

14 January 2011

**INFORMATION ON OSA-MODIFIED STARCH (INS 1450) REQUESTED FOR
JECFA EVALUATION 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):***
Octenyl succinic anhydride (OSA) modified starch; starch sodium octenyl succinate;
trade name is N-Creamer 46.
INS No. 1450; CAS# 66829-29-6; E1450

3. ***Names and addresses of basic producers (of the infant formula):***
Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA

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

PBM Products
204 N. Main St.
Gordonsville, VA 22942

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):***
Lisa Craig, Ph.D.
Director, Regulatory Affairs
Abbott Nutrition
625 Cleveland Avenue
Columbus OH 43215, USA
Phone: 614-624-3696
Fax: 614-727-3696
E-mail: lisa.craig@abbott.com



6. ***Justification for use:***

OSA modified starch can be used as an emulsifier in infant formula manufactured with a hydrolyzed protein source. Hydrolyzed proteins have different hydrophobic/hydrophilic characteristics than intact proteins; OSA modified starch stabilizes the hydrolyzed protein to create a more homogeneous mixture (stable emulsion), thus improving the delivery of nutrients to infants.

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 9 g/100 g in infant formula powder or ~12 g/liter, as consumed, and 2 g/100 ml or 20 g/liter in ready-to-feed formula. The maximum use level of OSA modified starch in formula is therefore up to 20 g/liter, as consumed.

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)?***

OSA Modified Starch is permitted in infant formula in the USA and Russia, and is permitted for use in formula for special medical purposes in the EU.

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

Toxicological data

- ✓ (i) Metabolic
- ✓ (ii) Short-term toxicity
- ✓ (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 1, 2011

