

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS) AND THE NEW ZEALAND HAZARDOUS SUBSTANCES AND NEW ORGANISMS (HSNO) ACT 1996

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01

**AUSTRALIAN INDUSTRIAL
CHEMICALS INTRODUCTION
SCHEME (AICIS)**

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AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

The Industrial Chemicals Act was passed by Parliament and received Royal Assent in March 2019. It creates a new framework for the regulation of imported and manufactured industrial chemicals. The Australian Industrial Chemicals Introduction Scheme (AICIS) replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on July 1, 2020.

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AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

Regulatory effort based on the likely risk of a chemical introduction.

- 6 categories of introduction with different regulatory requirements that are proportionate to the likely level of risk allowing government to focus pre-introduction assessment on higher risk chemical introductions.
- Increased focus on post-introduction evaluation and monitoring.

Lower risk chemical introductions have streamlined introduction pathways, resulting in reduced regulatory burden for industry. These changes mean:

- More incentive to introduce greener, safer new industrial chemicals, including replacing more hazardous existing chemicals;
- Reduced costs to businesses and consumers using lower risk chemicals; and
- Exempted and Reported introduction categories = reductions in the time taken to introduce the chemicals to market and a reduction in fees.

Higher risk chemicals — improved protections for the public, workers, and the environment.

- Ability to impose conditions of introduction on higher risk chemicals and refuse introduction of chemical if the risk can not be managed.

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

The legislation is contained primarily in the Industrial Chemicals Act 2019 (the Primary Act), the Industrial Chemicals (General) Rules, and the Industrial Chemicals Categorization Guidelines.

What is an Industrial Chemical?

Chemicals in Australia are regulated according to their use and AICIS regulates chemicals with an industrial use. A chemical is an industrial chemical if it's not for a therapeutic, food, agricultural, or veterinary use.

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02

CATEGORIZING AN
INTRODUCTION

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CATEGORIZATION



New chemicals for introduction to the market are to be self-classified by the entity seeking to introduce the chemical for risks to the human health and the environment.

Chemicals are classified using a hazard and an exposure matrix system for both human health and the environment to determine the risk that the chemical may pose.

Risk is a function of the hazard of the chemical and the exposure to the chemical during introduction and use.

INFORMATION NEEDED TO CATEGORIZE AN INTRODUCTION

- Chemical Identity
- Introduction Volume
- Introduction Concentration
- End use Concentration and Use
- Hazard Information
- Specified Class of Introduction
- Whether it is a Polymer
- Molecular Weight of Polymer
- International assessment status of chemical

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CATEGORIZATION



The Industrial Chemicals (General) Rules set out details for regulation of the import and manufacture of industrial chemicals in Australia. General Rules detail information needed when determining the introduction category.

The General Rules include details on:

- Categorization of industrial chemical introductions (what is exempted or reported);
- Reporting requirements and record keeping requirements; among other items; and
- Confidential business information (CBI) notifications and applications.

The General Rules frequently refer to the 'Guidelines'. These are the Industrial Chemicals Categorization Guidelines that contain technical details and requirements that industrial chemical importers and manufacturers need to use to categorize their chemicals.



CATEGORIES OF INTRODUCTION

New industrial chemicals are categorized into six different groups.

- **Listed Introductions**: the chemical is listed on the Inventory and Introduction and uses are within any and all terms of the listing, including any conditions.
- **Exempted Introductions** (very low risk): this category may include amongst others, chemicals that are only used for research and development in certain volumes, polymers/chemicals that are comparable to listed polymers/chemicals, and polymers of low concern and requires one off post introduction declaration.
- **Reported Introductions** (low risk): this category may include amongst others, chemicals that are only used for research and development in certain volumes, low-risk flavor, or fragrance blend introductions and requires a Pre-Introduction Report before introduction.
- **Assessed Introductions** (medium to high risk): once the indicative health and environmental risk is determined to fall under a medium to high-risk introduction then an assessment certificate is needed prior to introduction. This is the only category that leads to getting the chemical listed on the Inventory.
- **Commercial Evaluation Introductions**: for testing the market viability of the chemical which requires a pre-introduction risk assessment.
- **Exceptional Circumstances Introductions**: Ministerial authorization to allow urgent introduction to protect public health or the environment.

