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Notice of Modification to the *List of Permitted Preservatives* to Extend the Use of Dimethyl Dicarbonate in Certain Alcoholic Beverages

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0170

July 27, 2021



Canada

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (Regulations). Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on the Canada.ca website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada's Food Directorate received a food additive submission seeking approval for the use of dimethyl dicarbonate (DMDC) as a preservative in fruit wines (other than grape), cider, and perry¹. The requested maximum level of use for these beverages is 250 parts per million (ppm). Fruit wine and cider are standardized alcoholic beverages under sections [B.02.103](#) and [B.02.120](#), respectively, of the Regulations. The petitioner supports the use of DMDC at levels up to 250 ppm in both standardized and unstandardized ciders.

DMDC is already permitted for use in Canada as a preservative in unstandardized water-based non-alcoholic beverages² at a maximum level of 250 ppm, and in wine ([B.02.100](#)) at a maximum level of 200 ppm. The compositional standards for wine are such that DMDC is already permitted in fruit wine³ at the same maximum level of use (200 ppm). The rationale for requesting a higher level of use of 250 ppm DMDC in fruit wine and cider is that these alcoholic beverages can have a higher sugar content than grape wine, making them more susceptible to microbial spoilage than grape wine.

The results of the Food Directorate's evaluation of available scientific data support the safety of dimethyl dicarbonate for use at a level up to 250 ppm in the alcoholic beverages requested by the petitioner. Therefore, Health Canada has modified Part 3 of the [List of Permitted Preservatives](#) to extend the use of DMDC by adding the entry shown below to the list.

Modification to Part 3 of the *List of Permitted Preservatives*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
D.1	Dimethyl dicarbonate	(3) Cider; Fruit wine; Perry; Unstandardized alcoholic ciders ⁴	(3) 250 p.p.m.

¹ Perry is an unstandardized fruit wine type alcoholic beverage that is the product of the alcoholic fermentation of pear juice.

² Examples of unstandardized water-based non-alcoholic beverages are ready-to-drink tea; fruit-flavoured, sport or isotonic drinks; and diet soft drinks. Dealcoholized wine beverages are not included.

³ The standard for fruit wine (B.02.103) prescribes that fruit wine shall be the product of the alcoholic fermentation of the juice of sound ripe fruit other than grape, and in all other respects shall meet the requirements of the standard for wine (B.02.100).

⁴ The word "alcoholic" is used in the descriptor to differentiate from the unfiltered, unsweetened, non-alcoholic beverage made from apples that is called "apple cider", "sweet cider", "soft cider" or simply "cider", and that differs from "alcoholic" cider for which there is a standard in the Regulations.

The compositional standards for wine and fruit wine are such that DMDC is also permitted in flavoured (naming the fruit) wine ([B.02.105A](#)) because this standard refers to products that are fruit wine, a mixture of fruit wines, or a mixture of fruit wine and wine to which has been added herbs, spices, other botanical substances, fruit juices or a flavouring preparation. Thus, a flavoured fruit wine is permitted to contain DMDC in accordance with the provisions for use in fruit wine and wine, as applicable.

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of dimethyl dicarbonate for use as a preservative in certain alcoholic beverages. The assessment concluded that information related to allergenicity, chemistry, microbiology, nutrition, and toxicology supports the safety of dimethyl dicarbonate for use in these beverages at a level up to 250 ppm. Therefore, the Department has enabled these uses of dimethyl dicarbonate by adding to Part 3 of the [List of Permitted Preservatives](#) the new entry shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as dimethyl dicarbonate that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. The *Combined Compendium of Food Additive Specifications*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **July 27, 2021**, the day it was published in Part 3 of the [List of Permitted Preservatives](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

Health Canada's Food Directorate is committed to reviewing new scientific information on the safety in use of any food additive, including dimethyl dicarbonate. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**Dimethyl dicarbonate (NOM-0170)**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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