Petition to Add Sodium Gluconate to 7CFR205.605

Petitioner:

Bradford Soap Works, Inc.
200 Providence Street
West Warwick, RI 02893

Contact Person: Al Kendra
   Director of Quality
   (401) 381-6204
   Email: akendra@bradfordsoap.com

Item A:

Petition for the evaluation of Sodium Gluconate for inclusion on the National List of Non-agricultural (non-organic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients),”

Item B:

1. Substance Name:

Sodium Gluconate

2. Manufacturer’s Name:

Jungbunzlauer Inc.
7 Wells Avenue
Newton Center, MA 02459
USA

Telephone: (617) 969-0900

3. Intended Use of the Substance:

Soap bars made with from saponified vegetable oils are prone to become rancid by the action of certain trace heavy metals.\(^1,2\) The trace metals are often termed “pro-oxidant” since they enhance the process of rancidity by the attack of carbon-carbon double and triple bonds by oxygen. The resulting process cleaves carbon-carbon double and triple bonds in the soap creating lower molecular weight fatty acids and aldehydes\(^3\) that give rise to the off odor and color associated with rancidity. Chelation\(^4, 5, 6, 7\) effectively inactivates the metal ions which significantly reduce the incidence and rate of soap rancidity through oxidation. Sodium gluconate\(^7\) will be used as a chelator to reduce or prevent soap from becoming rancid.
4. Mode of Action:

Traditional soap manufacturing consists of the alkali metal saponification of fats and oils. Sodium and potassium hydroxides are used in this process to yield the sodium and/or potassium salts of the selected fats and/or oils. Soap is prone to become rancid by the action of certain trace heavy metals\(^1,2\). These trace metals such as iron, copper, magnesium and zinc and well as others are often found in soap. Soap is stabilized by using various amounts of chelators\(^4\), which bind to pro-oxidant metals preventing them from causing rancidity. The current chelators used in the bar soap industry include Sodium Pentetate, Tetrasodium Etidronate, EDTA and its salts, Ethylenediamine Disuccinic and its salts, among others. These chelators are extremely effective; however, they are not on the list of approved ingredients that can be used in certified organic products.

Other organic soaps have used a combination of certified organic citric acid and certified organic Vitamin E. These ingredients provide limited protection from rancidity as the data in this petition will demonstrate. Other ingredients that have been reviewed and determined not to be effective chelators include: phytic acid, sodium phytate, chamomile extract, rosemary extract, lecithin, and ascorbyl palmitate. In researching natural ingredients that provide effective prevention from rancidity, it has been determined that Sodium Gluconate is an effective chelator.

5. Substance Source and Manufacturing Description:

Sodium gluconate is manufactured by the fermentation of carbohydrate containing the raw material glucose syrup derived from maize. The product undergoes several purification steps and finally obtained in a highly purified form. Based on the production process as well as the raw materials used, sodium gluconate is not synthetic natural. The manufacturing flow chart is attached (Attachment 1)

6. Reviews:

There is no information available.

7. EPA, FDA and State Regulatory Agency Registrations:

Sodium gluconate’s International Registry Numbers and Classifications are attached. (Attachment 2)

Sodium gluconate is a GRAS substance, SCOGS Report #78, 21CFR182.6757, NTIS Accession Number: PB-238-675/2.

8. CAS Number:

527-07-1
9. Physical Properties and Chemical Mode of Action:

Sodium gluconate is the sodium salt of gluconic acid, produced by fermentation of glucose. It is a white to tan, granular to fine, crystalline powder, very soluble in water. Non corrosive, non toxic and readily biodegradable (98% after 2 days).

a. Chemical interactions – No interactions are known.

b. Toxicity/Environmental Persistence – Sodium gluconate is considered non-toxic and readily biodegradable.

c. Environmental Impact – Not listed by ACGIH, IRARC, NTP, or CA Prop 65

d. Human Health Effects – Listed as GRAS by the FDA.

e. Effects on Soil/Organisms/Crops/Livestock – There are no known negative effects.

f. Chemical Mode of Action- Chelating; Trace metal sequestering.

