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

Application should be addressed to:

The Secretary,
Technical Committee on the Drafting of the Food Regulations,
Food Safety and Quality Control Division,
Ministry of Health,
Level 3, Block E7, Parcel E, Federal Government Administration Centre,
62590 PUTRAJAYA
(Attn: Ms. Nik Shabnam Nik Mohd. Salleh/
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Guide for applicants

i) Where application for use of a previously unapproved items is sought, both Parts A and B must be provided.

ii) Where application is for the extension of the use of an approved items, only Part A need be provided.

iii) All information requested must be compiled in English or in Bahasa Malaysia.

iv) **Ten (10) copies** of the information requested must be supplied by applicant.

PART A

1. Name of Applicant (in Full and in BLOCK letters).

2. Business Address

3. Correspondence address (if different from 2)

4. E-mail address

5. Telephone / Fax No.

6. State:

   (a) Whether manufacturer of proposed additive, manufacturer's agent or food processor;

   (b) Whether this application is on behalf of a single firm or organization;

   (c) Whether this application is on behalf of the food processing industry or other firms or organizations;

   (d) if on behalf of the food processing or other industries or organizations, names and addresses of these.

7. State:

(a) chemical and/or common name of proposed additive (N.B.- Trade Names are not acceptable);

(b) specific type of food for which requested and classification of product under Food Regulations 1985 (State the proposed regulation number and reason);

(c) proposed minimum and maximum levels of use in each item shown in 7(b).

8. State the purpose of the additive in respect of each food listed in 7(b). Show evidence that the additive will have the intended physical or other technical results when added to the particular food (s) listed in item 7(b).

9. Show evidence as to whether or not the same objectives can be obtained by good manufacturing practices or by additives currently approved in Malaysia.

10. State the limits of the probable daily intake of the additive in the diet.

11. Give evidence of approval and state to your knowledge if approval has been rejected by any statutory body or authority.

12. State the chemical structure and formula of the additive and describe it in precise chemical terms and state all physical details.

13. State a recognized standard of purity for the additive, e.g. Joint FAO/WHO Expert Committee on Food Additives (JECFA), Food Chemicals Code, British Standards Institute, etc.

14. Show information regarding the stability and persistence of the additive in the food(s) in which it is to be used.

15. State the advantages which will occur to the consumer from the use of this additive.

16. If it is intended to use the additive in packaging materials state the maximum amount(s) (supported by evidence) that may be incidentally absorbed by the food (s) from the food packaging material.

17. Show evidence in the form of a request or requests from manufacturers of a specific type of food or foods setting out the purpose to be served by the additive and establishing the need for it.

18. (a) State the analytical method to determine the amount of additive in the raw, processed and/or finished food.

(b) State the analytical method to determine any substance formed in or on such food because of the use of the additive.

NOTE:

(i) The methods should be both accurate and specific, "Specific" here means that the additive (and any substances referred to in 19 (b) can be differentiated from all other compounds (including substances which may be used in place of the additive) or constituents which are present in the food containing the additive.

(ii) These methods must be such that they can be applied with consistent results by suitably equipped laboratory and trained personnel and should, where possible, be such that they can be used for food regulatory control.

19. Supply a summary of the pharmacological and toxicological information given in Clause (23) including a summary and bibliography of pertinent literature.

PART B

Information regarding Part B will be treated in confidence by the Technical Committee on the Drafting of the Food Regulations and no disclosure will be made.

20. Give an outline of the method of manufacture of the additive.

21. Give full details of the analytical controls used during the various stages of manufacturing, processing and packing

22. Show full details of pharmacological and toxicological investigations carried out according to the general terms of reference given in World Health Organization Technical Report, Series 144, "Procedures for the testing of intentional food additives to establish their safety for use". Briefly these require:

(a) acute, short term and long term (chronic) toxicity studies. Chronic toxicity data should be given for at least two species, one of which should be the dog and carried out over the major portion of the life span of the experimental animal. Chronic toxicity experiments should aim to give the data needed to establish a 'no-effect' level;

(b) reporting of any physiological effects and any abnormal reactions, including carcinogenesis, teratogenesis in pregnant species, sensitivity, tolerance or idiosyncrasy in response to the additive;

(c) biochemical information on the possible mode of action if available; metabolic studies to show rate, extent and mode of elimination;

(d) evidence of non-interference with essential dietary constituents

(e) summary and bibliography of pertinent literature.

NOTE : Checklist for the above items is as in Annex 1. For each title, at least ONE ORIGINAL copy of studies/articles should be submitted.

23. The information supplied in response to items 1 to 23 in the application should be attested to by a statutory declaration in some suitable form along the following suggested lines;

" I.....declare that the information set out in this application fully sets out the matters required and that the same are true to the best of my knowledge and belief and that no information has been withheld which might prejudice this application".

Signature.....

Declared before me.....this.....day of ..…..…….20.....

Commissioner of Oath

CHECKLIST FOR ORIGINAL ARTICLE OF TOXICOLOGICAL STUDIES

Name of Company:_____

Name of Food Additive:_____

Title		***Yes/No**	**No. of articles**
1.	Metabolism and toxicokinetics	☐	-------
2.	Short-term/ Subchronic toxicity	☐	-------
3.	Genotoxicity/Mutagenicity	☐	-------
4.	Chronic toxicity and carcinogenicity	☐	-------
5.	Reproduction and developmental toxicity	☐	-------
6.	Acute toxicity	☐	-------
7.	Immunotoxicity	☐	-------
8.	Allergenicity	☐	-------
9.	Food intolerance	☐	-------
10.	Neurotoxicity	☐	-------
11.	Human volunteer studies	☐	-------
12.	In-vitro studies as alternatives to in-vivo studies	☐	-------
13.	Skin and eye irritation and skin sensitization	☐	-------
14.	Other related studies	☐	-------

* Please tick (√) if “Yes”

Signature: _____

Name: _____

Designation: _____