

# ACCC research survey of Formaldehyde in Cosmetics

*Final report*



**November 2010**



**Australian  
Competition &  
Consumer  
Commission**

## Background

The Australian Competition and Consumer Commission (ACCC) play an important role in consumer product safety with statutory responsibilities under the *Competition and Consumer Act 2010* (CCA). The ACCC product safety Clearinghouse was established to more systematically identify and respond to emerging consumer product hazards and to initially investigate safety related contacts made to the ACCC's call centre. The Clearinghouse receives information about potentially hazardous consumer products through a variety of sources including: allegations or complaints from consumers and businesses, overseas regulatory actions, referrals from other agencies, injury and health care data, coroner's reports, scientific publications, the general media and market surveillance.

In late 2010, the ACCC identified a number of overseas reports and received anecdotal complaints from consumers and salon operators alleging excessive formaldehyde concentrations in cosmetics, particularly in hair straightening products. The ACCC also became aware, through routine liaison, that complaints had also been received by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and State Health Departments. The ACCC proposed that a research survey of formaldehyde concentrations in cosmetic products be undertaken in collaboration with NICNAS.

## Aim and Rationale

The aim of the survey was to provide an indication of whether there may be safety concerns or misleading or deceptive conduct associated with formaldehyde content in cosmetics. The survey was designed to determine the concentrations of formaldehyde in a representation of cosmetic products currently available in Australia. Implementing the survey would help establish the overall feasibility of the approach and would provide an indication of whether there may be more widespread problems in the marketplace. A further element was to determine whether products that contained formaldehyde or claimed not to contain formaldehyde, were correctly labelled. The results of the study were to be assessed in the first instance by the ACCC product safety area and NICNAS.

Formaldehyde is a recognised irritant and skin sensitiser, and has been linked to cancer in circumstances where there is chronic high exposure to gaseous formaldehyde, such as among embalmers.

Cosmetics are applied directly to the skin, nails and hair of consumers, often on a daily or nightly basis over long periods of time. Some cosmetic consumers exhibit strong habitual use and brand loyalty, using the same products daily over many years, giving rise to potential chronic exposure to the chemical ingredients. Workers in hair and nail salons may also be exposed to chemicals in cosmetic preparations they work with on a daily basis over long periods of time. Heat is often applied in hair salons by heating irons or hair dryers and this may increase the amount of volatile vapours.

In considering the justification and feasibility of undertaking a survey the ACCC determined that several fundamental criteria had been met:

- Reports, complaints and allegations had been received and they were sufficiently credible to justify further investigation.
- Potential for exposure was significant as cosmetics are extensively used by the Australian population on a daily basis.
- There was a clear basis for determining safe levels as comprehensive risk assessments had been recently undertaken by the NICNAS and other expert bodies such as the World Health Organisation International Agency for Research on Cancer (IARC).
- Safe limits as well as labelling requirements were set in legislation.

- Overt claims were made in relation to some products being formaldehyde free.
- Analytical testing for formaldehyde in cosmetics was available from accredited analysts.
- Products were available on the Australian market and were readily obtainable.

## Potential Hazard

The term "formaldehyde" is used to describe various mixtures of formaldehyde, water, and alcohol; the term "formalin" more precisely describes aqueous solutions, particularly those containing 37 % to 50 % formaldehyde and 6 % to 15 % alcohol stabilizer. Most formaldehyde enters commerce as formalin. Alcoholic solutions of formaldehyde are available for processes that require low water content. Paraformaldehyde, a solid, also serves as a source of formaldehyde gas. Formaldehyde gas, as such, is not available commercially.

Formaldehyde occurs naturally and can be found at low levels in plants and other naturally occurring substances. Formaldehyde is rapidly broken down in the environment and metabolised in the body. The Chemical Abstracts Service (CAS) number 50-00-0 applies to both formaldehyde gas and its aqueous or alcohol stabilised solutions. Exposure to formaldehyde through the use of cosmetics is a recognised hazard and regulations to manage this risk exist in many countries including Australia.

In 2006, the NICNAS published an assessment of formaldehyde<sup>1</sup> which found that it is readily absorbed in humans and experimental animals by all exposure routes. When inhaled, it reacts rapidly at the site of contact and is quickly metabolised in the respiratory tissue. Following acute exposure via inhalation, dermal and oral routes, formaldehyde is moderately toxic in animals. The critical health effects of formaldehyde for risk characterisation are sensory irritation, skin sensitisation and carcinogenicity.

Humans experience sensory irritation (eye, nose and respiratory tract irritation) at levels in air of 0.5 parts per million (ppm) formaldehyde gas and above. Evidence clearly indicates that formaldehyde solution is a skin irritant and a strong skin sensitiser.

Gaseous formaldehyde is a known eye and upper respiratory tract irritant in humans however there is insufficient data to a definitive no observed-effect level (NOEL). The lowest-observed-effect level (LOEL) for sensory irritation in humans is 0.5 ppm. The available human and animal data indicate gaseous formaldehyde is unlikely to induce respiratory sensitisation. Lung function tests suggest that asthmatics are no more sensitive to formaldehyde than healthy subjects. Limited evidence indicates that formaldehyde may elicit a respiratory response in some very sensitive individuals with bronchial hyperactivity, probably through irritation of the airways. No systemic toxicity was observed following repeated exposure to formaldehyde in animals and humans. Effects at the site of contact show clear dose-related histological changes (cytotoxicity and hyperplasia). A no-observed adverse-effect level (NOAEL) of 1 ppm (1.2 mg/m<sup>3</sup>) by inhalation and a NOAEL of 15 mg/kg bw/day by oral administration were identified for histopathological changes to the nasal tract and the fore- and glandular stomach in the rat, respectively. Formaldehyde is clearly genotoxic in vitro, and may be genotoxic at the site of contact in vivo. Overall, formaldehyde is considered to have weak genotoxic potential.

