CHEMLINKED

Guidance on Stability Study on Formula Milk Powder Products for Infants and Young Children (Trial)

婴幼儿配方乳粉产品稳定性研究指南（试行）

State Administration for Market Regulation

Release Date: Mar 24, 2021
Implementation Date : Mar 24, 2021

Translated by ChemLinked

Disclaimer

This is an unofficial document provided by **ChemLinked (**chemlinked.com**)**, a platform of REACH24H Consulting Group, as an informational service to assist non-Chinese companies to better understand the Asia Pacific regulatory environment and importation compliance requirements especially China Chemical, Cosmetic, Food and Agrochemical regulatory issues.

This document should only be used as a reference and in case of any discrepancy between the English and Chinese versions the original Chinese version shall prevail.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our Privacy Polices or contact us at food@chemlinked.com

Attachment

Guidance on Stability Study on Formula Milk Powder Products for Infants and Young Children

(Trial)

This Guidance is applicable to the attenuation of nutrients in formulations during the shelf life and other stability study work of formula milk powder products for infants and young children subject to application for registration, which is for reference by applicants.

I. Basic Principles

Stability study is a process of obtaining the law of product quality characteristics changing with time under the influence of various environmental factors through design of a test, and then accordingly providing supportive information on product formulation design, production technique settings, packaging material selection, product storage conditions and shelf life determination, *etc.*

The stability study shall be reasonably designed by combination with the physicochemical properties of food raw materials (including food additives), product formulation, technical conditions and packaging materials, *etc.*

II. Tested Sample and Test Items

(I) Tested sample

The tested sample shall be produced in compliance with the requirements of GB 23790 *"National food safety standard Good manufacturing practice for powdered formulae for infants and young children*" and commercial production conditions. The product formulation, production techniques and quality requirements shall be consistent with the contents stated in the registration application documents. Each product formulation shall undergo a stability study, and three batches of samples thereof shall be used respectively for the accelerated test and the long-term test. If different packaging materials are used for the same formulation, full evaluation shall be performed and at least one packaging material shall be selected for tests.

(II) Test items

All items specified in the national food safety standard (including labeling and identification requirements) shall be used as the test items. Items that are easy to change during the product shelf life and may affect product quality, safety and nutritional adequacy can be selected as key test items. The key test items shall at least include the items listed in the Annex below. In principle, the test items shall be tested by the applicant using the testing methods specified in the national food safety standard for foods for infants and young children. If there is no available national food safety standard or an international testing method is used, verification shall be completed. Where a qualified third party testing institution is entrusted to perform the testing, the reason shall be given.

(III) Testing frequency

All test items shall be tested at the beginning and at the end of the test. The testing frequency of key test items can be determined by the applicant based on the stability of the test items. The key test items listed in the Annex below shall be tested at the specific test time points specified by different test methods (accelerated test, long-term test).

III. Test Methods

(I) Accelerated test

1. Test period

The accelerated test period shall be one-fourth of the product shelf life, and must not be less than 6 months.

In an accelerated test, multiple test time points shall be set up to study the quality change of the product. For example, for an accelerated test with a test period of 6 months, the time points shall at least include “at the beginning and at the end of the test”, with no less than 2 time points in between, and the interval between each time point shall not be less than 1 month. The quality analysis results of the same batch of samples may be used as the data at the beginning of the test.

2. Test conditions

The accelerated test conditions can be determined by the applicant based on factors such as product characteristics and packaging materials, *etc.* Generally, a temperature of 37℃ ± 2℃ and a relative humidity (RH) of 75% ± 5% can be selected.

CHEMLINKED

SUBSCRIBE TO CHEMLINKED NOW

REMOVE FOOD REGULATORY BARRIERS
EXPEDITE ASIA MARKET ACCESS

· In-time regulatory information and market access requirements
· Supported by local and experienced technically adept technical team
· Strategic partnerships with competent authorities and industrial associations worldwide
· Customized consulting service for complete compliance solutions.

OUR SERVICES

Information
News, Alerts

Knowledge
Pedia-articles,
Regulatory Analysis, Market Insights, Reports

Databases
Regulatory Database,
English Translations, Lists/Inventories, Q&A

Training
Webinars, Online courses, Offline events

Solutions
Translation, Consultancy, Advertising,
Tailored Regulatory Report,
Business-matching services,
Tailored online and offline training

CHEMLINKED.COM
14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 (0)571 8609 4444 / Fax: +86 571 8700 7566 / E-mail: food@chemlinked.com
Visit our website for more information about AP food News & Regulation updates