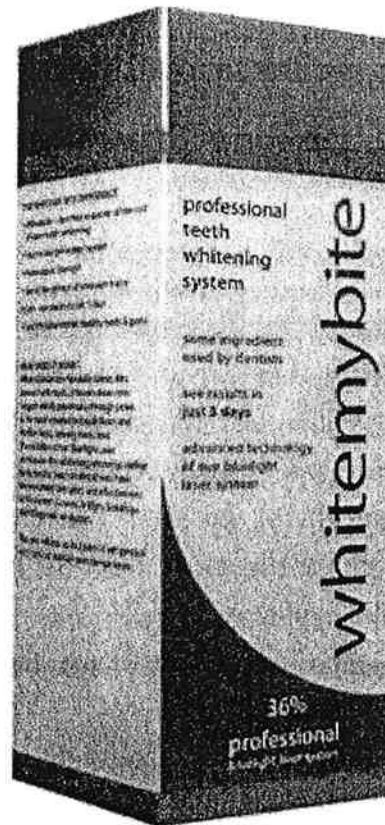




Australian
Competition &
Consumer
Commission

Over the Counter (OTC) Teeth Whitening Products Containing High Concentrations of Hydrogen Peroxide or Carbamide Peroxide



October 2011

1. BACKGROUND

Over recent years teeth whitening has become a common cosmetic procedure with an increasing number of products available directly to the public for do it yourself (DIY) teeth whitening. The main active bleaching ingredients present in these products are hydrogen peroxide and carbamide peroxide. The trend appears to be that increasingly high concentrations of these ingredients are being found in over the counter (OTC) consumer products.

There has also been an increase in recent media coverage on the high level concentrations of hydrogen peroxide and/or carbamide peroxide found in teeth whitening products, with recent allegations of injuries reported including damage to teeth and serious burns to gums and the mouth, resulting from the use of these products¹ (see example of injury below).

Hydrogen peroxide (H₂O₂) is the simplest peroxide (a compound with an oxygen-oxygen single bond) and an oxidizer. Hydrogen peroxide is a clear liquid, slightly more viscous than water. In dilute solution it appears colourless. With its oxidizing properties, hydrogen peroxide is often used as a bleach or cleaning agent. The oxidizing capacity of hydrogen peroxide is so strong that it is considered a highly reactive oxygen species. Hydrogen peroxide is naturally produced in organisms as a by-product of oxidative metabolism.

Carbamide peroxide is a solid comprising a one-to-one ratio of urea and hydrogen peroxide and is a more stable way to deliver hydrogen peroxide. Approximately 10 per cent carbamide peroxide is equivalent to 3.62 per cent of hydrogen peroxide. Carbamide peroxide releases oxygen on contact with moist tissues and is generally used to treat infections of the ear, mouth, skin, and mucous membranes and for softening and removal of ear wax.

Increasing widespread use of teeth whitening products is likely to increase incidence of harm. According to the Academy of General Dentistry, teeth whitening is a \$600 million p.a. industry, and is growing 15-20% each year. [2] <https://www.bacd.com/media/statistics.html>

In November 2007 a study by the British Academy of Cosmetic Dentistry^[1] found:

- A third of the population (32%) say they are ‘concerned by the look of their teeth’
- Approximately one fifth of people (18%) ‘usually conceal their teeth in photos’, including 19% of men and nearly a quarter of both 18-24 and 25-34 year-olds
- Only one in four people agree with the statement ‘I like my smile and would not change it’, and in fact, less claim to ‘always smile in photos’ than last year – down to 20% from 27%
- Over half of the representative sample now claims to visit their dentist regularly, a rise of 5% on last year (53% up from 48%)
- Nearly 60% of women visit the dentist regularly, above average and significantly more than men do - only 46% of males visit the dentist regularly
- Women are more inclined to believe a nice smile indicates a warm personality, whilst men consider it begets more success in life
- Over a quarter (27%) continue to believe that cosmetic dentistry can improve quality of life

¹ See media articles at: <http://www.choice.com.au/media-and-news/media-releases/2011%20media%20releases/whiter-teeth-craze-thrives-with-no-rules.aspx>, accessed 22 September 2011; and <http://www.canberratimes.com.au/news/local/news/general/lifes-a-bleach-until-someone-gets-hurt/2255177.aspx>, accessed 22 September 2011.
<http://www.ibisworld.com/industry/teeth-whitening-product-manufacturing.html>

2. SAFETY CONCERNS OF OTC TEETH WHITENERS

In the past, teeth whitening was a costly procedure that was usually performed by dentists on 'celebrities'. Over recent years the practice of teeth whitening has become significantly more prevalent and there has been a commensurate increase in the availability of over-the-counter (OTC) teeth whitening products. The service is also more commonly offered by non-dental practitioners such as beauty parlours and has become less expensive with the do-it-yourself option now readily available through OTC products at minimal cost. The concentration of the active peroxide bleaching agents available in OTC products seems also to have increased significantly.

