Food Additive Submission Checklist

To complete this form please select one of the options listed below to indicate the nature of the submission. For submissions that involve more than one food additive, please complete a separate Submission Checklist for each food additive.

We request that the completed checklist accompany the submission package. The package should be sent electronically through the Application Form for Pre-Market Submissions to the Food Directorate (Online Application Form).

For more information on how to prepare a food additive submission, please refer to Health Canada's A Guide for the Preparation of Submissions on Food Additives.

FOR USE BY HEALTH CANADA ONLY

Date of receipt:

Type of Food Additive Submission

1. Please place a checkmark in the appropriate box to indicate the nature of the submission:

☐ This is a submission for a new food additive, not approved for any use by Health Canada

☐ This is a submission requesting an extension of use to foods of an additive already approved by Health Canada for uses in other foods

☐ This is a submission requesting a change to the level of use in a food of an additive already approved for use by Health Canada

Petitioner Information

2. Name of petitioner (manufacturer, company, consultant, importer, etc.):

3. Full postal address:

No. and street

City

Country

Postal code

4. Contact information:

Primary
Country Code Aera Code Number

Alternative
Country Code Aera Code Number

E-mail

5. Alternative name and address for correspondence:

Description of the Submission

6. Title:

7. Date of submission: Day 1 Month 1 Year 2008

8. Name of the Food Additive as commonly used (also, please indicate the chemical, synonymous and trade names):

9. Chemical Identification of the substance (CAS No., Enzyme Commission No., other):

10. Is the food additive currently listed in one of the Lists of Permitted Food Additives which are available on (Health Canada's website) or **has a TMA** (Temporary Market Authorization) **been issued** for its use in any foods?

◯ Yes ◯ No ◯ Do not know

If you answered "yes" to the previous question above and were the petitioner of the previously approved submission, please list any new studies or any new relevant information that was not submitted as part of the previously approved submission:

11. Is the food additive subject to the New Substances Notification Regulations (NSNR)? If yes, do you intend to notify under the NSNR? If you do not intend to notify under the NSNR, please provide a rationale:

Checklist of enclosed information and data pursuant to Section B.16.002

12. Cover letter:
◯ Yes ◯ N/A

13. Specifications, Chemistry (B.16.002 a):
◯ Yes ◯ N/A

14. Intended use, Proposed levels of use (B.16.002 b):

◯ Yes ◯ N/A

15. Analytical method of food additive detection(B.16.002 c):

◯ Yes ◯ N/A

16. Technological justification (B.16.002 d):

◯ Yes ◯ N/A

17. Safety-related data (B.16.002 e):

◯ Yes ◯ N/A Exposure

◯ Yes ◯ N/A Toxicological Safety

◯ Yes ◯ N/A Microbiological Safety

◯ Yes ◯ N/A Nutritional Safety

18. Amounts of additive remaining in or on the food if level of use is consistent with GMP (B.16.002 f):

◯ Yes ◯ N/A

19. Proposed maximum limit for residue of the food additive in or on the finished food (if different from B.16.002 b)**, B.16.002 g**:

◯ Yes ◯ N/A

20. Proposed labelling (B.16.002 h):

◯ Yes ◯ N/A

21. A sample of the food additive (B.16.002 i):

This is not required at the time of providing your submission package but you should be prepared to provide a sample upon request.

22. If you selected "N/A" for any items listed, please provide a rationale for not providing this information:

Summary of the Submission

Please succinctly summarize the components of this submission, including, for example; the food additive's technical function and its intended use; if the additive is part of a preparation that includes other ingredients, full identification of the components and their proportions must be provided; the proposed use levels in the food or food categories; the estimated exposure to (intake of) the food additive; if known, the status of the food additive in other countries or according to the international Codex Alimentarius, including any internationally-established Acceptable Daily Intake (ADI) and/or other toxicological reference values; the advantages the additive provides over approved additives that have the same technological function; and any other important information.

Additional Information