

Modular assessment options—chemicals previously assessed in Australia

NICNAS may remit part of the notification fees for non self-assessed Standard, Limited and Polymer of low concern applications, where:

- the notified chemical or polymer is similar¹ to a chemical or polymer previously assessed by NICNAS, or
- the notified chemical or polymer is being notified at the same time as a similar chemical or polymer, or
- an assessment of the notified chemical by the Therapeutic Goods Administration (TGA), under the Therapeutic Goods Act 1989, is available, or
- an assessment of the notified chemical by the Australian Pesticides and Veterinary Medicines Authority (APVMA), under the Agricultural and Veterinary Chemicals Code Act 1994, is available, or
- an assessment of the notified chemical by Food Standards Australia New Zealand (FSANZ), under the Food Standards Australia New Zealand Act 1991, is available.

In the event that multiple circumstances apply, the reduced fee will not be additive.

General application requirements

If submitting a modular application, indicate this on the STD/LTD or PLC notification Form-1 and, as indicated, on the form, complete and submit the modular attachment. The attachment relates solely to the application under this category. Completing it does not, however, fulfil the requirements of the notification itself.

In all cases you must:

- have consent from the notifier and the holder of the data for the original assessment to use the assessment report for a NICNAS assessment
- address all relevant schedules of data requirements for the relevant assessment category—except in the case where the chemical has been previously assessed by NICNAS, copies of all available toxicity data (including that which has been previously assessed) in English, must be provided.

1 Modular assessment—similar to chemical previously assessed by NICNAS

Modular assessment applies where the chemical or polymer you are notifying is similar to one previously assessed by NICNAS. In this case NICNAS may remit:

- up to 40% of your paid application fee for a non-self assessed certificate application
- a further 20% of your paid application fee if the chemical or polymer notified has the same—or similar—use to the one previously assessed.

¹The term 'similar' is defined by specific criteria in the sections below.

These savings will depend on the scope of the original assessment, and any rebate will be paid once your assessment is complete. A reduction in fees does not apply if the original assessment was a self-assessment.

Criteria for similar chemical

For NICNAS to regard a chemical (polymers are considered separately, below) as similar to another chemical for the purposes of reducing fees, the chemical must be *prima facie* structurally identical or similar and must have been assessed at the same or a higher-level (that is, STD) notification category. An exception may be where the full scheduled suite of ecotoxicity and environmental fate data was assessed in the original lower level (that is, LTD) notification.

These identity and physico-chemical criteria must be met for the similar chemical:

- contains identical substructure/s that may play a critical functional role
- has the same or similar molecular weight
- has the same, or expected to be the same, molecular properties (for example, lipophilicity, electronic or steric parameters)
- has an octanol-water partition coefficient (Kow not log Kow) within the range of 50% to 200% of the previously assessed chemical.

In addition, the differences in identity must not be known to affect the toxicity profile of the chemical. This can be typically demonstrated where the chemical meets these criteria in comparison with the other chemical (although a comparison of other toxicity endpoints may be warranted in certain cases):

- acute oral toxicity—LD50 within the range of 50% to 200%
- aquatic toxicity—LC50 or EC50 within the range of 50% to 200%.

The chemicals must have the same classification in accordance with the Approved Criteria for Classifying Hazardous Substances.

Examples

These examples illustrate the types of chemicals that could meet the criteria for 'similar chemical':

1. Salts

Salts often demonstrate a similar pattern of activity when the active chemical form is independent of the counterion found in the preparation (that is, where the counterion toxicity is equivalent), and consequently identical *in vivo*.

Therefore, salts formed when the hydrogen of an acid is replaced by an alkali metal or a cation of equivalent solubility (for example, NH_4^+) may be suitable. Thus the Na^+ salt is reasonably expected to be closely similar in activity to that of the K^+ salt but quite different in activity to the Pb^+ salt. NICNAS will assess amine salts on case-by-case.

