

**Investigation of the composition and
use of permanent make-up (PMU) inks
in Australia**

**National Industrial Chemicals
Notification and Assessment Scheme
(NICNAS)**

November 2017

Table of Contents

| | |
|--|----|
| 1. Introduction..... | 4 |
| 2. Background | 4 |
| 3. Strategy..... | 4 |
| 4. Literature review..... | 5 |
| 5. Methods used to identify PMU ink brands and their chemical composition | 6 |
| 5.1 Strategy | 6 |
| 5.2 Using Google for desktop searches..... | 6 |
| 5.3 Systematic eBay and AliExpress search | 6 |
| 5.4 Search for PMU importers using Australian Border Protection data..... | 7 |
| 5.5 Survey of professional PMU tattoo artists and PMU Association in Australia | 7 |
| 5.6 In person interviews with PMU artists and APAN phone interview | 7 |
| 6. Results and analysis..... | 8 |
| 6.1 Methods..... | 8 |
| 6.1.1 Google search results | 8 |
| 6.1.2 Phone survey results..... | 9 |
| 6.1.3 Results from the Australian Border Force data search | 10 |
| 6.1.4 APAN phone interview | 10 |
| 6.1.5 Visits to PMU artists | 11 |
| 6.1.6 PMU training | 12 |
| 6.2 Chemicals in PMU inks | 12 |
| 6.3 Colour Index..... | 14 |
| 6.4 Other observations..... | 14 |
| 7. Current regulatory controls for PMU | 15 |
| 7.1 International regulations | 15 |
| 7.2 Regulatory controls in Australia..... | 16 |
| 7.2.1 State and Territory Government requirements..... | 16 |
| 8. Summary..... | 18 |
| 9. Recommendations..... | 19 |
| 10. References | 20 |
| 11. Appendix | 22 |

List of Tables

| | |
|--|----|
| Table 5.1: Vendor listings from AliExpress | 7 |
| Table 6.1: Types of inks available for the different brands | 9 |
| Table 6.2: Colour Index | 14 |
| Table A.1: Brands in use in Australia as identified from the different sources..... | 22 |
| Table A.2: PMU brands and their chemicals constituents identified | 23 |
| Table A.3: Colourants found in PMU inks and their common and chemical names.. | 25 |
| Table A.4: PMU colourants that may be present in inks used for body art tattooing . | 29 |
| Table A.5: Colourants with NICNAS assessments..... | 30 |

1. Introduction

In September 2016, NICNAS published a report on the chemical composition of inks and general practices regarding body art tattoos. We have now researched issues related to permanent make-up (PMU) or cosmetic tattooing. The follow-on work is discussed in this report including:

- activities related to PMU and
- the findings of the research.

The objectives of this project were to identify:

- human health concerns, if any, in publicly available literature on PMU inks
- PMU ink brands being manufactured and imported into Australia
- chemicals present within the PMU inks identified
- industry's concerns, if any, about PMU inks and procedures
- training for PMU practitioners in the safe use of inks and
- the regulations in place for the PMU industry to ensure best practice regarding chemicals.

2. Background

People wear make-up for a variety of reasons such as

- enhancing features or
- hiding perceived flaws.

As well as application of various cosmetic products, make-up also includes the application of semipermanent tattoos to different parts of the body. This is known as cosmetic tattooing or permanent make-up (PMU). PMU is mostly applied to the face; for example, to the eyebrows, eyelids and lips as well as to other parts of the body, such as the eyes, tongue, nipples and head. PMU is also performed by medical practitioners for disguising a medical condition or post-operative aesthetic issues.

PMU is performed using a procedure known as micro-blading or feathering. The tattoo is 'retouched' every few months. Unlike body art tattoos, which can be permanent / life-long, PMU is semi-permanent. It fades over a period of months to years. This is because, unlike body art tattoos, PMU ink is embedded into the upper part of the dermis using smaller needles. Eyeball tattooing is performed by injecting ink with a needle, underneath the top layer of the eye, onto the sclera. Very little is published on how tongue tattooing is done.

PMU is gaining popularity; however, information on the number of people getting PMU in Australia, their age and gender, is largely unknown. Also, there are no statistical data on the type and number of adverse skin reactions and dermatological complications due to the use of PMU inks.

3. Strategy

The strategy followed in this project included:

- searching published literature for information on the PMU industry and to identify any documented concerns with the use of PMU inks
- identifying PMU ink brands imported into Australia and the chemical composition of these inks
- surveying PMU ink importers, businesses and artists; we also contacted the Australian organisation, Aesthetics Practitioners Advisory Network (APAN) about current practices and concerns
- identifying regulatory controls for PMU internationally and in Australia
- making recommendations for future work to promote the safe use of PMU inks in Australia.

4. Literature review

Adverse effects of PMU reported in public literature include granulomatous dermatitis at the tattoo site, occurring any time between the application of PMU to a few weeks later (De Cuyper, 2015; Antonovich and Callen, 2005). This form of dermatitis has also been observed in non-tattooed areas of skin in a tattooed individual, with a report of an eyebrow tattoo leading to sarcoidosis in cheeks (Greywal and Cohen, 2016). Infections such as conjunctivitis and HIV are other health complications described for PMU (Garland et al., 2006; Straetemans et al., 2007). Adverse effects reported from removal of PMU by laser pulses are darkening and scarring of the skin, linked to PMU ink pigments reacting to the laser pulses (Kopera, 2006; Chang et al., 2002; Garland et al., 2006).

PMU inks are complex formulations that may contain organic and inorganic colourants. Colourants impart colour to the ink (and thus to the skin) and are the major components of the ink formulation. Around 100 colourants are currently used in PMU inks in Europe, with red and yellow colours being the most commonly used. Of the types of colourants identified in PMU inks, over 80% are organic and include monoazo-, diazo-, anthraquinone, phthalocyanine, indigoid, xanthene, aminoketone, natural dyes, oxazines, heterocycle, pyrrol ketone, quinolone and triarylmethane compounds. About 16% of the PMU colourants identified are inorganic compounds (Piccinini et al., 2016; Piccinini et al., 2015).

PMU inks may contain harmful impurities such as primary aromatic amines (PAAs) from azo colourants, polycyclic aromatic hydrocarbons (PAHs) in black inks, and metals such as aluminium and chromium. According to the Council of Europe (CoE) Resolution (2008)¹, PMU inks may contain chemicals that are not authorised for use in products that come into contact with skin, and which may be restricted for use in cosmetics and textiles (CoE, 2008). Many manufacturers consider the exact chemical composition of manufactured PMU inks to be proprietary information and are unwilling to release it (Piccinini et al., 2016).

5. Methods used to identify PMU ink brands and their chemical composition

5.1 Strategy

The following steps were taken to identify the potential PMU inks used in Australia and their chemical composition:

- we conducted general searches using Google and retail searches with eBay and AliExpress to identify PMU ink brands
- we then browsed websites pertaining to individual ink brands for information about PMU ink constituents (sourced from any available Safety Data Sheets (SDSs))
- we identified importers of PMU inks by reviewing the Australian Border Force database and then matched this information with the NICNAS registrant database
- we then surveyed importers to identify PMU inks being introduced into Australia
- we randomly selected businesses performing PMU in 4 major Australian cities, to collect information about PMU inks they were using
- we surveyed PMU industry professionals such as PMU artists and industry associations.

5.2 Using Google for desktop searches

Using Google, we searched the terms “cosmetic tattoo ink” and “microblading”, setting the search filter to “Australia only” to focus searches on PMU tattooists in Australia.

Information was collected from the first 5 search pages results.

This process was repeated using search terms “cosmetic tattooing”, “microblade” and “Cosmetic tattoo EU ResAP (2008)”. Using this method, we identified 30 businesses offering PMU services in Australia. We then searched these businesses’ websites to get information on the PMU inks in use.

We reviewed any available online SDSs for some PMU ink brands to identify the colourants present in the inks. This included SDSs for Biotouch, Nouveau Contour, KB Pro, and Kolorsource.

