

**MINISTRY OF HEALTH MALAYSIA**  
**FORMAT FOR THE APPLICATION FOR THE USE OF FOOD ADDITIVE**

**Application should be addressed to:**

The Secretary  
Expert Working Group on Food Additive  
Food Safety and Quality Division  
Ministry of Health  
Level 4, Menara Prisma,  
No. 26, Jalan Persiaran Perdana,  
Presint 3, 62675 PUTRAJAYA  
Website : <http://fsg.moh.gov.my>

**The purpose of application:**

- Proposal for a new food additive
- Proposal to amend an existing provision

**Declaration:**

I hereby declare that all particulars given in this form are true and correct.

Signature of Applicant :

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Name of Applicant :

\_\_\_\_\_

***Guidance Information on Requirement for Food Additive Application***

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1. Name and address of applicant:
2. E-mail/ telephone / fax no:
3. State:
  - a) Whether manufacturer of proposed additive, manufacturer's agent, food processor, on behalf of a single firm or organization, on behalf of the food processing industry or other firms or organizations;
  - b) Has the manufacturer of proposed additive made a commitment to provide data? (indicate contact person)
4. State:
  - a) Identity of the additive (as listed in Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36 if available; trade names are not acceptable)
    - i) Single substances,[e.g sorbic acid, sodium ascorbate]:
      - Chemical and/or common name of proposed additive

- ii) Simple mixtures, [e.g sorbitol syrup, lecithins]:
    - Chemical and/or common name of proposed additive
    - Chemical composition – identity of the components of the mixture
  - iii) Complex mixture not derived from botanical source, [e.g beeswax, shellac]:
    - Starting materials or source materials
    - Species, in case of animal origin
    - Chemical and/or common name of proposed additive
  - iv) Additives derived from botanical source, [e.g steviol glycosides from Stevia, rosemary extracts]:
    - The scientific (Latin) name (botanical family, genus, species, subspecies)
    - Synonyms (botanical name) that may be used interchangeably with the preferred scientific name
    - Common names (if a trivial or a common name is used extensively in the monograph, it should be firmly linked to the scientific name and part used).
    - The part used (e.g. root, leaf, seed, etc.)
    - Compounds classified according to their chemical structure (e.g. flavonoids, terpenoids, alkaloids, etc.)
    - Constituents being characteristic for the food additive (chemical fingerprint, markers)
  - v) Additives derived from microorganism
    - The microbial origin of food additives produced by fermentation or cultivation, including name of the microorganism, taxonomic classification of the microorganism and history of modification of the production organism
    - Whether the microorganism fulfils the requirements under Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) or etc.
    - Information on residual levels of toxins.
    - Information on the production process.
    - Information on the identity of residual intermediates or microbial metabolites in the final product.
- b) INS number and functional class (as listed in Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36 if available).
- c) Identify the proposed amendment:
- Malaysian Food Regulations 1985 (Regulation number) or
  - Codex GSFA (Food category number) or
  - Codex Commodity Standard (Codex STAND Number)
- d) The proposed maximum use level(s) of the proposed item (the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., “not-specified”).

5. Regulatory Impact Analysis (RIA).

- a) Please provide a brief outline of the proposal. This could include the following information:
- The problem that the regulation is attempting to solve, and the objectives;
  - Any preliminary options that are being considered; and
  - Information on whether it is a proposal for a new regulation, or to amend an existing regulation.
- b) Is your proposal likely to have any regulatory impact? If so please specify.
- c) Is your proposal likely to affect costs? If so, how?

6. Technological Data:

- a) Justification for use and technological need
- b) Justification that the use of the additive does not mislead consumer.
- c) Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

7. Safety Assessment Data:

- a) State a recognized standard of purity for the additive (evaluation by Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA), Food Standards Australia New Zealand, Food Chemicals Codex, British Standards Institute (BSI), etc.)
- b) State the dietary intake assessment of the additive (as appropriate).
- c) State the analytical method to determine the amount of additive in the raw, processed and/or finished food

8. Toxicological Data:

- a) Metabolic and pharmacokinetic studies
- b) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
- c) Epidemiological and/or clinical studies and special considerations
- d) Other data (as necessary)