Common side effects experienced by people using OTC peroxide-based teeth whitening products are tooth sensitivity, and gum and throat irritation. More significant health effects also include:

- painful chemical burns to the gums, mouth tissues and oesophagus
- blistering or ulceration of the mouth and throat
- marbled or unnatural coloured teeth
- sensitive and painful teeth, tissue "tingling", and headaches
- increased risk of tongue cancer for tobacco users

Although some over-the-counter bleaching products contain carbamide peroxide, most of them are H₂O₂ based, which has the potential to interact with DNA. Although there is concern with H₂O₂ carcinogenicity, there is insufficient research to support a conclusion. What studies have been able to show is that H₂O₂ is both an irritant and cytotoxic. Clinical studies have found a higher occurrence of gingival irritation when patients use bleaching materials with higher peroxide concentrations.

Hydrogen peroxide and carbamide peroxide injuries were last considered by the National Drugs and Poisons Schedule Committee (NDPSC) at its February 2005 meeting². Reports from that meeting indicated that tooth, soft-tissue and/or gingival sensitivity was very common when using peroxide generating tooth whitening products including carbamide peroxide. Other common side effects were enamel damage and increased marginal leakage of an existing restoration. Adverse reactions also included the possible overgrowth of opportunistic organisms with prolonged use. A report indicated that the hydroxyl radical by-product of carbamide peroxide had been associated with periodontal tissue damage and root resorption.

Earlier at the August and November 1993 NDPSC meetings, the Committee considered a review of the toxicity of hydrogen peroxide and agreed that hydrogen peroxide be exempt from scheduling at 3 per cent or less, classified as Schedule 5 from 3 per cent up to 6 per cent and all other concentrations placed in Schedule 6. The Committee particularly noted the toxicology data reports in reaching this decision including that in humans, ocular and respiratory effects could be serious at concentrations of greater than 10 per cent, 35 per cent and 40 per cent preparations in domestic accidents had been associated with mortality in children, and permanent injury had occurred in an adult with 35 per cent. Approximately 40 per cent preparations in domestic accidents had been associated with mortality in children, and permanent injury had occurred in an adult with 35 per cent exposure.

In Victoria in 2009 a beauty therapist was convicted and fined \$2000 as an unregistered person who performed "invasive or irreversible" procedures by whitening teeth in a beauty salon. The beauty therapist had applied a bleaching cream containing 6 per cent peroxide to a client's teeth as part of a

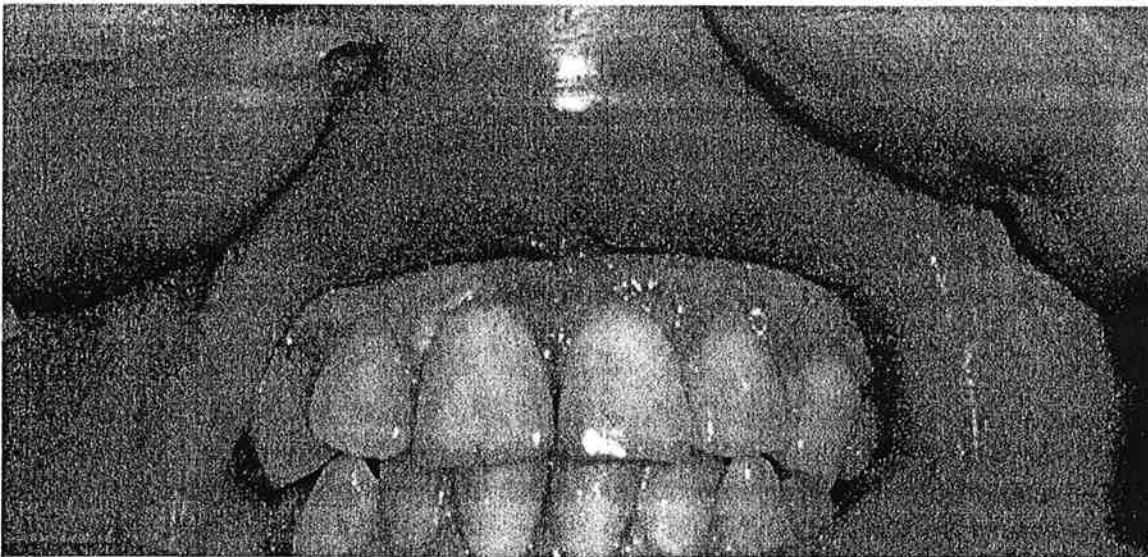
² The Scheduling Committee Record-of-Reasons for these decisions (see February and June 2005) are available at <http://www.tga.gov.au/archive/committees-ndpsc-record.htm>.

whitening procedure. After two rounds of cream, the teeth were placed under light, and the client then told to brush them. The woman found her teeth had become marbled in texture and her throat was sore; it was later diagnosed as burnt. Her gums became ulcerated shortly after. The decision potentially gave the Dental Practice Board of Victoria, the relevant prosecuting agency, a legal precedent with which to charge other unregistered people who perform teeth-whitening procedures. In our discussion you requested injury data relating to teeth whitening.

