

# **Medicines (Oral Dental Gums) (Labelling) Regulations 2003**

## **Table of Contents**

### **Enacting Formula**

#### **1 Citation and commencement**

#### **2 Definitions**

#### **3 Display of information on oral dental gum**

#### **4 List of ingredients**

#### **5 Manner in which particulars are to be stated**

**No. S 659**

### **MEDICINES ACT (CHAPTER 176)**

#### **MEDICINES (ORAL DENTAL GUMS) (LABELLING) REGULATIONS 2003**

In exercise of the powers conferred by sections 44, 46 and 54 of the Medicines Act, Mr Khaw Boon Wan, Senior Minister of State, Ministry of Finance, charged with the responsibility of the Minister for Health, hereby makes the following Regulations:

#### **Citation and commencement**

1. These Regulations may be cited as the Medicines (Oral Dental Gums) (Labelling) Regulations 2003 and shall come into operation on 1st January 2004.

#### **Definitions**

2. In these Regulations, unless the context otherwise requires —

“flavour” means a substance used as an ingredient of an oral dental gum solely to

impart a taste to the product;

“oral dental gum” shall have the same meaning as in the Medicines (Oral Dental Gums) (Specification) Order 2003 (G.N. No. S 662/2003).

### **Display of information on oral dental gum**

3. Every container of an oral dental gum or, where the container is immediately enclosed in a package, every package of an oral dental gum, shall be labelled with the following information:

- (a) the name of the oral dental gum or an appropriate description of the oral dental gum;
- (b) the list of the ingredients specified in accordance with regulation 4;
- (c) if the oral dental gum is manufactured or assembled in Singapore, the name and address of the manufacturer or person responsible for the assembly of the oral dental gum;
- (d) if the oral dental gum is imported, the name and address of the importer;
- (e) the batch reference given by the manufacturer of the oral dental gum to the batch of which it forms a part;
- (f) the date after which the oral dental gum should not be used; and
- (g) any particular precaution to be observed in use.

### **List of ingredients**

4.—(1) The list of ingredients referred to in regulation 3(b) (referred to in this regulation as the list of ingredients) shall be specified by volume or by mass in descending order.

(2) Subject to paragraph (3), the ingredients of an oral dental gum shall be specified in the list of ingredients by using nomenclature from the latest edition of the Codex Alimentus, British Pharmacopoeia, United States Pharmacopoeia, Chemical Abstracts Service or such other nomenclature as may be approved by the licensing authority.

(3) Where an oral dental gum contains tartrazine, it shall be specified in the list of ingredients as —

- (a) tartrazine;
- (b) colour (102); or
- (c) colour (FD and C Yellow No. 5).