The possible relationship between formaldehyde exposure and cancer has been studied extensively in experimental animals and humans. There is clear evidence of nasal squamous cell carcinomas from inhalation studies in the rat, but not in the mouse and hamster. Although several epidemiological studies of occupational exposure to formaldehyde have indicated an increased risk of nasopharyngeal cancers, the data are not consistent. The postulated mode of action for nasal tumours in rats is biologically plausible

<sup>1</sup> NICNAS November 2006, *Priority Existing Chemical Assessment No. 28 Formaldehyde*  
<[http://www.nicnas.gov.au/Publications/CAR/PEC/PEC28/PEC\\_28\\_Full\\_Report\\_PDF.pdf](http://www.nicnas.gov.au/Publications/CAR/PEC/PEC28/PEC_28_Full_Report_PDF.pdf)>.

and considered likely to be relevant to humans. There are also concerns of an increased risk for formaldehyde-induced myeloid leukaemia, however, the data are not considered sufficient to establish a causal association.

Compounds that release formaldehyde (formaldehyde donors) are often used in cosmetics as preservatives to prevent spoilage and health hazards as a result of microbiological contamination. Studies of the relationship between formaldehyde donors in cosmetics and formaldehyde contact allergy have shown a clear relationship between positive patch test reactions to formaldehyde donors and formaldehyde contact allergy.<sup>2</sup> Patients allergic to formaldehyde are often advised to avoid leave-on cosmetics preserved with formaldehyde releasing compounds such as; quaternium-15, diazolidinyl urea, DMDM hydantoin, or imidazolidinyl urea.

In terms of toxicity, many of the scientific studies involving animal feeding, eye or skin sensitivity were actually conducted using formalin as this is the most practical way of administering formaldehyde, which is a gas under ambient conditions. Formalin is a solution containing 37% w/w (= 40% w/v) formaldehyde in water. Paraformaldehyde is a solid polymer that changes into formaldehyde when heated (in slightly alkaline water) to 60 degrees celsius. Paraformaldehyde may be used as a basis for preparing a formalin solution.

In 2006, the World Health Organisation IARC published an updated Monograph on the Evaluation of Carcinogenic Risks to Humans for Formaldehyde<sup>3</sup>, which concluded that formaldehyde was a Group 1 carcinogen - known to cause cancer in humans.

In 2010, the US Government Accountability Office published a report on formaldehyde exposure from textiles<sup>4</sup>. The report noted that comprehensive reviews by the Department of Health and Human Services, the Environmental Protection Agency, and the World Health Organization have found that chronic inhalation exposure to formaldehyde may cause cancer. However, the report concluded the health risk of greatest concern associated with formaldehyde in clothing was allergic contact dermatitis resulting from dermal exposure. A form of eczema, allergic contact dermatitis affects the immune system and produces reactions characterized by rashes, blisters, and flaky, dry skin that can itch or burn. Irritant contact dermatitis was also recognised as another potential adverse health effect from dermal exposure to formaldehyde. This is also a form of eczema and has similar symptoms however; this condition does not affect the immune system. The use of some cosmetics and skin care products such as shampoos and sunscreens was also cited as a source of dermal exposure to formaldehyde.

## Regulations

There are several regulatory frameworks that are applicable to cosmetics in Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), within the Australian Government Department of Health and Ageing, regulates the introduction of industrial chemicals, including those used in cosmetics in Australia.

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<sup>2</sup> De Groot, A., White, I. R., Flyvholm, M.-A., Lensen, G. and Coenraads, P.-J. (2010), 'Formaldehyde-releasers in cosmetics: relationship to formaldehyde contact allergy', *Contact Dermatitis* 62: 18-31.

<sup>3</sup> IARC, Volume 88 2006, *Monograph on the Evaluation of Carcinogenic Risks to Humans for Formaldehyde* <<http://monographs.iarc.fr/ENG/Monographs/vol88/index.php>>.

<sup>4</sup> US Government Accountability Office Report to Congressional Committees, August 2010, *Formaldehyde in Textiles*, <<http://www.gao.gov/products/GAO-10-875>>.

Cosmetics are subject to the Cosmetics Standard 2007, which is made under the *Industrial Chemicals (Notification and Assessment) Act 1989* and came into force on 17 September 2007.<sup>5</sup> The Cosmetics Standard 2007 sets the standards for six cosmetic product categories which cover: face and nail products, skin moisturisers and sunbathing products, anti bacterial and anti-acne skin products, oral hygiene and anti dandruff products. Introducers of cosmetic products are also subject to the general obligations of the *Industrial Chemicals (Notification and Assessment) Act 1989* which apply to all introducers of industrial chemicals. Unless otherwise permitted, chemicals used in cosmetics must also be listed on the Australian Inventory of Chemical Substances (AICS), which is administered by NICNAS. The AICS can be annotated to include restrictions on the use of the chemical.