Injury data for OTC teeth bleaching is not easily available however anecdotal cases appear to be commonly seen by dentists. The Australian Dental Association (ADA) advises that when members of the public are damaged by teeth whitening OTC kits or by bleaching applied by a beautician or hairdresser, they will usually present to their dentist (somewhat embarrassed) after the event. The photograph below is of a lady whose gums were severely burned by application of a bleaching agent by a beautician. This evidence was provided to the ADA in response to a story the person saw on television, hoping she could help other un-suspecting people to avoid similar injury. The same injury could occur from an OTC product because the bleaching gel is not confined to the tooth surface and because the concentration of the peroxide could be too high.

The kinds of injuries from inappropriate teeth whitening seen by Australian dentists include:

- alteration to the surface enamel of the teeth
- reduced strength of dental filling materials
- damaged and inflamed gums
- chemical burns to the gums and oral soft tissues
- blistering of gums and oral tissues
- severe tooth sensitivity
- multi-coloured teeth, as a result of fillings, crowns and veneers not changing colour



© Australian Dental Association

Since 2010, there have been 5 recalls in the EU of dental whiteners with the most recent being a series of recalls for Crest dental whitening strips because they contained excessive hydrogen peroxide (range 2.2% – 7.8% w/w) and did not comply with the Cosmetics Directive 76/768/EC. http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm

3. CURRENT REGULATIONS

In Australia, teeth whitening products are classified as a cosmetic under the Cosmetics Standard 2007 (made under the *Industrial Chemicals (Notification and Assessment) Act 1989*). Under the Cosmetics Standard, oral hygiene products include products for care of the teeth and the mouth (other than desensitising toothpastes/gels) including dental bleaches/whiteners and denture cleansers and adhesives.

Section 5 of the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011³ (under the *Therapeutic Goods Act 1989*) explicitly lists dental bleaches or dental whiteners as the types of goods not considered to be therapeutic goods. Prior to the amendments in May 2011, the Excluded Goods Order excluded oral hygiene products from therapeutic goods legislation except when included in the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) schedule or required to be included in the Australian Register of Therapeutic Goods (ARTG) (provided the claimed benefits are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay). The decision in the October 2006 NDPSC Meeting noted that “dental bleaches or dental whiteners” were separately declared in the Excluded Goods Order not to be therapeutic goods, and this declaration did not limit itself to preparations not included in the [Poisons Standard]. Therefore, if these products are captured by a schedule entry, they will still not be therapeutic products and any required labelling would need to be specifically detailed in the Schedule entry’.⁴

2.1 Scheduling arrangements in the *Poisons Standard 2011*

The scheduling of hydrogen peroxide and carbamide peroxide in the Poisons Standard is intended to provide regulatory protections. Hydrogen peroxide and carbamide peroxide are both included in Schedules 5 and 6, and Appendix E and F of the Poisons Standard, depending on concentration and use pattern. With regard to use for tooth whitening:

- Preparations containing more than 6 per cent hydrogen peroxide (18 per cent carbamide peroxide) are Schedule 6 and must be labelled with the "POISON" signal word.
- Preparations containing 6 per cent or less hydrogen peroxide are Schedule 5.
- Preparations containing 3 per cent or less of hydrogen peroxide are exempt from scheduling.
- These preparations must also have various Appendix E First Aid Instructions and Appendix F Warning Statements and General Safety Directions. Triethanolamine is listed on Schedule 5 and appendix E and F of the Poisons Standard 2011.

According to the SUSMP Secretariat, the intent of the scheduling arrangements was that concentrations of >18 per cent carbamide peroxide and >6 per cent hydrogen peroxide were considered too high for those products through the classification of these concentrations as a “Poison”. The NDPSC Committee intended the classification into Schedule 6 would prevent products intended to be taken into the mouth from being sold OTC, however, in practice this intent is does not appear to be enforced by the state and territory health agencies that have responsibility for enforcing their legislation which reference to the Poisons Standard.

2.2 NICNAS

³ See: <<http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm>>, accessed 6 October 2011.

⁴ National Drugs and Poisons Schedule Committee, ‘Record of Reasons of Meeting 52 - February 2008’ <<http://www.tga.gov.au/pdf/archive/ndpsc-record-52.pdf>>, accessed 6 October 2011.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a statutory authority established under the Industrial Chemicals (Notification and Assessment) Act 1989 that sits within the Australian Government Department of Health and Ageing. NICNAS is responsible for regulating the introduction of industrial chemicals, including cosmetics, onto the market to ensure they are safe for human health and the environment and for administering the Australian Inventory of Chemical Substances (AICS).

Hydrogen peroxide is currently listed in the AICS but has not yet been assessed by NICNAS.

