DDWilliamson
Color With Confidence

To: Program Manager, USDA/AMS/TM/NOP
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From: Official Contact
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Purpose of request:

Technical Correction to § 205.606 beta-Carotene annotation

Item A
Petition to amend § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic"
(d) Colors derived from agricultural products;

from (3) beta-Carotene extract color, derived from carrots (CAS # 1393–63–1)

to (3) beta-Carotene extract color, derived from carrots or algae (CAS # 7235-40-7).

Justification:
In January 2007 D.D. Williamson and colorMaker petitioned to add beta-Carotene to § 205.606 of the National List. At that time, we requested the annotation "from carrots" and referenced two CAS numbers for beta-Carotene (1393-63-1) and (7235-40-7). We referenced (1393-63-1) in error as it is the CAS number for Annatto Extract not beta-Carotene.

Furthermore, our research over the past few years shows that at this time the only source of beta-Carotene that can be extracted using NOP compliant / nonsynthetic methods is algae. The algae derived beta-Carotene uses extraction methods of carbon dioxide (CO2), ethanol, or vegetable oil.

We request that you change the annotation to include "algae" as extracting beta-Carotene from carrots without the use of synthetic extraction solvents has proven to be difficult if not impossible.

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Chemical Name:	Annatto
Byname:	Annatto extract
CAS#:	1393-63-1

beta Carotene

Molecular Formula:	$C_{40}H_{56}$
Molecular Weight:	536.88 g/mol
Cas Number:	7235-40-7

Item B
Since beta-carotene derived from carrots has already been accepted onto the National List, responses in this section will focus on beta-carotene derived from algae.

1. **The substance's chemical or material common name.**
   Empirical Formula: $C_{40}H_{56}$ (carotenes)
   β, β-carotene (major component)
   natural β-carotene
   Beta-carotene
   carotenes (algae)
   mixed carotenes (algal carotenes)

2. **The manufacturer's name, address and telephone number.**
   CBI-deleted

3. **The intended or current use of the substance.**
   Beta-Carotene extract color derived from algae is an agricultural ingredient that would be used to color food and beverage products including, but not limited to, yogurts, dairy beverages, ice cream, pudding, confectionery, bakery products, and condiments.

4. **This substance will not be used for crop or livestock, handling or processing activities.**

5. **The source of the substance and a detailed description of its manufacturing or processing procedures.**
Beta-Carotene produced from natural strains of the algae *Dunaliella salina*, which is an algae grown in large saline lakes located in Whyalla, South Australia. Beta-Carotene is extracted from the algae using carbon dioxide (CO2), ethanol, or vegetable oil. Not less than 96 % total extracted coloring matters will be in the form of beta-Carotene.

6. **A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.**

There are many government reviews of beta-Carotene, and carotenoids in general have been used since antiquity to color human food.

Canadian Organic Regime – Permitted Substance List
Section 6.4 of Permitted Substance List - Colouring, natural – From non-synthetic sources only and shall not be produced using synthetic solvents and carrier systems or any artificial preservative.

The European Union (EU) recognizes beta-carotene derived from algae as 'algal carotenes', classified as E 160a (i) and allowed for use in most foods pursuant to 94/36/EC.

The United States Food and Drug Administration (FDA) recognizes both natural and synthetic forms of beta-Carotene as a color additive exempt from certification allowed for use in foods pursuant to 21 CFR 73.95. The FDA does not specify the natural sources from which natural beta-carotene can be derived.

The Food Chemical Codex (FCC) has developed a monograph for beta-Carotene. The monograph does not differentiate between natural or synthetic forms of beta-Carotene.

Japan Ministry of Health and Welfare (MHLW) recognizes beta-Carotene derived from algae as 'Dunaliella carotene', a food additive of natural origin, according to the List of Existing Food Additives.

The Joint FAO/WHO expert Committee on Food Additives (JECFA) has developed a monograph for beta-Carotene derived from algae, 'carotenes (algae)'.