2. Positional isomers

While an isomer has the same number and kind of atoms and hence the same molecular weight, it differs in the arrangement or configuration of the atoms. Positional isomers have the same empirical formula and unchanged chemical functional groups but have at least a single variation to the branch point of a

hydrocarbon chain—for example, normal-, iso- and anteiso- isomeric forms— or a change to the aromatic ring substitution position.

However, in heterocyclic ring systems, both the ring size and the number and ring position of heteroatoms should not change. The change in branching or substitution position should not be known to affect the toxicity profile of a chemical. For example, 2-ethyl hexanoic acid is classified with the risk phrase 'Possible risk of harm to the unborn child (R63)' whereas octanoic acid is not. The position of substitution of aromatic amines is known to affect the genotoxicity profile.

3. Stereoisomers

While a stereoisomer has identical chemical constitution, it differs in the arrangement of the atoms or groups in space (for example, optical and geometric isomers). Stereoisomers may meet the criteria for the similar chemical. However, the change in stereochemistry should not be known to affect the toxicity profile of the chemical (for example, where *in vivo* inter-conversion occurs).

4. Bio-isosterism

Chemicals related by a simple recognised change between two known groups with similar physical or chemical properties that impart similar biological properties to a chemical (for example, chlorine -Cl group replaced by a trifluoromethyl -CF₃ group or cyano -C≡N group) may meet the criteria for similar chemical.

5. Essential oils

Often essential oils from plants of the same species are regarded as different chemicals (with different CAS numbers), when separation has resulted in slightly different chemical profiles. Often these differences may have little or no impact on the eco-toxicological activity of the chemical.

6. Fatty acid resins

In many cases for chemicals that have a fatty acid chain such as alkyd resins, the fatty acid is not a determinant of chemical properties. Where the saturation profiles are similar (such as in the case of sunflower oil and soybean oil, or tung oil and linseed oil) one fatty acid may be substituted for another without significantly changing the properties of the chemical.

7. Animal and plant derived fatty acids

Fatty acid saturation profiles derived from animals and plants differ slightly; in cases where the saturation profile of the fatty acid has little impact on the pattern of activity, either type may meet the criteria as a similar chemical for the other.

Criteria for similar polymer

For NICNAS to regard one polymer as similar to another, the polymer must be assessed in the same notification category. In addition, the change in polymer identity must not be known to affect the toxicity profile of the polymer (for example, toxicity to algae is known to be highest for polyanionic polymers when the acid is on alternating carbons of the polymer backbone).

For NICNAS to regard one polymer as similar to the originally assessed polymer or primary polymer, the identity and physicochemical criteria (given below) must be met:

- contain the same linkages and functional groups, and
- water solubility within the range of 50% to 200%.

In addition, the notified polymer must be covered by one of these situations:

- the notified polymer contains one polymer constituent less than the originally assessed polymer or primary polymer
- the notified polymer contains a polymer constituent which is similar to a polymer constituent in the originally assessed polymer or primary polymer with all other polymer constituents the same. In this case all but one polymer constituent should be the same. Where there is a difference in a polymer constituent, the substituted one must meet the criteria for similar chemical. You need to provide data on the original and substituted polymer constituent to demonstrate this.
- the notified polymer is structurally identical to the originally assessed polymer or primary polymer. In some cases, a polymer may be manufactured by different reaction pathways and, in some cases, using different reactants. This can lead to the identification and naming of a particular polymer in more than one way, with different CAS registry numbers, although the polymers may be structurally identical (that is, contain the same linkages and functional groups). You need to provide information to support this.

NICNAS will take into account differences in molecular weight, low molecular weight species and functional group equivalent weight when determining your reduction in fees.

Criteria for similar use

Overall, a similar use is:

- one that does not require a change to the original exposure assessment and assessment conclusions and recommendations
- where the original assessment report states specific Secondary Notification circumstances of which the NICNAS Director must be notified (subsection 64(1) of the Act), the new use would not be considered similar whereby these circumstances would be met.

