

**AUSTRALIAN COMPETITION AND CONSUMER COMMISSION  
EXECUTIVE MINUTE**

Minute No xx / 2012

Parliamentary Secretary to the Treasurer

31<sup>st</sup> January 2012

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**Subject: Compulsory recall of teeth whitening products supplied by Pro Teeth Whitening (Aust) Pty Limited**

**Timing: Urgent**

**Recommendation:**

That you sign Consumer Protection Notice 1 of 2012 to certify that issue a recall notice should be issued without delay.

for two do-it-yourself teeth whitening products that contain unsafe concentrations of hydrogen peroxide.

And that you sign Consumer Protection Notice 2 of 2012 which is a recall notice to compel Pro Teeth Whitening (Aust) Pty Limited to recall the two do-it-yourself teeth whitening products.

Noted/Signed:

/ / 2012

**ISSUE**

In early December 2011, the ACCC provided you with a briefing about a series of voluntary recalls of do-it-yourself (DIY) teeth whiteners and the associated media release issued by the ACCC on 9 December 2011.

Since then the ACCC has contacted the known suppliers of DIY teeth whiteners and successfully sought voluntary recalls of 22 DIY teeth whitening products that contained unsafe concentrations of hydrogen peroxide and/or carbamide peroxide.

While most suppliers have cooperated with the ACCC, one supplier (Pro Teeth Whitening (Aust) Pty Limited) continues to supply products with declared concentrations of hydrogen peroxide in excess of the recognised safe limits.

The ACCC first raised their safety concerns with the supplier on date and has made several unsuccessful approaches to this supplier aimed at stopping the supply of the unsafe goods and recalling the goods already supplied.

The ACCC now recommends that you exercise your powers under the CCA and issue a compulsory recall notice without delay on the basis that the goods create an imminent risk of serious injury.

**KEY POINTS**

- Teeth whitening has become a common cosmetic procedure and numerous products are available directly to the public for DIY teeth whitening. The main active bleaching ingredients in these products are hydrogen peroxide and carbamide peroxide. The concentrations of these ingredients in DIY consumer

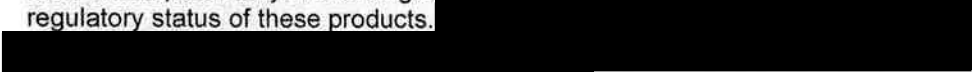
products have increased over time and injuries have been reported to Poisons Information Centres.

- Typical injury complaints from teeth whitening kits are: tooth sensitivity and gum and throat irritation. More serious injuries reported include:
  - painful chemical burns to the gums, mouth tissues and the oesophagus
  - blistering or ulceration of the mouth and throat
  - marbled or unnatural coloured teeth
  - sensitive and painful teeth, tissue "tingling", and headaches
  - potential increased risk of mouth and tongue cancer for tobacco users
  - the death overseas of a toddler from ingestion of a 3% solution of hydrogen peroxide
- The Australian Dental Association (ADA) has also reported that dentists are seeing an increasing number of patients presenting with mouth injuries attributed to home teeth bleaching.
- The ACCC is also aware of regulatory action being taken in the European Union and overseas injury reports associated with the use of these products.
- In Australia, the *Poisons Standard 2011* classifies preparations containing more than 6% hydrogen peroxide as Schedule 6 "POISONS". This classification was intended to restrict products intended to be taken into the mouth to below this concentration limit.
- The 6% hydrogen peroxide limit is also supported by expert clinical advice published by the Dental Board of Australia, the Australian Dental Association, and a scientific risk assessment published by the European Union Scientific Committee on Consumer Products.
- The ACCC has advised consumers who have purchased a DIY teeth-whitening kit to check the label and immediately cease using the product if it contains more than 6% hydrogen peroxide.
- Pro Teeth Whitening (Aust) Pty Limited supplies two DIY products containing syringes labelled as 9%, 12% and 16% hydrogen peroxide:
  - "brightwhite express - Advanced Teeth Whitening Kit" and
  - "PROTEETHWHITENING - Professional Teeth Whitening Pen".
- Other suppliers that were contacted by the ACCC promptly and voluntarily recalled their products if they exceeded the recognised safe limits for either hydrogen peroxide and/or carbamide peroxide. To date X different suppliers have recalled 22 different DIY teeth whitening kits.
- In Australia, the *Poisons Standard 2011* prescribes safety requirements such as warning labelling and concentration limits for potentially hazardous chemicals in consumer products. Enforcement of the *Poisons Standard 2011* is the responsibility of state/territory health agencies.