WORKING OUT THE INTRODUCTION CATEGORY



Every chemical introduction (import or manufacture) must be classified into one of the categories: Listed, Exempted, Reported, Assessed or Commercial Evaluation before it can be introduced in Australia.

Categorization is determined by two key factors:

1. Hazard characteristics
2. Exposure

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These two factors interact to define the level of risk and the appropriate regulatory pathway.



WORKING OUT THE INTRODUCTION CATEGORY

Step 1: Identify if the chemical is on the Inventory

- If chemical is already listed on the Australian Inventory of Industrial Chemicals (AIIC) then it is a Listed Introduction (provided your use aligns with the conditions of the listing) and there are no additional obligations

Step 2: Determine the hazard profile by looking at intrinsic risks:

- Human Health toxicity: irritation, sensitization, carcinogenicity, reproductive effects, etc.
- Environmental toxicity: aquatic toxicity, persistence, bioaccumulation, degradation potential

Step 3: Assess the exposure scenario:

- How the chemical will be used (industrial, consumer);
- Concentration in end use products;
- Frequency and duration of contact; and
- Environmental release potential (to air, water, soil).

Step 4: Combine hazard and exposure in a risk matrix by determining the Indicative Human Health Risk and the Indicative Environment Risk and then combining to determine category of introduction.

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RISK MATRIX – HUMAN HEALTH HAZARD BANDS



Human Health Hazard Bands

A

- Acute toxicity (harmful)
- Specific target organ toxicity after a single exposure (harmful or transient effects)
- Skin/eye irritation
- Aspiration hazard
- HMW polymer:
 - That has lung overloading potential; or
 - With other potential hazards.

B

- Acute toxicity (fatal or toxic)
- Specific target organ toxicity:
 - After a single exposure (significant toxicity); or
 - After repeated exposure.
- Skin/respiratory corrosion
- Eye damage
- Skin/respiratory sensitisation
- HMW polymer that:
 - Is water absorbing
 - Is reactive; or
 - Contains certain chemical elements.

C

- Carcinogenicity
- Mutagenicity
- Genotoxicity
- Reproductive toxicity
- Developmental toxicity
- Adverse effects mediated by an endocrine mode of action

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RISK MATRIX – HUMAN HEALTH EXPOSURE BANDS



Human Health Exposure Bands Based on:

1. Introduction volume (IV) (indicates size of population exposed) or the Human Health Categorization Volume (HHCV) which can either be the introduction volume or calculated using reduction factors (based on end uses)
2. Concentration (risk of toxicity related to concentration – the ‘dose’).
3. End-use (*e.g.* if end use is in cosmetics, tattoo ink or personal vaporisers lower thresholds apply).

Exposure Band 1	Exposure Band 2	Exposure Band 3	Exposure Band 4
<0.1% at introduction and for all end use	Human Health Categorization (HHCV) Volume ≤25 kg	Human Health Categorization (HHCV) >25 kg and ≤100 kg	Human Health Categorization (HHCV) >100 kg
No consumer end uses	<0.1% at introduction and for all end use; Includes a consumer end use	≤1% at introduction and end use	End use in tattoo inks or personal vaporizers



RISK MATRIX – ENVIRONMENT HAZARD BANDS

Environment hazard bands:

A	B	C	D
<ul style="list-style-type: none">• Harmful to any aquatic life• Has bioaccumulation potential• Industrial chemicals (other than polymers) that do not meet the criteria for ready biodegradability• Contains aluminium, chromium, copper, nickel, selenium, silver or zinc• Polymers that:<ul style="list-style-type: none">• Have an overall cationic charge at pH 4-9; or• Are not stable.	<ul style="list-style-type: none">• Toxic to any aquatic life	<ul style="list-style-type: none">• Very toxic to any aquatic life• Persistent and bioaccumulative	<ul style="list-style-type: none">• Persistent, bioaccumulative and toxic• Ozone depleting chemicals• Synthetic greenhouse gas• Contains arsenic, cadmium, lead or mercury• Adverse effects mediated by an endocrine mode of action