Product specification is attached. (Attachment 3)

GMO Statement is attached (Attachment 4)

10. Safety Information:

a. MSDS – Attached. (Attachment 5)

b. NIEHS – No substance report

11. Research Information:

Bar Soap Production and the use of Chelators:

Traditional soap manufacturing consists of the alkali metal saponification of fats and oils. Sodium and potassium hydroxides are used in this process to yield the sodium and/or potassium salts of the selected fats and/or oils. (The remainder of this petition will be specific to soap produced using vegetable oils, although the same issues/technical aspects would also apply to tallow based soap) Soap is prone to become rancid by the action of certain trace heavy metals. These trace metals such as iron, copper, magnesium and zinc and well as others are often found in soap. Soap is stabilized by using various amounts of chelators, which bind to pro-oxidant metals preventing them from causing rancidity. The current chelators used in the bar soap industry include Sodium Pentetate, Tetrasodium
Btidronate, EDTA and its salts, Ethylenediamine Disuccinic and its salts, among others. These chelators are extremely effective; however, they are not on the list of approved ingredients that can be used in certified organic products.

Other organic soaps have used a combination of certified organic citric acid and certified organic Vitamin E. These ingredients provide limited protection from rancidity as the data in this petition will demonstrate. Other ingredients that have been reviewed and determined not to be effective chelators include: phytic acid, sodium phytate, chamomile extract, rosemary extract, lecithin, and ascorbyl palmitate. In researching natural ingredients that provide effective prevention from rancidity, it has been determined that Sodium Gluconate (CAS No. 527-07-1, EINECS/ELINCS 208-407-7 (1)) is an effective chelator. The data that supports the effectiveness of Sodium Gluconate as compared to other chelators is present in Attachment 5.

Currently Sodium Gluconate is used alone in several non-certified organic finish product formulations. Extensive in-house evaluations (Attachment 1) indicate that Sodium Gluconate is approximately 70%-90% as effective as our current chelator system (positive control) and should be considered an acceptable alternative for bar soap products/marketers who need a more bio-degradable chelator component with good toxicological and biological profiles; has a more natural position than other useful chelators and chelates Fe^{2+}, Al^{3+} and other heavy metals that promote rancidity as well as Ca^{2+} at alkaline pH’s (traditional soap is an alkaline salt with a pH of about 10).

Additionally a production size study was completed that added Sodium Gluconate into soap base in the kettle stage. (Attachment 6) The results of this study demonstrate that Sodium Gluconate at a level of 0.4% is an effective chelator under typical manufacturing conditions.

12. Petition Justification Statement:

The lack of having an effective and approved chelator is severely limiting Bradford’s ability to pursue the marketing for certified organic soap products. This also limits the total bar soap industry from also offering a certified organic soap bars that are adequately protected from becoming rancid.

Impact to Bradford Soap Works:

Currently Bradford Soap Works Inc. markets a brand of bars soaps and soap liquids under the name of [CBI]. The products are made wholly from certified organic oils and use certified organic oils/ingredients to create different visuals and fragrances for each of the products.

The products were manufactured in the UK by a company which used to be a subsidiary of Bradford Soap Works Inc, but no longer is. The company is Bradford Personal Care LLC. The products were made in an organically certified manufacturing facility approved by the UK organic certification body, The Soil Association. The formulations are
approved by The Soil Association; therefore Bradford was permitted to carry the Soil Association logo. The Soil Association approved chelator system of, sodium pentetate and tetrarosodium etidronate. Since it has been brought to Bradford's attention these formulas don't meet the NOP standard, these products are no longer sold as certified organic products. However Bradford Soap Works Inc. wants to now manufacture these products in the USA, and follow the guidelines set down by the USDA. Our facility in Rhode Island has the soap manufacturing processes certified by QCS. However without an effective chelator that is NOP approved, Bradford is not able to manufacture these products. Not allowing an effective chelator that is on the NOP list will mean that Bradford lost [CBI] in existing sales with [CBI].

On a broader scope, Bradford's primary business is as a contract manufacturer of bar soaps and also a supplier of raw material soap noodles to other soap bar soap companies. The availability of Sodium Gluconate would impact Bradford's business as follows:

Attached is a spreadsheet (Attachment 8) assuming a number of key accounts in the USA take the products. The assumptions are speculative but in no way come close to the full potential of the brand if the majority of the US retail market stocked the brand. Bradford has taken a basket of customers, assumed a number of stores (not the total number) and assumed a level of sales of one unit per store per week, usually the minimum sales most retailers demand to keep specialty products like [CBI] in store. Bradford also assumed that not all products will be stocked by the retailer, and that the selling price to them is the same as for [CBI] currently.