7. **Information regarding EPA, FDA, and State Regulations.**
The United States Food and Drug Administration (FDA) recognizes both natural and synthetic forms of beta-Carotene as a color additive exempt from certification allowed for use in foods pursuant to 21 CFR 73.95. The FDA does not specify the natural sources from which natural beta-Carotene can be derived.

8. **The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contain the petitioned substance.**
The CAS Number for beta-Carotene is 7235-40-7. The **E**uropean **IN**ventory of **E**xisting **C**ommercial chemical **S**ubstances (EINECS) number for beta-Carotene is 230-636-6. In addition, the JECFA Monograph for beta-Carotene references the following additional numbers affiliated with beta-Carotene derived from algae, CODEX INS No. 160a(ii); CI (1975) No. 75130; CI (1975) No. 40800 (ß-Carotene).

   See attached examples of labels for products containing beta-Carotene.

9. **The substance's physical properties and chemical mode of action.**
Chemical formula: C40H56 (ß-Carotene)
Formula weight: 536.88 (ß-Carotene)
Description: Red to brown-ish red crystals usually solubilized in oil and sometimes suspended with emulsifiers to create a yellow to orange liquid

   Carotenes (algae) can be obtained by carbon dioxide (C02), ethanol, and vegetable oil extraction of the dried *Dunaliellasalina* (syn. *D. bardawil* and *D. Kone*). The main coloring principles are *trans*and *cis* -ß-carotene together with minor amounts of other carotenoids such asalpha-carotene and xanthophylls. Besides the color pigments, carotenes(algae) may contain lipids, naturally occurring in the source material, food grade vegetable oil, emulsifiers, and tocopherol added to retard oxidation of the pigment.

   The only NOP compliant solvents used for the extraction are carbon dioxide, ethanol, and vegetable oil. The main articles of commerce are suspensions in food grade vegetable oil or the liquids in oil made dispersible in water using food grade emulsifiers.

   The carotenoids extracted from algae are distinct and unique molecules. They are different from anthocyanins and betalains (other molecules used as natural colorings). Carotenoids are sensitive to light and heat, degrading rapidly under hight heat and/or direct sunlight. In addition, carotenoids display very strong antioxidant properties which now appear beneficial to human health. Beyond these unique properties, carotenoids do not interact with substances used in organic food production and have no impact on the environment.

Naturally derived beta-Carotene has been consumed for centuries and its consumption has the exact same impact upon the environment as organically grown, biodegradable fruits and vegetables.

10. **Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies**.
Please see the attached Material Safety Data Sheet (MSDS) and report from the National Toxicology Program (The National Institute of Environmental Health Sciences is one of the National Institutes of Health within the U.S. Department of Health and Human Services. The National Toxicology Program is headquartered on the NIEHS campus in Research Triangle Park, NC.).

11. **Research information about the substance.**
See the attached Bibliography. There are several leading researchers on carotenoids in the US including Minhthy L. Nguyen (formerly of Ohio State University, Columbus) and Steven J. Schwartz (Ohio State University, Columbus). In addition, there are many government reviews of beta-carotene, and carotenoids in general have been used since antiquity to color human food.

12. **(G) Justification Statements.**
(see above)

Respectfully Submitted,

D.D. WILLIAMSON & CO., INC.
A Kentucky corporation

By: Jennifer R. Guild
Jennifer R. Guild
(Name & Title)

COLORMAKER, INC.,
a California corporation

By: Stephen J. Lauro
(Name & Title)