Specifically the following must be the same:

- industry sector in which the chemical is used
- routes of human exposure
- types of workers exposed and the extent to which they are exposed
- routes of environmental release
- potential for public exposure
- volume range— <1 tonne, 1–3 tonnes, 3–10 tonnes, 10–30 tonnes, 30–60 tonnes and 60–100 tonnes. (Note: a use would not be considered similar if the increase in volume would lead to a change in the original risk assessment).
- the mode of introduction (for example, import or manufacture).

Notification requirements

You need to follow the normal notification procedures for a STD, LTD or PLC notification. You must address all NICNAS schedule of data requirements for the relevant assessment category. Where a variation of schedule requirements was accepted for particular endpoint/s in the original notification, you are not required to apply for a variation of schedule of data requirements for the same endpoint/s.

Data requirements

You must include all available data on the notified chemical or polymer as part of your submission. You can use information in the original assessment report to address particular endpoints under the schedule of data requirements.

You need to demonstrate that the criteria for similar chemical or polymer and similar use are met with the following (which will also be used for risk assessment):

- identity and composition of the chemical or polymer
- introduction and use concentrations
- use information
- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health
- label and MSDS for the chemical or polymer in the form in which it is introduced
- melting (or boiling) point, particle size, and partition coefficient in the case of chemicals
- particle size and water solubility in the case of polymers
- acute oral toxicity (typically for STD notifications)
- acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

Notes:

1. As there will always be a level of uncertainty associated with any chemical or polymer for which a complete suite of eco-toxicological tests have not been performed, a conservative approach to the assessment is necessary to minimise potential risks. NICNAS may ask you for additional data where new chemicals or polymers are of particular or known concern (for example, because of toxicity profile, persistence, or significantly different use patterns which may increase environmental and/or public exposure).
2. Although preferred, acute aquatic toxicity data may not be required in circumstances where the predicted environmental concentration (PEC) for the notified chemical is the same as in the original assessment—that is, volume and use is the same and where the Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) in the original assessment is ≤ 0.1 .

Your application should consist of:

- a completed modular attachment to the relevant STD or LTD or PLC form, as appropriate

- the assessment reference for example, STD/XXX for the chemical or polymer that has been previously assessed (included in the attachment)
- justification of why the chemical or polymer meets the 'similar' criteria (included in the attachment)—where the original notification used read across data the suitability of the read across data for the notified chemical should also be demonstrated
- a statement indicating whether you are applying for reduced fees based on similar use (included in the attachment)
- a list of other available information (for example, toxicity or environmental test data) on the previously assessed chemical or polymer that was not provided in the original NICNAS assessment (included in the attachment)—you must provide a copy of this data as part of the notification
- consent for you to use the data on company letterhead from the notifier/holder of the data for the original assessment (if you are not the original notifier).

Assessment processes

During screening, NICNAS will verify that the chemical or polymer meets the criteria for similar chemical or polymer and/or similar use. You will be advised of the results in a screening letter. NICNAS will then determine the appropriate fee rebate, based on the information included in your original NICNAS assessment and the amount of work required by NICNAS to assess hazard and exposure. You will receive your final rebate at the end of the assessment.

The 90-day statutory assessment timeframe applies for the STD, LTD and PLC applications. However, if the chemical or polymer being notified also has the same—or similar—use to a similar chemical or polymer previously assessed, NICNAS will normally complete its assessment in 28 days.

2 Modular assessment—secondary chemical

This certificate category is for a chemical or polymer notified at the same time as one that is similar and has a similar use (including notification of inseparable mixtures).

This category applies if two or more chemicals or polymers both meet the similar criteria and are notified for a non self-assessed certificate at the same time. You pay the full fee for one application, and a reduced fee for the others (contact NICNAS before submitting your application for further fees information).

Application requirements (except in the case of inseparable mixtures)

You must follow the normal procedures for a STD, LTD or PLC notification for the chemical or polymer considered to be the primary one. For secondary chemicals or polymers you need to complete the attachment to the relevant STD, LTD or PLC form.

Data requirements

You must provide all available data on both primary and secondary chemicals and polymers as part of your submissions. All relevant schedule of data requirements must be addressed for the relevant assessment category. If the schedule of data requirements is fulfilled from data on the primary and secondary chemicals or

polymers, you do not have to apply for a variation of schedule requirements. If an application for variation of schedule requirements is required, one application (and hence one fee) covers all notifications.