5.3 Systematic eBay and AliExpress search

We searched retail websites eBay and AliExpress using the terms “cosmetic ink” and “microblade ink” and identified over 50 brands of inks for sale by various vendors online and available to Australian businesses. It was not possible to identify the specific vendors selling to customers in Australia. Customers are able to contact vendors directly through these websites and organise the postage of products to commercial and non-commercial addresses. Vendors organise postage, which is part of the price of the items.

A concern with purchasing PMU inks from these sources is that some of the inks may be counterfeit. Manufacturers in USA and Europe provide contact details for their suppliers in Australia on their websites. The fact that the same brands sold on these retail websites have postage addresses originating elsewhere raises the possibility that the products are counterfeit. **Table 5.1** shows the brand names identified and the number of listings from the retail site AliExpress.

Table 5.1: Vendor listings from AliExpress

| Brand | Vendor listings |
|-------------|-----------------|
| BioTouch | 87 |
| Golden Rose | 7 |
| Chuse | 94 |
| Goochie | 8 |
| Famisoo | 1 |
| DSH | 42 |
| Hao Tattoo | 30 |

5.4 Search for PMU importers using Australian Border Protection data

We reviewed Australian Border Force data from 2010 onwards to identify importers and overseas suppliers of PMU inks.

To generate a preliminary list of importers and overseas suppliers, we searched the Importer and Goods Description fields:

- “cosmetic tat”
- “cosmetic pigment”
- “microblade”
- “permanent make up” and
- “permanent cosmetic”.

From the list, we identified 1607 transactions, 185 overseas suppliers and 175 importers. We then filtered the preliminary data set to remove duplicate entries for descriptors, importers and suppliers. We identified 10 PMU ink importers and obtained importers’ details from the NICNAS register. We contacted these registrants to see if they were willing to take part in the survey. Six importers participated in the survey.

5.5 Survey of professional PMU tattoo artists and PMU Association in Australia

We contacted 60 businesses performing PMU in Australia. Businesses were selected randomly using the Google searches. We identified a business’s specific location by adding the name of the location to the end of the search term “cosmetic tattoo”. For example we used “cosmetic tattoo Sydney” for businesses in Sydney and so on for businesses in Melbourne, Perth and Brisbane.

5.6 In person interviews of PMU artists and APAN phone interview

From the businesses we contacted, 2 PMU artists in Sydney volunteered to provide information about their practices and procedures. We also contacted APAN, a

member-based network for the beauty industry in Australia, to gain an insight into the PMU industry.

6. Results and analysis

6.1 Methods

6.1.1 Google search results

The information collated indicates that PMU inks are not manufactured in Australia. They are mainly imported from the US, Europe, South Korea, India and China. From the searches described above, we identified 30 Australian businesses that apply PMU and 13 brands of PMU inks used in Australia. The ink brands are:

- Biotouch
- Long Time Liner
- Ecuri, Kolorsource
- KB Pro
- KP Pigments
- A Permanent Solution
- BioEvolution
- Radiant
- Li Pigments
- Chi Australia
- Tri-lab Products Inc
- Amiea Derma Safe and Amiea Organic
- Swiss Color International.

All the above-mentioned PMU ink brands advertise through websites specific for these brands. Some of these websites (Biotouch, KB Pro, Nouveau Contour and Kolorsource) contain ink ingredient information in their SDSs, which we reviewed to identify the chemical constituents of the inks. The focus of these websites appears to be on promoting the PMU inks and highlighting the perceived safety of the procedures and inks.

For the brand Kolorsource, ink bottles carry either a “FDA approved” or “Not approved by FDA” advisory, in reference to the United States Food and Drug Administration (US FDA). We could not ascertain which of these particular inks were in use in Australia. The US FDA does not regulate PMU colourants.

Table 6.1 details the brands and types of PMU inks available from some of the manufacturers identified by Google search. The manufacturers have certain shades of ink colours advertised for specific areas of the body. We observed this advertising trend for all PMU ink brands. The chemical composition of PMU inks is provided in **Section 6.2**.

Table 6.1: Types of inks available for the different brands

| Brands | PMU Inks | | | | |
|---------------------------|--------------------------------|-----------|------|-------|-------|
| | Eyebrows | Eyeliners | Lips | Other | TOTAL |
| Biotouch | 9 | 7 | 10 | 35 | 63 |
| Kolorsource | 8 | | 3 | 2 | 13 |
| Long Time Liner | No ink information on website* | | | | |
| Ecuri | 8 | | - | - | 8 |
| A Permanent Solution | 11 | 7 | 15 | 19 | 52 |
| Chi Australia | Not classified | | | | 33 |
| Tri-lab Products Inc | Not classified | | | | 54 |
| Amiea | 22 | 7 | 24 | 15 | 68 |
| Swiss Color International | 12 | 8 | 23 | 33 | 76 |

**This brand has only 1 retailer in Australia who does not on-sell.*

6.1.2 Phone survey results

We chose 60 PMU providers from 4 major cities in Australia at random for a phone survey. Of the sixty PMU businesses contacted, six PMU service providers agreed to take part in a survey. The participants were either PMU artists or business managers who employed the PMU artists.

Through the survey, we identified 11 brands of inks that are currently used in Australia. We could not get information on the chemical composition of PMU inks from the surveys. The ink brands identified are:

- Trilab Colours
- Absolute Perfection
- Premier inks
- Face Ink
- Nouveau Contour
- Long Time Liner
- Dr Linda Dickson
- NBC Cosmetics
- Biotouch
- International Colours Chine
- Kolorsource
- Li Pigments.

6.1.3 Results from the Australian Border Force data search

From a review of the Australian Border Force data, we identified 10 PMU ink importers. Most of the importers had their own tattooing premises where they performed the procedures and also on-sold ink pigments to other PMU businesses. Six importers took part in the survey to obtain information about PMU ink brands and procedures. One of the importers indicated that they had ceased purchasing inks and now only imported equipment for applying PMU. The PMU ink brands imported into Australia are:

- Ameia
- MT Derm GMBH
- Kolorsource
- Li Pigments
- Lasting Impressions.

We were able to confirm that some of the brands identified in the Google search had been introduced into Australia. We established this through interviews with Australian businesses and suppliers and from the Australian Border Force data.

6.1.4 APAN phone interview

We contacted APAN, a member association for beauty therapists including PMU artists in Australia. They advised that there are currently 104 APAN-registered PMU artists in Australia.

The principal adviser for APAN indicated that they do not recommend any specific ink brands to their members. They do advise PMU artists that all inks purchased should conform to best practices, be compliant with regulations and recommendations based upon scientific evidence, and purchased from registered and licensed importers within Australia. They also recommend that the inks should meet the EU guidelines as per the updated ResAP(2008)1 resolution. The adviser believes the following 13 PMU ink brands are used in Australia. Importer information for these brands could not be ascertained from the adviser.

- Li Pigments
- Swiss Colour OS
- EverAfter Pigments
- A Permanent Solution
- Doreme
- Biotouch
- Pure Beau
- Nouveau Contour
- Kolorsource
- Cleo Colours
- NU
- KB Pro
- NPM.

A specific concern identified by APAN was the use of PMU inks purchased through retail websites (eBay or AliExpress). The concern related to the origin of manufacture of these inks being unknown, and the possibility that the inks were contaminated or contained chemicals that could cause harm to the body. APAN advised that these inks are cheaper and thus may provide a more economical option to business operators.

We confirmed that some of the brands identified in the Google search had been introduced into Australia. We established this through interviews with Australian businesses, APAN and importers identified from the Australian Border Force data. **Table A.1** in the Appendix lists the brands used in Australia.

6.1.5 Visits to PMU artists

We interviewed 2 PMU artists in person, who had been practising in the PMU industry for a significant time. These interviews addressed PMU processes and current industry concerns. Both artists were trained at overseas beauty schools.

