

# GNT

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2007 JAN 15 A 8:40

## **National List Petition For Hibiscus Juice Color**

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Hibiscus Juice Color

January 12, 2007

GNT USA, Inc. ▪ 660 White Plains Road ▪ Tarrytown, New York 10591  
Telephone 914.524.0600 ▪ Telefax 914.524.0681 ▪ [www.gntusa.com](http://www.gntusa.com)



GNT USA, Inc.  
660 White Plains Road  
Tarrytown, NY 10591

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January 12, 2007

Robert L. Pooler  
USDA/AMS/T&M/ National Organic Program  
Agricultural Marketing Specialist  
Room 4008-S, Ag Stop 0268  
1400 Independence Avenue, SW  
Washington, DC 20250

Subject: National List Petition Submission for Hibiscus Juice Color.

Dear Mr. Pooler:

GNT USA Inc. is petitioning hibiscus juice color for inclusion on the National List under Section 205.606:

Agricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)".

Hibiscus juice color is classified by the F.D.A as "exempt from certification" under 21CFR73.250, fruit juice color.

The proposed criteria for this category are as follow:

- The colors have to be manufactured from hibiscus
- The process has to be exclusively physical without any synthetic aid or adjuvant.
- The production methods have to be certified organic under the USDA-NOP standards.

Attached, please find the completed forms as well as the Material Safety Data Sheet, the Statement on Residue and the Organic Production Methods Certificate for hibiscus juice color.

If further information is required, please contact our main office in Tarrytown, New York at 914.524.0600.

Sincerely,

Amelie Hayte

Hibiscus Juice Color – January 12, 2007

1

The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

## Hibiscus Juice Color

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### ITEM A

The substance is being petitioned for inclusion on the National List under Section 205.606:

Non-organic agricultural substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

### ITEM B

1. Hibiscus Juice Color

2. Manufactured by:

GNT Nederland B.V.  
Industrieweg 26  
5731 HR Mierlo  
The Netherlands  
+31-492-663952

3. Intended and current use of the substance:

Food ingredient having coloring properties

4. The substance is being used as a food ingredient having coloring properties in diverse foods and beverages. The substance is added during the processing of the food product to impart color throughout the shelf life of the product.

## Hibiscus Juice Color

5. The source of the food ingredient is hibiscus.

The production process is on an entirely physical basis such as crushing, pressing, filtering and concentration by vacuum evaporation. Water, invert sugar and citric acid may be added during the manufacturing process.

6. Reviews by State, private certification programs or organizations:

GNT Nederland B.V., the production site of GNT Group, is under review and/or certification of the following organizations

- Dutch Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit - VWA)
- DNV Nederland - certification body for ISO 9001:2000, Dutch HACCP and GMP
- Skal Certification Organic Production - organic production and certification in the Netherlands are based on the EU-regulation (EEC) nr. 2092/91
- Skal Control Union World Group - organic production and certification in the Netherlands according to USDA Organic and NOP

7. FDA registration number: 18189116412

8. The Chemical Abstract Service (CAS) is not applicable.

The substance falls under the F.D.A regulation for “colors exempt from certification” 21CFR73.250, fruit juice color.

## **Hibiscus Juice Color**

9. N/A. The substance is intended for food application. It is 100% natural and is not formulated or processed with any synthetic aid or adjuvant
  10. See enclosed Material Safety Data Sheet (MSDS)
  11. The substance is made from hibiscus, which has a well-known history of consumption and which is Generally Recognized As Safe (GRAS).
  12. Petition Justification Statement
- G. Inclusion of a non-organically produced agricultural substance onto the National List, 205.606.

