KELLER AND HECKMAN LLP
SERVING BUSINESS THROUGH LAW AND SCIENCE®

1001 G STREET, N. W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TEL. 202.434.4100
FAX 202.434.4646
WWW.KHLAW.COM

WRITER'S DIRECT ACCESS

Melvin S. Drozen
(202) 434-4222
Drozen@khlaw.com

October 29, 2001

***Hand Delivered***

Geraldine June
Team Leader, Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
(HFS-822)
200 C Street, S.W.
Washington, D.C. 20204

**Re: Del Monte Temporary Marketing Permit**

Dear Ms. June:

On behalf of the Del Monte Corporation ("Del Monte"), we respectfully submit this request for a temporary marketing permit ("TMP") pursuant to 21 C.F.R. §130.17. As set forth below, Del Monte is requesting that the Agency permit the temporary use of the liquid carbohydrate sweeteners corn syrup or high fructose corn syrup (collectively, "liquid sweeteners") in its canned tomato products in lieu of the dry nutritive carbohydrate sweeteners ("dry sweeteners") now required by the standard of identity for canned tomatoes (21 C.F.R. § 155.190(a)(2)(iii)). The purpose of marketing the modified products is to evaluate their commercial viability so, if required by the Agency, the Company can prepare and file a petition to amend the standard of identity for canned tomato products to permit the use of liquid sweeteners. As required by 21 C.F.R. § 130.17(c), we submit the following information in support of this request in the order identified in the regulation.

1. 21 C.F.R. § 130.17(c)(1).

   Del Monte Corporation
   One Market @ The Landmark
   P.O. Box 193575
   San Francisco, CA 94119-3575

2. 21 C.F.R. § 130.17(c)(2).

   Del Monte is regularly engaged in producing canned tomato products.

02N-0178 LET 1

3. 21 C.F.R. § 130.17(c)(3).

Canned tomatoes -- 21 C.F.R. § 155.190(a)(2)(iii) (permits the use of dry nutritive sweeteners to offset the tartness of organic acids added to canned tomato products).

4. 21 C.F.R. § 130.17(c)(4).

Del Monte requests permission to use liquid sweeteners as an alternative to the dry sweeteners now permitted by 21 C.F.R. 155.190(a)(2)(iii). The specific level of liquid sweeteners used in the canned tomato products will be limited to the amount necessary to offset the tartness of added organic acids in the products, which would be identical to the §155.190(a)(2)(iii) requirement for the addition of dry sweeteners to such products. However, Del Monte needs to test market the modified canned tomato products in order to measure consumer acceptance, identify mass production problems, and assess commercial feasibility of such modified products.

5. 21 C.F.R. § 130.17(c)(5).

The use of liquid sweeteners as substitutes for dry sweeteners is widely practiced in the food products industry and accepted by consumers. These liquid sweeteners are generally recognized as safe for addition to food (21 C.F.R. §§ 184.1865 and 184.1866).

6. 21 C.F.R. § 130.17(c)(6).

The specific level of liquid sweeteners used in the canned tomato products will be limited to the amount necessary to offset the tartness of the products' added organic acids, and is identical to the §155.190(a)(2)(iii) requirement for the addition of dry sweeteners to such products. In all other respects, the test products will comply with the standard of identity for canned tomato products.

7. 21 C.F.R. § 130.17(c)(7).

Del Monte anticipates that the use of liquid sweeteners will result in significant cost savings and measurable health and safety gains for the employees involved in the production process. These benefits will take two forms:

(1) Liquid sweeteners are typically available at significantly lower costs compared to dry nutritive sweeteners. Del Monte estimates that it will experience substantial cost savings if it can substitute liquid sweeteners for dry sweeteners as an optional ingredient in the manufacture of canned tomato products. These savings in this typically low margin industry

would come at no health or nutritional cost to consumers. Cost savings in the manufacture of the product may result in economic benefit to consumers.

(2) The use of liquid sweeteners will also result in safer working conditions as part of the manufacturing process. Dry sweeteners typically are available in 50-pound bags, which must be manually handled as part of the manufacturing process. Back injuries are the most common form of injury among workers involved in manufacturing operations, and the number one cause of back injuries is lifting heavy objects. Lifting 50-pound bags of dry sucrose is a potential source of back injuries. Liquid sweeteners can be pumped into the manufacturing process through fixed piping systems, thus eliminating the need for heavy lifting.

8. 21 C.F.R. § 130.17(c)(8).

The use of liquid sweeteners may also benefit consumers by lowering their costs for canned tomato products. Moreover, the reduction in the cost of one ingredient (sweeteners) may allow the introduction of new products with more costly optional ingredients (*e.g.*, peppers, seasonings or flavors) at the same price point. Thus, the modified products may lead to a larger variety of canned tomato products available to consumers.

Because the standard of identity does not permit the use of liquid sweeteners, Del Monte has been unable to develop data sufficient to support a petition to amend the standard of identity at this time.

9. 21 C.F.R. 130.17(c)(9).