During the interviews, bottles of inks used were visually examined to identify the brands and the ingredients of the inks. We observed that the brand Li Pigments, listed exactly the same chemical ingredients on the label for 2 different ink shades, 'chocolate' (brown in colour) and 'nude' (beige in colour). It was also noted that the label on a red-coloured shade by Li Pigments listed FD&C (food, drugs and cosmetics) and D&C (drugs and cosmetics) dyes. FD&C and D&C are numbered identifiers given to coloured dyes by the US FDA. The PMU label did not list the identifying number of the dye additive, so the identity of the FD&C dye pigment present in the ink formulation could not be determined. Certain FD&C dyes are approved for use in cosmetics for topical applications but not in food or drugs.

One of the PMU artists indicated use of Nouveau Contour devices - a Netherlands based company, manufacturing ink pigments as well as tattooing devices.

PMU procedures are performed using machine-operated as well as hand-held tools called "pens" with detachable blades or hollowed needles. The blades or needles are used to make specific cuts to the area of the skin being tattooed, followed by embedding of the PMU ink into the cut. With machine-operated tools, the needle is held in a handheld pen, which is connected to a device that controls speed. These needles are of varying sizes (0.18 - 0.4 mm diameter), allowing the artist to apply the tattoo to different parts of the face by either shading, or dotting or drawing sharp/blunt lines. Smaller needles are used for the application of PMU to the eyes (between the eyelashes), whereas the larger needles are used for lips and brows. The other method of applying PMU is by using a freestanding pen with a sharp blade at the drawing end of the pen. This pen is unattached to any machine. The blade is used to penetrate the skin surface and ink is applied to the incision. Once the wound heals, the ink pigment gets 'locked' under the surface. The use of these non-machine operated "pens" is restricted for application to the eyebrows.

6.1.6 PMU Training

In Australia, PMU training is usually given by private training colleges. None of the Technical and Further Education (TAFE) institutes in NSW appear to offer a PMU study unit. The national register on vocational education training of PMU artists has 4 registered training organisations in Australia. There are also private, non-registered providers who offer training. Course length ranges from 2 days to 10 weeks and training costs range from \$3000 to \$10000. The depth of training given determines the course duration and cost. Some course fees include equipment and ink purchases. On an annual basis APAN conducts professional development workshops with reputable trainers on specific aspects of PMU.

The PMU artists we interviewed expressed concern at the quality of some of the training provided by private, non-registered schools. Some concerns included limited coursework and insufficient practical training, resulting in poorly-trained PMU practitioners. APAN concurred with this view.

6.2 Chemicals in PMU inks

NICNAS investigations of body art tattoo also identified chemicals used in some PMU ink brands - Biotouch and Pure Colors. In addition, the current activity identified chemical ingredients in the brands Nouveau Contour, KB Pro, Long Time Liner, Li Pigments, Derma International and Micro Colors. Information on chemical ingredients was obtained from the bottle labels and from SDSs obtained from Google searches. Some labels only identified the chemicals by the Colour Index Generic Name and/or Colour Index Constitution Number (C.I. number) of the colourants. The Chemical Abstracts Service registry number (CAS RN) was obtained for these colourants from data held by NICNAS and from SDSs.

The CAS numbers were compared against the Australian Inventory of Chemical Substances (AICS) to ascertain whether the colourants are listed on AICS. Two colourants, CAS RNs 15876-58-1 and 6358-30-1, manufactured by Pure Colors and KB Pro respectively, are not listed on AICS. CAS RN 6358-30-1 was used to describe C.I. Pigment Violet 23. However, NICNAS recently determined that the correct molecular structure of C.I. Pigment Violet 23 is represented by CAS RN 215247-95-3, which is listed on AICS. Investigation by NICNAS of body art tattoo inks identified CAS RN 15876-58-1 as an ingredient of one of the Pure Colors range of PMU inks. Products from the Pure Colors brand were available from an overseas supplier known to supply the Australian body art and PMU ink market. However, the brand Pure Colors has not been identified as used in Australia through activities to identify PMU inks in Australia (**Table A.1**).

The chemical component of CAS RN 25086-89-9 listed on the label was found to be a vinyl polymer, used by the manufacturer Nouveau Contour at concentration 1-5% in the inks. Almost all of the manufacturers use auxiliary agents such as glycerol, water and ethanol in the PMU ink formulations.

Forty chemical constituents identified in PMU inks likely to be used in Australia are listed in **Table A.2**. This is not an exhaustive list. The table also provides the C.I.

numbers for some of the identified colourants, CAS RNs, number of inks identified containing the colourant and type of colourants. The column 'shades containing pigments' contains the total number of inks by the various brands that contain the chemical. For example, three brands - Biotouch, KB Pro and Nouveau Contour contain CAS RN 1333-86-4, in eighty-six different types of PMU inks.

Twenty-four percent (24%) of the colourants in the identified brands are inorganic and seventy-six percent (76%) are organic colourants. This is a close representation of the data on PMU ink colourants identified by the CoE (Piccinini et al., 2016).

A number of the colourants listed below can be described using more than one CAS descriptor. For example, CAS RN 13463-67-7 encompasses the various forms of titanium dioxide, while CAS RN 1317-70-0 is specific for the anatase form. Also, CAS RNs 51274-00-1 and 20344-49-4 both describe yellow iron oxides; CAS RN 51274-00-1 is defined by its Colour Index entry (C.I. 77492) while CAS RN 20344-49-4 describes the elemental composition of the substance (iron hydroxide oxide (Fe(OH)O)).

The colourants CAS RN 13463-67-7 (alternate CAS RN 1317-70-0, titanium dioxide), CAS RN 1309-37-1 (red iron oxide), CAS RN 51274-00-1 (alternate CAS RN 20344-49-4, yellow iron oxide), CAS RN 1333-86-4 (carbon black) and CAS RN 12227-89-3 (alternate CAS RN 1317-61-9, black iron oxide) are used by 9 manufacturers and appear in over 50 PMU inks. All of these colourants, except CAS RN 1333-86-4, are inorganic colourants.

CAS RNs 68921-42-6 (alternatively 15792-67-3), 57455-37-5 (alternatively 12769-96-9), 1308-38-9, 12001-99-9, 17852-98-1, 15876-58-1, 68583-95-9, 12225-21-7, 15790-07-5, 14302-13-7 and 147-14-8 are organic and inorganic compounds containing the heavy metals barium, copper, chromium or aluminium. The exact percentage of heavy metals in the PMU ink formulation of these colourants is not known.

The colourants are listed by their chemical names in **Table A.3**.

The colourants listed in **Table A.3** were compared against the list of colourants in body art tattoo inks identified in the NICNAS report on body art tattoo inks published in 2016. The colourants common to both are provided in **Table A.4**.

The colourants assessed by NICNAS are indicated in **Table A.5**.

6.3 Colour Index

The C.I. database is maintained by the Society of Dyers and Colourists and the American Association of Textile Chemists and Colorists. A specific numbering system is followed for the Colour Index. **Table 6.2** provides information on the general system followed.

Table 6.2: Colour Index

| C.I. numbers | Types of colourants |
|---------------|---|
| 11000 - 19999 | Organic chemicals containing monoazo groups within their structure |
| 20000 - 39999 | Organic chemicals containing diazo groups |
| 40000 - 74999 | Organic chemicals with the general structure for stilbenes, diarylmethanes, triarylmethanes, xanthenes, acridine, quinolones, methines, thiazoles, indamines, indophenols, azines, oxazines, thiazines, aminoketones, anthraquinones, indigoids and phthalocyanines |
| 75000 - 76999 | Naturally occurring dyes |
| 77000 - 77999 | Inorganic pigments |

6.4 Other Observations

Further observations were made from the desktop searches and interviews of PMU industry professionals:

- PMU tattoo artists do not mix their inks with any auxiliary agents such as ethanol or glycerine, nor do they formulate the inks from powdered pigments. Inks are purchased in ready-to-use formulations. These inks may be mixed with water or with each other to either dilute them or obtain new shades. Inks from two different brands can also be mixed, to get the required shades of colour, although this practice is not recommended by the manufacturers.
- The most popular areas for cosmetic tattooing are the eyebrows and the eyelids, with different shades of black and brown colours being commonly used. Lip tattoos are next in popularity with shades of pink, orange and red preferred.
- Some PMU artists use inks normally used for body art tattoos to perform PMU procedures. This is because these colours are brighter and are believed to last longer. This does not conform to recommended best practice within the industry.
- Some of the businesses contacted offer areolar tattooing after mastectomies, described as medical tattoos. One of the PMU artists interviewed worked on a referral basis with Woy Woy Hospital, performing areolar tattoos for women who had undergone breast reconstruction surgery. PMU is also performed to correct pigmentation defects and scarring.
- None of the businesses that were surveyed said they purchased their inks from eBay or AliExpress. They all stated that they purchased directly from the manufacturers or from the suppliers located in Australia.