The circumstances under which medicines and chemicals (including cosmetic ingredients) are accessible by consumers are determined through a classification process known as scheduling. Chemicals are scheduled based on many criteria such as their; potential adverse effects, purpose, potential for abuse, safety in use and the need for the substance. Scheduling may require warning labelling, prohibit the use of a substance or restrict the amount or the way a substance can be used. Scheduling decisions are set out in the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard)<sup>6</sup> which is referenced in State and Territory legislation and enforced by agencies (usually health departments) in the jurisdictions. Cosmetic products that contain free formaldehyde exceeding the limits are in breach of the regulations which reference the Poisons Standard.<sup>7</sup>

Formaldehyde is restricted in cosmetics by virtue of specified limits for free formaldehyde in Schedules 2, 6 and Appendix C of the Poisons Standard, which includes the following limits for formaldehyde and paraformaldehyde, excluding their derivatives:

- 0.1 % of free formaldehyde in oral hygiene preparations
- 0.005 % per cent or more of free formaldehyde in aerosol sprays for cosmetic use
- 5 % or more of free formaldehyde in nail hardeners
- in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde except in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement "CONTAINS FORMALDEHYDE".

Most cosmetics therefore may not contain more than 0.05 per cent free formaldehyde unless they are labelled with the warning statement: CONTAINS FORMALDEHYDE. Aside from nail hardeners, the maximum permitted concentration in all cosmetics is 0.2 per cent or less of free formaldehyde for those that are correctly labelled.

These upper limits are the total limit for free formaldehyde in a cosmetic solution regardless of the sources. It is known that various compounds release formaldehyde and in many cases this is an intended preservative function of the ingredient. As is the case in the EU, the donor sources for free formaldehyde are not relevant to the maximum safe limit which is for the total concentration of free formaldehyde.

Another important feature of Australia's regulation of cosmetics is *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*<sup>8</sup> which requires that ingredients used in cosmetics be declared on the label. This standard enables consumers to identify ingredients to which they may be allergic or which they are concerned about, and allow comparison of various cosmetic products.<sup>9</sup> Free

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<sup>5</sup> Cosmetics Standard 2007 <[http://www.nicnas.gov.au/Current\\_Issues/Cosmetics/Cosmetic\\_Standard\\_PDF.pdf](http://www.nicnas.gov.au/Current_Issues/Cosmetics/Cosmetic_Standard_PDF.pdf)>.

<sup>6</sup> Standard for the Uniform Scheduling of Medicines and Poisons, < <http://www.comlaw.gov.au/Details/F2012L01200>>

<sup>7</sup> Also see Therapeutic Goods Administration website, 'The Poisons Standard', <<http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>>.

<sup>8</sup> Consumer Product Information Standards) (Cosmetics) Regulations 1991 <<http://www.comlaw.gov.au/Details/F2008C00244>>.

<sup>9</sup> See Product Safety Australia website, 'Mandatory standard—Cosmetics & toiletries—ingredients labelling' <<http://www.productsafety.gov.au/content/index.phtml/itemId/971654/fromItemId/971652>>.

samples and testers are not required to comply with the labelling standard and incidental ingredients present in low amounts (<1 %) do not have to be declared on the label. Formaldehyde may be incidentally present, or form in very small amounts, in some cosmetic preparations; however the maximum limits set through the Poisons Standard apply regardless.

The *Competition and Consumer Act 2010* also makes it an offence to engage in misleading and deceptive conduct and claims made in relation to marketing of products must be truthful. For example, the statement “formaldehyde free” appearing on the label of a cosmetic would be understood to mean the product contains no measurable amounts of formaldehyde.

Both the European Union and Canada have the same requirements as Australia allowing only low concentrations of formaldehyde to be present in cosmetics as a preservative, namely:

- Oral hygiene products - up to 0.1% w/w.
- Nail hardeners - up to 5% w/w.
- All other cosmetic products - up to 0.2% w/w.

The EU Cosmetic Directive 76/768/EC sets out the EU regulatory limits.<sup>10</sup>

The United Kingdom’s Cosmetic, Toiletry and Perfumery Association (CTPA) have published a fact sheet<sup>11</sup> on Brazilian Hair Straighteners which explains the relevant EU cosmetic requirements from this industry sector.

## Survey Methodology

A total of 32 different cosmetic products were purchased from trade and retail outlets in Sydney and Canberra by officers from the ACCC and NICNAS. The products purchased included:

- Chemical hair straightening products
- Chemical hair perming products
- Firm set hair gels/fixatives
- Hair bleaches/colourants
- Nail hardeners or combined nail varnish/polish with hardener
- Oral hygiene preparations/mouthwashes.

Where there were different versions of the same product line (for example mild vs. strong) the stronger version of the product was sampled. Two (duplicate) samples of each cosmetic product were purchased from the same outlet so that reference samples could be retained by the ACCC in the event that further assessment of the packaging or retesting was required.

Purchased samples were left in their original package, logged, photographed and the outside of the packing was marked with a sample number. One of each of the duplicate samples was sent by courier to the analytical laboratory and one was securely retained by the ACCC.

Sealed samples were received by the laboratory staff who signed for the samples and logged samples into their system.

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<sup>10</sup> ‘Scientific Committee on Cosmetics Products and non-food products, ‘*Opinion concerning a clarification on the formaldehyde and para-formaldehyde entry in Directive 76/768/EEC on Cosmetic Products*’, <[http://ec.europa.eu/food/fs/sc/sccp/out187\\_en.pdf](http://ec.europa.eu/food/fs/sc/sccp/out187_en.pdf)>.

