



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type:  Post Launch Change  Final Version Date: 10/10/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. **Application:**

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):**

**Medical Device Class, if applicable:**

**DUNS:** 11-856-3719

**Proprietary Name (If Applicable) and Established Name:** SoSweet Syrup

**Selling Unit NDC:** 31722-959-01 **Unit of Use NDC:** **UPC:** 031722959017

**UDI** **CVX Code:** **MVX Code:**

**Description:** SoSweet Syrup

**Active Ingredient(s):** Purified water, sucrose, glycerin, sorbitol and flavoring

**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)

**Address:** 800 Centennial Ave, Suite 1 **Address 2:**

**City:** Piscataway **State:** NJ **Zip:** 08854

**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)

**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788

**Product Therapeutic Classification:** Pharmacy compounding vehicle

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?  No

Is this product to be shipped to customers on dry ice?  No

**b. Contact for temperature excursion questions:**

**Name:** Soma Raju

**Number:** 732-529-0423

**Group E-mail:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)

**c. Special regulations for product in any states?**  No

Special returns requirements for this product?  No

**d. Store product (unit of sale) upright?**  No

Protect product (unit of sale) from light?  No

**e. Shelf life:**  Months

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No

If yes, enter class # a product kit?  No

If yes, list NDCs of component parts reverse numbered?  No

co-licensed?  No

latex-free?  Yes

preservative-free?  No

correctional institution block?  No

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Neither**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present** Sugar

**Country of Origin** USA

Is this product covered under the Trade Agreements Act (TAA)?  Yes

**Size:** 473 mL

**Strength:** N/A

**Dosage Form:** Clear syrup

**Product Shape:** N/A

**Product Color:** Colorless

**Product Imprint:** N/A

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In

**What is the NDC selling unit?** 1 Bottle of 473 mL Syrup (Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

Each

Inner/Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:** None

**II. Generic Equivalent to What Brand?:** Ora-Sweet

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**

**Rx billing unit to pharmacy:**

Each

Gram

Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?**  Yes

**Is product exempt from DSCSA?**  Yes

**If yes, select exemption:** Other exemption: (Write in) OTC product exempt from DSCSA

**Other exemption - Write in:**

**Is product repackaged?**  No

**Is product sold by manufacturer's exclusive distributor?**  Yes

**Has FDA granted waiver/exception/exemption for product?**  No

**If yes, attach documentation from FDA.**

**GLN:** 0331722498975

**GCP:**

**If yes, was original product purchased direct from mfr?**

**Provide source manufacturer for repackaged product**

## ITEM AND PACKING INFORMATION

| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                               |             | Depth                  | Width | Height |               |                   |
| Box/Carton/Bundle/Inner Pack: | 1.4         | 2.76                   | 2.76  | 7      | 53.32         | 1                 |
| Case:                         | 8.85        | 8.25                   | 6.25  | 8.5    | 438.28        | 6                 |
| Pallet:                       |             |                        |       |        |               |                   |

## GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure                              | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|-------------------|-------|---------|---------------------|
| <input checked="" type="checkbox"/> Item/Each         | 1                 |       |         |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |         |                     |
| <input checked="" type="checkbox"/> Case              | 6                 |       |         |                     |
| <input type="checkbox"/> Pallet                       |                   |       |         |                     |

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)** \$17.70

**As of date:** 7/16/2019

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**



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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  No
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- No (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes
- Controlled Substance Code
- Controlled by State(s)?  No  Yes
- Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?:  No

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
If Yes, is it managed with a pharmacy registry?   
Website URL:

Med Guide Required  No  
Limited Distribution Requirement   
Comments / Details: (For example, iPledge program?)

REMS:  No  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:   
Wholesale distributor support:   
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

Registry:  No  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