- The ACCC enforces a mandatory information standard for cosmetics ingredients labelling, which requires that all ingredients used in a product are listed on the label. This is intended to enable consumers to identify the presence of ingredients to which they may be allergic, sensitive or otherwise concerned about, and to allow comparison of different products.

**ADDITIONAL INFORMATION IN confidence**

- The DIY teeth whitening products supplied by Pro Teeth Whitening (Aust) Pty Limited also appear not to comply with the mandatory standard for cosmetics ingredients labelling. Pro Teeth Whitening (Aust) Pty Limited also appears to have made potentially misleading or deceptive claims about the safety and regulatory status of these products.



Comment [J2]: Should we disclose this?

Ruth Mackay  
Product Safety Branch

**COMMONWEALTH OF AUSTRALIA**

Competition and Consumer Act 2010

Consumer Protection Notice No. 1 of 2012

**CERTIFICATION THAT A RECALL NOTICE FOR CONSUMER GOODS SHOULD  
BE ISSUED WITHOUT DELAY IN CASE OF DANGER TO THE PUBLIC**

I, DAVID BRADBURY, Parliamentary Secretary to the Treasurer, pursuant to subsection 132J (1)(b) of the *Competition and Consumer Act 2010*, CERTIFY that a recall notice for consumer goods of a kind specified below should be issued without delay as it appears to me that such goods create an imminent risk of serious injury.

Particulars of Goods:

"bright white express - Advanced Teeth Whitening Kit" and  
"PROTEETHWHITENING - Professional Teeth Whitening Pen"

supplied by Pro Teeth Whitening (Aust) Pty Limited.

Dated this    day of    2012

DAVID BRADBURY  
Parliamentary Secretary to the Treasurer

**COMMONWEALTH OF AUSTRALIA**

Competition and Consumer Act 2010

Consumer Protection Notice No. 2 of 2012

**COMPULSORY RECALL OF CONSUMER GOODS**

Whereas

- (i) the person specified in Division 1 of the Schedule to this Notice ("the supplier"), in trade and commerce, is the supplier of consumer goods of a kind specified in Division 2 of this Notice ("the goods");
- (ii) it appears to me that the goods are goods of a kind which will or may cause injury to a person; and
- (iii) it appears to me the supplier has not taken satisfactory action to prevent the goods causing injury to any person;

I, DAVID BRADBURY, Parliamentary Secretary to the Treasurer, pursuant to subsection 122 (1) of Schedule 2 of the *Competition and Consumer Act 2010*, issue this NOTICE which, pursuant to section 123 of Schedule 2 of the *Competition and Consumer Act 2010*, REQUIRES the supplier take the actions specified in Division 3 of the Schedule to this Notice to recall the goods and pursuant to section 123 of Schedule 2 of the *Competition and Consumer Act 2010*, DIRECT that the action specified in Division 3 of the Schedule to this Notice be carried out in the manner specified in Division 4 of the Schedule to this Notice.

**THE SCHEDULE**

Division 1: The Supplier

Pro Teeth Whitening (Aust) Pty Limited  
ACN 135 042 107  
PO Box 2696, Wellington Pt. QLD 4160

Comment [JS3]: Has an ASIC company extract been obtained? What is its registered office?

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Division 2: Particulars of the Goods

"bright white express - Advanced Teeth Whitening Kit" and  
"PROTEETHWHITENING - Professional Teeth Whitening Pen"

Division 3: Recall Action

Take action within one (1) day commencing on the day on which this Notice is registered on the Federal Register of Legislative Instruments to recall the goods.

Comment [JS4]: Is this sufficient time?

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- a) recall the goods;
- b) disclose to the public the nature of a dangerous characteristic of the goods, specifically that the goods, as set out on their labeling, contain 9%, 12% or 16% hydrogen peroxide, which exceeds the recognised safe limit of 6% weight/weight as set by the *Poisons Standard 2011*, expert clinical advice, and published scientific risk assessments; and
- c) inform the public that the supplier undertakes to do whichever of the following the supplier thinks is appropriate:
  - (i) replace the goods;
  - (ii) refund to a person to whom the goods were supplied (whether by the supplier or by another person) the price of the goods.

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Comment [JS5]: It seems appropriate to add this wording – it is taken from s123 of the ACL

Division 4: Manner in which the recall actions are to be taken conducted.

Comment [JS6]: Are there other steps that should be taken?

