



**26BB database ingredient list update - 'sodium fluoride'**  
**[DLM=For-Official-Use-Only]**

Gerry Dendrinios to: Laykhoo Choo

21/11/2013 03:42 PM

Hi Lay Khoo,

The restriction field entry in the 26BB ingredient database for 'sodium fluoride' has been updated in accordance with Listing Notice 6 (2013), as follows:

- "Permitted for use only when the route of administration is dental. For use in products only when the dosage form is a paste, powder or gel and the product is for dental hygiene. Permitted for use only in combination with at least one of the therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations. The concentration of fluoride ion must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation must comply with the requirements of the Required Advisory Statements for Medicine Labels. Any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay."

Cheers,

Gerry

**Gerry Dendrinios**

Departmental Officer

Pre-market Assessment

Office of Complementary Medicines

Phone: 02 6232 8838 Fax: 02 6203 1657

Email: [gerry.dendrinios@tga.gov.au](mailto:gerry.dendrinios@tga.gov.au)

Therapeutic Goods Administration

Department of Health

PO Box 100

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----- Forwarded by Gerry Dendrinios/TGA/Health on 21/11/2013 03:33 PM -----

From: ELF Helpdesk  
To: Gerry Dendrinios/TGA/Health  
Cc: Angeliza Querubin/TGA/Health, David Tattersall/TGA/Health, ELF Helpdesk, Laykhoo Choo/TGA/Health, Meenu Mathur/TGA/Health, Sharon De Rota/TGA/Health  
Date: 14/11/2013 12:04 PM  
Subject: Re: Therapeutic Goods (Listing) Notice 2013 (No. 6) registered on FRLI - request to update validation rules [DLM=For-Official-Use-Only]  
Sent by: Clare Hedditch

Dear Gerry

The validation rules have been updated as per the below advice for Sodium fluoride.

Kind regards,

Clare

**ELF Help Desk**

Electronic Listing Facility  
Office of Complementary Medicines

Phone: 1800 773 312

Fax: 02 6232 8577

Email: [elf](#)

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Department of Health  
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Gerry Dendrinis

Dear ELF team, Listing Notice 6 (2013) - So...

13/11/2013 03:08:06 PM

From: Gerry Dendrinis/TGA/Health  
To: ELF Helpdesk  
Cc: Laykhon Choo/TGA/Health; Meenu Mathur/TGA/Health; David Tattersall/TGA/Health; Angeliza Querubin/TGA/Health  
Date: 13/11/2013 03:08 PM  
Subject: Therapeutic Goods (Listing) Notice 2013 (No. 6) registered on FRLI - request to update validation rules [DLM=For-Official-Use-Only]

Dear ELF team,

Listing Notice 6 (2013) - Sodium fluoride - was registered on FRLI on 12 Nov 2013.

Could you please update the validation rules accordingly. I note that the AAN 'fluoride' is an existing equivalent of 'sodium fluoride' in the validation rules.

Thanks,

Gerry

**Gerry Dendrinis**

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----- Forwarded by Gerry Dendrinis/TGA/Health on 13/11/2013 02:49 PM -----

From: Bless Carter/TGA/Health  
To: Jennifer Burnett/TGA/Health; Elizabeth Armer/TGA/Health; Angeliza Querubin/TGA/Health; Gerry Dendrinis/TGA/Health  
Cc: Terry Lee/TGA/Health; Madeleine Spies/TGA/Health; Kenneth Teoh/TGA/Health; Marlene Keese/TGA/Health; Mark

Gladman/TGA/Health [REDACTED] Bart Shanahan/TGA/Health [REDACTED] Jenni  
Pyne/TGA/Health [REDACTED] Will Freebairn/TGA/Health [REDACTED] Matthew  
Swainson/TGA/Health [REDACTED] Norman Kalagayan/TGA/Health [REDACTED] Paul Maxwell  
Shepherd/TGA/Health [REDACTED] Lyndal Spear/TGA/Health [REDACTED] Katherine  
Fleming/TGA/Health [REDACTED] Junling Tian/TGA/Health [REDACTED] Navreen  
Kular/TGA/Health [REDACTED] Josephine Lumb/TGA/Health [REDACTED] Sarah  
Todd/TGA/Health [REDACTED]

Date: 12/11/2013 05:30 PM  
Subject: For information: FRLI Registration advice - Therapeutic Goods (Listing) Notice 2013 (No. 6)  
[DLM=For-Official-Use-Only]

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[REDACTED]  
----- Forwarded by Bless Carter/TGA/Health on 12/11/2013 05:28 PM -----

From: <fri [REDACTED]>  
To: <bless.carter [REDACTED]>  
Date: 12/11/2013 04:41 PM  
Subject: FRLI Registration advice - Therapeutic Goods (Listing) Notice 2013 (No. 6)

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Dear Bless,

The following instrument has been registered on the Federal Register of Instruments on 12/11/2013:

F2013L01925, Therapeutic Goods (Listing) Notice 2013 (No. 6), original  
R20131111L004.

Regards,

Staff of the Federal Register of Legislative Instruments

For assistance with this message or any FRLI matter, please contact:

The Federal Register of Legislative Instruments  
Office of Parliamentary Counsel  
63 Denison Street DEAKIN ACT 2600  
E-mail: fri [REDACTED]  
Phone: (02) 6282 7348  
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