- PMU ink imports are growing, as established from the survey with PMU ink importers. This may be because of the general public's growing demand for PMU procedures. Some importers buy their stock on a monthly basis, while some purchase stock quarterly.

7. Current regulatory controls for PMU

7.1 International regulations

The Council of Europe (CoE) is an international organisation in Europe. It comprises 47 European countries, including the 28 countries that are members of the European Union (EU). According to a CoE article published in 2016 and fact sheets published by the US FDA in 2015, the PMU industry is loosely regulated in Europe and the USA.

CoE ResAP resolutions (ResAP(2003)2 and ResAP(2008)1) contain recommendations to regulate the composition, labelling, use and risk assessment of tattoo inks including PMU inks. These recommendations do not have any legal status unless adopted by a specific country. The ResAP resolutions also contain negative lists of substances (colorants, aromatic amines) that should not be used in PMU inks.

The ResAP resolutions:

- establish maximum concentrations for some impurities
- encourage establishing a positive list of substances proved to be safe under certain conditions and
- provide criteria for the safety assessment of the chemicals used (Piccinini et al., 2016).

They also have recommendations to regulate the composition, labelling, use and risk assessment of tattoo inks including PMU inks.

Some EU member countries, specifically Austria, Denmark, Latvia, Belgium, France, Norway, Germany and the Netherlands, have a specific national legal framework in place, based on CoE ResAP(2003)2 and ResAP(2008)1. Italy, Malta, Romania, and to some extent Czech Republic, Finland and Slovakia regulate tattooing practices and premises, but not according to the recommendations made in the CoE ResAPs.

Australia, Canada, Japan and USA have federal and state authorities that regulate tattoo processes and hygiene conditions. Regulations in Australia are discussed in **Section 7.2**.

The US FDA does not regulate colourants used in the PMU inks, nor does it require premarketing submission of safety data from manufacturers and distributors (Piccinini et al., 2016; Piccinini et al., 2015; LeBlanc et al., 2012). The US FDA has the authority to take action to protect public health, which was demonstrated in 2004, when certain body art tattoo inks were recalled after the FDA was made aware of complications associated with body art tattooing.

New Zealand is the only non-European country to have incorporated the CoE recommendations. The New Zealand Environmental Protection Authority (NZ-EPA) has guidelines based upon the CoE recommendations that include a list of substances that should not be present in tattoo inks. This list is not mandatory but it represents best practice guidance to prevent adverse health effects. The Tattoo and Permanent Makeup Substances Group Standard was also developed to manage the chemical risks associated with tattoo and permanent makeup substances (Piccinini et al., 2015; Piccinini et al., 2016; LeBlanc et al., 2012; NZ-EPA, 2012).

7.2 Regulatory Controls in Australia

Currently there is no nationally uniform legal framework in Australia with specific controls for the regulation of the PMU industry. Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (ICNA Act), chemical ingredients of PMU inks are required to be listed on the Australian Inventory of Chemical Substances (AICS) before they can be imported into or manufactured in Australia, unless otherwise authorised under the ICNA Act. Chemicals not listed on the AICS can generally only be introduced following notification to and assessment by NICNAS.

The Poisons Standard, a legislative instrument made under the *Therapeutic Goods Act 1989* (Cwlth), classifies medicines and poisons into Schedules for inclusion by reference in the relevant legislation of the States and Territories for the protection of public health. It promotes uniform labelling and packaging requirements throughout Australia. Listings in Schedules 2, 3, 4, 8 and 9 pertain to medicines and chemicals used in research/testing, whereas listings in Schedules 5, 6, 7 and 10 are relevant to chemicals that are available for use in the workplace and by the general public. As PMU inks are regarded as workplace chemicals, Schedules 5, 6 or 7 apply to them. Chromium, barium and copper are listed as Schedule 6 of the Poisons Standard, so PMU inks that are available to consumers and contain barium, chromium, lead and antimony above a certain concentration are to be labelled with the signal word "Poison". However, products packaged and sold solely for use in the workplace are exempt from this labelling requirement.

Model Work Health and Safety (WHS) Regulations administered by SafeWork Australia become legally binding when these model provisions are enacted by state and territory jurisdictions. WHS Regulations specify that hazardous chemicals in the workplace must be correctly labelled and a SDS must be provided on supply. SafeWork Australia also administers the Hazardous Chemical Information System (HCIS), a database of hazard classifications and exposure standards for many workplace chemicals. Professionally applied PMU inks are considered workplace chemicals and, therefore, any relevant state or territory WHS regulations apply to these inks. According to the HCIS, chromium and barium are considered hazardous workplace chemicals if they are present at concentrations $\geq 0.1\%$.

7.2.1 State and Territory Government Requirements

Regulations and advice for the PMU industry from Australian state regulatory authorities are focused on equipment hygiene, age restrictions for tattoo recipients,

and preventing criminals from operating in tattooing premises. There are no specific restrictions on the composition of PMU inks.

- **New South Wales:** Skin penetration procedures are regulated by the *Public Health Act 2010* and *Public Health Regulation 2012* implemented by NSW Health. A factsheet, targeted towards tattooists and other professionals conducting skin penetration procedures, outlines how businesses must comply with this legislation (NSW Health, 2013). PMU artists and business operators are not required to hold a practising licence from Fair Trading NSW; however, PMU artists are required to be registered with local councils. The PMU premises need to meet the operational requirements set out by the local council including premise surfaces, lighting, and ventilation. Premises must also be equipped with appropriate wash basins, liquid soaps, and single use towels. In 2016, an amendment was made to the *Public Health Regulations 2012* designating eyeball and tongue tattooing as skin penetration procedures (NSW Health, 2016).
- **Queensland:** Queensland has implemented the *Tattoo Industry Act 2013* to regulate the body art tattooing industry. The main purpose of this Act is to minimise the risk of criminal activity found within the tattooing industry. Although PMU operational procedures are very similar to body art tattooing, it is not clear whether PMU is included in this Act. A factsheet published by the Queensland Health Department indicates that, even though the skin is not penetrated to the same depth in PMU as in body art tattooing, both involve similar processes. Therefore, PMU artists are required to possess the necessary infection control qualifications and provide clients with aftercare instructions (Queensland Health Department, 2015).
- **Victoria:** In Victoria, skin penetration and tattooing procedures are regulated by the *Public Health and Wellbeing Act 2008* and *Public Health and Wellbeing Regulations 2009*. Personal care and body art practitioners, which include tattooists and PMU providers, are required to register the premises in which they conduct their business with the local council. The premises must meet certain infection control requirements as set out by the regulations, which include: being in a clean, sanitary and hygienic condition; having easily accessible hand washing facilities; personal hygiene requirements for the practitioners; and certain sterilisation requirements for articles used for skin penetration. There is no provision requiring tattoo or PMU practitioners to have undergone specific training. An amendment to the *Summary Offences Act 1966* prohibits certain skin penetration practices (e.g. tattooing, scarification and genital piercing) on persons under the age of 18, and provides penalties for this offence. A factsheet published by the Department of Health's Communicable Disease Prevention and Control Unit provides guidance to people contemplating any tattooing procedure, including PMU. It includes advice regarding good hygiene practices and operational requirements, and the risks involved, as well as tattoo aftercare and complications from tattoo removal (Health Victoria, 2010).

