



## Ice Cream Color

### Product Data Sheet

Version: 1 DS US EN 02-10-2021

#### Description

Ice Cream Color is a reddish brown, dark liquid, produced by extraction of annatto pigments from the seeds of the annatto tree ( *Bixa orellana* L.) using aqueous potassium hydroxide. The major coloring principle is norbixin.

#### Material no:

70445

#### Ingredients:

Water, Annatto extract, Potassium hydroxide.

#### Raw Material; Source; Origin; Function

Water; Water; North America; Carrier

Annatto extract; Norbixin; Annatto seed; Africa/South America/North America; Color

Potassium hydroxide; Synthetic; North America; Acidity regulator

#### Palm Oil

The ingredients used for this product are not derived from palm oil.

#### Contaminants

This product meets the US Regulations in the Code of Federal Regulations (CFR) and FCC monographs for heavy metals (where applicable). Pesticides are listed in 40 CFR.

#### Enzymes

No enzymes used in the production of this product.

#### Natural status

According to existing US regulations there is no definition of the naturalness of colors. Therefore Oterra has established a position on naturalness of colors based on NATCOL (Position on the Definition of the term "Natural color") and CODEX positions.

#### Product Status: Natural derived color (N2)

This is a color substance that is derived from plant, animal, mineral or microbiological source. The color substance is derived through traditional processing and/or appropriate physical processing (including distillation and solvent extraction).

The process does not modify the chemical nature of the chromophore of the coloring substance, however, intentionally renders the color substance more suitable for use in targeted food applications.

(Above refers to the NATCOL Position on the Definition of the term 'Nature derived color')

#### Microbiological method references

Total Viable Count = CMMEF Chapter 8.72

Total Yeasts and Moulds = BAM Chapter 18



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Total Enterobacteriaceae = CMMEF Chapter 9.62  
Aerobic Sporeforming Bacteria = AACC 42-40 mod.  
Sulphite reducing clostridia = ISO 15213  
Salmonella sp. = AOAC 2013.01 - VIDAS  
Listeria monocytogenes = AOAC 2013.10 – VIDAS  
E. coli = CMMEF Chapter 9.933  
S. aureus = BAM Chapter 12

Tested according to monitoring plan

## California Proposition 65

Oterra colors comply with the State of California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as Proposition 65. This product does not contain levels of contaminants or by-products that require a warning label.

## Non-irradiation

Oterra hereby declares that our color products have not been irradiated in its manufacturing.

## Sewage sludge

Oterra hereby declares that our color products are free of sewage sludge.

## BSE / TSE

The raw materials used for this product do not represent a risk regarding Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

## Production site

Manufactured by Oterra, LLC, USA

## Supplier's certifications

Certifying body Bureau Veritas (BVC): FSSC 22000

## GMP practices

Each production and warehouse site must maintain local GMPs and Food Safety procedures and comply with local regulations. These guiding principles are based on the Global Food Safety Initiative requirements as related to FSSC 22000, TS 22002-1, ISO 22000, Codex Alimentarius Food Hygiene, plus our customers' and our own demands concerning food hygiene and food safety.

## Pasteurization

This product has not been pasteurized. Please refer to the Flow Sheet document for further information of the process.

## Foreign bodies

Filter: Max 2 mm

## Packaging

**Size** 4x1 US GAL

**Type** 4X1 Gallon Case

## Characteristics



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Material used for packaging: Cardboard box with divider and 4x1 gal White HDPE bottles with cap  
Empty tare weight of packaging: app. 1198 g (2.61 lb)  
Dimensions of box: 12.5 in x 12.5 in x 12.5 in  
Height pallet: Stable height is 4 boxes  
Number of boxes/pallet: 9 boxes in one layer x 4 layers.  
Max 36 boxes/pallet.

US pallet (Wood) 40 in x 48 in x 5 in + plastic wrapping.



Conversion factors: (weight) 1 KG = 2.20462 LB or 1 G = 0.00220462 LB; (length) 1 mm = 0.0393701 inches.