Consumers will be able to distinguish the products being marketed under the TMP from other canned tomato products because "corn syrup" or "high fructose corn syrup" will be identified on the test products' ingredient lists instead of sugar. The products will be distributed under the Del Monte, Contadina, and S&W Brand labels. *See* attached sample labels.

10. 21 C.F.R. §§ 130.17(c)(10).

Del Monte requests a permit to market test products throughout the United States, for a period of fifteen (15) months. To fully evaluate consumer acceptance, identify mass production problems, and assess commercial feasibility of such modified products, Del Monte believes that it is important to distribute the products throughout the United States for the entire fifteen month period permitted by the regulations. Del Monte would like to commence the test concurrent with its year-2002 pack season, which begins approximately July 1, 2002.

11. 21 C.F.R. § 130.17(c)(11).

Del Monte anticipates distributing 5.6 million cases of the modified product of stewed and diced tomato products. The tomato products that would be covered by the TMP are packed on a seasonal basis over an approximately eight-week time period. For the reasons set forth in paragraph 10 above, and because production, logistics and labeling issues make packing of a different quantity impractical, Del Monte proposes to package the quantity indicated.

12. 21 C.F.R. § 130.17(c)(12).

Because consumer taste preference may vary from state to state, Del Monte believes it is necessary to distribute the test product throughout the United States to determine the commercial viability of the test products.

13. 21 C.F.R. § 130.17(13).

The modified products will be manufactured by Del Monte Corporation at the following address:

Del Monte Corporation
10652 Jackson Avenue
Hanford, CA 93230

14. 21 C.F.R. § 130.17(c)(14).

For the reasons set forth in paragraph 10 above, the test products will be distributed throughout the United States.

15. 21 C.F.R. § 130.17(c)(15).

N/A

16. 21 C.F.R. § 130.17(c)(16).

For the reasons set forth in paragraph 10 above, Del Monte believes it is necessary to distribute the test products throughout the United States.

* * *

We look forward to the Agency's response to Del Monte's TMP application. In the meantime, should you have any questions, please feel free to contact us, preferably by telephone, facsimile or e-mail, so that we may respond to your questions immediately.

Cordially yours,

Melvin S. Drozen

cc: William J. Spain
Timothy S. Ernst

85% OUTSIDE OF LABEL
2P 0 1 2 3 4 5 0 6 7 8 9 0 R 2L

## Nutrition Facts

Serving Size [illegible] (120g)
Servings Per Container [illegible]

| Amount Per Serving | |
|---|---|
| Calories [illegible] | |
| | % Daily Value* |
| Total Fat [illegible] | 0 |
| Saturated Fat [illegible] | 0 |
| Cholesterol [illegible] | 0 |
| Sodium [illegible] | 15 |
| Total Carbohydrate [illegible] | 3 |
| Dietary Fiber [illegible] | 8 |
| Sugars [illegible] | |
| Protein [illegible] | |
| Vitamin A [illegible] • Vitamin C [illegible] | |
| Calcium [illegible] • Iron [illegible] | |

*Percent Daily Values are based on a 2,000 calorie diet

INGREDIENTS: TOMATOES, TOMATO JUICE, HIGH FRUCTOSE CORN SYRUP, SALT, DEHYDRATED ONIONS, GREEN PEPPERS, CELERY, CALCIUM CHLORIDE, CITRIC ACID, SPICE


DISTRIBUTED BY DEL MONTE FOODS
SAN FRANCISCO, CA 94105
PACKED IN U.S.A.

## CHEESEBURGER MACARONI

1 lb. ground beef
1 cup chopped onion
1 can (14 1/2 oz.) DEL MONTE® Original Recipe Stewed Tomatoes
1 cup elbow macaroni
1 1/2 cups shredded Cheddar cheese

1. Brown meat and onion in large skillet; drain.
2. Add tomatoes and 1 cup water; bring to boil.
3. Stir in macaroni; cover and simmer 10 minutes or until done.
4. Stir in cheese. Serve with extra cheese, if desired.

Prep and Cook Time: 15 minutes. 4 Servings

- Vine-Ripened, Packed Fresh
- A good source of VITAMINS A and C
- No artificial flavors or preservatives

TO MAINTAIN PRODUCT QUALITY AFTER OPENING, REFRIGERATE IN COVERED GLASS OR PLASTIC CONTAINER.

PLEASE RECYCLE

0 24000 01323 5

WHEN WRITING TO US, PLEASE COPY THE STAMPED CODE FROM THE END OF THE CAN - OR REFER TO THE CODE WHEN CALLING 1-800-543-3090, MON.-FRI. 8 A.M.-5 P.M., PACIFIC TIME.