- **Western Australia:** Requirements for businesses operating skin penetration procedures are described in the *Code of Practice for Skin Penetration Procedures 1998* as adopted by the *Health (Skin Penetration Procedures) Regulations 1998*. This code covers practices such as tattooing, body piercing, acupuncture, depilatory waxing, electrolysis, skin lancing and PMU. The code approaches skin penetration practices from a work cleanliness and hygiene viewpoint in order to minimise infections. PMU must be performed in accordance with the code, particularly in relation to sterilising appliances. The *Health (Miscellaneous Provisions) Act 1911* provides penalties for tattooing minors.
- **South Australia:** A factsheet issued in 2012 provides information on the health risks associated with body art tattoo inks (Government of South Australia, 2012). The focus of the factsheet is to inform the general public about age restrictions when getting a tattoo, health risks and post-tattooing aftercare. Under the *Tattooing Industry Control Act 2015*, body art tattooists are required to notify the business to the commissioner for Consumer Affairs. PMU businesses are exempt from this notification process (Government of South Australia, 2017). SA Health publishes guidelines on the 'Safe and hygienic practice of skin penetration'. These guidelines state that operators for PMU (referred to as micropigmentation or cosmetic tattooing) must follow the same guidelines for hygiene and sterilisation as for body art tattooing (South Australian Health Commission, 2004).
- **Tasmania:** Under the *Public Health Act 1997*, the Department of Health and Human Services publishes *Guidelines for Tattooing*, which contains advice for tattooing practices focusing on the health and safety, and hygiene requirements in tattoo parlours. It is applicable to all persons who perform tattooing procedures, including PMU artists. Factsheets published by the Hobart and Launceston city councils state that any person performing skin penetration procedures is required to have a licence and the premises must be registered with the local councils (City of Hobart, 2017, City of Launceston, 2017).
- **Northern Territory:** Guidelines published by the Department of Health recommend that beauty therapists and hairdressers who undertake activities that penetrate the skin, or may unintentionally penetrate the skin, be vaccinated against Hepatitis B. PMU is included as a skin penetration procedure so these guidelines apply to PMU service providers. Businesses also need to be registered with the Environmental Health Office (Northern Territory Department of Health Environmental Health Branch, 2014).

8. Summary

We have identified some businesses performing PMU in Australia and the brands of inks used. We have collected information about brands of ink imported into Australia, the chemical composition of these inks, PMU processes and practices, and training

from 6 PMU ink importers, 6 PMU service providers, 2 PMU artists and 1 PMU industry organisation.

Of the 60 PMU service providers contacted, we obtained information from 6 providers. Three of these were from NSW, 2 from Victoria and 1 from Western Australia. We interviewed 2 PMU artists from NSW in person. Of the 10 PMU ink importers identified, 6 provided information. Of these, 3 are located in NSW and 1 each in Victoria, Western Australia and South Australia.

We identified over 50 brands of PMU inks, from the abovementioned sources. From these, 29 brands are known to be imported and used in Australia. Of these, ink containers from 3 brands were visually examined during in-person interviews. From the 29 brands known to be used in Australia, chemical ingredients for 10 brands were identified either from the labels or SDSs. No testing was undertaken to confirm that the composition of the inks was as shown on the label or SDS.

The limited practical training available to PMU artists was identified as a concern. Other concerns identified were:

- The importation of potentially counterfeit PMU inks from retail websites such as eBay and AliExpress
- Use of inks designed for body art tattooing, and/or mixing of inks between brands to obtain specific shades of colours. These do not conform to recommended best practice in the industry.

9. Recommendations

This activity identified that PMU artists can undertake limited training before they perform PMU on the Australian public. It also identified the possibility that inks being used may contain chemicals that should not be used in PMU.

We also identified the use of body art tattoo inks for PMU. This is despite the relevant professional association recommending against this. The chemical constituents in the inks were not confirmed by quantitative laboratory analysis, so it is not known if they meet the labelling requirements of the Poisons Standard or WHS.

We recommend that the State and Territory governments:

- consider whether PMU artists should undertake specific training to allow them to perform PMU safely, particularly as the practice requires selection of appropriate chemicals for injection near the eyes, on the lips and in other delicate organs
- monitor compliance of the labelling and use of PMU inks with the Poisons Standard and WHS regulations. Some amines that may be found in PMU inks are prohibited for use in tattoo inks in the Poisons Standard.

10. References

- Antonovich DD, Callen JP (2005). Development of sarcoidosis in cosmetic tattoos. *Arch Dermatol*, vol. 141(7), pp 869-872.
- Chang SE, Kim KJ, Choi JH, Sung KJ, Moon KC, Koh JK (2002). Areolar cosmetic tattoo ink darkening: a complication of Q-switched alexandrite laser treatment. *Dermatol Surg*, vol. 28, pp 95-96.
- City of Hobart (2017). Public Health Risk Activities - Tattooing and Piercing [Online]. Available: <https://www.hobartcity.com.au/Business/Tattooing-and-piercing-businesses>
- City of Launceston (2017). Tattooing, Piercing and Acupuncture [Online]. Available: <https://www.launceston.tas.gov.au/Business-and-Development/Health-Regulations/Tattooing-Piercing-and-Acupuncture#Tattooing-2>
- Council of Europe (CoE) (2008). Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up). Adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers' Deputies.
- De Cuyper, C (2015). Complications of cosmetic tattoos. *Curr Probl Dermatol*, vol. 48, pp 61-70.
- Garland SM, Ung L, Vujovic OV, Said JM (2006). Cosmetic tattooing: A potential transmission route for HIV? *Aust N Z J Obstet Gynaecol*, vol. 46(5), pp. 458-9.
- Government of South Australia (2012). Tattooing - Know the Risks [Online]. Available at: https://www.agd.sa.gov.au/sites/g/files/net2876/f/2012-tattooing-factsheet_0.pdf?v=1491451787
- Government of South Australia, Consumer & Business Services (2017). Tattoo Industry [Online]. Available at: <https://www.cbs.sa.gov.au/licensing-and-registration/tattoo-industry/>
- Greywal T, Cohen PR (2016). Cosmetic tattoo pigment reaction. *Dermatol Online J*, 22(7), pii 13030/qt3rc114rg.
- Health Victoria (2010). Health information sheets for clients -Tattooing [Online]. Available at: <https://www2.health.vic.gov.au/about/publications/factsheets/Health%20information%20sheets%20for%20clients%20-Tattooing>
- Kopera D (2006). Adverse effects of cosmetic tattooing: an illustrative case of granulomatous dermatitis following the application of permanent makeup. *Arch Dermatol*, vol. 142(10), pp 1364.
- LeBlanc PM, Hollinger KA, Klontz KC (2012). Tattoo Ink-Related Infections - Awareness, Diagnosis, Reporting, and Prevention. *N Engl J Med*, vol. 367(11), pp 985-987.
- New Zealand Environmental Protection Authority (NZ-EPA) (2012). Guidelines for tattoo and permanent makeup substances, March 2012.
- Northern Territory Department of Health Environmental Health Branch (2014). Public and Environmental Health Guidelines for Hairdressing, Beauty Therapy and Body Art [Online]. Northern Territory Department of Health. Available at: <http://digitallibrary.health.nt.gov.au/prodjspui/handle/10137/1151>
- NSW Health (2013). Environmental Health Factsheet: Tattooing and other body art - hygiene standards [Online]. Available at: <http://www.health.nsw.gov.au/environment/factsheets/Pages/tattooing.aspx>.