Bibliography

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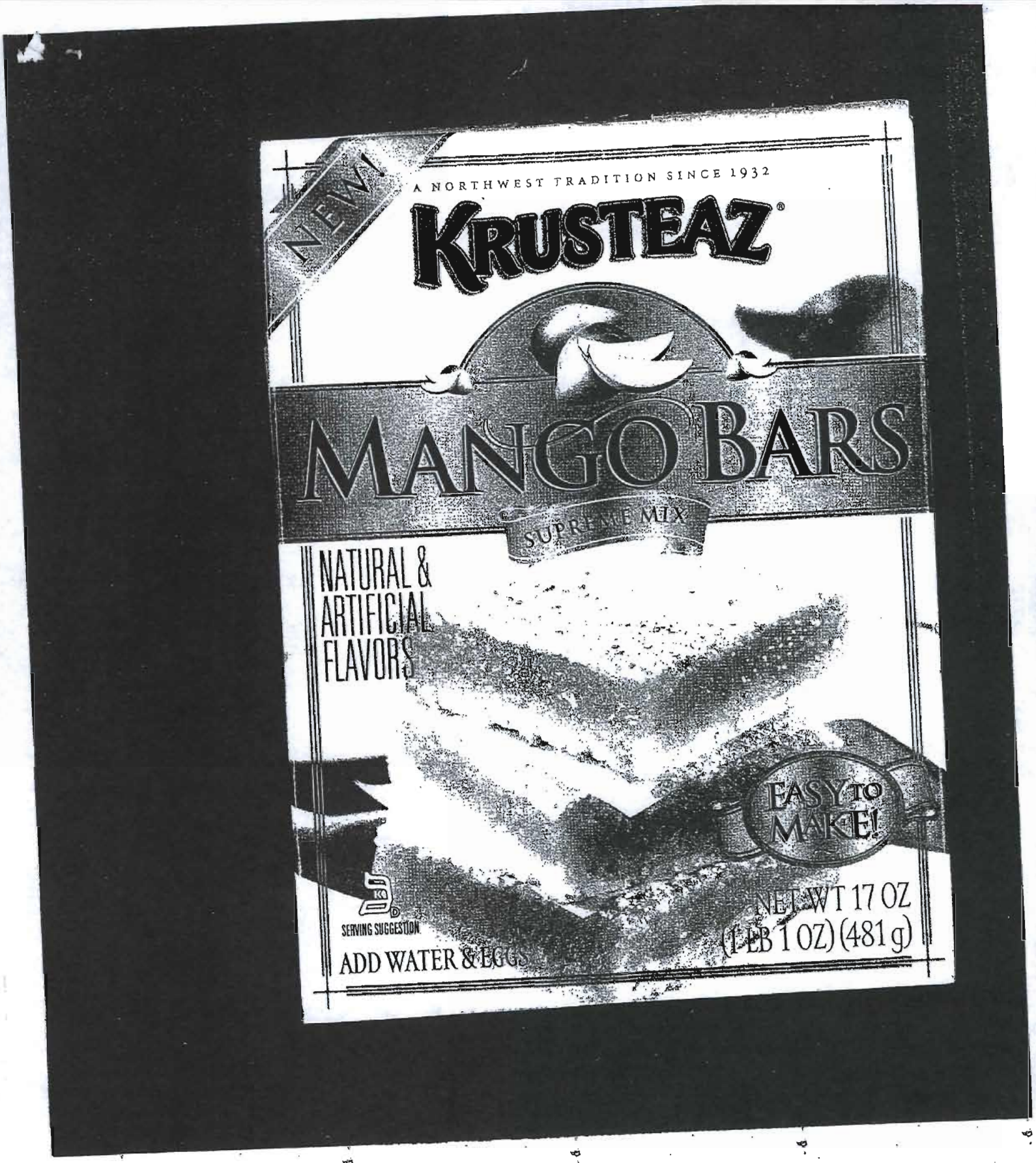
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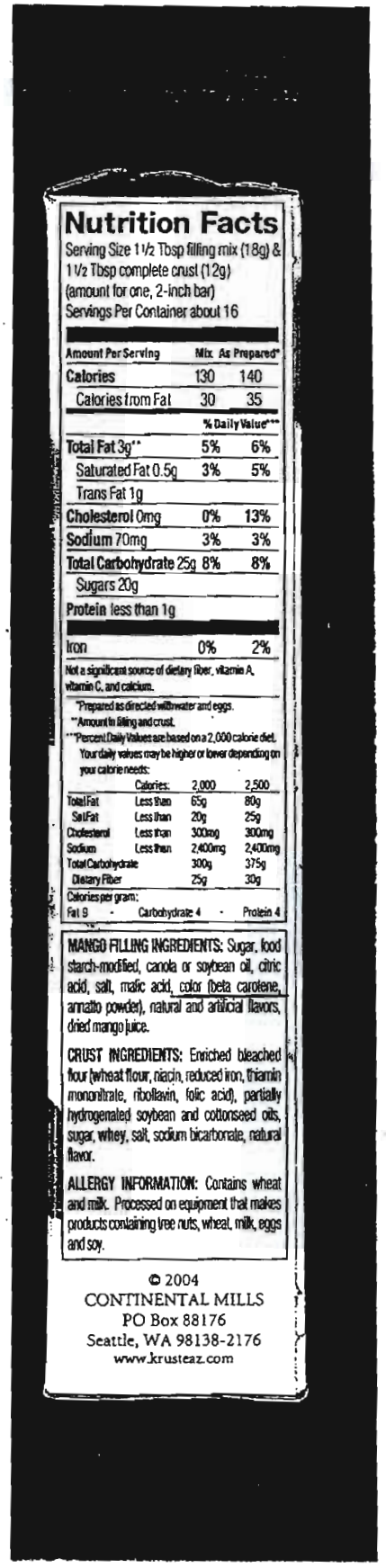