- a) Lodge a completed recall notification via the online form of the Product Safety Recalls Australia website at [www.recalls.gov.au](http://www.recalls.gov.au); and
- b) In all recall communications, describe the hazard as follows:

"Users of the goods may suffer irritation or inflammation to the gums and mouth due to the excessively high concentration of hydrogen peroxide"
- c) In all recall communications, describe the defect of the goods as follows:

"The goods are labelled as containing 9%, 12% or 16% hydrogen peroxide, which exceeds the recognised safe limit of 6% weight/weight as set by the *Poisons Standard 2011*, expert clinical advice, and published scientific risk assessments"
- b) Publish aAdvertise this written recall notice prominently on the website [www.pro-teeth-whitening.com](http://www.pro-teeth-whitening.com) for a period of at least [x] days, which shall include the following:
  - (i) the words: "Product Safety Recall";
  - (ii) a description of the goods;
  - (iii) a photograph or drawing of the goods;
  - (iv) a description of the dangerous characteristic of the goods in the following terms:

"The goods, as set out on their labeling, contain 9%, 12% or 16% hydrogen peroxide, which exceeds the recognised safe limit of 6% weight/weight as set by the *Poisons Standard 2011*, expert clinical advice, and published scientific risk assessments"
  - (v) a statement of the hazard in the following terms:

"Users of the goods may suffer irritation or inflammation to the gums and mouth due to the excessively high concentration of hydrogen peroxide"
  - (vi) a section titled 'What to do', which explains the immediate action customers are to take, for example, cease use immediately and return product to the place of purchase for a full refund;

Comment [JS7]: Can this be done? The website seems to provide for notification of a voluntary recall but not a compulsory recall. Is this necessary if a mandatory recall is to be carried out?

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Comment [JS8]: Do you want this Notice to be published or a product safety notice? I assume the latter. These elements have been taken from p8 of the recalls guideline. Do you want to be more prescriptive – regarding size of notice, font size, use of a red hatched border with red safety triangle etc. A form of notice could also be drafted and annexed. E.g. p10 of the recalls guideline. This paragraph could read "Publish a written recall notice ... in the terms and form of Annexure A to this Notice".

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~~(vii)~~ a section titled 'Contact details' which explains who customers should contact to receive a refund or have the product repaired or replaced. Include business and after hours telephone numbers, and email and website addresses; and

c) ~~Write~~ Send a letter to all known customers to whom it has supplied the goods, which must ~~have~~ been supplied and provide a copy of this recall notice

**Comment [JS9]:** Do you want to be more prescriptive about the contents of the letter? A form of letter could also be annexed. If a form of written notice is annexed, it could be sent with the letter.

(i) inform such customers of the issuance of this Notice;

(ii) enclose a copy of this Notice;

(iii) describe the hazard as follows:

*"Users of the goods may suffer irritation or inflammation to the gums and mouth due to the excessively high concentration of hydrogen peroxide"*

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(iv) describe the dangerous characteristic of the goods as follows:

*"The goods, as set out on their labeling, contain 9%, 12% or 16% hydrogen peroxide, which exceeds the recognised safe limit of 6% weight/weight as set by the Poisons Standard 2011, expert clinical advice, and published scientific risk assessments"*

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~~d)~~; and

~~f)d)~~ Use best endeavours to ensure that ~~Arrange for~~ all known ~~retailers to whom it has supplied the goods, or which it is otherwise aware was a retailer of the goods, were supplied to~~ publicly display a written recall notice ~~this recall notice~~ at their places of business for a period of at least [x] days, which shall include the elements referred to at subparagraphs (b)(i) to (b)(iv) above; and

**Comment [JS10]:** Do you want this Notice to be published or a product safety notice? I assume the latter. Do you want to be more prescriptive – regarding size of notice, font size etc. A form of notice could also be drafted and annexed. E.g. along the lines of p10 of the recalls guideline

e) ~~U~~ If the supplier undertakes to repair, replace or refund the price of the goods, to all persons to whom the goods were supplied as required under sections 123 and in accordance with section 124 of Schedule 2 of the *Competition and Consumer Act 2010*;

(i) it must replace the goods with similar consumer goods which; and

A. do not contain the dangerous characteristic identified in this Notice; and

B. comply with any safety standards in force in respect of the goods; and

(ii) the cost of the replacement, including any necessary transportation costs, must be paid by the supplier; and

~~h)f)~~ Arrange for the safe disposal of all goods returned ~~under~~ pursuant to the recall at a safe chemical disposal facility.

**Comment [JS11]:** Although not beyond doubt, there is a good argument that this is a valid requirement for a recall. Is there a safe use for any of the products? Is this manner of disposal necessary?

Dated this    day of    2012

DAVID BRADBURY  
Parliamentary Secretary to the Treasurer