- NSW Health (2016). Environmental Health Factsheet: Eyeball Tattooing [Online]. Available at: <http://www.health.nsw.gov.au/environment/factsheets/Pages/eyeball-tattooing.aspx>.
- Piccinini P, Bianchi I, Pakalin S, Senaldi C (2015). Safety of tattoos and permanent make-up: Compilation of information on legislative framework and analytical methods. Publications Office of the European Union, Luxembourg.
- Piccinini P, Pakalin S, Contor L, Bianchi I, Senaldi C (2016). Safety of tattoos and permanent make-up: Final report. Publications Office of the European Union, Luxembourg.
- Queensland Health Department (2015). Tattooing - What I need to know - What should I ask [Online]. Available at: <http://conditions.health.qld.gov.au/HealthCondition/condition/20/40/137/tattooing-what-i-need-to-know-what-should>
- South Australian Health Commission (2004). Guidelines on the safe and hygienic practice of skin penetration [Online]. Available at: <http://www.sahealth.sa.gov.au/wps/wcm/connect/3d4e0b8046c253089530fd22d29d99f6/skin-penetration-guide-10feb05.pdf?MOD=AJPERES&CACHEID=3d4e0b8046c253089530fd22d29d99f6>
- Straetemans M, Katz LM, Belson M (2007). Adverse reactions after permanent-makeup procedures. N Engl J Med, vol. 356(26), pp 2753.

11. Appendix

Table A.1: Brands in use in Australia as identified from the different sources

| Brands | Google search | PMU artist survey | Border Protection data | APAN |
|-----------------------------|---------------|-------------------|------------------------|------|
| Trilab Colours | √ | √ | | |
| Absolute Perfection | | √ | | |
| Premier inks | | √ | | |
| Face Ink | | √ | | |
| Nouveau Contour | √ | √ | | √ |
| Long Time Liner | √ | √ | | |
| Dr Linda Dickson | | √ | | |
| NBC Cosmetics | | √ | | |
| Biotouch | √ | √ | | √ |
| International Colours China | | √ | | |
| Kolorsource | √ | √ | | √ |
| Li Pigments | √ | √ | √ | √ |
| Ameia | √ | | √ | √ |
| MT Derm GMBH | | | √ | |
| Lasting Impressions | | | √ | |
| Ever After Pigments | | | | √ |
| A Permanent Solution | √ | | | √ |
| Doreme | | | | √ |
| Pure Beau | | | | √ |
| Cleo Colours | | | | √ |
| NU | | | | √ |
| NPM | | | | √ |
| KB Pro | √ | | | √ |
| Ecuri | √ | | | |
| Swiss Color International | √ | | | |
| Chi Australia | √ | | | |
| KP Pigments | √ | | | |
| BioEvolution | √ | | | |
| Radiant | √ | | | |

Table A.2: PMU brands and their chemical constituents identified from publicly available sources

| | PMU ink brands | C.I. Index | CAS RN | Shades containing pigment | Type |
|----|--|------------|--------------------------|---------------------------|-------------------------|
| 1 | Biotouch, KB Pro, Nouveau Contour | 77266 | 1333-86-4 | 86 | Organic ^{1, 2} |
| 2 | Nouveau Contour | - | 7440-44-0 | 6 | Organic ² |
| 3 | Biotouch, Pure Colors, Long Time Liner, Li Pigments, Derma International, Micro Colors, KB Pro, Kolorsource, Nouveau Contour | 77499 | 12227-89-3 (1317-61-9)* | 97 | Inorganic |
| 4 | Pure Colors, KB Pro | 42090:2 | 68921-42-6 (15792-67-3)* | 2 | Organic |
| 5 | Pure Colors, Derma International, KB Pro, KB Pro | 77007 | 57455-37-5 (12769-96-9)* | 4 | Inorganic |
| 6 | Pure Colors, KB Pro, Nouveau Contour | 77288 | 1308-38-9 | 19 | Inorganic |
| 7 | Biotouch, Pure Colors | 77289 | 12001-99-9 | 3 | Inorganic |
| 8 | Biotouch, | 45370:1 | 596-03-2 | 1 | Organic |
| 9 | Biotouch, Pure Colors, Kolorsource | 15850:1 | 5281-04-9 | 13 | Organic |
| 10 | Biotouch | 12085 | 2814-77-9 | 2 | Organic |
| 11 | Pure Colors, Kolorsource | 15850:2 | 17852-98-1 | 6 | Organic |
| 12 | Biotouch, Pure Colors, Long Time Liner, Li Pigments, KB Pro, Kolorsource, Nouveau Contour | 77491 | 1309-37-1 | 126 | Inorganic |

| | PMU ink brands | C.I. Index | CAS RN | Shades containing pigment | Type |
|----|--|------------|--------------------------|---------------------------|-----------|
| 13 | Pure Colors | 45410:2 | 15876-58-1 | 1 | Organic |
| 14 | Biotouch, Pure Colors | 16035:1 | 68583-95-9 | 7 | Organic |
| 15 | Biotouch, Kolorsource | 77742 | 10101-66-3 | 4 | Inorganic |
| 16 | Biotouch | 77510 | 25869-00-5 | 1 | Inorganic |
| 17 | Biotouch, Pure Colors, Long Time Liner, Li Pigments, Derma International, Micro Colors, KB Pro, Nouveau Contour, Kolorsource | 77891 | 13463-67-7 (1317-70-0)* | 362 | Inorganic |
| 18 | Biotouch, Pure Colors, Long Time Liner, Li Pigments, KB Pro, Nouveau Contour, Kolorsource | 77492 | 51274-00-1 (20344-49-4)* | 97 | Inorganic |
| 19 | Biotouch, Pure Colors, KB Pro | 19140:1 | 12225-21-7 | 8 | Organic |
| 20 | Biotouch, Pure Colors | 15985:1 | 15790-07-5 | 4 | Organic |
| 21 | Micro Colors | 71130 | 5521-31-3 | 1 | Organic |
| 22 | KB Pro | 56298 | 36888-99-0 | 1 | Organic |
| 23 | KB Pro | 11781 | 68134-22-5 | 1 | Organic |
| 24 | KB Pro | 18792 | 65212-77-3 | 1 | Organic |
| 25 | KB Pro | 19140 | 1934-21-0 | 1 | Organic |
| 26 | KB Pro | 74265 | 14302-13-7 | 1 | Organic |
| 27 | KB Pro | 24400 | 2429-74-5 | 1 | Organic |
| 28 | KB Pro | 51319 | 6358-30-1 | 1 | Organic |
| 29 | Kolorsource | - | 4086-70-8 | 1 | Organic |
| 30 | Kolorsource | 17200 | 3567-66-6 | 1 | Organic |
| 31 | Nouveau Contour | 45430 | 16423-68-0 | 3 | Organic |
| 32 | Nouveau Contour | 73360 | 2379-74-0 | 9 | Organic |
| 33 | Nouveau Contour | 15985 | 2783-94-0 | 4 | Organic |

| | PMU ink brands | C.I. Index | CAS RN | Shades containing pigment | Type |
|----|-----------------|------------|------------|---------------------------|---------|
| 34 | Nouveau Contour | 74160 | 147-14-8 | 9 | Organic |
| 35 | Nouveau Contour | 12490 | 6410-41-9 | 7 | Organic |
| 36 | Nouveau Contour | 56110 | 84632-65-5 | 13 | Organic |
| 37 | Nouveau Contour | 65300 | 4051-63-2 | 5 | Organic |
| 38 | Nouveau Contour | - | 25086-89-9 | 13 | Polymer |
| 39 | Nouveau Contour | 56300 | 30125-47-4 | 8 | Organic |
| 40 | Nouveau Contour | 16035 | 25956-17-6 | 6 | Organic |

* Alternate CAS descriptor used to identify the chemical.

1. CAS RN 1333-86-4 pertains to carbon black, which is obtained from the incomplete combustion of natural gas or petroleum and the exact chemical composition is unknown. Therefore, in this report it has been classified as organic. The C. I. Index places this chemical with inorganic pigments.
2. The CAS descriptors 1333-86-4 and 7440-44-0 represent distinct substances. However, there are similarities in the production methods and resulting end products for CAS RN 1333-86-4 and CAS RN 7440-44-0.

