

## 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.<sup>1, 2</sup> 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<sup>3</sup> that give rise to the off odor and color associated with rancidity. Chelation<sup>4, 5, 6, 7</sup> effectively inactivates the metal ions which significantly reduce the incidence and rate of soap rancidity through oxidation. Sodium gluconate<sup>7</sup> 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<sup>1, 2</sup>. 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<sup>4</sup>, 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-288-675/2.

#### 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 <sup>7</sup>; 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

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 (CAS No. 527-07-1, EINECS/ELINECS 208-407-7 (I)) 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

[CBI  
DELETED]

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 tetrasodium 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]. [CBI Deleted]

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 even 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. [CBI Deleted]

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. [CBI Deleted]

Based on this analysis the potential annual sales, using these assumptions is [CBI] [CBI Deleted]

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 [CBI Deleted] 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. [CBI Deleted]

#### 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.

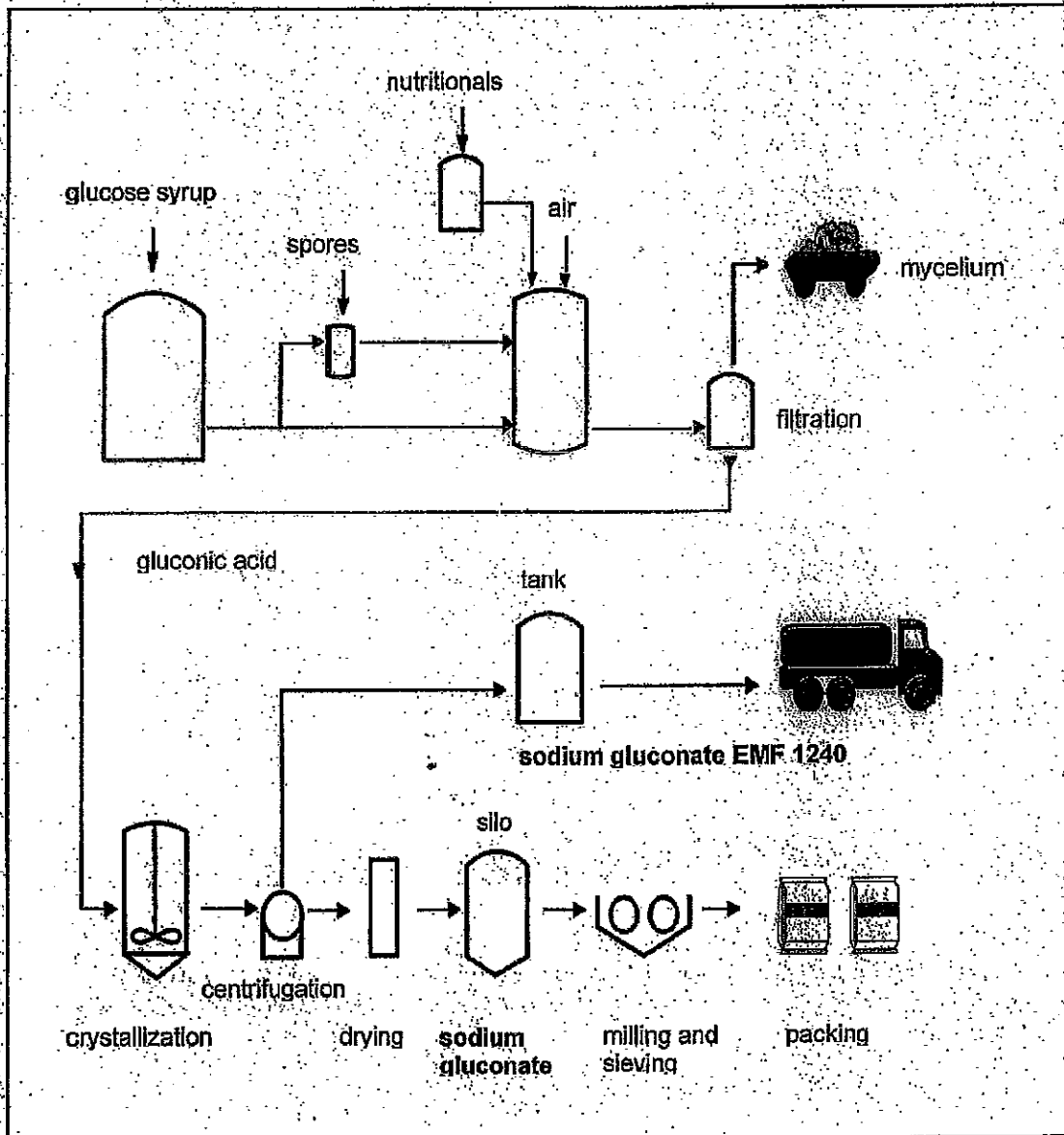
This reluctance to develop products means that the natural/organic market for personal care products is not developing at the rate it should be. This is therefore restricting the growth of the organic raw material suppliers who grow oils to supply this market, again hampering the organic message. It 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