Del Monte® Quality

# Stewed Tomatoes

## ORIGINAL RECIPE

WITH ONIONS, CELERY AND GREEN PEPPERS

MADE FROM FAVORITE MEALS SEE RECIPE ON BACK FRESH TOMATOES

NET WT. 14 1/2 OZ. (411 g)

2P 0 1 2 3 4 5 0 6 7 8 9 0 R 2L
85% OUTSIDE OF LABEL

85% OUTSIDE OF LABEL
2P 0 1 2 3 4 5 6 7 8 9 0 R 2L

DELICIOUS ITALIAN RECIPE ON BACK

# Contadina®

RECIPE READY

# DICED TOMATOES

In Rich, Thick Juice with

## ROASTED GARLIC

NET WT. 14.5 OZ. (411g)

35644 2L AD 5.01 UNL R1

## Nutrition Facts

Serv. Size 1/2 cup (122g)
Servings Per Container about 3 1/2

| Amount Per Serving | |
|---|---|
| **Calories** 45 Calories from Fat 0 | |
| | **% Daily Value*** |
| **Total Fat** 0g | 0% |
| Saturated Fat 0g | 0% |
| **Cholesterol** 0mg | 0% |
| **Sodium** 560mg | 23% |
| **Total Carb.** 10g | 3% |
| Dietary Fiber less than 1g | 4% |
| Sugars 7g | |
| **Protein** 1g | |
| Vitamin A 4% • Vitamin C 25% | |
| Calcium 6% • Iron 4% | |

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: TOMATOES, TOMATO JUICE (TOMATO PUREE, WATER), HIGH FRUCTOSE CORN SYRUP, SALT, ROASTED GARLIC, TOASTED ONION, GARLIC POWDER, NATURAL FLAVOR, CITRIC ACID, SPICES, CALCIUM CHLORIDE.



DISTRIBUTED BY
CONTADINA FOODS, INC.
SAN FRANCISCO, CA 94105
PACKED IN U.S.A.

## Garlic Chicken Mozzarella

Prep: 5 minutes Cook: 25 minutes Servings: 4

- *4 boneless, skinless chicken breast halves*
- *1 Tbsp. olive oil*
- *1 can (14.5 oz.) CONTADINA® Recipe Ready Diced Tomatoes with Roasted Garlic*
- *1 can (8 oz.) CONTADINA Tomato Sauce*
- *4 slices mozzarella cheese*
- *Hot cooked pasta*

1. **Cook** chicken in oil in large skillet over medium-high heat, 3 minutes per side or until golden brown; drain.
2. **Pour** undrained diced tomatoes and tomato sauce over chicken; bring to boil. Reduce heat. Cover and simmer 15 minutes or until chicken is no longer pink.
3. **Place** cheese slices over chicken and tomatoes. Cover and cook 1 minute or until cheese is melted. Serve over hot cooked pasta.

*For more Contadina® Italian recipes, visit us at www.contadina.com*

FPO

We'd like to hear from you! Please write to Contadina Consumer Services, P.O. Box 193575, San Francisco, CA 94119-3575, and copy the stamped code from the end of the can – or refer to the code when calling 1-888-668-2847 Monday - Friday 8 a.m. - 5 p.m. Pacific Time.

To maintain product quality after opening, refrigerate in covered glass or plastic container.

0 24000 25306 8

2P 0 1 2 3 4 5 6 7 8 9 0 R 2L
85% OUTSIDE OF LABEL

S&W

*S&W Original Recipe Stewed Tomatoes, made from fresh premium sun-ripened California tomatoes with onion, celery and bell pepper, add a tasty homestyle touch to any meal.*

***S&W – Simply Wonderful*** ™

For a fresh homemade taste, just heat and serve as a delicious side dish, or use for making sauces, stews, soups, chicken and meat dishes.

INGREDIENTS: SLICED TOMATOES, TOMATO JUICE, HIGH FRUCTOSE CORN SYRUP, SALT, DEHYDRATED ONION DEHYDRATED CELERY, DEHYDRATED BELL PEPPER, CALCIUM CHLORIDE, CITRIC ACID AND NATURAL FLAVORINGS

© 2001 DISTRIBUTED BY
S&W FINE FOODS, INC.
SAN FRANCISCO, CA
94105.
PRODUCT OF U.S.A.

TO MAINTAIN PRODUCT QUALITY AFTER OPENING REFRIGERATE IN GLASS OR PLASTIC CONTAINER

0 11194 36723 7

SW 36723 2L AO 5.01

S&W

# ORIGINAL RECIPE

PREMIUM

## STEWED TOMATOES

Sliced with Bell Pepper & Onion

Net Wt. 14 1/2 oz (411 g)

PREMIUM QUALITY S&W SINCE 1896

## Nutrition Facts

Serving Size 1/2 cup (123g)
Servings Per Container about 3 1/2

**Amount Per Serving**

**Calories** 35 Calories from Fat 0

| | % Daily Value* |
|---|---|
| **Total Fat** 0g | 0% |
| Saturated Fat 0g | 0% |
| **Cholesterol** 0mg | 0% |
| **Sodium** 270mg | 11% |
| **Potassium** 150mg | 4% |
| **Total Carbohydrate** 7g | 2% |
| Dietary Fiber 2g | 7% |
| Sugars 5g | – |
| **Protein** 1g | |

Vitamin A 10% • Vitamin C 20%
Calcium 4% • Iron 8%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

PLEASE RECYCLE