

14 January 2011

**INFORMATION ON XANTHAN GUM (INS 415) 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):***  
Xanthan Gum; trade name is NovaXan 200™; IUPAC Name is 9H-xanthene.  
INS No. 415; CAS#: 11138-66-2; E415
  
3. ***Names and addresses of basic producers (of the infant formula):***  
Abbott Nutrition  
625 Cleveland Avenue  
Columbus OH 43215, 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):***  
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:***  
Xanthan gum increases the thickness (viscosity) of infant formula, which improves the physical characteristics of the formula. The thickening of infant formula can result in improvements in infant feeding tolerance.
  
7. ***Food products and food categories within the GSFA in which the compound is used, including use level(s):***  
Proposed for use as a thickener up to 1 g/kg, as consumed, in food category 13.1 infant formulae, follow-on formulae and formulae for special medical purposes for infants.



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)?*

Xanthan gum 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 and pharmacokinetic studies
- ✓ (ii) Short-term toxicity
- ✓ (iii) Epidemiological and/or clinical studies and special considerations
- ✓ (iv) Other data
  - absence of allergens data

***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