Based on this analysis the potential annual sales, using these assumptions is [CBI]. As you will appreciate, only the future will tell exactly which retailers take the product, and into how many stores, but as you can appreciate this number is a very realistic estimate of potential sales, with an upside that is several times larger than this number. In summary to non-availability of Sodium Gluconate will mean that Bradford will lose [CBI] in existing sales, and will not be able to avail itself of the potential of new business to an estimated value of [CBI]. In total as you will see from below this is a very conservative estimate of a loss of [CBI] at the very least.

**Impact to Bar Soap Industry:**

Currently there are a number of potential brand marketers who are deterred from launching their own products made from certified organic oils due to the lack of an available, natural chelator, which has an acceptable level of risk in relation to keeping a bar of soap from going rancid. This reluctance to develop products means that the natural/organic market for personal care products is not developing at the rate it should be. This is therefore restricting the growth of the organic raw material suppliers who grow oils to supply this market, again hampering the organic message. It has also opened the door for imitation products to fill the space that should be occupied by products which are truly trying to adhere to the ethics, objectives and aims of the organic movement. Several products are currently on the market, making organic claims, which are being allowed to foster as there is a
demand for organic products which is not being fulfilled. Bradford aims to fill those needs and push out the products, which for a long time have damaged the image of the organic industry.

References

4) Chelation:
   *The formation or presence of bonds (or other attractive interactions) between two or more separate binding sites within the same ligand and a single central atom. A molecular entity in which there is chelation (and the corresponding chemical species) is called a 'chelate'. The terms bidentate (or didentate), tridentate, tetradentate, ... multidentate are used to indicate the number of potential binding sites of the ligand, at least two of which must be used by the ligand in forming a 'chelate'. For example, the bidentate ethylenediamine forms a chelate with CuI in which both nitrogen atoms of ethylenediamine are bonded to copper. (The use of the term is often restricted to metallic central atoms.) The phrase 'separate binding sites' is intended to exclude cases such as [PtCl₃(CH₂=CH₂)]⁺, ferrocene and (benzene)tricarbonylchromium in which ethene, the cyclopentadienyl group and benzene, respectively, are considered to present single binding sites to the respective metal atom, and which are not normally thought of as chelates.*

PAC, 1994, 66, 1077 (Glossary of terms used in physical organic chemistry (IUPAC Recommendations 1994)) on page 1094
Red Book, p. 147
5) *Versene™ Chelating Agents for Personal Care Formulations*, The Dow Chemical Company, Form No. 113-01504-1107AMS (2007)
Production Flow Chart
Sodium Gluconate and Sodium Gluconate EMF 1240

- glucose syrup
- nutritionals
- spores
- air
- filtration
- mycelium
- gluconic acid
- tank
- sodium gluconate EMF 1240
- crystallization
- drying
- sodium gluconate
- milling and sieving
- packing

Version 11.07, supersedes 05.04
## International Registry Numbers and Classifications

### Sodium Gluconate

<table>
<thead>
<tr>
<th>EINECS No. (EC No.)</th>
<th>European Inventory of Existing Chemical Substances</th>
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<tr>
<td>CAS No.</td>
<td>Chemical Abstracts Service, USA</td>
<td>527-07-1</td>
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<tr>
<td>EU Food additive</td>
<td></td>
<td>E 576</td>
</tr>
<tr>
<td>Customs Tariff Number</td>
<td>according to harmonised system</td>
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<td>AICS</td>
<td>Australian Inventory of Chemical Substances, Australia</td>
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<td>DSL</td>
<td>Domestic Substances List, Canada</td>
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</tr>
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<td>ECL</td>
<td>Existing Chemicals List, Korea</td>
<td>KE-17676</td>
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<tr>
<td>ENCS No. (MITI No.)</td>
<td>Existing and New Chemical Substances, Japan</td>
<td>(2)-1410</td>
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<tr>
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<td>Philippine Inventory of Chemicals and Chemical Substances, Philippines</td>
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<tr>
<td>TSCA No.</td>
<td>Toxic Substances Control Act, USA</td>
<td>527-07-1 (CAS No.)</td>
</tr>
<tr>
<td>FDA (Food and Drug Administration, USA)</td>
<td>Code of Federal Regulations</td>
<td>21 CFR Ch. 1 § 182.6757</td>
</tr>
<tr>
<td>CTFA, INCI</td>
<td>Cosmetic, Toiletry and Fragrance Association, USA, International Cosmetic Ingredients (INCI)</td>
<td>Listed as sodium gluconate</td>
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<tr>
<td>WGK</td>
<td>Water Hazard Classes, Germany</td>
<td>1 (KBwS = 5223)</td>
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<tr>
<td>EDP No.</td>
<td>Swiss Federal Office of Public Health</td>
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(new regulation in place since 08/2005)
## Product Specification