The ACCC is guided by risk assessments conducted by NICNAS, and in the absence of a published risk assessment will seek interim risk advice on industrial chemicals from NICNAS. The ACCC has written to NICNAS in relation to the safety of peroxides in OTC dental whiteners.

Safe Work Australia's current occupational safety guidelines list hydrogen peroxide at concentrations above 5 per cent as a hazardous substance on the Hazardous Substance Information System (HSIS).

2.3 National dental industry views

Australian Dental Association and Dental Board of Australia

According to the Australian Dental Association (ADA), only dentists should use tooth whitening (bleaching) agents incorporating hydrogen peroxide at concentrations exceeding 3 per cent or carbamide peroxide exceeding 9 per cent. The ADA states that while weak solutions of hydrogen peroxide have been used in the oral cavity for many years with few problems, when used in higher concentrations the potential for adverse effects on the oral tissues is high.

These views are also shared by the Dental Board of Australia. In their November 2010 Interim Policy on Teeth Whitening and Bleaching, the Dental Board stated:

*'Teeth whitening/bleaching, is an irreversible procedure on the human teeth and any tooth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent, should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching.'*⁵

In addition to the previously described effects, direct exposure of the skin, eyes and mucous membranes to hydrogen peroxide may cause severe irritation or burns, while ingestion may cause irritation to the oesophagus and stomach resulting in bleeding or sudden distension. Percolation of hydrogen peroxide into the pulpal tissues via exposed dentine and enamel fractures can lead to pulpal inflammation. For these reasons, the ADA are of the view that it is necessary to take great care when handling and using hydrogen peroxide bleaching agents especially in the higher concentrations. See ADA policy at: <http://www.ada.org.au/about/policies.aspx>.

2.4 International Standards

European Union

⁵ The Interim Policy was developed by the Dental Board of Australia under section 39 of the *Health Practitioner Regulation National Law Act* as in force in each state and territory.

In 2007, the European Union Scientific Committee on Consumer Products released their scientific "Opinion on Hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products", and concluded that:

- The use of toothpastes, mouth rinses and tooth whiteners containing up to 0.1 per cent hydrogen peroxide does not pose a risk to the health of the consumer. Toothpastes and mouth rinses should not contain more than 0.1 per cent hydrogen peroxide.
- The use of tooth whitening products containing 0.1 to 6 per cent hydrogen peroxide entails potential risks for the consumer. These risks increase with increasing concentration of hydrogen peroxide and frequency of application.
- Potential risks of the use of tooth whiteners containing between 0.1 and 6 per cent hydrogen peroxide can be limited if tooth whitening is done properly with the approval and under the supervision of a dentist. The specific situation of each individual should be taken into account prior to treatment.
- Additional research is needed on the use of tooth whitening products over longer time periods.
- Use of tooth whitening products containing more than 6 per cent is not considered safe for use by consumers.

The European Cosmetics Directive 76/768/EC currently sets out a list of substances which cosmetic products may not contain, outside the restrictions and conditions laid down (Annex III). See <http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/#h2-consolidated-version-of-cosmetics-directive-76/768/eec>. The Directive addresses the use of hydrogen peroxide in hair care preparations, skin care preparations, nail hardening preparations and oral hygiene products and, more specifically, lists the maximum authorized concentration for hydrogen peroxide in finished cosmetic oral hygiene products:

- 0.1 per cent of H₂O₂, present or released.

In September 2011, the European Council adopted a directive on tooth whitening, which strengthens consumer protection whilst allowing dentists to legally supply products for tooth whitening, which release or contain up to 6% hydrogen peroxide. Following the Council's decision, tooth whitening products containing between 0.1% and 6% of hydrogen peroxide, clinical examination and first treatment by a dentist will be required, to ensure the absence of risk factors or oral pathologies, after which the patient will be able to continue the treatment by him or herself.

Products containing up to 0.1% of hydrogen peroxide will still continue to be freely available to the consumers on the market. The use of these products by persons younger than 18 years will not be allowed. Tooth whitening products containing more than 6% of hydrogen peroxide will continue to be prohibited. Member States will have 12 months to transpose the Directive into national legislation after its publication in the Official Journal of the European Union. It is expected that the amended European directive will be published during October 2011.

United States and Canada

While the content of hydrogen peroxide (and equivalent) in oral hygiene products available in EU should not exceed 0.1%, considerably higher concentrations are available in products sold in other countries, including the United States.

In 1983, the US Food and Drug Administration (FDA) approved both hydrogen peroxide and carbamide peroxide as oral antiseptic agents (FDA, 1983). The products of 10-15% carbamide peroxide and 1.5-3% hydrogen peroxide preparations are classified in Category I, which includes agents that are generally recognised as safe (GRAS) and effective. In 2003, a subcommittee of the FDA concluded that hydrogen peroxide is safe at concentrations of up to 3 percent, but that there

was insufficient data available to permit final classification of its effectiveness at 1.5 to 3 percent concentrations for long-term over the counter (OTC) use as an antigingivitis/antiplaque agent.