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RISK MATRIX – ENVIRONMENT EXPOSURE BANDS

1. Does the introduction involve a designated kind of release to the environment?

- Yes – Exposure band 4 -release (intentional during use to land, biota, natural waterways or municipal water supplies, air or release in end use for example fire-fighting, offshore ocean)
- No – Exposure band 1 to 4, depending on environment categorization volume

2. Environment Categorization Volume (ECV)

- ECV = Introduction Volume (IV) or calculated using reduction factors (based on end uses)

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Exposure Band 1	Exposure Band 2	Exposure Band 3	Exposure Band 4
Environment Categorization Volume (ECV) ≤ 25 kg	Environment Categorization Volume (ECV) > 25 kg and $\leq 1,000$ kg	Environment Categorization Volume (ECV) $> 1,000$ kg and $\leq 10,000$ kg	Designated kind of release Environment Categorization Volume (ECV) $> 10,000$

RISK MATRIX – CATEGORY DETERMINATION



Category determination using the results from the Indicative Human Health and Environment Risk Categories

		Indicative Human Health Risk		
		Very low	Low	Medium-high
Indicative Environment Risk	Very low	Exempted	Reported	Assessed (exceptions apply)
	Low	Reported	Reported	Assessed (exceptions apply)
	Medium-high	Assessed (exceptions apply)	Assessed (exceptions apply)	Assessed (exceptions apply)

Medium to high risk to human health **or** the environment authorized by an assessment certificate *i.e.* Health, Environment focus, or those that have a focus on both

SPECIFIED CLASSES OF INTRODUCTION

Increased level of concern as greater potential for:

- Particular hazards.
- High levels of human or environmental exposure.

Increased information requirements, extra reporting, and record requirements.

Examples: UV filter; article with end use in food contact; personal vaporizer; tattoo ink; biochemical; GM products; Polyhalogenated organic chemicals; Persistent gases; highly branched organic chemicals; those whose end uses are biocides; and those involved with designated release into environment.

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UPDATES



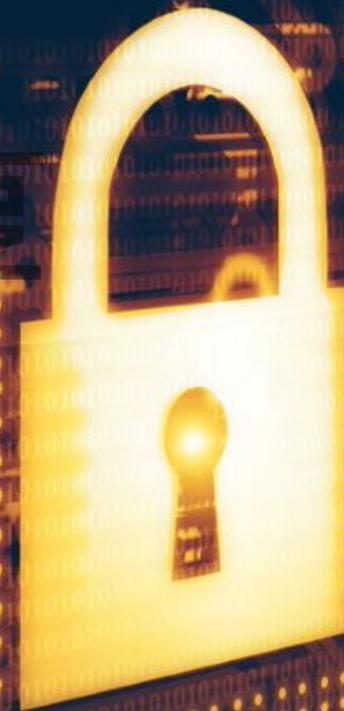
- September 2025- AICIS added 118 chemicals to its list of high-hazard substances which are categorized in human health hazard bands C or D, or environmental hazard bands C or D – highest hazard bands. This is in addition to the 600 entries added in September of 2024
- AICIS will have an annual update cycle for its Categorization Guidelines, aligning with their registration period from Sept 1st to Aug 31st of each year with public consultation on proposed changes and a 6-month transition period
- July 2025 – AICIS introduced measures to simplify compliance with Specific Information Requirements (SIR) for industrial chemicals to enhance search functionality and updated and expanded guidelines clarifying criteria for submitting information to AICIS with upgraded SIR online forms
- Fees and Charges –remain the same for the 2025-26 registration year
- Version 3 of the Categorization Guidelines - refined requirements for introducers to demonstrate the absence of specific target organ toxicity after repeated exposure and bioaccumulation potential
- December of 2024 -AICIS updated the AIC (inventory) by adding new chemicals and also removing some from the inventory and some substances were classified based on updated risk assessments

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**INVENTORY AND
CONFIDENTIAL BUSINESS
INFORMATION**

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INVENTORY



The AICIS inventory is an inventory of industrial chemicals defined by industrial use and is referred to as the Australian Inventory of Industrial Chemicals (AIIC).