**Sodium Gluconate**  
USP / FCC / EC

<table>
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<tr>
<th>Characteristic</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Product name</strong></td>
<td>Sodium Gluconate</td>
</tr>
<tr>
<td><strong>EC No.</strong></td>
<td>208-407-7</td>
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<tr>
<td><strong>CAS No.</strong></td>
<td>527-07-1</td>
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<tr>
<td><strong>E-No.</strong></td>
<td>E 576</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td>White to tan, granular to fine, crystalline powder; very soluble in water, sparingly soluble in alcohol, insoluble in ether.</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>Conforms</td>
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<tr>
<td><strong>Chloride</strong></td>
<td>Max. 50 mg/kg</td>
</tr>
<tr>
<td><strong>Sulphate</strong></td>
<td>Max. 100 mg/kg</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>&lt; 2 mg/kg</td>
</tr>
<tr>
<td><strong>Heavy metals</strong></td>
<td>&lt; 10 ALTE/kg</td>
</tr>
<tr>
<td><strong>Reducing substances</strong></td>
<td>Max. 0.5 %</td>
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<tr>
<td><strong>Assay</strong></td>
<td>99.0 - 101.0 %</td>
</tr>
<tr>
<td><strong>pH value (10% solution)</strong></td>
<td>6.5 - 7.5</td>
</tr>
</tbody>
</table>

We herewith confirm that this product meets the requirements of the latest edition of the US Pharmacopeia (USP), the Food Chemicals Codex (FCC) and the Commission Directive 2000/53/EC. All analytical methods are in accordance with the latest requirements of the USP, the FCC or equivalent methods. Test methods are available on request.

Version 02.07, superseded 05.01  
1/1  
SG_S01_US
# GMO Position

This position paper is valid for the Jungbunzlauer manufacturing sites Pernhofen / Austria, Ladenburg / Germany and Marckolsheim / France.

The following Jungbunzlauer products:

<table>
<thead>
<tr>
<th>Category</th>
<th>Products</th>
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</thead>
<tbody>
<tr>
<td>Citric Acid</td>
<td>Citric Acid, LIQUINAT® Citric Acid Solution, Trisodium Citrate Dihydrate</td>
</tr>
<tr>
<td>Gluconates</td>
<td>Glucono-delta-Lactone, Sodium Gluconate</td>
</tr>
<tr>
<td>Specialities</td>
<td>Citro DC, CITROCOAT® and other coated products, CITROFOL®, ESSICCUM®, subisalt®</td>
</tr>
<tr>
<td>Special Salts</td>
<td>Calcium Lactate Gluconate, Monosodium Citrate, Potassium Gluconate, Tricalcium Citrate, Trinatrium Citrate, Tripotassium Citrate, Trisodium Citrate Anhydrous</td>
</tr>
<tr>
<td>Sweeteners</td>
<td>Erythritol</td>
</tr>
<tr>
<td>Xanthan Gum</td>
<td>Xanthan Gum</td>
</tr>
</tbody>
</table>

are manufactured by fermentation or are based on fermentation derived products.

**Micro-organisms - Production Strains**
Jungbunzlauer currently does not use genetically modified production strains* for the manufacture of above mentioned food additives.

*no GMO in the meaning of Directive 90/219/EC and as amended in Directive 2001/18/EC.

**Fermentation Raw Materials**
Jungbunzlauer works together solely with raw material suppliers who can exclude the processing of genetically modified organisms (GMO).
Jungbunzlauer purchases raw materials (e.g. glucose syrup) upon a NON-GMO agreement, if they are derived from crops for which genetically modified varieties exist (e.g. Bt maize).
The raw material suppliers need to have an Identity Preserved (IP) system in place in the case the crops originate from a country or region where GMO varieties of the crops in question are available for commercial purposes.

**Regulation on Genetically Modified Food and Feed**

**Regulation on GMO Traceability**

In view of the rapid advancement of modern biotechnology and the changing framework of laws and regulations of the European Community and its member states a statement on the usage of genetically modified organisms can only reflect the past and present situation. As soon as new European and National regulations on this matter will be published we commit ourselves to apply these immediately.