Table A.3: Colourants found in PMU inks and their common and chemical names

| C.I. Index | CAS RN | Common chemical names | CAS preferred name |
|------------|-------------------------|---|--|
| 77266 | 1333-86-4 | Pigment Black 7 | Carbon black ¹ |
| - | 7440-44-0 | Activated Carbon; Carbon Black | Carbon ¹ |
| 77499 | 12227-89-3, 1317-61-9* | Pigment Black 11; Black iron oxide | C.I. Pigment Black 11 |
| 42090:2 | 68921-42-6, 15792-67-3* | Pigment Blue 78; Food Blue 2:1; FD&C Blue No. 1 Lake | Benzenemethanaminium, <i>N</i> -ethyl- <i>N</i> -[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo-, inner salt, aluminum salt (1:?) |
| 77007 | 57455-37-5, 12769-96-9* | Ultramarine Blue; Ultramarine Violet; Pigment Violet 15 | C.I. Pigment Blue 29 |
| 77288 | 1308-38-9 | Pigment Green 17 | Chromium(III) oxide (Cr ₂ O ₃) |

| C.I. Index | CAS RN | Common chemical names | CAS preferred name |
|------------|-------------------------|---|---|
| 77289 | 12001-99-9 | Chrome Oxide (Hydrated) Green; Cr ₂ O(OH) ₄ | C.I. Pigment Green 18 |
| 45370:1 | 596-03-2 | D&C Orange No. 5; Solvent Red 72 | Spiro[isobenzofuran-1(3 <i>H</i>), 9'-[9 <i>H</i>]xanthen]-3-one, 4', 5'-dibromo-3',6'-dihydroxy- |
| 15850:1 | 5281-04-9 | D&C Red No. 7; Pigment Red 57:1 | 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[2-(4-methyl-2-sulfophenyl) diazenyl]-, calcium salt (1:1) |
| 12085 | 2814-77-9 | D&C Red No. 36; Pigment Red 4 | 2-Naphthalenol, 1-[2-(2-chloro-4-nitrophenyl) diazenyl]- |
| 15850:2 | 17852-98-1 | Pigment Red 57:2 | 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[2-(4-methyl-2-sulfophenyl) diazenyl]-, barium salt (1:1) |
| 77491 | 1309-37-1 | Pigment Red 101 | Iron(III) oxide (Fe ₂ O ₃) |
| 45410:2 | 15876-58-1 | Pigment Red 174; D&C Red No.27 aluminium lake; D&C Red No.28 aluminium lake | Spiro[isobenzofuran-1(3 <i>H</i>), 9'-[9 <i>H</i>]xanthen]-3-one, 2', 4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, aluminum salt (3:2) |
| 16035:1 | 68583-95-9 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, aluminum complex; Pigment Red 273 | C.I. Food Red 17:1 |
| 77742 | 10101-66-3 | Manganese Violet; Pigment Violet 16 | Diphosphoric acid, ammonium manganese(3+) salt (1:1:1) |
| 77510 | 25869-00-5 | Pigment Violet 27; Pigment Blue 27; Ammonium ferric hexacyanoferrate | Ferrate(4-), hexakis(cyano-κC)-, ammonium iron(3+) (1:1:1), (OC-6-11)- |
| 77891 | 13463-67-7, 1317-70-0* | Pigment White 6; Anatase | Titanium dioxide (TiO ₂) |
| 77492 | 51274-00-1, 20344-49-4* | Yellow iron oxide; Iron hydroxide oxide (Fe(OH)O); Iron(III) oxide hydroxide | C.I. Pigment Yellow 42 |
| 19140:1 | 12225-21-7 | 1 <i>H</i> -Pyrazole-3-carboxylic acid, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-, aluminum complex | C.I. Pigment Yellow 100 |
| 15985:1 | 15790-07-5 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[(4- | C.I. Pigment Yellow 104 |

| C.I. Index | CAS RN | Common chemical names | CAS preferred name |
|------------|-------------------------------------|---|---|
| | | sulfophenyl)azo]-, aluminum complex; Food Yellow 3:1 | |
| 71130 | 5521-31-3 | Pigment Red 179 | Anthra[2,1,9- <i>def</i> 6,5,10- <i>d'e'f'</i>]diisoquinoline-1,3,8,10(2 <i>H</i> ,9 <i>H</i>)-tetrone, 2,9-dimethyl |
| 56298 | 36888-99-0 | Pigment Yellow 139 | 2,4,6(1 <i>H</i> ,3 <i>H</i> ,5 <i>H</i>)-Pyrimidinetrione, 5,5'-(1 <i>H</i> -isoindole-1,3(2 <i>H</i>)-diylidene)bis- |
| 11781 | 68134-22-5 | Pigment Yellow 154 | Butanamide, N-(2,3-dihydro-2-oxo-1 <i>H</i> -benzimidazol-5-yl)-3-oxo-2-[2-[2-(trifluoromethyl)phenyl]diazonyl]- |
| 18792 | 65212-77-3 | Pigment Yellow 183 | Benzenesulfonic acid, 4,5-dichloro-2-[2-[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1 <i>H</i> -pyrazol-4-yl]diazonyl]-, calcium salt (1:1) |
| 19140 | 1934-21-0 | D&C Yellow No. 5; Acid Yellow 23; Solvent Yellow 57; Food Yellow 4 | 1 <i>H</i> -Pyrazole-3-carboxylic acid, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[2-(4-sulfophenyl)diazonyl]-, sodium salt (1:3) |
| 74265 | 14302-13-7 | Copper, [1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17,22,23,25-decachloro-29 <i>H</i> ,31 <i>H</i> -phthalocyaninato(2-)-N29,N30,N31,N32]-, (SP-4-2)- | C.I. Pigment Green 36 |
| 24400 | 2429-74-5 | Direct Blue 15 | 2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(2,1-diazenediyl)]bis[5-amino-4-hydroxy-, sodium salt (1:4) |
| 51319 | 215247-95-3, 6358-30-1 [#] | Pigment Violet 23 | Diindolo[2,3- <i>c</i> :2',3'- <i>n'</i>]triphenodioxazine, 9,19-dichloro-5,15-diethyl-5,15-dihydro- |
| 17200 | 3567-66-6 | D&C Red No. 33; Acid Red 33 | 2,7-Naphthalenedisulfonic acid, 5-amino-4-hydroxy-3-(2-phenyldiazonyl)-, sodium salt (1:2) |
| 45430 | 16423-68- | D&C Red No. 3; Acid Red 51; | Spiro[isobenzofuran-1(3 <i>H</i>), |

| C.I. Index | CAS RN | Common chemical names | CAS preferred name |
|------------|------------|--|---|
| | 0 | Food Red 14 | 9'-[9 <i>H</i>]xanthen]-3-one, 3', 6'-dihydroxy-2',4',5',7'-tetraiodo-, sodium salt (1:2) |
| 73360 | 2379-74-0 | D&C Red No. 30; Pigment Red 181; Vat Red 1 | Benzo[<i>b</i>]thiophen-3(2 <i>H</i>)-one, 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[<i>b</i>]thien-2(3 <i>H</i>)-ylidene)-4-methyl- |
| 15985 | 2783-94-0 | Sunset Yellow; D&C Yellow No. 6; Food Yellow 3 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[2-(4-sulfophenyl)diazenyl]-, sodium salt (1:2) |
| 74160 | 147-14-8 | Pigment Blue 15 | Copper, [29 <i>H</i> ,31 <i>H</i> -phthalocyaninato(2-)-κ <i>N</i> ²⁹ , κ <i>N</i> ³⁰ ,κ <i>N</i> ³¹ ,κ <i>N</i> ³²]-, (SP-4-1)- |
| 12490 | 6410-41-9 | Pigment Red 5 | 2-Naphthalenecarboxamide, <i>N</i> -(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy- |
| 56110 | 84632-65-5 | Pigment Red 254 | Pyrrolo[3,4- <i>c</i>]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- |
| 65300 | 4051-63-2 | Pigment Red 177 | [1,1'-Bianthracene]-9,9',10,10'-tetrone, 4,4'-diamino- |
| 56300 | 30125-47-4 | Pigment Yellow 138 | 1 <i>H</i> -Isoindole-1,3(2 <i>H</i>)-dione, 4,5,6,7-tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1 <i>H</i> -inden-2-yl)-8-quinolinyl]- |
| 16035 | 25956-17-6 | Food Red 17; FD&C Red No. 40 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[2-(2-methoxy-5-methyl-4-sulfophenyl)diazenyl]-, sodium salt (1:2) |

* Alternate CAS descriptor used to identify the chemical.