Presently, all extracoronal tooth bleaching products remain unclassified by the FDA. This includes all peroxide-based products used in the in-office, dentist-dispensed products for at-home use, OTC products and products used in non-dental settings.

In Canada, all tooth whitening systems (unless they contain fluoride) are considered cosmetics. In terms of regulatory requirements, manufacturers must submit a cosmetic notification form to Health Canada, accompanied by safety and labelling information. Health Canada does not 'approve' notifications, but submitted information is reviewed to assess that all requirements have been satisfied. Ultimately, the safety of a cosmetic product is the responsibility of the manufacturer.

Under Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (Hotlist)⁶, if an oral cosmetic contains more than 3 per cent hydrogen peroxide (or equivalent), notifiers must submit evidence that the product does not cause the saliva or soft tissue of the oral cavity to exceed 3 per cent hydrogen peroxide, and is safe when used as directed. Evidence may include analogue studies from recognized sources or independent clinical research. According to the Hotlist, the conversion factor between hydrogen peroxide and carbamide peroxide is 3 per cent to 10 per cent, respectively. No maximum concentration limit however has been specified.

New Zealand

The Cosmetic Products Group Standard 2006 (pursuant to section 96B of the Hazardous Substances and New Organisms Act 1996) specifies the maximum authorized concentration for hydrogen peroxide in finished cosmetic oral hygiene products at 0,1 per cent of H₂O₂, present or released.⁷

In April 2011, the New Zealand Environmental Risk Management Authority (now Environmental Protection Authority (EPA)) proposed that dentists be the only people allowed to administer teeth whitening treatment when the products contain more than 3.6 percent bleach. In June 2011, the EPA published its decision specifying a higher maximum concentration limit for teeth whiteners containing hydrogen peroxide. In its decision⁸, the EPA amended the Dental Products (Subsidiary Hazard) Group Standard 2006 under the Hazardous Substances and New Organisms Act 1996 to specify that a person must not supply, offer to supply, or advertise a tooth-whitening product containing or releasing between 7% and less than 8% hydrogen peroxide, unless the product is accompanied by relevant precautionary statements (specified in the Standard), and that person is a dentist; a registered oral health practitioner; or a non-registered tooth-whitening practitioner who is under the supervision of a dentist. In summary:

- 7% hydrogen peroxide will continue to be sold and used without restriction
- Products containing more than 7% hydrogen peroxide will be subject to some restrictions on their sale and use being:
 - Cosmetic Teeth Whitening Practitioners may continue to use products containing 7-12% hydrogen peroxide
 - Products containing more than 12% hydrogen peroxide will only be able to be used under the supervision of a dentist

The Authority's decision also includes requirements for labelling of OTC teeth whitening products such as those found in a Chemist, Supermarket, Beauty Salon, Spa or Gym.

⁶ See: <<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste-eng.php>>, accessed 5 October 2011.

⁷ See: Schedule 5 – Components Cosmetic Products Must Not Contain Except Subject to the Restrictions and Conditions Laid Down.

⁸ <http://www.nzctwa.org.nz/images/ERMA200472%20-%20Decision.pdf>

4. SURVEY OF PRODUCTS CURRENTLY AVAILABLE

In response to reports of injuries from teeth whitening products, a survey of teeth whitening products currently available for direct sale to the public was conducted in Canberra. Samples of products from retail outlets representing the extent of the market were sourced and two identical samples of each product were purchased. Products available online were also identified. Most products sampled declared the concentrations of the active bleaching agents however these concentration have not yet been confirmed by analytical testing. The duplicate samples of each product will be retained for purposes where further testing is needed, or in the event where the test sample is not returned or access to the product label is necessary.

The following sample details were also recorded and chain of custody was established.

- full details of the product purchase such as; place/date of purchase, manufacturer/importer, brand, model, batch, country of origin, and any relevant claims recorded;
- visible unique reference marks placed on the outside of the products;
- each of the samples photographed together (front and back views);
- all sample acquisition details and corresponding photographs inputted onto a spreadsheet.

4.1 Description of products

A total of seven products were purchased from retail stores in Canberra including Priceline and Terry White Chemist, Belconnen, ACT (see table below). The products appear to be the extent of products readily available/ representative of the market in Canberra (not including products currently available online).

Of the seven products, four products list carbamide peroxide/hydrogen peroxide as an ingredient:

- The White My Bite range lists carbamide peroxide at 22 per cent and 36 per cent. Note: the Professional brand of the White My Bite range incorporates the use of a BlueLight laser system/transmitter.
- The Hollywood Nights product lists hydrogen peroxide at 3.5 per cent.
- The White Glo product lists carbamide peroxide as an ingredient but does not specify the percentage. Note: the Australian distributor of this product has indicated to the ACCC that its carbamide peroxide level is at 8 per cent.

A range of claims have been printed on the respective products including: 'clinically proven', 'clinically proven results', 'safe', 'safe and effective formula', 'dentist developed', 'enamel-safe', 'ideal for use in shower', 'bleach free', 'prevents tartar', 'controls tartar', 'fights plaque', 'prevents cavities', 'strengthens enamel'.