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## Hibiscus Juice Color

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Hibiscus Juice Color

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		✓		The substance is not synthetic. It is derived from hibiscus only, processed by physical means like crushing, pressing, filtering and concentration by vacuum evaporation (See attached process flow chart). During the processing, no chemical solvents are used. The production is GMP certified and organic wastes are used for animal feed according to specific EC legislation related to the animal feed sector.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		✓		All raw materials and processing adjuvant are derived from all-natural sources. The production methods are certified organic under the USDA-NOP standards. (See attached certificate)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		✓		The substance is manufactured from natural sources only and is therefore not harmful to the environment.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			✓	The substance contains only the natural constituents of the processed hibiscus. Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		✓		There is no indication for detrimental chemical interaction of hibiscus extracts with other materials.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			✓	This substance is intended for food application
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			✓	This substance is intended for food application
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		✓		The substance is from natural sources only (hibiscus, citric acid, invert sugar, water). Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		✓		This substance is intended for food application. In case of accident-caused release the products are completely biodegradable.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		✓		The substance is actually beneficial for human health. It is fruit based and rich in antioxidants like e.g. anthocyanins.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		✓		The substance is manufactured from natural sources that have been consumed for years on a daily basis. Furthermore, the raw materials are known to have beneficial effects on human health.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		✓		Currently, there is no GRAS exemption for color additives. For the F.D.A., all colors are considered artificial and are categorized under "certified" or "exempt from certification".
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		✓		See attached statement on residues

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production?** Substance Hibiscus Juice Color

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		✓		The substance is formulated from natural sources only and is processed only with water and physical processing. The production methods are certified organic under the USDA-NOP standards.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		✓		The process is not intended to chemically change the substance. The hibiscus is concentrated with the help of water and physical processing. Therefore, the properties of the substance are similar to the properties of the fruit.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		✓		The substance itself does not occur naturally, but it only contains natural constituents of the processed hibiscus.
4. Is there a natural source of the substance? [§205.600 b.1]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant
5. Is there an organic substitute? [§205.600 b.1]		✓		The amount of raw materials that is processed for hibiscus juice color is not commercially available as organic. A period of 10 years has been estimated as a minimum to be able to produce organically the amount of raw materials necessary.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	✓			The substance is 100% natural but cannot be produced organically yet, as the raw materials are not commercially available as organic. Only The production methods are certified organic under the USDA-NOP standards. (see attached certificate)
9. Is there any alternative substances? [§6518 m.6]		✓		All other colors "exempt from certification" are non-organic and are processed or formulated with the aid of synthetic substances. To avoid any synthetic ingredients in organic food, only organic, or as an interim solution non-organic, fruit and vegetable juice colors can be used to impact color and partly nutritive values to consumers' food.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		✓		The substance is needed, as no organic color is available yet. Only time is necessary to have enough farmers and lands to produce hibiscus organically in the quantity, quality and form requested by the food industry and the consumers.

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.



**Category 3. Is the substance compatible with organic production practices?**

Substance Hibiscus Juice Color

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	✓			The substance is currently used in organic products. E.g. organic yogurt, ice cream, juices, dried fruits, etc.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			✓	The substance is from natural sources only and does not contain any synthetic ingredients or processing aid like solvents or emulsifiers. The production methods are certified organic under the USDA-NOP standards.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	✓			Since the substance is derived only from natural sources it is compatible with sustainable agriculture and production.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	✓			The substance does contain almost all natural and valuable constituents of the processed hibiscus.
5. Is the primary use as a preservative? [§205.600 b.4]		✓		This is not a preservative
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			✓	This substance is not formulated or processed with any synthetic aid or adjuvant. This is a food having coloring properties.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;		✓		
b. toxins derived from bacteria;		✓		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		✓		
d. livestock parasiticides and medicines?		✓		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		✓		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

# NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____	Substance: _____																
<p><b>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right; font-weight: bold;">Criteria Satisfied?</td> </tr> <tr> <td>1. Impact on humans and environment</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility &amp; consistency</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)								
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<p><b>B. Substance fails criteria?</b></p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p><b>C. Proposed Annotation:</b> _____</p> <p>_____</p> <p><b>Basis for annotation:</b></p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																
<p><b>D. Final Board Action &amp; Vote:</b> Motion by: _____ Second: _____</p> <p><b>Vote:</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> <td></td> </tr> <tr> <td>Allowed<sup>1</sup></td> <td>Prohibited<sup>2</sup></td> <td>Handling</td> <td></td> </tr> <tr> <td>No restriction</td> <td>Deferred<sup>4</sup></td> <td>Rejected<sup>3</sup></td> <td></td> </tr> </table> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p> <p style="text-align: center;">1—substance voted to be added as "allowed" on National List</p> <p>Annotation: _____</p> <p style="text-align: center;">2—substance to be added to "prohibited" paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p style="text-align: center;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="text-align: center;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____</p>		Agricultural	Nonagricultural	Crops		Synthetic	Not synthetic	Livestock		Allowed <sup>1</sup>	Prohibited <sup>2</sup>	Handling		No restriction	Deferred <sup>4</sup>	Rejected <sup>3</sup>	
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<p><b>E. Approved by NOSB Chair to transmit to NOP:</b></p> <p>_____</p> <p>Dave Carter, NOSB Chair <span style="float: right;">Date _____</span></p>																	
<p><b>F. NOP Action:</b> Include in FR to amend National List: <input type="checkbox"/></p> <p>Return to NOSB <input type="checkbox"/> Reason: _____</p> <p>_____</p> <p>Richard H. Mathews, Program Manager <span style="float: right;">Date _____</span></p>																	

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____	Substance: _____																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																									
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## STATEMENT ON RESIDUES

**GNT USA Inc.** hereby confirms that:

The raw materials used for EXBERRY® products originate from direct cultivation and suppliers are obliged to comply with the legal European requirements governing the cultivation of fruits and vegetables. Other raw materials of supplying companies have to comply to the current European legislations for the specific material before it is purchased.

### **Pesticides:**

Any pesticide residues left on or in the raw materials designed for the manufacture of EXBERRY® products do not exceed the maximum residue limit specified in *the Council Directive 90/642/EEC of November 27, 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables and its amendments.*

Any pesticide residues in EXBERRY® products do not exceed the maximum residue limits specified in the *Directive 90/642/EEC* (and amendments).

So far, neither organochlorine pesticides nor organophosphorus pesticides have been traced in our products. The same applies to other pesticide residues, with the current limits of determination being as follows:

- ... organochlorine pesticides: 0,001 - 0,005 mg/kg
- ... organophosphorus pesticides: 0,005 - 0,010 mg/kg
- ... other pesticide residues: 0,005 - 0,010 mg/kg

### **Heavy metals:**

Regarding the maximum levels for heavy metals there are no defined maximum levels for EXBERRY® products (fruit and vegetables concentrates) within the European legislation.

Our EXBERRY® products do normally not exceed the following max levels:

Arsenic	< 3 mg/kg
Cadmium	< 1 mg/kg
Mercury	< 1 mg/kg
Lead	< 10 mg/kg
Heavy metals (as lead)	< 40 mg/kg

### **Mycotoxins:**

EXBERRY® products are in compliance with the current European food legislation (*Directive 1525/97/EC, 194/97/EC, etc.*).

To ensure compliance with the above mentioned regulations, all raw materials and semi-finished products designed for the production of EXBERRY® products are regularly screened for pesticide residues, heavy metals and other contaminants.

The frequency of the analyses depends on the processing of the raw materials. The raw materials for EXBERRY® products are normally processed per campaign or season, depending on the amount of processed raw material a certain number of samples are taken and analysed.

Residues statement: EU-31/08/05

**EXBERRY® is a registered Trade Mark of GNT mbH, Germany**

**EXBERRY® Natural Colours are produced by GNT Nederland B.V., Netherlands**

The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

# GNT

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## PROCESS FLOW DIAGRAM

### EXBERRY® Fruit and Vegetable Juice Color

**CONFIDENTIAL**

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Process Flow Diagram No. : USA-not applicable 19/6/06

**EXBERRY® is a registered Trade Mark of GNT International B.V., Netherlands**  
**EXBERRY® is produced by GNT Nederland B.V., Netherlands**

The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

# CERTIFICATE

CERTIFICATE N°: C803789NOP-01.2005  
REGISTRATION N°: SKAL-INT 803789

Field of attention:

**Organic production methods  
USDA-NOP**

Issued to:

**GNT Nederland BV  
Mierlo, NETHERLANDS  
Project in: NETHERLANDS**

Standard:

**The National Organic Programme of the United States Department of Agriculture and Skal  
International Standards**

**Date of certification: 9 November 2005**

Skal International declares to have inspected the unit(s), and/or product(s) of the above mentioned client, and have found them in accordance with the standards mentioned above. This certificate covers the unit(s), and/or product(s) as mentioned in the authenticated annex of this certificate.