### Batch number information

5-10 digit code produced by ERP (SAP) system. No intelligence attribute to the code. We have defined a global procedure for batch tracing and it will be conducted within 8 hours.

### Remaining shelf life

Total shelf life less than 8 months: 50 % left of shelf life upon delivery is guaranteed.

Total shelf life more than 8 months: At least 4 months left at the time of delivery

### Shelf life after opening the containers

If products are opened or kept at other temperatures than recommended, Oterra cannot guarantee full shelf life and quality of the product.

However, to the best of our knowledge and based on our expertise, products containing preservatives, acetic acid or our OS-products can normally be kept at ambient temperature for a couple of days. All other products should be kept cold and used within 1-2 days. Please contact your Oterra representative for such requests.

### Headquarters:

Oterra A/S  
Agern Allé 24  
DK-2970 Horsholm



## **Ice Cream Color**

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Tel. +45 35 15 56 00

### **US office:**

Oterra, LLC

9015 W Maple St

Milwaukee, WI 53214

Tel. 414-607-5700

Customer service: 888-289-2218

### **Emergency number**

24/7 number is +45 35 15 56 00.

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## Ice Cream Color

### Product Information

Version: 1 PI US EN 02-05-2022

#### Description

Ice Cream Color is a reddish brown, dark liquid, produced by extraction of annatto pigments from the seeds of the annatto tree (*Bixa orellana* L.) using aqueous potassium hydroxide. The major coloring principle is norbixin.

#### Packaging:

**Material no:**  
70445

**Size:**  
4x1 US GAL

**Type:**  
4X1 Gallon Case

#### Physical Properties

**Color:** Reddish brown

**Form:** Liquid

**Solubility:** Water soluble

#### Application

**Usage**  
Foods generally.

Please consult Chapter 21 of the CFR for current legislation, as restrictions within specific food applications may apply. Legislations are not globally harmonized, therefore it is advised to consult regulations for the intended market against final application.

Depending upon the application, processing and quantity used, this color can yield shades from yellow to orange.

#### Directions for use

Mix thoroughly before use, as pigment may settle during storage. Can be added directly to the food product or diluted in soft/distilled water, depending upon the application. Do not mix with calcium salts.

#### Storage and handling

**Temperature:** 4 - 8 °C / 39 - 46 °F  
**Conditions:** Cool, Protect from light

**Ambient transport preferred, refrigerated transport allowed.**

#### Shelf life

183 days in unopened containers at 39 – 46°F (4 – 8°C). This color may be stored at 50 – 86°F (10 – 30°C), but the pigment strength may be decreased. This does not pose a food safety risk.



## Ice Cream Color

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### Technical Data

#### Strength:

Annatto/norbixin:

1.05 - 1.15%

#### pH:

12.40 - 12.80 (10% w/w liquid in dem. water)

#### Relative density:

1.00 - 1.10

#### Odor:

Characteristic

Microbiological quality	
Total Viable Count:	≤ 1000 cfu/g
Total Yeasts and Moulds:	≤ 100 cfu/g
Total Enterobacteriaceae:	≤ 10 cfu/g
Aerobic Sporeforming Bacteria:	No specification available
Sulphite reducing clostridia:	No specification available

Pathogens	
<i>Salmonella sp.:</i>	Absent in 375g
<i>Listeria monocytogenes:</i>	Absent in 25g
<i>E. coli:</i>	Absent in 1 g
<i>S. aureus:</i>	Absent in 1 g

### Legislation

This color is in full compliance with 21 CFR Part 73.30 and is approved for use in food. It is exempt from certification.

### Ingredients

Water, Annatto extract, Potassium hydroxide.

### Labeling

Labeling of this product for the ingredient statement should be according to the FDA regulations, 21CFR 101.22. For example: annatto extract (color); colored with annatto extract.

### California Proposition 65

Oterra colors comply with the State of California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as Proposition 65. This product does not contain levels of contaminants or by-products that require a warning label.

### Dietary status

Kosher:

Kosher Pareve Incl. Passover

Halal:

Certified

Vegetarian:

Yes

### Technical support

Oterra's Application and Product Development Laboratories and personnel are available if you need further information.