

Date: Nov 18, 2024 1:29:35 AM

Section 1 Type of Registration

1a. FOREIGN REGISTRATION

1b. INITIAL REGISTRATION: **13669147832**

PIN NUMBER:hC7x7E66

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? Yes No

1c. PREVIOUS OWNER'S TITLE : PREVIOUS OWNER'S NAME : PREVIOUS OWNER'S REGISTRATION NUMBER :

Section 2 Facility Name/Address Information

FACILITY NAME: ECO DINE MANUFACTURING SOLUTIONS (OPC) PRIVATE LIMITED

FACILITY NAME SUFFIX: Company

FACILITY STREET ADDRESS, Line1: 19-6-t-434 Cozy Corner, Bldg Hoighe Bazar Road, Mangalore Mangalore

FACILITY STREET ADDRESS, Line2:

CITY: Dakshina Kannada

STATE/PROVINCE/TERRITORY: Karnataka

ZIP CODE (POSTAL CODE): 575001

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 974 1923704

FAX NUMBER (Include Area/Country Code): 91 974 1923704

E-MAIL ADDRESS: contact@floraecodine.com

Section 3 Preferred Mailing Address Information

(Complete this section only if different from Section 2, Facility Name/Address Information)

If information is the same as section 2, check the box:

NAME: ECO DINE MANUFACTURING SOLUTIONS (OPC) PRIVATE LIMITED

ADDRESS, Line1: 19-6-t-434 Cozy Corner, Bldg Hoighe Bazar Road, Mangalore Mangalore

ADDRESS, Line2:

CITY: Dakshina Kannada

STATE/PROVINCE/TERRITORY: Karnataka

ZIP CODE (POSTAL CODE): 575001

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 974 1923704

FAX NUMBER (Include Area/Country Code): 91 974 1923704

E-MAIL ADDRESS: contact@floraecodine.com

Section 4 Parent Company Name/Address Information

(If applicable and If different from sections 2 and 3). If information is the same as another section, check which section:

- Section 2 - Facility Address Information
 Section 3 - Preferred Mailing Address Information
 None of the above

NAME OF PARENT COMPANY: ECO DINE MANUFACTURING SOLUTIONS (OPC) PRIVATE LIMITED

PARENT COMPANY SUFFIX: Company

STREET ADDRESS OF PARENT COMPANY, Line 1: 19-6-t-434 Cozy Corner, Bldg Hoighe Bazar Road, Mangalore Mangalore

STREET ADDRESS OF PARENT COMPANY, Line2:

CITY: Dakshina Kannada	STATE/PROVINCE/TERRITORY: Karnataka
ZIP CODE (POSTAL CODE): 575001	
COUNTRY/AREA: INDIA	
PHONE OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): 91 974 1923704	
FAX # OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): 91 974 1923704	
E-MAIL ADDRESS OF INDIVIDUAL AT PARENT COMPANY: contact@floraecodine.com	

Section 5 Emergency Contact Information

For foreign facilities, FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

If information is the same as another section, check which section:

- Same as Facility Address (Section 2)
- Same as U.S. Agent Information (Section 7)
- None of the above

INDIVIDUAL'S TITLE:	INDIVIDUAL'S TITLE OTHER:
INDIVIDUAL'S NAME:	
INDIVIDUAL'S MIDDLE NAME:	
INDIVIDUAL'S LAST NAME:	
TITLE:	
EMERGENCY CONTACT PHONE (Include Area/Country Code): 91 974 1923704	
E-MAIL ADDRESS: contact@floraecodine.com	

Section 6 Trade Names

(If this facility uses trade names other than that listed in section 2 above, list them below (E.G., "also doing business as," "facility also known as")):

ALTERNATE TRADE NAME #1: _____

Section 7 United States Agent

(To be completed by facilities located outside any state or territory of the United States, District Of Columbia, or The Commonwealth of Puerto Rico)

NAME OF U.S. AGENT: AMERICAN REGULATORY COMPLIANCES INC.

ADDRESS, Line 1: 21 BRIDLE PATH RD, Ossining

ADDRESS, Line 2: _____

CITY: Crotonville	STATE: New York
ZIP CODE (POSTAL CODE): 10562	COUNTRY/AREA: UNITED STATES

PHONE NUMBER (Include Area/Country Code): 914 3594972

EMERGENCY CONTACT PHONE NUMBER (Include Area Code): 914 3594972

FAX NUMBER (Include Area/Country Code): _____

EMAIL ADDRESS: info@americancompliances.com

Section 8 Seasonal Facility Dates of Operation

Optional - Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis.

For Harvest 1

Start Month: _____ End Month: _____

For Harvest 2

Start Month: _____ End Month: _____

<input type="checkbox"/>	18. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3													

<input type="checkbox"/>	34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	37. NONE OF THE ABOVE FOOD CATEGORIES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If the food categories listed above do not apply, then print the applicable food category or categories.

NATURALLY COMPOSTABLE ARECA PALM LEAF DISPOSABLE NATURALLY COMPOSTABLE SAL LEAF DISPOSABLE
 NATURALLY COMPOSTABLE BAGASSE (SUGAR CANE PULP) DISPOSABLE BIODEGRADABLE ARECA PALM LEAF PLATES,
 BOWLS, TRAYS

Other Activity Conducted

Section 10 - Owner, Operator or Agent in Charge Information

Provide the following information, If different from all other sections on the form. If information is the same as another section of the form, Check which section:

- Section 2 - Facility Address Information
- Section 3 - Preferred Mailing Address Information
- Section 4 - Parent Company Address Information
- Section 7 - US Agent Address Information

NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE: Mr. Valerian Louis Fernandes

STREET ADDRESS, Line 1: 19-6-t-434 Cozy Corner, Bldg Hoighe Bazar Road, Mangalore Mangalore

STREET ADDRESS, Line 2:

CITY: Dakshina Kannada STATE/PROVINCE/TERRITORY: Karnataka

ZIP CODE (POSTAL CODE): 575001

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 974 1923704

FAX NUMBER (OPTIONAL; Include Area/Country Code): 91 974 1923704

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): contact@floraecodine.com

Section 11 Inspection Statement

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12 Certification Statement

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Name of the Submitter: Mr. Valerian Louis Fernandes

CHECK ONE BOX



A. OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)



B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line1: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line2: -N/A-

CITY: -N/A-

STATE/PROVINCE/TERRITORY: -N/A-

ZIP CODE (POSTAL CODE): -N/A-

COUNTRY/AREA: -N/A-

PHONE NUMBER (Include Area/Country Code): -N/A-

FAX NUMBER (Optional; Include Area/Country Code): -N/A-

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): -N/A-
