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# **Survey of levels of Dimethyl Fumarate (DMF) concentrations in desiccant sachets as an indicator of the potential presence of DMF in footwear and bag articles supplied in Australia**

*A project involving the Australian Competition and Consumer Commission and the Council of Textile and Fashion Industries Australia (TFIA)*

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**Australian  
Competition &  
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Commission**

## Background

Dimethyl fumarate or 2-Butenedioic acid dimethyl ester (DMF) is an anti-fungicide used to stop mould forming in leather and other consumer goods during transport and storage. It may be impregnated into desiccant sachets inside the packaging of leather and fabric covered furniture sofas and shoes but it may also be applied directly onto the surface of products.

## Potential Hazards

DMF is a potent contact sensitiser of the skin, causing itching, irritation, redness, burns, and, in some cases, acute respiratory difficulties. The reaction can be induced in some individuals at very low concentrations (as low as 1 part per million), producing extensive, pronounced eczema that is difficult to treat. In the UK, over a thousand people claimed to have suffered contact dermatitis from DMF in Chinese-made sofas around 2007 to 2009. The so called 'Toxic Sofa Syndrome' was characterised by a persistent dermatitis on the areas of the body in contact with the sofas (i.e. back of thighs, buttocks and back).

Under the Australian Consumer Law (ACL) provisions of the *Competition and Consumer Act 2010* (CCA), suppliers are obliged to report to the ACCC any serious injuries associated with the use of products they supply. Analysis of complaints and injury reports by the ACCC indicates a very low number of alleged injuries associated with the textile, clothing and footwear (TCF) sector. There are no injury reports consistent with 'Toxic Sofa Syndrome' and the few complaints of dermatitis associated with footwear (mostly thongs) appear to relate to exposure to latex or rubber compounds such as thiurams—not DMF.

## Regulations and Standards

Chemicals introduced onto the market in Australia are required to be listed on the Australian Inventory of Chemical Substances (AICS) which is administered by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). DMF is listed on the AICS however; it has not been assessed by NICNAS.

In Australia agricultural and veterinary chemicals such as biocides generally require registration for use in Australia with the Australian Pesticides and Veterinary Medicines Authority (APVMA). Under

the *Agricultural and Veterinary Chemical Code Regulations 1995*, substances or mixtures declared not to be agricultural chemical products are:

Any mould inhibitor for use in the manufacture of paper, glue, plywood, carpets, or any surface coating (including paint), if:

- a) the mould inhibitor is incorporated into the product during manufacture as part of the manufacturing process; and
- b) the manufactured product is not claimed to have any effect as a pesticide.

DMF is not registered with APVMA for use as a biocide in Australia.

Although consumer goods should be safe and suitable for use generally, there are currently no specific regulatory limits around DMF in consumer goods made under the CCA.

In the European Union, the European Commission announced a permanent ban of DMF on 15 May 2012 under Regulation EC 1907/2006, Annex XVII. This regulation states DMF shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg; Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market.<sup>1</sup>

## Survey

### *Rationale and Aim*

The ACCC's rationale and purpose for testing was to gain an understanding of the extent that DMF may be present in TCF articles in Australia. Based on EU experience, it was determined that an initial investigation into DMF should focus on desiccant sachets packed with imported footwear (leather and non-leather), leather clothing and other clothing such as jeans. It was noted that imported leather and fabric covered furniture may also be packaged or wrapped with desiccant sachets to prevent mould in transit.

Desiccant sachets that were packed in close proximity to a representative range of consumer goods (mostly shoes and some bags) were sourced from national suppliers. ACCC staff collected some

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:128:0001:0003:EN:PDF>

desiccant sachets accompanying goods directly from retail outlets with the permission of the retailers. Samples that were deemed unsuitable for analysis due to potential cross contamination or samples having insufficient and/or vague details recorded about the origin of the sample were not analysed. A total of 177 desiccant sachets were ultimately deemed suitable for analysis for DMF. Should those sachets reveal concentrations of DMF above the around 25 mg/kg, additional testing of the article for potential migration of DMF would then be conducted.

Concentrations of DMF above 1 mg/kg in the desiccant sachets do not equate to potential harmful human exposure to DMF from the article. A 2011 study by (Stefanelli et al) found that the desiccant sachets packed within a shoe box had concentrations of DMF 25 times higher than the shoe vamp and 50 times greater than the whole shoe). (Stefanelli et al - Bulletin of Environmental Contamination and Toxicology (2011) 86:428–432 DOI 10.1007).

