

14 January 2011

**INFORMATION ON THE ADDITIVE PECTIN (INS 440) FOR USE IN INFANT
FORMULA AND FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED
FOR INFANTS**

1. ***Proposal for inclusion submitted by:***

International Special Dietary Foods Industries (ISDI)

2. ***Name of compound; trade name(s); chemical name(s):***

Pectin (no other commonly used chemical names or synonyms)

Chemical Identification: INS 440
CAS Number 9000-69-5

JECFA evaluation: 25th JECFA (1981);
ADI not specified

3. ***Names and addresses of basic producers (of the infant formula):***

Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, IN. 47721-0001
USA

4. ***Has the manufacturer made a commitment to provide data?***

Yes.

5. ***Identification of the manufacturer that will be providing data (Please indicate contact person):***

Peter Van Dael, PhD
Vice President, Global Regulatory and Nutrition Sciences
Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, IN. 47721-0001
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6. ***Justification for use:***

Pectin is used as a gelling agent, thickener, stabilizer, and emulsifier. In FSMP formulations may lack the natural emulsification properties of whole protein, which provides stability. Stabilizers are therefore a technological requirement for these products to ensure both palatability and prevention of separation of the formula after reconstitution.



7. ***Food products and food categories within the GSFA in which the compound is used, including use level(s):***

Proposed use is as an emulsifier in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants.

Proposed use levels are up to a maximum of 1 g per 100 mL of product ready for consumption (consistent with current EU maximum level and product category of use).

GSFA Food Products and Food Categories in which the compound is currently used:

| Food Category No. | Food Category | Max Level | Year Adopted |
|-------------------|-------------------------------|-----------|--------------|
| 14.1.2.1 | Fruit juice | GMP | 2005 |
| 14.1.2.3 | Concentrates for fruit juice | GMP | 2005 |
| 14.3.1 | Fruit nectar | GMP | 2005 |
| 14.1.3.3 | Concentrates for fruit nectar | GMP | 2005 |

8. ***Is the compound currently used in food that is legally traded in more than one country? (please identify the countries); or, has the compound been approved for use in 2 or more countries (please identify the countries)?***

The additive pectin is currently permitted in special medical purpose infant formula products in the EU and affiliated countries, and in the USA the FDA has no objection to its use in exempt formula products.

9. ***List of data available (please check, if available):***

Toxicological data

- ✓ (i) Metabolic
- ✓ (ii) Short-term toxicity, long-term toxicity, reproductive toxicity, developmental toxicity studies in animals
- ✓ (iii) Epidemiological and/or clinical studies and special considerations
- ✓ (iv) Other data
 - analytical methodology

Technological data

- ✓ (i) Specifications for the identity and purity of the listed compounds (specifications applied during development and toxicological studies; proposed specifications for commerce)

- ✓ (ii) Technological and nutritional considerations relating to the manufacture and use of the listed compound

Intake assessment data

- ✓ (i) Levels of the listed compound used in food or expected to be used in food based on technological function and the range of foods in which they are used
- ✓ (ii) Estimation of dietary intakes based on food consumption data for foods in which the compound may be used

Other information as necessary

10. Date on which data could be submitted to JECFA:

December 2011