<sup>11</sup> Cosmetic, Toiletry and Perfumery Association (CTPA), ‘*Information Sheet on the Safety of “Brazilian” Hair Straighteners*’ <<http://www.ctpa.org.uk/document.aspx?fileid=2093>>.



Photograph 1 – Cosmetic samples analysed

## Analytical method

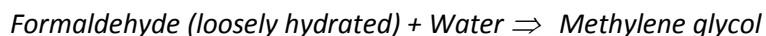
Analysis was undertaken by Leeder Consulting (now SGS Leeder Consulting) using a validated method of High Pressure Liquid Chromatography (HPLC). Leeder Consulting are accredited by the National Association for Testing Authorities (NATA) for the analysis of formaldehyde in solutions and solids. The method is a standard published methodology which is relied on in many jurisdictions including the European Union. The Practical Quantification Limit (PQL) specified by the analyst was 5 milligrams/kilogram (mg/kg) equivalent to 5 parts per million (ppm). This is sufficiently sensitive to determine compliance with the safe limits of 2000 ppm or 0.2 % for most cosmetics. The PQL refers to the lowest concentration that can be reliably measured within specified limits of precision and accuracy for a specific laboratory analytical method during routine laboratory operating conditions in accordance with best practice standards

## Analytical and regulatory considerations

The results reported are for the concentration of “free formaldehyde” in the samples as received and analysed by the laboratory. This is consistent with the regulatory limits for cosmetics which are also stipulated in the Poisons Standard for “free formaldehyde”. Various donor compounds release formaldehyde and in many cases this is an intended preservative function of the ingredient in the cosmetic. The donor sources for free formaldehyde do not alter the safe limits set through the Poisons Standard, which are for the total concentration of free formaldehyde in the cosmetic regardless of the origins.

There are a quite a number of different synonyms that have been used to describe formaldehyde solutions including; Formalin, Formic aldehyde, Methanal, Methaldehyde, Methyl aldehyde, Methylene oxide, Morbicid Acid, Oxomethane, Oxomethylene.

Despite the well established hazard of formaldehyde exposure from either gaseous and aqueous sources, some suppliers have used alternative terms to obfuscate the presence of formaldehyde or have contended that formaldehyde (gas) is not present in the cosmetic as it is the hydrated form (methylene glycol), or it is an ingoing donor ingredient such as thiazolidine-4-carboxylic acid. In cosmetics the formaldehyde used is mostly supplied as formalin, the aqueous form of formaldehyde because formaldehyde the molecule (CH<sub>2</sub>O<sub>2</sub>) will be a gas under ambient conditions. A formalin solution will contain a mixture of formaldehyde and water molecules which readily associate to form methylene glycol molecules. Methylene glycol is also used as a synonym for formalin and is the bound hydrated form of formaldehyde. This reaction is reversible, but the equilibrium lies far to the right.



As water or formaldehyde is removed from the system, it will start turning methylene glycol into formaldehyde. It is free formaldehyde, rather than methylene glycol, that enters the chemical reactions of fixation when biological specimens are fixed using formalin. There is always a large reservoir of methylene glycol that instantly replaces formaldehyde molecules that are removed from the solution by reaction and combination with the specimen being fixed<sup>12</sup>. The terms “available formaldehyde” and “total formaldehyde” refer to formaldehyde which is held or trapped in another chemical form, but can readily release formaldehyde. “Free formaldehyde” refers to all formaldehyde in aqueous solution which is not bound to a formaldehyde donor, whether in a bound hydrated form (methylene glycol) or loosely hydrated. Methylene glycol readily releases formaldehyde under conditions as simple as room temperature water evaporation.

In Australia, industrial chemicals which are produced incidentally are not required to be separately listed on the AICS provided that the chemical which gives rise to the commercial value is listed. This is in clear recognition that it is the chemical (solute) that is of regulatory and safety interest and not the range of equilibrium products formed during its use under the conditions of use. Methylene glycol is therefore not listed on AICS for use in Australia, even though formalin, which is predominantly chemically comprised of methylene glycol in water, has been in use for innumerable years, because the permission is attached to the listing of formaldehyde on AICS.

As part of the analysis the laboratory were also asked to investigate the potential for conversion of the formaldehyde donor compound Thiazolidine-4-carboxylic acid (T-4-CA) to free formaldehyde as a result of the analysis. The analyst stated that T-4-CA solutions, prepared in both pure solvent and in a formaldehyde-free cosmetic sample, were analysed using the same analytical procedures as used for formaldehyde. Formaldehyde, as the 2,4-dinitrophenylhydrazine derivative, was detected in the above solutions. The initial level of converted formaldehyde was 0.16%w/w of T-4-CA in solutions but this eventually increased to 0.81% after 6 hours of sample preparation and derivatisation. The conversion of T-4-CA was recorded as below:

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<sup>12</sup> Pearse AGE (1980) Histochemistry, Theoretical and Applied, 4th ed. Vol. 1. Preparative and Optical Technology. Churchill-Livingstone, Edinburgh  
Fox CH, Johnson FB, Whiting J, Roller RP (1985) Formaldehyde fixation. Journal of Histochemistry and Cytochemistry 33: 845-853



Hours after preparation Formaldehyde as %w/w of T-4-CA

1 hour 0.16

2.5 hours 0.26

6.5 hours 0.81

It indicates that a low percentage of T-4-CA is converted to free formaldehyde during analysis as the result of hydrolytic cleavage. The impact of this conversion on the overall quantification of free formaldehyde would depend on the level of free formaldehyde detected in samples and the level of T-4-CA in samples. While the presence of T-4-CA in cosmetic products has some effect on the level of formaldehyde detected, the level of conversion during the analysis would be less than 1%w/w of T-4-CA in the sample. This would not have a significant impact on the quantification of formaldehyde when there is a significant amount of formaldehyde (1% w/w or greater) detected in the samples.