Nutrition Facts

Serving Size 1 1/2 Tbsp filling mix (18g) & 1 1/2 Tbsp complete crust (12g) (amount for one, 2-inch bar)
Servings Per Container about 16

Amount Per Serving	Mix	As Prepared*
Calories	130	140
Calories from Fat	30	35
		% Daily Value* **
Total Fat 3g**	5%	6%
Saturated Fat 0.5g	3%	5%
Trans Fat 1g		
Cholesterol 0mg	0%	13%
Sodium 70mg	3%	3%
Total Carbohydrate 25g	8%	8%
Sugars 20g		
Protein less than 1g		
Iron	0%	2%

Not a significant source of dietary fiber, vitamin A, vitamin C, and calcium.

*Prepared as directed with water and eggs.
**Amount in filling and crust.
***Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 · Carbohydrate 4 · Protein 4

MANGO FILLING INGREDIENTS: Sugar, food starch-modified, canola or soybean oil, citric acid, salt, malic acid, color (beta carotene, annatto powder), natural and artificial flavors, dried mango juice.

CRUST INGREDIENTS: Enriched bleached flour (wheat flour, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), partially hydrogenated soybean and cottonseed oils, sugar, whey, salt, sodium bicarbonate, natural flavor.

ALLERGY INFORMATION: Contains wheat and milk. Processed on equipment that makes products containing tree nuts, wheat, milk, eggs and soy.