The AICS entry for CAS RN 6358-30-1 has been replaced by CAS RN 215247-95-3, which more accurately describes the structure of C.I. Pigment Violet 23

1. The CAS descriptors 1333-86-4 and 7440-44-0 represent distinct substances. However, there are similarities in the manufacturing process and resulting end products for CAS RN 1333-86-4 and CAS RN 7440-44-0.

Table A.4: PMU colourants that may be present in inks used for body art tattooing

| C.I. Index | CAS RN | Common chemical name | CAS preferred name |
|------------|------------|--|--|
| 77266 | 1333-86-4 | Pigment Black 7 | Carbon black |
| 77499 | 12227-89-3 | Pigment Black 11 | C.I. Pigment Black 11 |
| 42090:2 | 15792-67-3 | FD&C Blue No. 1 | Benzenemethanaminium, <i>N</i> -ethyl- <i>N</i> -[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo-, inner salt, aluminum salt (3:2) |
| 77007 | 57455-37-5 | Ultramarine Blue | C.I. Pigment Blue 29 |
| 77288 | 1308-38-9 | Pigment Green 17 | Chromium(III) oxide (Cr ₂ O ₃) |
| 77289 | 12001-99-9 | Chromium hydroxide green | C.I. Pigment Green 18 |
| 45370:1 | 596-03-2 | D&C Orange No. 5 | Spiro[isobenzofuran-1(3 <i>H</i>), 9'-[9 <i>H</i>]xanthen]-3-one, 4', 5'-dibromo-3',6'-dihydroxy- |
| 15850:1 | 5281-04-9 | D&C Red No. 7 | 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[2-(4-methyl-2-sulfophenyl) diazenyl]-, calcium salt (1:1) |
| 12085 | 2814-77-9 | D&C Red No. 36 | 2-Naphthalenol, 1-[2-(2-chloro-4-nitrophenyl) diazenyl]- |
| 15850:2 | 17852-98-1 | Pigment Red 57:2 | 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[2-(4-methyl-2-sulfophenyl) diazenyl]-, barium salt (1:1) |
| 77491 | 1309-37-1 | Pigment Red 101 | Iron(III) oxide (Fe ₂ O ₃) |
| 45410:2 | 15876-58-1 | Pigment Red 174 | Spiro[isobenzofuran-1(3 <i>H</i>), 9'-[9 <i>H</i>]xanthen]-3-one, 2', 4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, aluminum salt (3:2) |
| 16035:1 | 68583-95-9 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-, aluminum complex | C.I. Food Red 17:1 |
| 77742 | 10101-66-3 | Manganese Violet | Diphosphoric acid, ammonium manganese(3+) salt (1:1:1) |

| C.I. Index | CAS RN | Common chemical name | CAS preferred name |
|------------|-------------|---|--|
| 77510 | 25869-00-5 | Pigment Violet 27 | Ferrate(4-), hexakis(cyano- κC)-, ammonium iron(3+) (1:1:1), (OC-6-11)- |
| 77891 | 13463-67-7 | Pigment White 6 | Titanium dioxide (TiO ₂) |
| 77492 | 51274-00-1 | Yellow iron oxide | C.I. Pigment Yellow 42 |
| 19140:1 | 12225-21-7 | 1 <i>H</i> -Pyrazole-3-carboxylic acid, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-, aluminum complex | C.I. Pigment Yellow 100 |
| 15985:1 | 15790-07-5 | 2-Naphthalenesulfonic acid, 6-hydroxy-5-[(4-sulfophenyl)azo]-, aluminum complex | C.I. Pigment Yellow 104 |
| 74265 | 14302-13-7 | Copper, [1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17,22,23,25-decachloro-29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, (SP-4-2)- | C.I. Pigment Green 36 |
| 51319 | 215247-95-3 | Pigment Violet 23 | Diindolo[2,3- <i>c</i> :2',3'- <i>n</i>] triphenodioxazine, 9,19-dichloro-5,15-diethyl-5,15-dihydro- |
| 74160 | 147-14-8 | Pigment Blue 15 | Copper, [29 <i>H</i> ,31 <i>H</i> -phthalocyaninato(2-)- κN^{29} , κN^{30} , κN^{31} , κN^{32}]-, (SP-4-1)- |
| 12490 | 6410-41-9 | Pigment Red 5 | 2-Naphthalenecarboxamide, <i>N</i> -(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazanyl]-3-hydroxy- |
| 56110 | 84632-65-5 | Pigment Red 254 | Pyrrolo[3,4- <i>c</i>]pyrrole-1,4-dione, 3,6-bis(4-chlorophenyl)-2,5-dihydro- |

Table A.5: Colourants with NICNAS assessments

| C.I. Index | CAS RN | CAS preferred name | IMAP assessment [#] |
|------------|------------|---|------------------------------|
| 77266 | 1333-86-4 | Carbon black | Tier 2 |
| 77007 | 57455-37-5 | C.I. Pigment Blue 29 | Tier 1 |
| 77288 | 1308-38-9 | Chromium(III) oxide (Cr ₂ O ₃) | Tier 1 |
| 12085 | 2814-77-9 | 2-Naphthalenol, 1-[2-(2- | Tier 1 |

| C.I. Index | CAS RN | CAS preferred name | IMAP assessment# |
|------------|------------|---|------------------|
| | | chloro-4-nitrophenyl diazenyl]- | |
| 77491 | 1309-37-1 | Iron(III) oxide (Fe ₂ O ₃) | Tier 1 |
| 77891 | 13463-67-7 | Titanium dioxide (TiO ₂) | Tier 2 |
| 77492 | 51274-00-1 | C.I. Pigment Yellow 42 | Tier 1 |
| 77499 | 1317-61-9 | Iron(IV) oxide (Fe ₃ O ₄) | Tier 1 |
| 24400 | 2429-74-5 | 2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(2,1-diazenediyl)]bis[5-amino-4-hydroxy-, sodium salt (1:4) | Tier 2 |
| 77492 | 20344-49-4 | Iron hydroxide oxide, (Fe(OH)O) | Tier 1 |
| 77891 | 1317-70-0 | Anatase (TiO ₂) | Tier 2 |
| 17200 | 3567-66-6 | 2,7-Naphthalenedisulfonic acid, 5-amino-4-hydroxy-3-(2-phenyldiazenyl)-, sodium salt (1:2) | Tier 1 |
| 73360 | 2379-74-0 | Benzo[<i>b</i>]thiophen-3(2 <i>H</i>)-one, 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[<i>b</i>]thien-2(3 <i>H</i>)-ylidene)-4-methyl- | Tier 1 |
| 74160 | 147-14-8 | Copper, [29 <i>H</i> ,31 <i>H</i> -phthalocyaninato(2-)-κN ²⁹ ,κN ³⁰ ,κN ³¹ ,κN ³²]-, (SP-4-1)- | Tier 1 |
| 12490 | 6410-41-9 | 2-Naphthalenecarboxamide, <i>N</i> -(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy- | Tier 1 |
| - | 7440-44-0 | Carbon | Tier 1 |
| 15850:1 | 5281-04-9 | 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[2-(4-methyl-2-sulfophenyl) diazenyl]-, calcium salt (1:1) | Tier 1 |

#Tier 1 represents a list of chemicals that were assessed and are not considered to pose an unreasonable risk to the health of workers and public, and the environment based on their use. Tier 2 contains a list of chemicals which were identified as requiring further investigation during Tier 1 assessment phase.