It is important to note that the limits for formaldehyde in cosmetics are to protect human health and that these safety limits are based on a comprehensive risk assessment undertaken by the NICNAS who are the appropriate national expert authority responsible for conducting risk assessments on industrial chemicals, which include cosmetic ingredients.

## Summary of results

The table below provides a summary of the analytical results and the regulatory compliance for each product.

| No. | PRODUCT DESCRIPTION   | RESULT | STATUS*       |
|-----|---|--------|---------------|
| 1   | Schwarzkopf Strait Styling Glatt                              | ND     | Compliant     |
| 2   | Keratin Complex Infusion Therapy Thermo Shine                 | ND     | Compliant     |
| 3   | Innovative perm system  | 12     | Compliant     |
| 4   | Keratin Complex Smoothing Therapy                             | 22000  | Non-Compliant |
| 5   | De Lorenzo Performance Permanent Wave                         | ND     | Compliant     |
| 6   | De Lorenzo Instant Restructurant                              | ND     | Compliant     |
| 7   | Irene Gari Cosmetics Cover Your Gray Mascara Dark Brown       | 180    | Compliant     |
| 8   | Indola Profession Natural & Essentials Permanent Caring Color | 6      | Compliant     |
| 9   | Hantesis Color Collection Cream w/ Corallina Officinalis      | ND     | Compliant     |
| 10  | L'Oreal Color Supreme Coloration Anti-age                     | ND     | Compliant     |
| 11  | Sculpture Gel Spray   | 5      | Compliant     |
| 12  | Schwarzkopf Strong Styling Hairspray                          | ND     | Compliant     |
| 13  | Redken for Men Holding Gel Grip Tight                         | ND     | Compliant     |
| 14  | Davines Natural Tech Bio_O Invisible Oat Gel Hyper Hold       | ND     | Compliant     |
| 15  | ATV Design Network Snap Shot                                  | ND     | Compliant     |
| 16  | Redwin sensitive skin Sorbolene moisturiser                   | 120    | Compliant     |

|    |  |       |               |
|----|--|-------|---------------|
| 17 | Sally Hansen Hard As Nails                                     | ND    | Compliant     |
| 18 | Cutex 3 in 1 Strengthener                                      | ND    | Compliant     |
| 19 | Poshe Nail Strengthening Treatment                             | 9     | Compliant     |
| 20 | Essie Millionails  | 8300  | Compliant     |
| 21 | O.P.I. Original Nail Envy                                      | 8200  | Compliant     |
| 22 | 1000 hour Eyelash Adhesive                                     | ND    | Compliant     |
| 23 | Lash Me Professional Reusable Eyelashes                        | ND    | Compliant     |
| 24 | Locks Lash Eyelash Extension Glue                              | 13000 | Non-Compliant |
| 25 | Palmer`s Cocoa Butter Formula with Vitamin E                   | ND    | Compliant     |
| 26 | Coles Moisturiser with SPF 15                                  | ND    | Compliant     |
| 27 | Johnson`s Moisture day cream                                   | ND    | Compliant     |
| 28 | Vaseline dry skin conditioning lotion with Vit.A, E & B5 200mL | ND    | Compliant     |
| 29 | Colgate Plax multi protection freshmint Alcohol Free           | ND    | Compliant     |
| 30 | Coles Smart Buy Mouthwash 500mL                                | ND    | Compliant     |
| 31 | Oral B Tooth and Gum Care Alcohol Free Mouth Rinse             | ND    | Compliant     |
| 32 | Listerine FreshBurst Antiseptic Mouthwash                      | ND    | Compliant     |

**ND** = Non detection at a Practical Quantification Limit of 5 milligrams/kilogram which is equivalent to 5 parts per million (ppm)

\* Compliance status is determined against the relevant limit set in the Standard for the Uniform Scheduling of Medicines and Poisons

## Status of ingredients declared on the label

Unless the subject of a specific NICNAS notification permit or certificate, or subject to an exemption from notification under a limited range of conditions, all chemical ingredients used in cosmetics must be listed on the AICS, which is administered by NICNAS. These requirements are aimed at ensuring that cosmetic ingredients have a history of safe use or, in the case of new chemicals, have been assessed by NICNAS as being safe for the proposed use. The suppliers of chemicals must also be registered with NICNAS as an 'introducer' of an industrial chemical.