Inventory will add new listings for chemicals introduced under assessment certificates, 5 years after the certificate has been issued and certificate holders may apply for early listing.

The Inventory is searchable on the AICIS website either by chemical identity or AICIS Approved Chemical Name (AACN) along with Terms of Listing which can include conditions of introduction or use (*i.e.* volume permitted to be introduced or condition on where chemical is allowed to be introduced or used).

- If the introduction is outside any condition of introduction or use it is not a listed introduction and if it is not categorized into the Exempted or Reported category the introducer/manufacture must apply to vary the Inventory before introduction.
- If one applies for a variation to the Inventory, it goes through an assessment process like the process of applying for an assessment certificate and requires a fee.

CBI UNDER AICIS



- An introducer may apply to have the following types of information protected as CBI:
 - The chemical's identity using a generic chemical or an AICIS Approved Chemical Name (AACN).
 - The chemical's introduction details (*e.g.* exact function of a chemical in a product (use), exact concentrations, exact introduction volumes, customers) *via* a Generalized End Use (GEU).
- Process to get an AACN or GEU requires an application for CBI protection at the same time as the application or report is made.
- Must satisfy criteria that balances commercial prejudice and the public interest and if it does it becomes 'protected information'.
- All CBI applications are submitted online through AICIS Business Services.
- When there is no CBI claim being made information on chemical identity and the end use will be published in Assessment Statements, Commercial Evaluation Authorizations, Inventory listings, Evaluation Statements.
- AICIS will not publish personal details about applicants and businesses.

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AICIS APPROVED CHEMICAL NAME (AACN)

An AACN is a generic or 'masked' chemical name.

- The AACN is published instead of the chemical's full name to protect a chemical's identity and will be used if approved.
- When applying for CBI protection of your chemical's identity, AICIS will expect that a proposed AACN is provided. If not, one will be created, granted the CBI application is approved. This will be done by only changing one part of the chemical's name (*i.e.* an AACN with one level of masking).
- A chemical name must be masked by replacing specific parts of the full chemical name with a related generic name that could represent various specific parts that would disclose the chemical's full identity.





AICIS APPROVED CHEMICAL NAME (AACN)

An AACN must:

- Use the minimal amount of masking that will protect the identity (these are called masking levels and start at level 1).
- Do not mask the part of the chemical known to cause toxicity or environmental fate concerns (unless justification on why this is needed can be provided).

If masking above level 1 is required, this justification should be based on scientific or technical reasons as to why a particular level of masking won't provide adequate protection of the chemical identity.

Items of interest:

- An AACN can be the same as a masked name for the same chemical used in an overseas jurisdiction.
- Proposed AACN will be reviewed to determine whether it is acceptable, including whether it has been created in accordance with guidance.
- If an AACN has been issued for the same chemical to a previous introducer, gov. will assign the same AACN (as each chemical can only have one AACN). One may contact government to confirm whether a current AACN inventory listing found covers a chemical to be manufactured/imported.
- CBI status reviewed 5 years after each approval, reviewed if continued protection with an AACN is still required, and will not consider changes to the approved AACN.

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GENERALIZED END USE (GEU)

Publication of a chemical introduction include its end use and may include:

- The chemical's function;
- Its use in specific types of product(s);
- The industrial sector it will be used in; and
- Specific end use or a generalized end use (does not include concentration and volume information).

A generalized end use (GEU) is a general description of the end use for an industrial chemical that is published instead of the specific end use. One must apply for protection of a specific end use as confidential business information (CBI). If approved, GEU will be used for 5 years and after 5 years must re-apply to continue CBI protection.

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FLAGGING CBI INFORMATION

- Introducer may “flag” other information provided to AICIS.
- Any information flagged as CBI will not be published.
- If the government later decides there is public interest in its publication and those details are necessary to inform the public about risks associated with that chemical, applicant will be notified and given an opportunity to make a CBI application before any information is published (within 20 working days).
- Flag CBI information at the time you submit an application or report or anytime any information is provided to AICIS (*i.e.* “call or information”, information provided as part of audit, *etc.*).