### *Involvement of the TFIA*

Over recent years, the Council of Textile and Fashion Industries Australia (TFIA) has issued a number of media statements indicating that TCF articles imported into Australia commonly contained concentrations of chemicals that were hazardous to consumers.

The ACCC was therefore keen to include the TFIA in the procurement of samples to ensure that any areas that were of particular concern were included in the survey. The samples provided by the TFIA were analysed and tested at a suitable laboratory by the ACCC. Unfortunately other samples were not collected in accordance with the required procedures and could not be included (for example cross contamination occurred and some products associated with the sachets could not be identified).

### *Sampling Methodology*

Sampling kits and detailed instructions were prepared and supplied by the ACCC. Sample kits included:

- Box of 25 zip lock plastic sample bags
- Suitable pen or marker to write on the plastic sample bags
- Set of plastic tweezers or a glove
- Blank spreadsheet to record the sample details
- Simple step instructions (below)
- Large return addressed envelope to the ACCC for up to 25 individual samples.

Simple step instructions were to ask collectors to:

- Record all details on the record sheet provided.
- Make a note if the sachet makes a claim to being 'DMF free'.
- Each sachet must only be handled with a glove on (provided in the kit) to prevent cross contamination.
- Place a single sachet in the snap lock clear bags provided.
- Mark the bag clearly with a sample number that corresponds with the record sheet details.
- Each designated collector should attempt to obtain 10 or more individual sachets.
- Once all the individual sachets have been collected and all sample details recorded on the sheet provided place in the kit envelope marked with the name of the collector and the date and return to the TFIA or ACCC.

The ACCC commissioned a NATA accredited laboratory (SGS Leeder Consulting) based in Melbourne, Victoria for testing. Samples deemed suitable for testing were removed from their sample bags and the samples were then extracted in Ethyl Acetate. Samples were then analysed using a gas chromatogram-mass spectrometer (GC-MS) using direct injection – a method usually used for the analysis of DMF.

The Practical Quantification Limit (PQL) for the analysis of DMF was 0.01 mg/kg (or parts per million).

### *Results*

- DMF was detected at low concentrations in only 12 of the 177 desiccant sachets tested.
- No desiccant sachet samples had concentrations of DMF above the range 25 – 50 mg/kg which is the level where the article would be tested for potential migratable concentrations.
- Nine of the 12 samples had detections at concentrations below 1 mg/kg.
- Concentrations were low ranging from 0.06 mg/kg – 4.8 mg/kg (parts per million).
- The average concentration found in the desiccant sachets where DMF was present, was 0.88 mg/kg.
- Only three sachet samples had concentrations of DMF above 1 mg/kg. These were:
  - 1.4 mg/kg - (PV Shoe, 'Beachcombers/Bowen' sample)
  - 1.7 mg/kg - (Womens L Shoe, 'Siren/Dolly' sample)
  - 4.8 mg/kg - (Sneaker, 'Wild Rhino/Kess' sample).

## Conclusions and Recommendations

While limited in scope, the results of this survey indicate that footwear and bags currently supplied onto the Australian market are unlikely to contain any DMF.

In the small proportion of cases, where DMF is present in the desiccant sachets accompanying consumer goods the concentrations are well below the threshold of 25 mg/kg, where additional testing of the article for potential DMF migration may be justified.

Based on published scientific literature, where DMF may be present in the desiccant material accompanying shoes/bags, the concentrations likely to migrate to consumers from the use of the goods are extremely low and well below levels where adverse health effects would occur.

Australians wear footwear and textile garments for hours every day over their lifetime. Despite this extensive daily exposure to TCF products there are very few reports of injury associated with the use of these products. It is estimated that around 8 million pairs of footwear are supplied onto the market in Australia each year with very few incidents of injury reported. On the basis of the absence of injury data it would appear that footwear is one of the largest and safest categories of consumer goods supplied in Australia.

While these survey results do not indicate there is a problem with DMF in consumer goods supplied in Australia, the ACCC will continue to investigate mandatory injury reports associated with TCF articles and credible evidence of unsafe consumer goods. The ACCC is fully committed to identifying genuine consumer product hazards and to taking decisive action where sound evidence and scientific principles indicates there is a basis to do so.