**In Summary**
1) Jungbunzlauer does not use genetically modified microorganisms for the fermentation step of above-mentioned food additives.
2) Above-mentioned Jungbunzlauer food additives are no genetically modified organisms as such and they do not contain genetically modified organisms.
3) There are no labelling requirements for above-mentioned Jungbunzlauer food additives according to Regulations (EC) No 1829/2003 and 1830/2003.

April 2007
(Version 8)
MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMERCIAL PRODUCT NAME: Sodium Gluconate
COMPANY/SUPPLIER: Jungbunzlauer Inc.
7 Wells Avenue
Newton Centre, MA 02149
Emergency Phone: 1-617-968-0800; 8:30 - 5:00 M-F Eastern Time
24 Hour Emergency Phone Number: CHEMTREC 1-800-424-9300

PRODUCT USE: foods, pharmaceutical, sequestering agent, metal cleaner, paint stripper, aluminum deoxidizer, bottle washing preparations, rust removal, chrome tanning, metal plating, mordant in dyeing.

2. COMPOSITION, INFORMATION ON INGREDIENTS

CHEMICAL NAME OF THE MATERIAL: Sodium Gluconate
CHEMICAL FORMULA: C₆H₁₀O₇Na
CHEMICAL FAMILY: salt of organic acid
SYNONYMS: Gluconic acid, sodium salt; pentahydroxyhexanolic acid, sodium salt; penta-hydroxy-caprolactic acid, sodium salt
CAS Reg. No.: 527-07-1
EC NR.: 208-407-7
HAZARDOUS IMPURITIES: None

3. HAZARDS IDENTIFICATION

Emergency Overview: Fine white to yellowish crystalline powder with no odor or a slightly pleasant odor, soluble in water, considered non-toxic.

Most Important Hazard: None

Inhalation: Dust may cause irritation of mucous membrane and respiratory tract.
Eye contact: No data available
Skin contact: No data available
Ingestion: No data available
Chronic: No data available
Carcinogen status: None

4. FIRST AID MEASURES

General advice: No hazards which require special first aid measures. If you feel unwell, seek medical advice.
Inhalation: Move to fresh air. If symptoms persist, call a physician.
Skin contact: Wash off with soap and plenty of water. If skin irritation persists, call a physician.
Eye contact: Flush eyes with water as a precaution. If eye irritation persists, consult a specialist.
Ingestion: Drink water as a precaution. Consult a physician if necessary.
Protection of first-aiders: No hazards which require special first aid measures.
### MATERIAL SAFETY DATA SHEET

**JUNGBUNZLAUER INC.**

**Product:** Sodium Gluconate

**Review Date:** 5/4/2005

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
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<tbody>
<tr>
<td>Flash Point</td>
<td>Not Applicable</td>
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<tr>
<td>Flammable Limits</td>
<td>Not available</td>
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<tr>
<td>Autocignition temperature</td>
<td>&gt;200 °C</td>
</tr>
</tbody>
</table>

**Suitable extinguishing media:** water, water spray, dry powder, foam, carbon dioxide (CO2)

**Extinguishing media which must not be used for safety reasons:** None

**Hazardous decomposition products:** carbon oxides

**Special protective equipment:** Use personal protective equipment including self-contained breathing apparatus when fighting fire in enclosed area.

**Specific methods:** Standard procedure for chemical fires.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Avoid dust formation.

**Environmental precautions:** Dispose according to federal, state and local authorities.

**Methods for cleaning up:** Sweep up and shovel. After cleaning, flush away traces with water.

### 7. HANDLING AND STORAGE

**HANDLING**

**Technical measures/Precautions:** No special technical protective measures required.

**Safe handling advice:** No special handling advice required.

**STORAGE**

**Technical measures/Storage conditions:** Keep tightly closed in a dry and cool place.

**Incompatible products:** No special restrictions on storage with other products.

**Packaging material:** Store in original container.

### 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

**Engineering measures:** Provide general dilute ventilation.

**Exposure limit(s):** None established for this ingredient. Use OSHA PEL, ACGIH TLV for nuisance dusts of 5 mg/m³.

**Personal protection equipment:**

- **Respiratory protection:** NIOSH approved dust respirator
- **Hand protection:** Gloves
- **Eye Protection:** Safety glasses
- **Skin and body protection:** Lightweight protective clothing
- **Hygiene measures:** Handle in accordance with good industrial hygiene and safety practice.
# MATERIAL SAFETY DATA SHEET