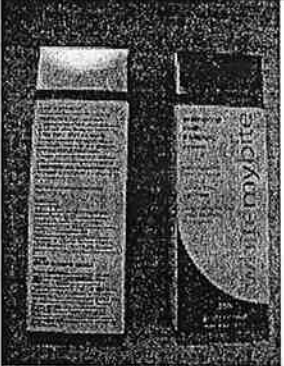
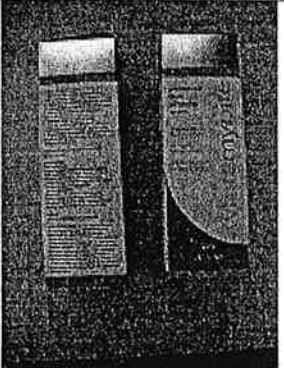

Products available online

A range of teeth whitening DIY products have also been recently advertised online to the public via the Living Social website (<http://livingsocial.com>).

One such product, Arctic White⁹, is described as containing 22 per cent carbamide peroxide as well as triethanolamine. Arctic White appears to be owned by a business registered in Victoria (VIC B2342097K) but no other details are provided. The ACCC have requested that Victorian Department of Health investigate whether this product complies with the requirements of the Poisons Standard.


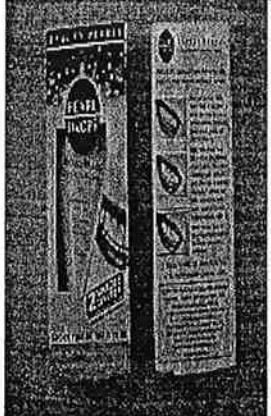

Another product, B'Dazzled¹⁰, has indicated its products are professional strength and contain 8 per cent hydrogen peroxide or 24 per cent carbamide peroxide. The B'Dazzled products are distributed by Nouveau Smiles Pty Ltd in New South Wales, and have 149 listed businesses that stock their product in Australia.


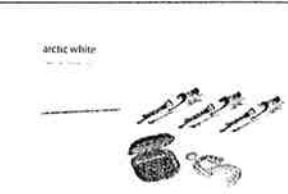
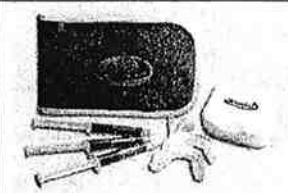
4.2 Table of products purchased

No.	Product Type	Date of Purchase	Product Name	Supplier Details Import/distributor/manufacturer	Product Claims/ Other Details (Batch No:)	Photograph
1	Teeth whitening treatment kit	08/09/11	White My Bite Bluelight Laser System-professional teeth whitening system 36%	White My Bite Pty Ltd is a wholly owned Australian Company PO Box 349 COBURG VIC 3058 PH: (03) 9354 8963 FAX: (03) 9354 8963 E: info@whitemybite.com.au W: www.whitemybite.com.au	An innovative home laser whitening treatment. Active ingredient 36% Carbamide Peroxide Do not use this product if you are pregnant, lactating are under the age of 16, are allergic to any of the ingredients listed have health problems, periodontal disease, poor gum health, wear braces, had recent oral surgery, decayed teeth, exposed roots or jaw problems POISON KEEP OUT OF REACH OF CHILDREN	
2	Teeth whitening treatment kit	08/09/11	White My Bite Professional teeth whitening system 22% sensitive	White My Bite Pty Ltd is a wholly owned Australian Company PO Box 349 COBURG VIC 3058 PH: (03) 9354 8963 FAX: (03) 9354 8963 E: info@whitemybite.com.au W: www.whitemybite.com.au	Recommended for anyone who wants to bleach their teeth safely yet effectively. Our 22% Strength formula delivers excellent results without compromise and without fuss! Active ingredient 22% Carbamide Peroxide Do not use this product if you are pregnant, lactating are under the age of 16, are allergic to any of the ingredients listed have health problems, periodontal disease, poor gum health, wear braces, had recent oral surgery, decayed teeth, exposed roots or jaw problems POISON KEEP OUT OF REACH OF CHILDREN	
3	Teeth whitening treatment kit	08/09/11	White Glo Express Whitening System	Developed and formulated by Barros Laboratories Pty Ltd, Australia Barros Laboratories Pty Ltd	New Express Whitening Fast Acting Formula! Double the strength of the original White Glo formulation Cuts down treatment time to five minutes Convenient and Effective- ideal for use in the shower. CAUTION: This product is not to be	

⁹ See: <http://www.arcticwhite.com.au/index.html>.

¹⁰ See: <http://www.bdazzled.com.au/index.html>.