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04

RECORD KEEPING AND
ANNUAL REPORTING

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OBLIGATIONS OF AN INTRODUCER

- Ensure business is registered.
- Be familiar with the details of the chemical introduction –check all ingredients in product against Inventory.
- Understand the category of introduction.
- Apply for pre-introduction risk assessment, or submit declaration report, if needed.
- Keep records of introduction. An introducer must keep records about the introduction for 5 years, one must keep records to indicate what information was used to determine the category of introduction
- Give info if requested. AICIS can ask for info/records and obligated to provide; may be in relation to a certificate application or as part of monitoring and compliance activities.

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RECORD KEEPING AND REPORTING

1. Keep records about the introduction for 5 years.
2. Keep records to indicate what information was used to determine the category of introduction and registration level.
3. Access the following online forms through the AICIS business portal:
 - Registration of your business;
 - Submission of pre-introduction reports;
 - Certificate and authorization applications (via portal or attachment of validated IUCLID dossier);
 - Confidential business information (CBI) applications; and
 - Inventory-related and other processes (*e.g.* changing certificate holders, variations).

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ANNUAL REPORTING



The registration year is from September 1st to August 31st, and an introducer will need to submit a declaration every year. The level of reporting is proportional to the risk level of the introduction, and the reporting obligations apply to all 6 introduction categories.

Requires the introducer to answer a few simple questions and complete a legal declaration via their online form in the AICIS Business portal.

SUBMITTING AN ANNUAL DECLARATION



Must be completed by the introducer.

Name all of the industrial chemicals introduced or lists of products is not required.

1: Sign in to your AICIS Business Services account and go to the Annual Declaration tile.

2: Click 'Submit annual declaration' in the Actions column next to the applicable registration year

3: Select all the introduction categories that apply to the chemicals imported or manufactured during the registration year. Example: If all the chemicals introduced were listed on the Inventory, then select 'Listed Introductions'.

4: Check the declaration boxes to indicate that:

- All of your introductions were authorized under sections 25 to 30 of the Industrial Chemicals Act 2019; and
- The information you have given is true, correct and complete.

5: Enter your full name and job title.

6: Click 'submit'.

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05

**NEW ZEALAND
HAZARDOUS SUBSTANCES AND
NEW ORGANISMS (HSNO) ACT
1996**

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NEW ZEALAND HSNO



The Environmental Protection Authority (EPA) administers and regulates new **hazardous substances** and organisms under the Hazardous Substances and New Organisms (HSNO) Act 1996 in New Zealand.

Definition of Hazardous substance (Section 2 of HSNO Act):

A hazardous substance is any substance that has **one or more** of the following hazardous properties or can form a substance with such properties:

- Explosiveness;
- Flammability;
- an ability to oxidize;
- Corrosiveness;
- toxicity (including chronic toxicity);
- ecotoxicity, with or without bioaccumulation; or
- which on contact with air or water generates a substance with any 1 or more of the properties specified above.

The following products are exempted from HSNO:

- Substance only used in lab and used for scientific research, teaching, and R&D, Radioactive substances, Pharmaceuticals, Food, Articles and Infectious substances

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NEW ZEALAND HSNO

Individual Substance Approvals or Group Standards

- All hazardous substances imported, manufactured, or used in New Zealand must have an approval under the Act and if an existing approval is not available, a notification is required. If your product is not approved, you may need to apply for an approval.
- Under HSNO, the term substance includes both single chemicals as well as mixtures of chemicals (*i.e.*, formulated products).
- Two main approval pathways under HSNO for which products can be approved under
 - Group Standard Approval – covers similar substances collectively
 - Individual (Standalone) Approval – applies to a unique or high-risk product.

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NEW ZEALAND HSNO

Individual Substance Approvals or Group Standards

What are Groups Standards?