In Australia, the Work Health and Safety Regulations<sup>13</sup> require the manufacturer or importer of a hazardous chemical to prepare a Safety Data Sheet (SDS) for the chemical. Additionally, a supplier must provide the manufacturer or supplier's current SDS for the hazardous chemical on first supply to a workplace and upon request. An SDS, previously called a Material Safety Data Sheet (MSDS), is a document that provides

<sup>13</sup> <http://www.safeworkaustralia.gov.au/sites/swa/model-whs-laws/model-whs-regulations/pages/regulations>

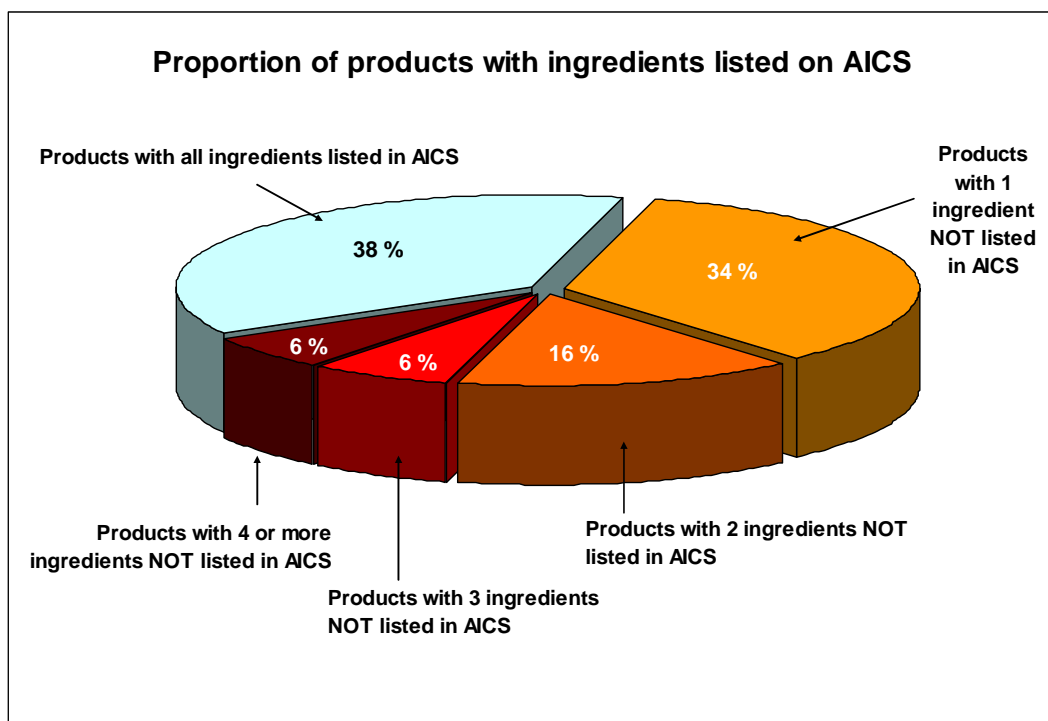
information on the properties of hazardous chemicals and how they affect health and safety in the workplace.<sup>14</sup>

As the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* requires that ingredients used in cosmetics be declared on the label - this enables consumers to identify ingredients to which they may be allergic or which they are concerned about, and allow comparison of various cosmetic products. (See Cosmetic ingredients required to be declared on the label). In addition to being declared on the label, AICS can be annotated to include restrictions on the use of the chemical.

As part of the survey NICNAS audited the chemical ingredients listed in each product via the AICS. This aspect of the survey provided important insights for both agencies into the proportion of sampled ingredients and products that appear to comply with the ACCC ingredient labelling requirements and NICNAS listing requirements.

As part of the survey, ACCC transcribed the ingredients listed on all the sampled products and provided this information to NICNAS to verify whether the chemical was listed on the AICS. Of the 32 products surveyed, only 12 (~38%) products had all the declared ingredients listed on the AICS. Of the remaining 20 products, an average of two ingredients per product were found that were not listed on the AICS. Two products had substantial labelling deficiencies, with one product having eight ingredients not listed on the AICS and another product not having an ingredient list at all.

Looking at the products as a whole, there were a total of 478 ingredients declared on the 32 different products and a total of 35 ingredients were not listed on the AICS. Seven per cent of all the ingredients declared on the product labels (35 of 478) were therefore not listed on AICS. The two products that were found to have excessive formaldehyde did not declare formaldehyde as ingredients. One product, Keratin Complex Smoothing Therapy, had made explicit marketing claims that the product was formaldehyde free.



<sup>14</sup> <http://www.safeworkaustralia.gov.au/sites/swa/whs-information/hazardous-chemicals/sds/pages/sds>

## Findings

- The ACCC in collaboration with NICNAS successfully conducted a survey of free formaldehyde concentrations in a range of cosmetic products.
- Of the 32 products tested, free formaldehyde was detected in 10 products with 2 products found to have concentrations of free formaldehyde above the safe limit of 0.2% for products with a warning statement.
- NICNAS reaffirmed their advice to the ACCC that the limits for formaldehyde in cosmetics set in the Poisons Standard reflect the recognised safe limits and that products that exceed these limits are considered unsafe.
- The rate of non compliance with the safe limits specified in the Poisons Standard was >6%.
- The products with excessive levels of formaldehyde and the supplier details were:

**i) Keratin Complex Smoothing Therapy** (Formaldehyde concentration 22,000 mg/kg or 2.2%)

Importer/distributor: Dateline Imports Pty Ltd  
Banksmeadow, NSW 2019, Australia

**ii) Locks Lash Eyelash Extension Glue** (Formaldehyde concentration 13,000 mg/kg or 1.3%)












Importer/distributor: Beauty Secrecy Corp Pty Ltd  
14 Short Street Dandenong, VIC 3175, Australia








## Outcomes

Following the completion of the cosmetics survey the ACCC completed a number of actions including:

- Discussing the analytical results with NICNAS who reaffirmed that the Poisons Standard reflects the formaldehyde limits determined to be safe by NICNAS and that cosmetic products that exceed these limits are unsafe.
- Immediately negotiating recalls of the products that exceeded the safe limits (Keratin Complex Smoothing Therapy and Locks Lash Eyelash Extension Glue).
- Issuing a media statement about the hazard and the recall actions.
- Notifying the State and Territory health agencies responsible for enforcement of the Poisons Standard alerting them to the issue and seeking their cooperation in investigating reports of other potentially non-compliant cosmetics being supplied.
- Requesting that NICNAS advise the workplace health and safety agencies relevant to industrial chemicals in the jurisdictions and liaise with the Australian Customs Service in relation to the issue.
- Negotiated further recalls of products that were subsequently found to exceed the safe limits.
- Writing directly to 150 hair salons that may have stocks of unsafe hair straighteners about the recall actions and safety concerns in case suppliers had downplayed the need for salons to cease use of the recalled product.
- Submitting responses to two salon industry web sites that had inaccurate or unclear content in relation to the recent recalls.
- Published information and consumer advice on the Product Safety Australia website.
- Requested that the industry association ACCORD publish an article about the issue in their next regulatory bulletin to the industry. The article alerted industry to the issue and advised what the regulatory requirements were.
- Prepared a report of the survey and provided the results/data to other regulatory agencies that have an interest in the issue of chemicals or cosmetics.

## Summary of Products Surveyed

| Product Type          | Product Name  | Sample Photograph   |
|-----------------------|---|---|
| Hair Straightener     | Schwarzkopf<br>Strait Styling<br>Glatt Hair<br>Straightener<br><br>1 x 82ml Balm<br>2 X 40 ml   |      |
| Hair Straightener     | Keratin<br>Complex<br>infusion<br>therapy<br>Thermo shine<br>Coppola<br>Designer Hair<br>Care 74 ml   |      |
| Hair perm system      | Innovative<br>Perm system<br>1  |     |
| Hair Straightener     | Keratin<br>Complex<br>smoothing<br>therapy<br>Natural<br>Keratin<br>Smoothing<br>Coppola<br>Designer Hair<br>Care 237ml                                   |    |
| Hair permanent wave   | De Lorenzo<br>Performance<br>Permanent<br>Wave for<br>resistant hair<br>100ml   |    |
| Hair structurant      | De Lorenzo<br>Instant<br>restructurant<br>light weight<br>leave in hair<br>treatment for<br>all types of<br>hair 20ml                                     |    |
|                       |   |   |
| Hair colourant/bleach | Irene Gari<br>Cosmetics<br>Cover Your<br>gray -<br>Mascara Dark<br>brown for<br>women 7g  |    |
| Hair colourant/bleach | Indola<br>Profession<br>Natural &<br>Essentials<br>permanent<br>caring color<br>Coloration<br>permanente<br>6.04 dark<br>blonde<br>natural<br>copper 60ml |    |
| Hair colourant/bleach | Hantesis<br>Color<br>Collection<br>Color cream<br>with Corallina<br>Officinalis<br>Ultra light<br>bright 10.00<br>100ml                                   |   |
| Hair colourant/bleach | L'Oreal Color<br>Supreme<br>coloration<br>anti-age<br>10.13 Biege<br>50ml   |  |
|                       |   |   |
| Hair fixative         | Sculpture Gel<br>Spray 250 ml<br>pump   |  |

|                      |   |   |
|----------------------|---|---|
| Hair fixative        | Schwarzkopf-Strong Styling Hairspray Maximum Hold 4 - 200ml pump                                |    |
| Hair fixative        | Redken for men holding gel grip tight medium control, gel fixant                                |    |
| Hair fixative        | Davines Natural Tech Bio_O Invisible Oat Gel Hyper Hold Holding Factor 07 any kind of hair 40ml |    |
| Hair fixative        | ATV Design Network Snap Shot Superhold finishing spray Natural look hair food 250ml pump        |   |
| Moisturiser          | Redwin sensitive skin Sorbolene moisturiser with 10% plant derived glycerine                    |  |
| Nail hardener/Polish | Sally Hansen-Hard as Nails Hard as Wraps-Powerful Acrylic Gel 13 ml                             |  |
| Nail hardener/Polish | Cutex- 3 in 1 Strengthener Base, top coat and strengthener-nail treatment                       |  |

|                      |  |   |
|----------------------|--|---|
| Nail hardener/Polish | Poshe nail strengthening treatment basecoat 15 ml four in one                    |    |
| Nail hardener/Polish | essie millionails Ultimate nail strengthener step 1 15ml                         |    |
| Nail hardener/Polish | O.P.I Original Nail Envy Natural Nail Strengthener Maximum strength formula 15ml |    |
| Eyelash glue         | 1000 hour-eyelash adhesive   |   |
| Eyelash glue         | Lash Me Professional Reuseable Eyelashes Stephanie eyelashes glue included       |  |
| Eyelash glue         | Locks Lash eyelash extension glue black 10ml                                     |  |
| Moisturiser          | Palmer's Cocoa Butter Formula with Vitamin E Moisturiser 400ml pump              |  |

|             |  |  |
|-------------|--|--|
| Moisturiser | Coles Moisturiser with SPF 15 Moisture for soft smooth skin  |   |
| Moisturiser | Johnson's softer, smoother more radiant Moisture day cream   |   |
| Moisturiser | Vaseline dry skin conditioning lotion with vitamins A, E & B5- 200ml Non greasy and quickly absorbed |   |
| Mouthwash   | Colgate Plax multi protection freshmint- Alcohol Free Mouthwash 50ml                                 |  |

|           |  |   |
|-----------|--|---|
| Mouthwash | Coles Smart Buy Mouthwash 500ml Mouthwash 500ml                            |  |
| Mouthwash | Oral B Tooth and Gum Care Alcohol Free Mouth Rinse Mouthwash- 500ml bottle |  |
| Mouthwash | Listerine FreshBurst Antiseptic Mouthwash- 250ml bottle                    |  |

