

MEDICINES ACT
(CHAPTER 176, SECTIONS 44, 46 AND 54)

MEDICINES
(ORAL DENTAL GUMS) (LABELLING)
REGULATIONS

ARRANGEMENT OF REGULATIONS

Regulation

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[1st January 2004]

Citation

1. These Regulations may be cited as the Medicines (Oral Dental Gums) (Labelling) Regulations.

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 (O 19).

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).

(4) Any flavour used as an ingredient of an oral dental gum shall be specified in the list of ingredients by the word “flavour” or the ingredients of the flavour.

(5) A substance shall not be required to be specified in the list of ingredients of an oral dental gum if it is present only as a trace which could not reasonably have been removed during or after manufacture.

(6) The licensing authority may, on the application by a product licence holder, allow any ingredient of an oral dental gum to be

specified as “other ingredient” in the list of ingredients if the licensing authority is satisfied that —

- (a) revealing the ingredient in the list of ingredients would prejudice a trade secret; and
- (b) inclusion of the ingredient in the oral dental gum is unlikely to be harmful to any consumer.

Manner in which particulars are to be stated

5.—(1) All particulars required by these Regulations to be shown by the labelling of any container or package of an oral dental gum shall —

- (a) be specified in English;
- (b) be clearly legible;
- (c) be printed in an indelible manner; and
- (d) appear conspicuously in a prominent position on such container or package so as to be easily read by an intending purchaser or user of the oral dental gum under normal conditions of purchase or use.

(2) Where a container which is in the form of a bubble, blister or other sealed unit is part of a continuous series comprising a sheet or strip of like containers, regulation 3 shall be taken to have been complied with if the particulars required to be stated are displayed at regular intervals on the sheet or strip of such containers.

(3) Where the package immediately enclosing a container referred to in paragraph (2) is itself in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages, regulation 3 shall be taken to have been complied with if the particulars required to be stated are displayed at frequent intervals on the sheet or strip of such packages.

[G.N. No. S 659/2003]