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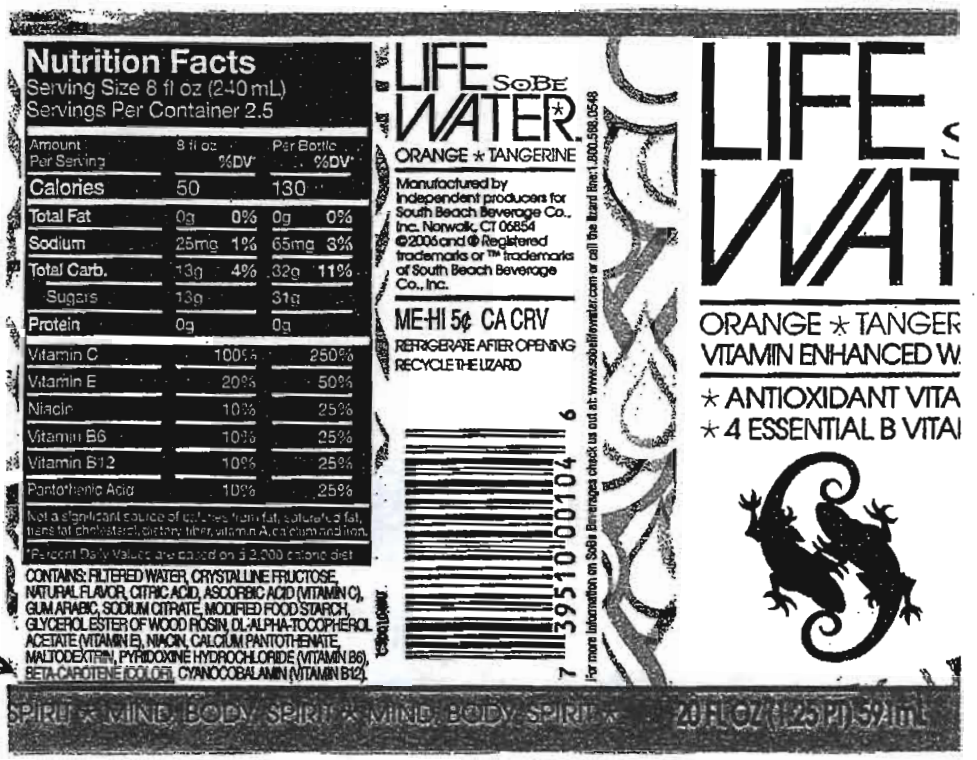

Nutrition Facts

Serving Size 8 fl oz (240 mL)
Servings Per Container 2.5

Amount Per Serving	8 fl oz	%DV*	Per Bottle	%DV*
Calories	50		130	
Total Fat	0g	0%	0g	0%
Sodium	25mg	1%	65mg	3%
Total Carb.	13g	4%	32g	11%
Sugars	13g		31g	
Protein	0g		0g	
Vitamin C		100%		250%
Vitamin E		20%		50%
Niacin		10%		25%
Vitamin B6		10%		25%
Vitamin B12		10%		25%
Pantothenic Acid		10%		25%

Not a significant source of calories, total fat, saturated fat, trans fat, cholesterol, dietary fiber, vitamin A, or calcium and iron.

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

CONTAINS: FILTERED WATER, CRYSTALLINE FRUCTOSE, NATURAL FLAVOR, CITRIC ACID, ASCORBIC ACID (VITAMIN C), GUM ARABIC, SODIUM CITRATE, MODIFIED FOOD STARCH, GLYCEROL ESTER OF WOOD ROSIN, DL-ALPHA-TOCOPHEROL ACETATE (VITAMIN E), NIACIN, CALCIUM PANTOTHENATE, MALTODEXTRIN, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6), BETA-CAROTENE (COLOR), CYANOCOBALAMIN (VITAMIN B12).