If you are applying for exempt information based on confidentiality, you typically only have to complete one application (and hence pay one fee) for all notifications.

You need to submit the following for the secondary chemical or polymer, to demonstrate that the criteria for similar chemical or polymer and similar use is met (this will also be used for the risk assessment):

- information on the identity and composition of the chemical or polymer
- information on use
- information on introduction and use concentrations
- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health
- label and MSDS for the chemical or polymer in the form that it is introduced
- melting (or boiling) point, particle size, and partition coefficient in the case of chemicals
- particle size and water solubility in the case of polymers
- acute oral toxicity (typically for STD notifications)
- acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

Notes:

1. As there will always be a level of uncertainty associated with any chemical or polymer for which a complete suite of eco-toxicological tests have not been performed, NICNAS takes a conservative approach to assessment—to minimise risks. Where new chemicals or polymers are of particular or known concern—for example, because of toxicity profile, persistence or significantly different use patterns which may increase environmental as well as public exposure—you may be asked for additional data.
2. Although preferred, acute aquatic toxicity data may not be required in circumstances where the Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) for the primary chemical is ≤ 0.1 .

Application requirements (inseparable mixtures of similar chemical/polymers)

A reduction in fees applies with inseparable mixtures where the components meet the criteria for similar polymer (with the exception of the water solubility criteria) or these criteria for chemicals:

- contains an identical substructure or substructures that may play a critical functional role (the difference in structure or substructure must not be known to effect the toxicity profile of the chemical)
- has the same or similar molecular weight (for example, minor variation in chain length)

- has the same, or expected to be the same, molecular properties (for example, lipophilicity, electronic or steric parameters).

You must follow the normal notification procedures for a STD, LTD or PLC notification for the chemical or polymer of highest concentration (the primary one). You need to complete the attachment to the relevant STD/LTD or PLC form for all secondary chemicals or polymers.

Each of your notification packages—for both primary and secondary chemicals and polymers—must contain:

- information on the identity and composition of the chemical or polymer
- information on use
- information on introduction and use concentrations
- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health.

Your notification package for the primary chemical or polymer must contain:

- required physico-chemical and eco-toxicological data—in accordance with the Schedule of Data Requirements—on the inseparable mixture, and
- the Label and MSDS for the chemical or polymer in the form that it is introduced

as part of the notification package for the primary chemical or polymer.

You do not have to include this information in your notification package for the secondary chemicals or polymers.

You must address all NICNAS schedule data requirements for the relevant assessment category. You do not need to apply for a variation if the schedule data requirements are met from your data on the inseparable mixture. If you need to apply for a variation of schedule requirements, you only need to complete one application (and hence pay one fee) to cover all notifications.

If you are applying for exempt information based on confidentiality, you typically only have to complete one application (and hence pay one fee) for all notifications.

Assessment processes (including inseparable mixtures)

During screening, NICNAS will verify that the chemical or polymer meets the criteria for similar chemical or polymer and/or similar use. You will be advised of the results in a screening letter. NICNAS will then produce an assessment report covering both the primary and secondary chemicals or polymers. The normal statutory 90-day assessment timeframes apply.

3 Modular assessment—an assessment of the notified chemical or polymer by the APVMA, TGA or FSANZ is available

You must follow the normal notification procedures for a STD, LTD or PLC notification, address all NICNAS schedule data requirements for the relevant

assessment category, and provide all available data on the notified chemical or polymer as part of your submission.

The amount of the fee you will save depends on the scope of the original assessment.

You will receive your rebate when NICNAS completes its assessment.

NICNAS is currently working with the Australian Pesticides and Veterinary Medicines Authority (APVMA), Food Standards Australia New Zealand (FSANZ), and the Therapeutic Goods Administration (TGA) to develop ways for these bodies to provide their assessment reports to NICNAS. Contact NICNAS if you wish to use the modular assessment option.