- Pre-approved EPA authorizations for groups of substances with similar hazards and uses
- Designed for efficiency –allows quick market entry for common products
- Importers and manufacturers self-assign products to a suitable group standard (keeping justifications for the grouping on file)
- 2020 group standards - this is the current set of group standards that are in force (i.e., Cleaning Products Group standard 2020, Adhesives Group Standard 2020, Cosmetic Products Group Standard 2020)
- They incorporate the GHS-7-based classification system



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NEW ZEALAND HSNO

Individual Substance Approvals or Group Standards

What are Individual Substance Approvals?

- New chemicals not covered by group standards
- Substances with unique or higher-risk hazards
 - Requires a formal application to the EPA
 - Detailed risk assessment (human health and environment)
 - Public notification and possible consultation
 - EPA issues a decision and assigns specific approval conditions



NEW ZEALAND HSNO



New Zealand Inventory of Chemicals (NZIoC), what if it is already listed?

- Listing on the NZIoC is important but does not automatically mean one can import or manufacture without further consideration. The NZIoC is a database of all the hazardous chemical components of products approved under group standards. Note that non-hazardous chemicals are not required to be listed but that does not mean that all listed chemicals are hazardous.
- A NZIoC listing means that the substance is recognized in New Zealand and has been assessed for regulatory purposes.
- A new chemical approval is not required if used in a way that is already approved.
- NZIoC also lists the approval status for a hazardous substance (i.e., whether a hazardous substance can be only used on its own or used in a product covered by a group standard).
- The listing simplifies the approval process because the EPA does not treat it as “new”.
- If listed you must check if the substance is hazardous and check if a group standard applies (i.e., your substance fits its hazard classifications, use, concentration limits and is thus covered by an existing approval).
- There is an obligation to keep a record of the decision, and in the case of group standards, there may be an obligation to ensure that your chemical component is included in the New Zealand Inventory of Chemicals (NZIoC).
- No action is required if the substance is non-hazardous or it fits a group standard, and you follow all its controls; otherwise, you may need a group standard assignment or individual approval before import and manufacture.

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NEW ZEALAND HSNO



Step by Step Practical Approach:

- Step 1: Identity the Substance –identity the chemical name and CAS numbers, mixture composition (all ingredients and composition), hazards, intended use
- Step 2: Classify the substance (GHS 7) – can use EPA’s classification tool, compare against the NZ GHS 7 hazard classes and for mixtures calculate hazards using ingredient data and concentration cut-offs
- Step 3: Check NZIoC and check if a Group Standard applies –each standard will specify the scope (type of substance and use covered), Hazard classification limits and Conditions (i.e., labelling, storage, disposal)
 - If it does not fit any group standard move to Step 4
- Step 4: Determine if Individual Approval is required which requires a formal EPA application and risk assessment. Must wait for EPA approval before importing or manufacturing, and follow any specific controls in your approval document
- Step 5: Keep compliance Documentation including classification records, SDS, labels, records of import, distribution and any disposal

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HOW WE AT INTERTEK CAN HELP

- **Regulatory Review:** Analyzing product lines for compliance under global regulations.
- **Modeling:** Run model to anticipate possible questions.
- **Preparation:** Developing notification dossiers under global regulations.
- **Science:** Providing technical input into the dossier preparation and assessment process.
- **Confidential Business Information:** Developing confidentiality substantiation and compliant generic names.
- **Interpretation:** Determining your obligations to respond to mandatory and voluntary chemical inquiries.
- **Documentation:** Preparing mandatory and voluntary responses to government initiatives.
- **Surveillance:** Tracking draft and final risk assessment notices and proposed risk management measures.
- **Smart Planning:** Providing strategic advice regarding impact of proposed risk management measures.
- **Consultation:** Working with the regulatory authorities on matters relating to any proposed hazard-assessment outcomes and risk management measures for your chemicals.

Analysis of Key Details:

Sales Channel	Supply Chain
Finished products (articles), chemical substances and mixtures	Determination of certification requirements
Determination of reporting requirements	Development of notification/reporting strategies
Development of confidentiality claim substantiation language	Determination of timelines

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