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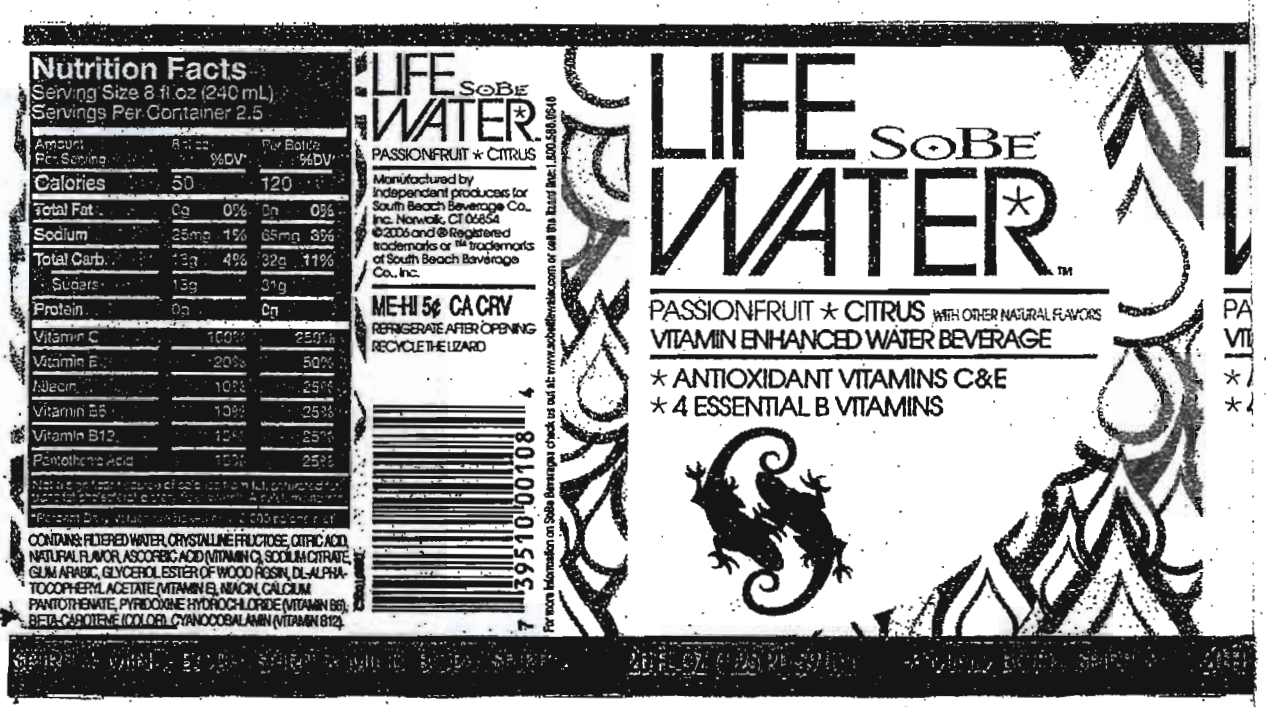
SPIRIT * MIND, BODY, SPIRIT * MIND, BODY, SPIRIT * 20 FL OZ (1.25 PT) 592 mL


Nutrition Facts
Serving Size 8 fl oz (240 mL)
Servings Per Container 2.5
Amount Per Serving
8 fl oz
%DV*
Per Bottle
%DV*
Calories
50
120
Total Fat
0g
0%
0g
0%
Sodium
25mg
1%
65mg
3%
Total Carb.
13g
4%
32g
11%
Sugars
13g
31g
Protein
0g
0g
Vitamin C
100%
250%
Vitamin E
20%
50%
Niacin
10%
25%
Vitamin B6
10%
25%
Vitamin B12
10%
25%
Pantothenic Acid
10%
25%
CONTAINS: FILTERED WATER, CRYSTALLINE FRUCTOSE, CITRIC ACID, NATURAL FLAVOR, ASCORBIC ACID (VITAMIN C), SODIUM CITRATE, GUM ARABIC, GLYCEROL ESTER OF WOOD ROSIN, DL-ALPHA-TOCOPHERYL ACETATE (VITAMIN E), NIACIN, CALCIUM PANTOTHENATE, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6), BETA-CAROTENE (COLOR), CYANOCOBALAMIN (VITAMIN B12).
LIFE SoBe WATER*
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MATERIAL SAFETY DATA SHEET

Rev.:01

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name and Code	Natural Carotene WD 20 AP	483001
Chemical name	β-carotene	
Chemical Formula	$C_{40}H_{56}$ (carotenes)	
Supplier	D.D. Williamson Ireland Ltd. Little Island Business Park Co. Cork Ireland Tel: +353 21 4353821 Fax: +353 21 4354328	
Emergency Telephone Number	+353 21 4353821	

2. COMPOSITION / INFORMATION ON INGREDIENTS

Natural Carotene WD 20 AP is the extract of natural carotenoids; rendered water soluble using a blend of maltodextrin, modified starch, sugar and MCT oil. Dl-α-tocopherol & ascorbic acid are added as anti-oxidants.

