

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC

(Use FDA booklet titled: "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" for completing Form FDA 2541a.)

FORM APPROVED: OMB NO. 0910-0037  
EXPIRATION DATE: 8/31/05

See OMB Statement on back of page.

A. PRODUCT

Name, Form or Style, and Packing Medium:

pH: (Before Acidification)

Governing Regulation:

- low-acid (21 CFR 108.35/113)
acidified (21 CFR 108.25/114)

Type of Submission:

- new
replaces
cancels

Process Use:

- scheduled
alternate for
emergency for

FCE

SID

B. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE)

HEATING MEDIUM (e.g., Steam, water, immersion or spray, steam-air)

1. Still (Horizontal, Vertical, None, Perforated)
2. Agitating (End over End, Axial, Continuous, Batch)
3. Hydrostatic (Inner Chain, Outer Chain, Both Inner and Outer Chain, Single Chain, Multiple Chain)
4. Flame
5. Other (explain)
6. Acidified (Maximum Equilibrium pH, Method of Acidification, Acidifying Agent, Pasteurization Method, Preservative Used, Concentration)

CONTAINER TYPE:

- 1. Tinplate/Steel Can (2-piece, Welded)
2. Aluminum Can (3-piece, Cemented)

- 3. Glass or Ceramic
4. Flexible Pouch (specify material):

- 5. Semirigid (specify material): Lid, Body, Seal Method
6. Other (specify):

PROCESS ESTABLISHMENT SOURCE (Limit entry to 30 characters)

DATE LAST ESTABLISHED

PROCESS RECOMMENDATIONS ATTACHED?

YES NO

C. CRITICAL FACTORS: AS DILINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY (Check or Describe)

None of the following NO
Maximum Water Activity (aw) MW
Consistency / Viscosity CV
Value
Units
Method Name
Temperature
Container Position in Retort CP
Nesting of Containers NC
Fill Method (check applicable method) FM
Hand or Volumetric
Vibrating or Tumble
Other (specify)
% Solids SO
Solid to Liquid Ratio (wt. to wt.) SL
Drained wt./Net wt. Ratio DW
Arrangements of Pieces in Container AP
Formulation Changes FC
Preparation Method PM
Product Quality PQ
Matting Tendency MT
Layer Pack LP
Max. Flexible Pouch/Semirigid Container Thickness in Retort MP
Max. Residual Air (Flexible Pouch/Semirigid Container) MR
Particle Size PS
Syrup Strength SS
Starch Added SA
Max. %
Type
Other Binder OB
Min. % Moisture of Dry Ingredients MM
Other (specify) OT



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Food and Drug Administration  
LACF Registration Coordinator (HFS-618)  
Center for Food Safety & Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740

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