Australian Toy Association

REQUIREMENTS FOR CHEMICALS

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Introduction

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Chemicals in toys and children's products may be covered by multiple regulations and regulators

Suppliers need to be aware of **all** applicable requirements and how to ensure compliance with them, i.e. requirements for toys plus requirements for chemicals plus …

There are similar sets of requirements in other markets, but they are generally not aligned

You can't assume that it is legal to sell in Australia just because it is sold in the US or Europe

Agenda / Objectives

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Agenda

1. Products affected
2. General Requirements
3. Requirements for Specific Product Categories
4. Questions

Participants should:

- Understand which of their products are affected by requirements for chemicals;
- Be able to identify the requirements that would apply to any product;
- Be able to determine and evaluate relevant documents intended to show compliance with applicable requirements;
- Know where to go for help when needed.

Regulators

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- NICNAS (National Industrial Chemicals Notification and Assessment Scheme)
  Manages the introduction of chemicals to Australia
  https://www.nicnas.gov.au/

- SafeWork / WorkSafe (By State)
  Labelling of chemicals in the workplace
  Requirement for a SDS for hazardous chemicals
  https://www.safeworkaustralia.gov.au/

- TGA (Therapeutic Goods Administration) / State Departments of Health
  Manage the SUSMP (Standard for the uniform scheduling of medicines and poisons)
  Labelling of consumer goods
  http://www.tga.gov.au/

- ACCC (Australian Competition and Consumer Commission)
  Manage the safety of consumer products
  Specific product requirements
  https://www.productsafety.gov.au/

Chemical Products

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- Generally particles or fluids
- Not ‘articles’
  - https://www.nicnas.gov.au/register-your-business/chemical-and-registration/what-is-an-article
- Examples
  - Modelling compounds / Slime
  - Crayons / Pencil Cores / Pen Ink
  - Paints
  - Cosmetics
  - Chemistry sets

General Requirements – Introduction of Chemicals

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- Regulated by NICNAS
- Only applies to the introducer, i.e. manufacturer or importer
  - For manufacturers

    Mixing A and B without a chemical reaction gives a mixture of A and B – No chemical introduced

    Mixing A and B with a chemical reaction to get C – Chemical C is introduced
  - For importers

    All ingredients in the mixture
  - Doesn't apply to chemicals bought locally
- Requirements
  - Introducer must be registered with NICNAS
    - Various levels depending on value of chemicals introduced
    - Value determined as landed cost of manufactured product, e.g. total cost of pen, rather than value of actual chemical
  - Chemicals or their ingredients must be on the Australian Inventory of Chemical Substances (AICS) and meet any conditions specified there

General Requirements – Introduction of Chemicals (Ctn'd)

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- Documentation
  - Anything that gives you the ingredients, e.g. SDS (Safety Data Sheet), Formulation, Toxicological Risk Assessment, etc.
  - Confirm compliance by reviewing ingredients on AICS https://www.nicnas.gov.au/

Issues	Possible Responses

The supplier wants to keep his formulation confidential	• The supplier (or a third party lab) can do the evaluation.
	• You'll want a reliable document confirming compliance
	  • A properly formatted SDS with a statement in section 15
	  • A laboratory report

An ingredient is not on the AICS	• Naturally occurring • Exemption options https://www.nicnas.gov.au/notify-your-chemical/chemicals-exempt-from-notification • Apply for a search of the confidential section of the AICS https://www.nicnas.gov.au/chemical-inventory-AICS/confidential-AICS • Find a different formulation • Apply for an assessment

NICNAS Reforms

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- Separate Webinar on Oct 12
  - Presented by NICNAS
  - Specifically directed to the impact to our industry
- Moving from Pre-market assessment model to Post-market audit model

General Requirements – Hazardous Chemicals – SDS Sheets

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- Regulated by State WorkSafe or SafeWork Departments
- Requirements
  - Chemicals classified as hazardous according to the GHS (Globally Harmonised System of chemical classification) must have an SDS

