

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:

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

- Glass or Ceramic
Flexible Pouch (specify material):

- Semirigid (specify material): Lid, Body, Seal Method
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 (a_w) 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

D. SCHEDULED PROCESS (Do *not* write in shaded areas -- Check appropriate box and enter numerical values on dashed lines.)

FCE: _____

SID: _____


CONTAINER DIMENSIONS				CAPACITY UNITS	SCHEDULED PROCESS <i>(Check Only One in Each Column)</i>				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER <i>(Specify)</i>			
Cont. No.	Diameter or Length	Height or Width	Height or Maximum Pouch or Semirigid Container Thickness	<input type="checkbox"/> Oz. <input type="checkbox"/> Gal. <input type="checkbox"/> ML <input type="checkbox"/> Other	Step No.	Temp (°F)	Process Time (Minutes)	Sterilization Temp (°F)	Least Sterilizing Value of the Scheduled Process	Thruput	Headspace	Speed				Maximum Weight	Minimum Net Weight	Minimum Free Liq. at Closing	Minimum Container Closing Machine Gauge Vacuum	Temp. (± 3° F)
						LACF						Acidified or a _w Controlled			<input type="checkbox"/> F ₀ <input type="checkbox"/> Other F Value Death Rate (z): _____ Ref. Temp.(T): _____ <input type="checkbox"/> IS Value <input type="checkbox"/> Other: _____					
Min.IT	Process Time	Process Temp.	Min.IT	Process Time	Process Temp.	<input type="checkbox"/> Fill <input type="checkbox"/> Center <input type="checkbox"/> N/A	<input type="checkbox"/> Hold Time <input type="checkbox"/> Other <input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Net <input type="checkbox"/> Gross <input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A		<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A		
Inches & Sixteenths	Inches & Sixteenths	Inches & Sixteenths				°F	Minutes	°F		Containers per Minute	Inches	RPM	Inches	Number	Inches	Ounces	Ounces	Ounces	In. Hg.	
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COMMENTS: _____

FOR FDA USE ONLY

PLANT NAME / ADDRESS

 PREFERRED MAILING ADDRESS

AUTHORIZED INDIVIDUAL


FULL NAME *(Please Type or Print)*

 SIGNATURE

TELEPHONE NUMBER

 DATE

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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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