DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Food Process Filing for Acidified Method (Form FDA 2541e)

Note: There are separate process filing forms for each of the following: Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d); Food Process Filing for Acidified Method (Form FDA 2541e); Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f); and Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g).

USE FDA INSTRUCTIONS ENTITLED "Instructions for Electronic Submission of Form FDA 2541e (Food Process Filing for Acidified Method)"

Food Canning Establishment (FCE) Number:

09403

Submission Identifier (SID):

20250701001 (YYYYMMDD###)

SECTION A

PRODUCT INFORMATION

Note: Section A.1 (Food Product Group) requests optional information.

1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.

Other

2. Enter Product Name (e.g., salsa (mild, medium, hot), artichokes (marinated), peppers (red or green), etc.).

Fruit Cocktail (Pieces, tidbit, dice, cut) in Light Syrup with mango juice

3. What is the form of the product?

Cut; Diced; Pieces

4. What is the packing medium?

Syrup

SECTION B

GOVERNING REGULATION

1. Acidified (Product is an acidified food and is governed by 21 CFR 108.25 and 21 CFR Part 114)

SECTION C

CONTAINER TYPE

Note: If the product is not packaged in one of the container types identified below, select Other.

- 1. Aluminum/Tinplate/Steel Can
 - a) What is the shape of the container? Cylindrical
 - b) How many pieces are used to construct the container?
 - ii, 3-pieces Do you use perforated divider plates? No How is the side seam sealed? Welded

SECTION D

CONTAINER SIZE

Note: You are required to complete either D.1 (Dimensions) or D.2 (Volume). You may complete D.2 if you intend to select the thermal process mode in Section G as: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; or 3) Steam Jacketed Kettle.

If you are completing D.2 because you intend to select HTST, Hot Fill and Hold, or Steam Jacketed Kettle, and if 1) your product is a cheese product under Section A.1, and 2) you have identified "Other" under Section C, you may indicate "Not Applicable" in your response to D.2. In all other circumstances, if you are completing D.2 in accordance with the directions in paragraph 1, you may not select "Not Applicable."

For all other circumstances, complete D.1. Section D.3 (net weight) is optional information.

1. Dimensions: <u>Container Dimension Assistance</u>

a) 401 Diameter 411 Height (Use for cylindrical shapes) (see accompanying instructions for proper coding)

3. Net Weight (Optional): 30 . 0 (enter in ounces)

SECTION E

PROCESSING METHOD: ACIDIFICATION

1. What is the natural pH of the low-acid ingredient(s) before acidification? 05 . 00

2. What is the finished equilibrium pH of the product after acidification? 03 . 90

3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower? 4 Hours

4. Method of Acidification: Direct Batch

5. Acidifying Agent(s):

Citric Acid

 $\textbf{6. Microbial Preservative}(s) \ \text{critical to the scheduled process:} \\$

Microbial Preservative Concentration (%)

None

SECTION F PROCESS SOURCE

1. What is the Process Source?

FSC

Attach support documentation:

File Name	File Size (MB)		
<u>HPT-250558.pdf</u>	3.9962		
Total Size:	3.9962		

2. What is the date of the Process Source Document (mm/dd/yyyy)? 05/29/2025

SECTION G

PROCESS MODE

G. Process Mode:

 $\label{thm:thm:thm:equation} \mbox{Heating Tunnel - Hot Air, Steam or Water (water cascade, water immersion, water spray)}$

SECTION H

CONTAINER AND CONTAINER CLOSURE TREATMENT

Not applicable.

SECTION I SCHEDULED PROCESS

Col.1	Col.2	Col.3	Col.4	Col.5	Col.6	Col.7	Col.8			-	Col.9			Col.10	Col.11
Process No.	Step	Temperature		Process Temperature		Thruput (Containers per Minute)		a. Reel Speed		Turn of Reel		e. Cooker Capacity	f. Frequency Strokes per Minute	Maximum Fill Weight	Other
		Min, Initial	Minutes		Other F Ref T: 200.0 z: 16.0 (°F only)						Feet (per minute)			Fill	
Number	Number	^o Fahrenheit	See above	^o Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number	Ounces	
01	1	141.8	24.0	208.2	0.36						3.70			17.63	

SECTION J ADDITIONAL INFORMATION (OPTIONAL)

If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information. File size is limited to 50MB. Acceptable file types are: jpg, doc, docx, txt, xls, xlsx, pdf, gif, rtf, avi, asf, mov, qt, avchd, mpg, mp4, and wmv.

Attach support documentation, picture, schematic, or video:

Attachment Type	File Name	File Size (MB)
Other	TDR-250528 TROFCO.pdf	4.0291
	Total Size:	4,0291

Comments:

Maximum syrup brix of finish product was 19 Brix. Maximum particulate size was 1-1/2*1-9/16*3/4 inch.

Full Name: THANATH KETSARIN

Establishment Name: TROPICAL FOOD INDUSTRIES CO., LTD. State or Province: Samut Sakhon Country (other than U.S.): THAILAND

Date (mm/dd/yyyy): 07/01/2025 **Telephone Number:** 66-990636446

Under the terms and provisions of Title 18, Section 1001, United States Code, in any matter within the jurisdiction of the executive branch of the Government of the United States it is a criminal offense to falsify, conceal, or cover up a material fact; make any materially false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

If your process filing appears to be fabricated, the product on this form will not be in compliance with 21 CFR 108.25(c)(2). A process filing appears fabricated when it contains parameters that cannot be reconciled with one another, such that the filing does not describe a process that could actually be carried out. If we determine that your process filing appears fabricated, we will delete the filing from our system and notify you. We will not consider you to have complied with 21 CFR 108.25(c)(2) until you submit a completed process filing that does not appear to be fabricated.