    Applies to all supplies
  - Chemicals supplied for use in workplaces must be labelled in accordance with the GHS
- Documentation
  - Supplier may provide information to show that the chemical is not classified as hazardous under the GHS.
    - SDS Sheet – Evaluate for validity
    - Laboratory report
  - Formulation
    - Possible to make a reasonable estimate using the rules in the GHS along with information in the AICS, the SafeWork HCIS (Hazardous Chemical Information System), and ECHA (European Chemicals Agency)

      http://www.hcis.safeworkaustralia.gov.au/HazardousChemical
    - Can be used to determine if it needs evaluation by a more qualified person

General Requirements – Hazardous Chemicals – SDS Sheets (Ctn'd)

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- Considerations for Australian SDS Sheets
  - Only required if the chemical is classified as hazardous
  - Format according to GHS and SafeWork guidelines
    https://www.safeworkaustralia.gov.au/sds
  - Include:
    - Information on Australian supplier
    - Australian emergency contacts, Poison Centre
    - Information on the chemical in relation to Australian regulations, e.g. AICS and SUSMP
  - Evaluation
    - Created by a qualified person
    - Check that all required information is included
    - Date of creation or review – Should be within 5 years
    - Check consistency of information, e.g. first aid and protective equipment is aligned with the hazards specified
- Don't forget to evaluate the chemical's suitability for the application
  - A Toxicological Risk Assessment would help with this

General Requirements – Poisons Standard (SUSMP) – Labelling

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- Overall management by the TGA, but determined by the Scheduling Committee and regulated by State Health Departments
- Requirements
  - Chemicals that are Scheduled Poisons must be labelled in accordance with the Standard
  - Applies to all chemicals sold to consumers
- Documentation
  - Supplier may provide information to show that the chemical is not a scheduled poison
    - SDS sheet (would need statement in Section 15) – Evaluate for validity
    - Laboratory Report
  - Formulation
    - Review each ingredient for inclusion in the Standard

https://www.tga.gov.au/publication/poisons-standard-susmp

General Requirements – Poisons Standard (SUSMP) – Labelling (Ctn'd)

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- Considerations for the SUSMP
  - Unique to Australia
  - Updated regularly (approximately every 6 months)
    - Latest version available here - https://www.tga.gov.au/publication/poisons-standard-susmp
  - Document is hard to read and search – Uses names, many duplications and exceptions
    - NICNAS assessments can be helpful
    - Not aligned with the GHS – Chemicals that aren't hazardous can be scheduled poisons and vice versa
  - Labelling requirements are also hard to evaluate
    - Recommend having a qualified laboratory assessment for labelling requirements
  - Number of Schedules
    - Generally increasing severity; Schedule 5 = Caution; Schedule 6 = Poison; etc.
  - Appendices are also important
    - Appendix A = Exempted products
    - Appendix B = Exempted poisons
    - Others – Labelling and other requirements

Requirements for Specific Product Categories - Note that all applicable requirements apply

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- Toys (plus coatings on moneyboxes, pencils and paintbrushes plus erasers resembling food)
  - Migration of certain elements
    - AS/NZS 8124.3 and .7
    - Mandatory requirement (CPN No. 1 of 2009 and ACN No. 2007/46)
    - Can use other Standards so long as the results are validated
    - Specifically concerned with the hazard from licking, sucking and swallowing, i.e. does not consider any issue from skin contact
  - Chemical toys (Chemistry sets / Other specific chemical toys)
    - AS 8124.4 and .5
    - Voluntary requirement
    - Updated European documents require GHS labelling
  - Organic chemicals in toys
    - AS/NZS 8124.9, .10 and .11
    - Apply specific clauses selectively
    - Voluntary requirement and more normally rely on the general requirements

Requirements for Specific Product Categories (Ctn'd)

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- Cosmetics
  - Anything intended to be applied to the body, e.g. includes face paint
  - Ingredient review for prohibited and restricted cosmetic chemical (not just whether it's in AICS)
  - Labelling review in accordance with Consumer Product Information Standard (Cosmetics) 1991 and Amended 1998 and 2008
  - Cosmetics Standard 2007 would only apply if some therapeutic value is claimed e.g. UV protection.
  - Laboratory review is best, but ensure that they are checking Australian requirements
  - Plus toy requirements if applicable

Requirements for Specific Product Categories (Ctn'd)