Ingredient	Colour Index No.	CAS No.	EINECS No.
β-carotene	75120	33261-80-20	251-431-8

3. HAZARDS IDENTIFICATION

Health hazards	None identified
Physical / chemical hazards	None identified
Environment hazards	None identified

4. FIRST AID MEASURES

Ingestion	Rinse mouth with water. Drink at least 250ml of milk or water for dilution. Do not induce vomiting. In severe cases obtain medical attention.
Inhalation	Remove to fresh air. In the event that there is a reaction to this product, keep at rest and seek medical attention.
Skin contact	Colour may stain the skin but is harmless, once the skin has been washed. Remove contaminated clothing. Wash affected areas with warm water and mild detergent, and rinse well to alkalinity removed. In case of persisting irritation, obtain medical attention.
Eyes contact	Flush eyes with plenty of clean water with eyelids held wide open for at least 15 minutes. It is advisable to seek medical attention.

5. FIRE-FIGHTING MEASURES

Extinguishing media	CO_2, foam, dry chemicals, water.
Hazardous thermal Decomposition products	None identified
Special measures	For fires involving this material do not enter any enclosed or confined fire space without proper protective clothing and equipment.
Specific hazards	None identified.
Protection of fire-fighters	Protective clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Use appropriate personal protection (see section 8)
Environmental precautions	If the substance has contaminated surface water, inform the local authorities.
Small spillages	Per large spillages, or may be flushed with large volumes of water, (avoiding splashing and aerosols), provided the washings do not enter natural waterways directly.
Large spillages	Should be contained by the use of sand or other inert material, transferred to a suitable container and disposed of in compliance with local by-laws.

7. HANDLING AND STORAGE

Handling	Wear the recommended protective clothing and equipment.
Storage	Store in the original container in a cool location and protected from exposure to air, heat and light.
Shelf life	Minimum 9 months.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General precautions	Handle in accordance with good occupational hygiene and safety practices. Avoid contact with skin and eyes.
Ventilation	Good local ventilation.
Respiratory protection	Use suitable dust mask or breathing apparatus where aerosols created.
Eye protection	Splash goggles and or visor
Skin protection	Work clothing and rubber or vinyl gloves.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	A deep orange mobile liquid.
Odour	Faint odour
pH	~4
Flash point (°C)	>100°C
Auto-flammability	Not applicable
Boiling point	~100°C
Melting point	Not applicable
Vapour pressure	Not available
Specific gravity	1.05 ± 0.02
Solubility	Dispersible in water

10. STABILITY AND REACTIVITY

Stability	Stable under normal conditions (see section 7. for recommendations on handling and storage)
Conditions to avoid	None identified.
Materials to avoid	Contact with acidic media and strong oxidising agents.
Hazardous combustion or decomposition products	Not to be expected.

11. TOXICOLOGICAL INFORMATION

Approved for use in foods by EC.

12. ECOLOGICAL INFORMATION

Natural Carotene WD 20 AP is biodegradable. Do not allow to enter natural waterways.

13. DISPOSAL PROCEDURES

Waste disposal method	Sanitation landfill or incineration in accordance with local, state and federal regulations.
Treatment of empty containers	As above

14. TRANSPORT INFORMATION

Not classified as dangerous according to EU regulations.

UN-number not assigned	CEFIC-code not assigned
ADR Class not classified	Hazard label nr not assigned
IMDG-code not classified	Kemler code not assigned
RID-code not classified	IATO/ICAO-code not classified

15. REGULATORY INFORMATION

This product complies with the EC (E 160a) directive.

16. OTHER INFORMATION

The above information is based on current knowledge at the time of publication and is given in good faith. D.D. Williamson implies no warranty as to the suitability of the product for any particular purpose. Purchasers should make their own tests to determine the suitability of the product for a particular purpose. Reference should be made to a Product Data Sheet regarding the Quality or Specification of the product.

The information contained in this data sheet does not constitute an assessment of workplace risks. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use.

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