



Health  
Canada

Santé  
Canada

Your health and  
safety... our priority.

Votre santé et votre  
sécurité... notre priorité.

# **Notice of Modification to the *List of Permitted Food Additives with Other Generally Accepted Uses* to Enable the Use of Glycerol Ester of Gum Rosin and Glycerol Ester of Tall Oil Rosin as Density Adjusting Agents in Beverages Containing Citrus or Spruce Oils**

**Notice of Modification – *Lists of Permitted Food Additives***

**Reference Number: [NOM/ADM-0018]**

**November 29, 2013**

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada 

## Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug 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. 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 has received two separate food additive submissions seeking approval for the use of glycerol ester of gum rosin and glycerol ester of tall oil rosin, respectively, as density adjusting agents at a maximum level of use of 100 parts per million (p.p.m.) in beverages containing citrus oils. Glycerol ester of wood rosin, a similar food additive, is permitted for use in beverages containing citrus or spruce oils for the same purpose and at the same level of use.

The results of Health Canada's evaluation of available scientific data support the safety of glycerol ester of gum rosin and glycerol ester of tall oil rosin when used in beverages containing citrus or spruce oils as is permitted for glycerol ester of wood rosin. Further, the safety in use and the technical function of glycerol ester of wood rosin, glycerol ester of gum rosin and glycerol ester of tall oil rosin support their use in a manner that provides the choice of using only one or a combination of any of the three, provided the total level of use does not exceed 100 p.p.m.

Since glycerol ester of gum rosin and glycerol ester of tall oil rosin are food additives that were not previously permitted for use in Canada, Health Canada published the [Notice of Proposal to Enable the Use of Glycerol Ester of Gum Rosin and Glycerol Ester of Tall Oil Rosin as Density Adjusting Agents in Beverages Containing Citrus or Spruce Oils](#) on May 2, 2013, requesting comments. Comments were received by the Department as a result of this publication. However, no new scientific information was provided to the Department that changed the conclusion of the safety evaluation. Since the conclusions of the evaluation remain as described in the notice of proposal, Health Canada has modified the *Lists of Permitted Food Additives* as indicated below.

**Modification to the *List of Permitted Food Additives with Other Generally Accepted Uses*:**

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Purpose of Use	Column 4 Maximum Level of Use and Other Conditions
G.3.1	Glycerol ester of gum rosin	Beverages containing citrus or spruce oils	Density adjusting agent	100 p.p.m. If glycerol ester of tall oil rosin or glycerol ester of wood rosin or both are also used, the total must not exceed 100 p.p.m.
G.3.2	Glycerol ester of tall oil rosin	Beverages containing citrus or spruce oils	Density adjusting agent	100 p.p.m. If glycerol ester of gum rosin or glycerol ester of wood rosin or both are also used, the total must not exceed 100 p.p.m.

These modifications set out a maximum level of use for glycerol ester of gum rosin and glycerol ester of tall oil rosin, when used singly or in combination with one another or with glycerol ester of wood rosin, in beverages containing citrus or spruce oils. Since these modifications allow for the use of combinations of glycerol ester of gum rosin, glycerol ester of tall oil rosin and glycerol ester of wood rosin, at a combined maximum level of use of 100 p.p.m. in any combination, the existing conditions of use for glycerol ester of wood rosin have also been modified. Specifically, the entry in Column 4 of Item G.4 of the [\*List of Permitted Food Additives with Other Generally Accepted Uses\*](#), which sets out the maximum level of use for glycerol ester of wood rosin in these beverages, has been modified, as indicated in the table below.

**Consequential Modifications to the *List of Permitted Food Additives with Other Generally Accepted Uses*:**

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Purpose of Use	Column 4 Maximum Level of Use and Other Conditions
G.4	Glycerol ester of wood rosin	Beverages containing citrus or spruce oils	Density adjusting agent	100 p.p.m. If glycerol ester of gum rosin or glycerol ester of tall oil rosin or both are also used, the total must not exceed 100 p.p.m.

In addition, the French name of the additive as it appears under item G.4 in the [\*Liste des additifs alimentaires autorisés ayant d'autres utilisations généralement acceptées\*](#) has been changed from "Ester glycérique de la colophane" to "Esters glycériques de résine de bois" to align with

the name used in the International Numbering System for Food Additives CAC/GL-36-1989. It should be noted that this change does not prevent the use of the term "ester glycérique de la colophane" in the list of ingredients on food labels as it is considered an acceptable synonym for "esters glycériques de résine de bois".

## Rationale

Health Canada's Food Directorate has completed two separate pre-market safety assessments, one for glycerol ester of gum rosin and the other for glycerol ester of tall oil rosin, when used as density adjusting agents in beverages containing citrus or spruce oils.

The safety assessments of the two additives considered the toxicological and chemical aspects of the proposals.

Based on the results of the safety assessments, Health Canada's Food Directorate considers that the data support the safety of glycerol ester of gum rosin and glycerol ester of tall oil rosin when used under the conditions set out in the table above. The Department has therefore enabled the use of these food additives as described in that table.

## Other Relevant Information

Glycerol ester of gum rosin and glycerol ester of tall oil rosin used in beverages containing citrus or spruce oils sold in Canada must meet the food-grade specifications for these additives set out in the most recent edition of the *Food Chemicals Codex* (FCC). FCC is a compendium of standards for the purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

## Notification – Summary of Comments

In response to the [\*Notice of Proposal to Enable the Use of Glycerol Ester of Gum Rosin and Glycerol Ester of Tall Oil Rosin as Density Adjusting Agents in Beverages Containing Citrus or Spruce Oils\*](#), Health Canada received the following comments.

A comment was received expressing concern about the limited number of toxicological studies specific to glycerol ester of gum rosin and glycerol ester of tall oil rosin and the group ADI that was considered during the safety assessment. The concern was due to certain compositional differences of both glycerol ester of gum rosin and glycerol ester of tall oil rosin compared to glycerol ester of wood rosin. Health Canada considered this issue and confirmed that, although there is potential for variability in the composition of these food additives, the available scientific information indicates that there are significant similarities in the chemical composition of the three glycerol esters and that the use of glycerol ester of gum rosin and glycerol ester of tall oil rosin as density adjusting agents in beverages containing citrus or spruce oils does not constitute a health concern. In addition, it was noted that the United States Food and Drug Administration

(US FDA) has established the same group ADI as Health Canada and that the FCC has specifications for the glycerol ester of all three rosins.

Another comment was received raising the more general concern about soft drink consumption and its contribution to obesity. However, no scientific information about the safety of these food additives was included with the comment.

Lastly, a comment was received from an industry association in support of the approval of glycerol ester of gum rosin and glycerol ester of tall oil rosin, as described in the proposal.

## Implementation and Enforcement

The above modification came into force on November 29, 2013, the day it was published in the [\*List of Permitted Food Additives with Other Generally Accepted Uses\*](#).

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 any new scientific information on the safety in use of any food additive, including glycerol ester of gum rosin and glycerol ester of tall oil rosin. Anyone wishing to submit new scientific information on the use of these additives 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 "**glycerol ester of gum rosin and/or glycerol ester of tall oil rosin**" in the subject line of your e-mail.

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

251 Sir Frederick Banting Driveway  
Tunney's Pasture, PL: 2202C  
Ottawa, Ontario, K1A 0K9  
E-mail: <mailto:bcs-bipc@hc-sc.gc.ca>