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- Crayons
  - Due diligence for Asbestos

    http://austoy.com.au/members-only/safety-compliance

    http://www.border.gov.au/Busi/cargo-support-trade-and-goods/importing-goods/prohibited-and-restricted/asbestos
    - If formulation includes talc, test each shipment for asbestos or have a QA system that can trace tested inputs through to the finished individual items
      - Test to AS 4964
      - Use an accredited laboratory
      - Ensure clear link to actual shipment
    - If formulation doesn't include talc, provide proof of that
      - Test to GB 5009.269
      - Retest annually
    - Customs agents must be prepared to confirm that there is no asbestos in the shipment so they need to understand and believe in your process and have relevant documentation to support the answer.
  - Plus toy requirements

Questions (1)

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- I think the European used a C.I. number. Do you know how we can found CAS number if supplier only provide C.I. number?

  The CI number refers to a colour index and is not a unique identifier for a chemical.

  Europe does have an EC number, but there is always an equivalent CAS number

  NICNAS recommend to always use the CAS number for searches on AICS

- Is charcoal counted as a chemical product?

  To clarify: Stick for drawing

  If supplied in a way that is intended to leave a residue, e.g. a pencil or as a powder, then it is a chemical.

  However, it may be classified as naturally occurring if removed from the natural environment by purely manual, mechanical means and in this case wouldn't need to be in the AICS.

- So is chalk a chemical?

  Yes, for the same reason as the charcoal stick.

Questions (2)

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- Is the AICS is based on CAS number?

  Yes, the CAS number is the unique identifier for a chemical

- Is the amount determined by weight or volume or both?

  For classification, the concentrations of solids and liquids are specified by weight and the concentrations of gases are specified by volume.

- If hazardous does the % volume used in product matter? e.g. if they contain 0.01%-10% is categories as not hazardous?

  Yes, the concentration matters.

  The Safe Work guidelines and the GHS provide guidance on the classification of mixtures. The classification depends on the nature and category of the hazard as well as the concentration.

  Having said that, it would be unusual for a chemical with a concentration of less than 0.1% to cause a hazardous classification on its own. However, multiple chemicals can add together to cause a hazardous classification even when they wouldn't individually.

Questions (3)

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- If you are suppling into the NZ market do you need a NZ SDS?

  Hazardous substances in NZ are managed by the EPA. There are mandatory requirements as follows:

  – You must have provided your contact information to the EPA
  – Your product must be approved for use in NZ
  – Your product must have a current SDS
  – Your product must be labelled correctly
  – Your product must be packaged properly

  The EPA also uses the GHS so its SDS requirements are generally aligned with those of Australia, the UK and the US. However, like each of those markets, there are specific requirements in that the SDS needs to include:

  – Name and contact details of the NZ supplier and NZ emergency contact details
  – HSNO regulatory information, including the HSNO approval number or title of the group standard, if relevant

- Does the SUSMP have a document that we can check if poison or not?

  The link to the latest version of the SUSMP can be found here - https://www.tga.gov.au/publication/poisons-standard-susmp

  As mentioned, the document works on chemical name rather than CAS number and has multiple schedules and appendices. It is therefore difficult for a lay person to be sure whether a chemical is scheduled or not and also to work out the labelling requirements.

Questions (4)

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- Is coloured chalk covered by AS/NZS 8124.3

  Compliance with AS/NZS 8124.3 is a mandatory requirement for children's toys. If the coloured chalk is sold for use by children, then it would be reasonable to treat it as a toy and insist on compliance with 8124.3. If it is sold for use by an educator, then it is not a toy and compliance would not be required.

- If the chemistry set contain hazardous chemical then do we need the SDS

  Yes, you must have a SDS for any hazardous chemical, regardless of the product.

- Do erasers count as chemical products?

  Erasers are not liquids or particles and are not intended to leave a trace so they would be articles rather than chemicals

Questions (5)

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- Do beeswax and/or paraffin candles count as chemical products?

  Beeswax is a chemical, but may not be caught by NICNAS requirements if it can be characterised as naturally occurring.

  Candles are chemicals as there is a chemical change during use

- How is glue on children's stickers handled? Does it require special testing?

  A normal sticker would be characterised as an article and so not subject to chemical requirements.

  A sticker intended to be applied to the skin, e.g. a fake tattoo would be characterised as a cosmetic and so chemical and cosmetic requirements would apply