**Summary of Declared Ingredients Listing Status on the  
Australian Inventory of Chemical Substances**

| <b>Products</b>   | <b>All ingredients listed in AICS</b> | <b>No of Ingredients not listed on AICS</b> | <b>No of Ingredients not listed on AICS</b> | <b>No of Ingredients not listed on AICS</b> | <b>No of Ingredients not listed on AICS</b> |
|---|---------------------------------------|---|---|---|---|
|   |                                       | <b>1</b>                                    | <b>2</b>                                    | <b>3</b>                                    | <b>4+</b>                                   |
| Schwarzkopf Strait Styling Glatt                              |                                       | ✓   |   |   |   |
| Keratin Complex Infusion Therapy Thermo Shine                 |                                       | ✓   |   |   |   |
| Innovative perm system  |                                       | ✓   |   |   |   |
| Keratin Complex Smoothing Therapy                             |                                       | ✓   |   |   |   |
| De Lorenzo Performance Permanent Wave                         |                                       |   |   |   | ✓   |
| De Lorenzo Instant Restructurant                              |                                       |   | ✓   |   |   |
| Irene Gari Cosmetics Cover Your Gray Mascara Dark Brown       |                                       | ✓   |   |   |   |
| Indola Profession Natural & Essentials Permanent Caring Color |                                       |   |   | ✓   |   |
| Hantesis Color Collection Cream w/ Corallina Officinalis      |                                       |   |   |   | ✓   |
| L'Oreal Color Supreme Coloration Anti-age                     |                                       |   |   | ✓   |   |
| Sculpture Gel Spray   | ✓                                     |   |   |   |   |
| Schwarzkopf Strong Styling Hairspray                          | ✓                                     |   |   |   |   |
| Redken for Men Holding Gel Grip Tight                         |                                       |   | ✓   |   |   |
| Davines Natural Tech Bio_O Invisible Oat Gel Hyper Hold       |                                       |   | ✓   |   |   |



|  |           |           |          |          |          |
|--|-----------|-----------|----------|----------|----------|
| ATV Design Network Snap Shot                                   | ✓         |           |          |          |          |
| Redwin sensitive skin Sorbolene moisturiser                    |           | ✓         |          |          |          |
| Sally Hansen Hard As Nails                                     | ✓         |           |          |          |          |
| Cutex 3 in 1 Strengthener                                      |           | ✓         |          |          |          |
| Poshe Nail Strengthening Treatment                             |           | ✓         |          |          |          |
| Essie Millionails  | ✓         |           |          |          |          |
| O.P.I. Original Nail Envy                                      | ✓         |           |          |          |          |
| 1000 hour Eyelash Adhesive                                     |           | ✓         |          |          |          |
| Lash Me Professional Reusable Eyelashes                        | ✓         |           |          |          |          |
| Locks Lash Eyelash Extension Glue                              | ✓         |           |          |          |          |
| Palmer`s Cocoa Butter Formula with Vitamin E                   |           | ✓         |          |          |          |
| Coles Moisturiser with SPF 15                                  |           |           | ✓        |          |          |
| Johnson`s Moisture day cream                                   | ✓         |           |          |          |          |
| Vaseline dry skin conditioning lotion with Vit.A, E & B5 200mL |           |           | ✓        |          |          |
| Colgate Plax multi protection freshmint Alcohol Free           | ✓         |           |          |          |          |
| Coles Smart Buy Mouthwash 500mL                                | ✓         |           |          |          |          |
| Oral B Tooth and Gum Care Alcohol Free Mouth Rinse             |           | ✓         |          |          |          |
| Listerine FreshBurst Antiseptic Mouthwash                      | ✓         |           |          |          |          |
| <b>TOTAL</b>   | <b>12</b> | <b>11</b> | <b>5</b> | <b>2</b> | <b>2</b> |

**Note:** Status is based on the ingredients declared on the product label and checked against the AICS by NICNAS staff.

## Excerpts from the Standard for the Uniform Scheduling of Medicines and Poisons<sup>15</sup> relevant to Formaldehyde

**Schedule 2 Pharmacy Medicine** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.

FORMALDEHYDE (excluding its derivatives) for human therapeutic use **except:**

- (a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or
- (b) in other preparations containing 0.2 per cent or less of free formaldehyde.

**Schedule 6 Poison** – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

FORMALDEHYDE and PARAFORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except:**

- (a) for human therapeutic use;
- (b) in oral hygiene preparations;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;
- (d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement:  
PROTECT CUTICLES WITH GREASE OR OIL;
- (e) in all other cosmetic preparations; or
- (f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement:  
CONTAINS FORMALDEHYDE.

**APPENDIX C** – Substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use.

FORMALDEHYDE PARAFORMALDEHYDE (excluding its derivatives):

- (a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;
- (b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;
- (c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; or
- (d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde **except** in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.

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<sup>15</sup> As at 2010