**JUNGBUNZLAUER INC.**
**Product:** Sodium Gluconate
**Review Date:** 5/4/2006

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Form</td>
<td>granular/powder</td>
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<tr>
<td>Color</td>
<td>white/off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>none to slightly pleasant</td>
</tr>
<tr>
<td>pH (10% solution)</td>
<td>6.5-7.5</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>not volatile</td>
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<tr>
<td>Vapor density</td>
<td>not applicable</td>
</tr>
<tr>
<td>Boiling point</td>
<td>not established</td>
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<tr>
<td>Evaporation rate</td>
<td>0</td>
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<tr>
<td>Coefficient of water/oil distribution</td>
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<tr>
<td>Melting point/temperature</td>
<td>170-175 °C</td>
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<tr>
<td>Decomposition temperature</td>
<td>196-198°C</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Bulk density</td>
<td>850 ± 150 kg/m3</td>
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<tr>
<td>Explosive properties</td>
<td>none</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Water solubility (20°C)</td>
<td>375 g/kg solution</td>
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<tr>
<td>Solubility in other solvents: Alcohol</td>
<td>(20°C) Insoluble</td>
</tr>
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</table>

## 10. STABILITY AND REACTIVITY

- **Stability:** Stable at normal conditions
- **Conditions to avoid:** Keep containers dry and tightly closed to avoid moisture absorption and contamination.
- **Materials to avoid:** Strong oxidizers
- **Hazardous decomposition products:** No decomposition if stored normally. Thermal decomposition can lead to release of irritating gases and vapors.

## 11. TOXICOLOGICAL INFORMATION

- **Acute toxicity:** LD₅₀ (i.v./rabbit) = 7800 - 8700 mg/kg (1)
- **Local effects:** no data available
- **Chronic toxicity:** no data available
- **Human experience:** Health injuries are not known or expected under normal use.

## 12. ECOLOGICAL INFORMATION

- **Mobility:** completely soluble
- **Persistence and degradability:**
  - Chemical oxygen demand (COD) = 807 mg O₂/g
  - Biochemical oxygen demand within 5 days (BOD₅) = 507 mg O₂/g
- **DIN EN 28888 (OECD 302B):** Readily biodegradable (98% after 2 days)
- **Bioaccumulation:** No data available
- **Ecotoxicity effects:**
  - Toxicity to fish = LD₅₀ > 10,000 mg/l
  - Toxicity to bacteria = EC₀ > 5,000 mg/l
13. DISPOSAL CONSIDERATIONS
Waste from residues/unused products
Any disposal practice must be in compliance with local, state and federal laws and regulations (contact local or state environmental agency for specific rules).

14. TRANSPORT INFORMATION
Not a Hazardous Material for DOT shipping.

15. REGULATORY INFORMATION
Sodium Gluconate is generally recognized as safe (GRAS) by USA FDA.
Listed European Food Additive E676
The ingredients are listed on the TSCA Inventory List.

CERCLA (Comprehensive Response Compensation, and Liability Act): Not hazardous

SARA Title III (Superfund Amendments and Reauthorization Bill): Not Considered Hazardous
Foreign Inventory Status
Canadian DSL (Domestic Substance List)
Canada WHMIS – not regulated

To the best of our knowledge, Jungbunzlauer Citric Acid Anhydrous does not contain any contaminants or by-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act.

16. OTHER INFORMATION
HMIS Rating: Health = 0, Fire = 0, Reactivity =0


Information contained herein is believed to be accurate. However, it is provided solely for the customer’s consideration, investigation and verification. Jungbunzlauer Inc. hereby specifically disclaims any and all warranties expressed or implied, regarding the accuracy and completeness of such information, and makes no representation with respect thereto.
Attachment 6
Sodium Gluconate

Chelator Comparison Study

**Purpose:** To evaluate sodium citrate and sodium gluconate as viable chelators for use in traditional soap products.

**Start Date:** May 1, 2008

**End Date:** July 21, 2008

**DOE (Design of Experiment):**

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<th>Code</th>
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<td>Sodium Gluconate</td>
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Printed: 3/13/2009
Protocol:
Each chelator was roller milled into unpreserved, dried (11-4% water) vegetable soap base produced at Bradford Works, Inc. Unchelated roller milled base served as the negative control. The milled base (in pellet form) was then added to a gas wash bottle containing a wet filter paper on the bottom, purged with oxygen (O₂), sealed and placed in a 40°C oven. The bottles were periodically observed for soap discoloration, and brown spot formation indicative of rancidity. Additionally, each sample was subjected to olfactory evaluation after the six (6) week oven incubation. A strong, pungent, off-odor is indicative of rancidity.

