



NICNAS Alert No.7

June 2007

DIETHYLENE GLYCOL IN TOOTHPASTE

Introduction

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), located within the Australian Government Health and Ageing portfolio, is the Australian Government regulator for industrial chemicals including cosmetics. NICNAS carries out public, occupational health and environmental risk assessments of industrial chemicals to ensure their safe use.

Some imported toothpastes have recently been found to contain diethylene glycol (DEG).

Currently products such as toothpastes, and the chemicals they contain, are regulated as either cosmetics by NICNAS or therapeutic goods by the Therapeutic Goods Administration (TGA), depending on their characteristics and their performance claims.

Toothpastes and similar products are generally excluded from TGA regulation if the benefits claimed to result from their use are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay. However they are regulated by the TGA if:

- other claims are made; or
- the product is scheduled according to the Poisons Standard; or
- they are required to be on the Australian Register of Therapeutic Goods.

The situation will be similar in future when planned cosmetic reforms are underpinned by legislation. There are currently no medicines, including toothpastes, containing DEG as an allowable ingredient approved for general sale in Australia.

Cosmetic product manufacturing and individual sale of products are regulated through State and Territory legislation.

Labelling requirements

If products contain chemicals that may be hazardous to the user or to the general public, States and Territories may impose controls over availability, packaging and labelling through their poisons legislation.

There are mandatory labelling requirements for cosmetics under the *Trade Practices Act 1974*. Ingredients must be listed on product labels, in descending order calculated either by mass or volume. This enables consumers to identify ingredients to which they may be sensitive and compare various cosmetic products.

The presence of DEG as an ingredient in toothpaste is required to be disclosed through labelling, although disclosure of the concentration in the product is not mandated.

Safety requirements

The Product Safety Section of the Australian Competition and Consumer Commission (ACCC) has overall policy responsibility for monitoring the conduct and outcomes of consumer goods safety recalls in Australia. The ACCC's Recalls Australia website contains details of the recall of Excel toothpaste containing diethylene glycol – refer http://www.recalls.gov.au/view_recall_detail.php?Recall_ID_Auto=14910

Under the *Trade Practices Act 1974*, a statutory warning to consumers of possible risks of using specified goods can be issued.

The *Special Gazette* of 12 June 2007 has a warning notice to the public on imported toothpaste containing DEG at:

<http://www.ag.gov.au/portal/govgazonline.nsf/a51e77a0661e155cca256cf4001d02d9/0eee1bbffa492945ca2572f800163fbc!OpenDocument>

NICNAS Requirements

Product registration is not required under NICNAS. However each ingredient of a product introduced into Australia through import or manufacture must be on the Australian Inventory of Chemical Substances (AICS), or be assessed as a new chemical for its health and environmental effects before being introduced. Because DEG is listed on the AICS it is considered an existing chemical and does not require assessment.

However, if concerns about an existing chemical are raised, NICNAS can undertake an existing chemical risk assessment, and this is done on a priority basis. The NICNAS legislation has provision for including "conditions of use" for a chemical on the AICS, which would apply to any import or manufacture of that chemical.

Health Hazard Information

NICNAS has undertaken an initial review of the available published data on DEG.

DEG is a water soluble, clear syrupy liquid. It is almost completely absorbed following ingestion. The effects of DEG have been best described in animals, where it exhibits low acute oral toxicity. It causes mild skin and eye irritation. Repeated, long-term oral exposure of DEG to animals causes renal (kidney) toxicity.

Potential risks of DEG in Toothpaste

NICNAS has compared the toxicity data with the potential doses of DEG, based on media reports that the concentration of DEG in some imported toothpastes in Australia is up to 4.6%. These comparisons indicate that there is unlikely to be concern for short-term exposures to DEG in these products. However, there is a significantly higher risk, particularly for children, from long-term exposure to these reported levels of DEG.

Although the toxicity data are considered to be limited, NICNAS considers DEG at the reported concentrations in toothpaste could pose a risk of health effects for some consumers from repeated, long-term exposure.

NICNAS is proposing to initiate a more in-depth review of DEG to determine whether further regulatory action is needed either through labelling or restriction on use in products.

For further information including relevant State/Territory contacts please contact NICNAS at:

Ph: 1800 638 528 **Email:** info@nicnas.gov.au