N o.	Produ ct Type	Date of Purchase	Product Name	Supplier Details Import/distributor/manuf acturer	Product Claims/ Other Details (Batch No:)	Photograph
				Factory 4 4 Skyline Place Frenchs Forest NSW 2086 AUSTRALIA www.whiteglo.com	consumed. Use by children under 12 years of age or pregnant women is not recommended. People who have braces, colitis, bad gums, exposed roots, ulcers, and periodontal disease must not use this product. Avoid prolonged contact of the bleaching gel with the gums. If tooth sensitivity or adverse symptoms cease use immediately.	
4	Teeth whitening treatment kit	08/09/11	Rapid White Tooth Whitening 1 Week Tooth Whitening System	Distributed by Chemcorp International 7 Box Road Taren Point NSW 2229 Australia PH: +61295260777 FAX: +61295260799 Email: info@chemcorp.com.au www.rapidwhite.com.au	Whitens teeth up to 4 shades whiter Sensitive Action formula For adult use only Prevents stains re-occurring and controls tartar Clinically proven Rapid action	
5	Gloss tooth whiten er	08/09/11	Beauty Pearls- Pearl Drops Gloss Tooth Whitener	Made in England by Church and Dwight UK Ltd for Church and Dwight (Australia) Pty. Ltd. Unit 1 108 Old Pittwater Road BROOKVALE NSW 2100 www.churchdwhite.com.au www.pearldrops.com.au enquiries@churchdwhite.com.au freecall 1800222999	Active ingredient: 0.22% sodium fluoride Pearl Drops is a specialist tooth whitener that helps restore the natural whiteness and shine of your teeth. Not suitable for children 6 years and under	
6	Whiten ing Wand	08/09/11	Hollywood Nights Whitening Wand- Pearl Drops	Made in UK and USA for Church and Dwight (Australia) Pty. Ltd. Unit 1 108 Old Pittwater Road BROOKVALE NSW 2100 www.churchdwhite.com.au www.pearldrops.com.au enquiries@churchdwhite.com.au freecall 1800222999	Contains Hollywood Nights Whitening Wand and Beauty Pearls Gloss Tooth Whitener- Active ingredient Sodium Fluoride 0.22% w/w Whitens teeth up to 6 shades Whiter in just 7 days	

No.	Product Type	Date of Purchase	Product Name	Supplier Details Import/distributor/manufacturer	Product Claims/ Other Details (Batch No:)	Photograph
7	Professional Intensive whitening tooth polish	08/09/11	Pearl Drops Professional Intensive Whitening Tooth polish	Made in England by Church and Dwight UK Ltd for Church and Dwight (Australia) Pty. Ltd. Unit 1 108 Old Pittwater Road BROOKVALE NSW 2100 www.churchdwhite.com.au www.pearldrops.com.au enquiries@churchdwhite.com.au freecall 1800222999	With the same whitening ingredient used by dentists. Clinically proven to leave teeth sparkling clean and white Active ingredient 0.988 w/w Sodium Monofluorophosphate	
8	Teeth Whitening Kit	Not yet purchased	Arctic White Advanced 2 Week Whitening Kit	N/A provided	The whitening serum contains carbamide peroxide along with a unique polymer gel to adhere to your teeth for the optimal contact time, as well as a refreshing, natural mint flavour. (22% Carbamide peroxide, carbomer, glycerin, EDTA, triethanolamine). Arctic White's whitening gel contains optimal concentration of Carbamide Peroxide – potent, but safe. FAQ <i>What if I swallow the whitening gel?</i> Every time you use your dental whitening system you will inevitably swallow a small amount of whitening gel. This is normal and, except for the taste, there are no hazards for most people who swallow small amounts of gel.	
9	Teeth Whitening Kit	Not yet purchased	B'Dazzled 2 Week Teeth Whitening Kit	Nouveau Smiles Pty Ltd P.O. Box 3168 ERINA NSW 2250 P. 1300 880 004 FAX. (02) 43653329	Safe on Enamel ingredients All B'Dazzled Teeth Whitening Gels are SAFE, Highly Effective and Guaranteed to Get Your Teeth White We are 100% Australian owned and made B'Dazzled is a PROFESSIONAL strength (8% Hydrogen Peroxide =24% Carbamide Peroxide) brilliant whitening system that can lighten your teeth up to 9 shades with the results lasting up to 2 years! FAQ What is the strength of the gel, my dentist says he uses 10%, 16% or 24%? There is no gel on the market that is a 10% or 16% Hydrogen peroxide that is used for 'at home' treatment by dentists. This is Carbamide peroxide that is usually worn over	

N o.	Produ ct Type	Date of Purch ase	Product Name	Supplier Details Import/distri butor/manuf acturer	Product Claims/ Other Details (Batch No:)	Photograph
					<p>night or for a much longer period of time than Hydrogen peroxide. B'Dazzled uses 8% Hydrogen peroxide for speedy results and to minimize dehydration of the teeth.</p>	

5. RECOMMENDATIONS

It is recommended that ACCC:

- Reiterate the written request to the National Industrial Chemical Notification and Assessment Scheme (NICNAS) requesting their risk assessment advice on the acceptable/unacceptable concentrations of peroxides bleaches in OTC teeth whiteners as a matter of priority.
- If the NICNAS opinion has not been provided by the time of the meeting, the issue will be again raised at the next meeting of the Cosmetic Interface Working Group by the ACCC in November.
- Collectively email the relevant poisons contacts in the State and Territory health agencies alerting them to the availability of unsafe teeth whiteners that may not comply with the Poisons Standard. This email would also be copied to the Secretariat for the National Coordinating Committee on Therapeutic Goods who are responsible for nationally consistent interpretation and enforcement of the Poisons Standard.
- In concert with the State and Territory health agencies, contact suppliers of OTC products containing unacceptable concentrations of hydrogen/carbamide peroxide and negotiate voluntary product safety recalls or if necessary, recommend mandatory recalls to the PST.
- In the event, there is any difficulty with consistent interpretation of the requirements in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) by the State and Territory health agencies, write to the SUSMP Secretariat asking for written confirmation that the current concentration limits set in Schedule 5 of the Poisons Standard apply to OTC teeth whitening products or request that they amend the Standard so that the requirements are clear to all State and Territory health agencies.
- Enhance the existing cosmetic information or develop specific education material for teeth whitening products for the Product Safety Australia (PSA) website. Links to the Australian Dental Association (ADA) website and the dedicated teeth whitening site www.teethwhiteningfacts.com.au . A more proactive campaign to increase awareness of the risks could also be considered.
- Conduct a mail out to suppliers of these types of products reminding them of mandatory reporting obligations under the ACL.

Email correspondence – Australian Dental Association

-----Original Message-----

From: Peter Alldritt [mailto:palldritt@roseparkdental.com.au]
Sent: Thursday, 15 September 2011 8:26 AM
To: Wallner, Peter
Subject: Teeth Whitening Products

Mr Peter Wallner
Australian Competition & Consumer Commission
Product Safety Area

Dear Peter,

Re : Australians at risk of injury from teeth whitening

Thankyou for the opportunity to discuss over the counter (OTC) teeth whitening products on the phone on Monday.

I was reassured to learn that your department has identified the potential for misuse and damage by inappropriate teeth whitening kits. I was particularly alarmed by your discovery that some of the products you investigated contained concentrations of carbamide peroxide as high as 22% and 36%. I can confirm that these concentrations are much higher than dentists would usually prescribe for their patients.

The Australian Dental Association (ADA) shares your concerns and in May 2011 launched a dedicated website www.teethwhiteningfacts.com.au to help the public understand the alternatives available for teeth whitening. It also highlights the dangers of teeth whitening performed without a dentist's diagnosis and treatment prescription (ie OTC products and services provided by beauticians and hairdressers). The ADA also launched a public awareness campaign and received considerable media coverage over the following 3 months. Hopefully the message is starting to penetrate the community that teeth whitening can be perilous if not prescribed by a registered dental practitioner.

You may be aware that in May the CHOICE consumer group also, coincidentally, issued a media release entitled "Whiter Teeth Craze Thrives With No Rules". There was also an article in the June edition of CHOICE magazine.

In our discussion you requested injury data relating to teeth whitening. Unfortunately the ADA is in a similar position to the ACCC in that it has only anecdotal evidence of damage from teeth whitening. When members of the public are damaged by teeth whitening OTC kits or by bleaching applied by a beautician or hairdresser, they will usually present to their dentist (somewhat embarrassed) after the event. I have attached a photograph of a lady whose gums were severely burned by application of a bleaching agent by a beautician. This lady provided this evidence to the ADA in response to a story she saw on television, hoping she could help other un-suspecting people to avoid similar injury. The same injury could occur from an OTC product because the bleaching gel is not confined to the tooth surface and because the concentration of the peroxide could be too high.

The kinds of injuries we see from inappropriate teeth whitening include:

- alteration to the surface enamel of the teeth
- reduced strength of dental filling materials
- damaged and inflamed gums
- chemical burns to the gums and oral soft tissues
- blistering of gums and oral tissues
- severe tooth sensitivity
- multi-coloured teeth, as a result of fillings, crowns and veneers not

changing colour.

I am told that in South Africa there has recently been a ban placed on teeth whitening outside of a dental practitioner's prescription. The General Dental Council in the UK are currently investigating a number of complaints against non-dental personnel (ie beauticians and hairdressers) who have caused harm to their customers by teeth whitening.

In Australia, the Dental Board of Australia states "Teeth whitening/bleaching is an irreversible procedure on human teeth and any tooth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent, should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching."

Worksafe Australia's current guidelines list hydrogen peroxide at concentrations above 5% as a hazardous substance.

The ADA welcomes any action which progresses the safety of the public and protects them from injury by inappropriate use of OTC kits and administration of teeth whitening by non-dental personnel. Please let me know if the ADA can assist your department any further.

Kind regards,

Dr Peter Alldritt.
Chairman, Oral Health Committee
Australian Dental Association.