This certificate is in force until further notice, provided that the above-mentioned client continues meeting the conditions as laid down in the client contract with Skal International. Based on the annual inspections that Skal International performs, this certificate is updated and kept into force.

Date of certification:  
9 November 2005

Place and date of issue:  
Zwolle, 9 November 2005



Skal International is officially  
accredited by the United States  
Department of Agriculture

Declared by:

On behalf of the Managing  
Director

Mr. J. Huisman  
Certifier

Skal International  
P.O. Box 161  
8000 AD Zwolle  
The Netherlands  
<http://www.skalint.com>  
tel.: +31(0)38-426.01.00

# MATERIAL SAFETY DATA SHEET

## EXBERRY®

### Generic MSDS for EXBERRY® Products

Product No. : not applicable

May be used to comply with OSHA's Hazard Communication Standard. 29 CFR 1910.1200 Standard must be consulted for specific requirements. If any item is not applicable, or no information is available, the space must be marked to indicate that.

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#### SECTION I. Product Identification

---

Manufacturer's name: **GNT International B.V.**

Telephone number: +31 - (0)492 668141  
Address: P.O. Box 94, 5731 AB Mierlo, The Netherlands

Product name: **EXBERRY® Generic MSDS for EXBERRY®  
Product No. : not applicable**

Botanical family: not applicable  
Formula: Preparation manufactured from:  
fruits invert sugar  
vegetables citric acid

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#### SECTION II. Hazardous ingredients/Identity Information

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Specific chemical identity; CAS #; ACGIH TLV (Units); OSHA PEL (Units); STEL (Units)

Not applicable. Foodstuff.

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#### SECTION III. Physical/Chemical Characteristics

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Boiling point: 215-230 °F  
Vapor pressure: < 50 mbar (70 °F)  
Vapor density (AIR=1): not available  
Solubility in water: soluble

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The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

Appearance and odor:	viscous and aromatic
Specific gravity (H2O=1):	1,28 - 1,38
Percent volatile, by volume (%):	not available
Evaporation rate (butyl acetate=1):	not available (very small)
Freezing point:	less than 0 °F

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#### SECTION IV. Fire and Explosion Hazard Data

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Flash point (method used):	not available
Flammable limits:	not available
LEL:	not available
UEL:	not available
Extinguishing media:	water etc.
Special fire fighting procedures:	not necessary
Unusual fire and explosion hazards:	none known

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#### SECTION V. Reactivity Data

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Stability	
Unstable:	no
Stable:	yes
Conditions to avoid:	not applicable
Incompatibility (materials to avoid):	strong acids and bases, sulfides and sulfites
Hazardous polymerization	
May occur:	no
Will not occur:	certain
Conditions to avoid:	not applicable

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#### SECTION VI. Health Hazard Data

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Route(s) of entry	
Inhalation:	no
Skin:	no
Ingestion:	yes
Health hazards (acute and chronic)	
Carcinogenicity:	no
NTP:	no
LARC monographs:	no
OSHA regulated:	no
Signs and symptoms of exposure:	foodstuff, no health hazards



Medical conditions generally aggravated by exposure:

In case of contact with eyes, remove contact lenses and rinse immediately with plenty of water. Contact physician if irritation persists.

Emergency and first aid procedures:

not necessary

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## SECTION VII. Precautions for Safe Handling and Use

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Steps to be taken in case material is released or spilled: clean with water

Waste disposal method: same as foodstuffs. Observe local, State and Federal Regulations. Do not incinerate sealed containers.

Precautions to be taken in handling and storing: special precautions are not necessary.

Other precautions: not necessary

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## SECTION VIII. Control Measures

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Respiratory protection (specify type)

Ventilation

Local exhaust:	not necessary
Special:	not necessary
Mechanical:	not necessary
Other:	not necessary

Protection gloves: not necessary (strong coloring foodstuff)

Eye protection: not necessary

Other protective clothing or equipment: not necessary

Work/hygienic practices: same as foodstuffs