Results:
Discussion

Each sample was exposed to moisture, heat and oxygen (O₂) that provides the necessary conditions known to produce soap rancidity. Unchelated soap base (519992-2968-Negative Control) became totally rancid during the testing interval. The soap turned completely brown and exhibited the characteristic rancid off-odor. The current Penta-sodium Pentetate/Tetrasodium EDTA chelator mixture (290379) performed well throughout the trial (519992-2967 Positive Control). The soap remained a normal pale beige color with no indication of soap discoloration or any off odor.

Sodium citrate (519992-2973) did not provide adequate stability to the soap base, providing only about 20% effectiveness as compared to the positive control. A repeat test of sodium citrate at 0.25% and 0.40% in Veg-S was conducted. The test was terminated after 3 days as rancidity developed at both levels.

Test results (ref. Chart 1) indicate that sodium gluconate (519992-2072) is approximately 70% as effective as the current chelator system (Positive Control). Based on these results, sodium gluconate should be considered an acceptable alternative for soap stability for customers who need a more bio-degradable chelator component since: it has good toxicological and biological profiles; has a more natural position than other useful chelators; and chelates Fe²⁺, Al³⁺ and other heavy metals (so-called pro-oxidant metals), as well as Ca²⁺ at alkaline pH’s (traditional soap is an alkaline salt with pH of 10). Sodium gluconate is currently used alone in several commercial, non-certified organic, products produced by Bradford Soap Works, Inc. These products have proved to be stable and commercially acceptable.

Conclusion:

Results indicate that sodium citrate does not provide adequate soap stability as unchelated soap with sodium citrate (519992-2973) became rancid. A repeat experiment verified these results. Therefore sodium citrate is not considered to be an acceptable soap stabilizer.
Sodium gluconate (519992-2972), however, did provide approximately 70% stability protection of the positive control (519992-2967). The experimental results, in addition to commercial experience, indicate that sodium gluconate is an acceptable soap stabilizer that could find application in the certified organic market place for soap products.

E. George
July 21, 2008
Sodium Gluconate-Kettle Soap Stability Study II

Purpose: To evaluate the stability and effectiveness of adding sodium gluconate in Veg-S kettle soap

Start Date: January 6, 2009
End Date: March 6, 2009

DOE (Design of Experiment):

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Protocol: Molten (214°F) unchelated Method type Veg-S kettle soap was kettle made and additions made in the kettle as follows:

1. **Negative control**: No chelators were added and the soap was dried on an APV drier. (ref. Lot 20735)
2. **Sodium gluconate**: Was added at 0.35% to additional molten (198°F) unchelated kettle soap and dried on an APV drier. (ref. Lot 20731)
3. **Positive control**: Standard Method vegetable soap kettle preserved with pentasodium pentetate/tetrasodium eldronate dried on an APV drier.
4. Approximately 100 grams of each dried base, was added to a gas wash bottle containing a wet filter paper on the bottom, purged with oxygen (O₂), sealed and placed in a 45°C.
oven. The bottles were periodically observed for soap discoloration and pcox odor indicative of rancidity.

Results

![Diagram of Sodium Gluconate in Production and Catted Vegetable Kettle Soap]

**Rancidity Rating:**

- 0 = Total rancidity
- 25 = Very mild color; several rancid spots; noticeable rancid odor
- 50 = Moderate discoloration; several rancid spots; off-odor
- 75 = Slight base darkening; a few small, observable rancid spots; typical odor
- 100 = Good base color and odor; no observable rancidity

**Incubated in gas-wash bottles for 8 weeks @ 45°C**

**Chart 1
Test Results**

The negative control (Lot 20735) became totally rancid during the test period with severe soap browning and a malodor. Sodium gluconate added to molten kettle soap (Lot 20731) produced excellent results with only one small brown spot observed during the eight week study. The color and odor was excellent. The positive control exhibited no discoloration or malodor.
Conclusions:

The experiment validates that sodium gluconate is an effective soap chelator under manufacturing conditions.

E. George
3/6/2006
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**TOTAL ANNUAL SALES** [CBI]