excel format from the EPA website. Confidential listings are excluded from the database search tool and Excel files.

The search function is based on CAS number with limited searching available on chemical names.

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 NZIoC

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. In addition, a confidential section will be maintained on the NZIoC (see Section on confidentiality). Requests for information under the Official Information Act may require the EPA to release information to other parties.

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

Fees

There are no fees associated with notification of new chemicals for the NZIoC.