- 1) Thomsenn, E.G., and C.R. Kemp, *Modern Soap Making*, MacNair-Dorland, New York, 147-153 (1937)
- 2) Davidsohn, J., E.J. Better, and A. Davidsohn, *Soap Manufacture*, vol. I, Interscience, New York, 303-305 (1953)
- 3) *Organic Chemistry*, Morrison and Boyd, 3<sup>rd</sup> edn., Allyn and Bacon, Inc., Boston, MA. (1979) 1062-1063
- 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  $[PtCl_3(CH_2=CH_2)]^-$ , 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)
- 6) Considine, Glenn D., ed., *Van Nostrand's Encyclopedia of Chemistry*, 5th edn., J. Wiley and Sons, Inc., Hoboken, NJ, 322-324 (2005)
- 7) *Concise Encyclopedia of Chemical Technology*, vol.1, 5<sup>th</sup> edn., J. Wiley and Sons, Inc., Hoboken, NJ, 463-467 (2007)
- 8) *The Merck Index*, 14<sup>th</sup> edn., Merck and Co, Inc., Whitehouse Station, NJ, 769 entry:4456 (2006)

**Production Flow Chart**  
**Sodium Gluconate and Sodium Gluconate EMF 1240**



# International Registry Numbers and Classifications

Jungbunzlauer

Attachment 2  
Sodium Gluconate

## Sodium Gluconate

<b>EINECS No. (EC No.)</b> European Inventory of Existing Chemical Substances	208-407-7
<b>CAS No.</b> Chemical Abstracts Service, USA	527-07-1
<b>EU Food additive</b>	E 576
<b>Customs Tariff Number</b> according to harmonised system	29181600
<b>AICS</b> Australian Inventory of Chemical Substances, Australia	listed
<b>DSL</b> Domestic Substances List, Canada	listed
<b>ECL</b> Existing Chemicals List, Korea	KE-17676
<b>ENCS No. (MITI No.)</b> Existing and New Chemical Substances, Japan	(2)-1410
<b>PIGCS</b> Philippine Inventory of Chemicals and Chemical Substances, Philippines	listed
<b>TSCA No.</b> Toxic Substances Control Act, USA	527-07-1 (= CAS No.)
<b>FDA (Food and Drug Administration, USA)</b> Code of Federal Regulations	21 CFR Ch. 1 § 182.6757
<b>CTFA, INCI</b> Cosmetic, Toiletry and Fragrance Association, USA International Cosmetic Ingredients (INCI)	listed as sodium gluconate
<b>WGK</b> Water Hazard Classes, Germany	1 (KBwS = 5223)
<b>EDP No.</b> Swiss Federal Office of Public Health	not listed (new regulation in place since 08/2005)



# Attachment 3

## Sodium Gluconate

Jungbunzlauer Inc.  
7 Wells Avenue  
Newton Centre, MA 02459  
USA  
Phone +1-617-969 0900  
Fax +1-617-964 2821  
www.jungbunzlauer.com

### Product Specification

### Jungbunzlauer

#### Sodium Gluconate

USP / FCC / EC

Product name	Sodium Gluconate	$C_6H_{11}NaO_7$
EC No.	208-407-7	
CAS No.	527-07-1	
E-No.	E 576	
Characteristics	White to tan, granular to fine, crystalline powder; very soluble in water, sparingly soluble in alcohol, insoluble in ether.	
Identification		conforms
Chloride		max. 50 mg/kg
Sulphate		max. 100 mg/kg
Lead		< 2 mg/kg
Heavy metals		< 10 mg/kg
Reducing substances		max. 0.5 %
Assay		99.0 - 101.0 %
pH value (10% solution)		6.5 - 7.5

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 2000/63/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, supersedes 05.01

1/1

SG\_S01\_US

# Attachment 4

## Sodium Gluconate

**Jungbunzlauer**

### GMO Position

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

The following Jungbunzlauer products

<b>Citric Acid</b>	Citric Acid LIQUINAT® Citric Acid Solution Trisodium Citrate Dihydrate
<b>Gluconates</b>	Gluconic-delta-Lactone Sodium Gluconate
<b>Specialities</b>	Citro DC CITROCOAT® and other coated products CITROFOL® ESSICUM® sub4salt®
<b>Special Salts</b>	Calcium Lactate Gluconate Monosodium Citrate Potassium Gluconate Tricalcium Citrate Trimagnesium Citrate Tripotassium Citrate Trisodium Citrate Anhydrous
<b>Sweeteners</b>	Erythritol
<b>Xanthan Gum</b>	Xanthan Gum

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**

The regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed that replaces the regulations (EC) No 1139/98, 49/2000 and 50/2000 is not applicable to above-mentioned Jungbunzlauer food additives.

#### **Regulation on GMO Traceability**

The regulation (EC) No 1831/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC is not applicable to above-mentioned Jungbunzlauer food additives.

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 1831/2003.

April 2007  
(Version 8)

**MATERIAL SAFETY DATA SHEET**

JUNGBUNZLAUER INC.

Product: Sodium Gluconate

Page 1 of 4

Review Date: 5/4/2005

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

COMMERCIAL PRODUCT NAME Sodium Gluconate  
 COMPANY/SUPPLIER Jungbunzlauer Inc.  
 7 Wells Avenue  
 Newton Centre, MA 02149  
 Emergency Phone 1-617-969-0900; 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  $C_6H_{11}O_7Na$   
 CHEMICAL FAMILY salt of organic acid  
 SYNONYMS Gluconic acid, sodium salt; pentahydroxyhexanoic acid, sodium salt; pentahydroxycaproic 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

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Review Date: 5/4/2005

## 5. FIRE FIGHTING MEASURES

FLASH POINT

Not Applicable

FLAMMABLE LIMITS

Not available

Autoignition temperature

>200 °C

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/m<sup>3</sup>.

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

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Review Date: 5/4/2005

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

## 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	LD01.v./rabbit = 7600 - 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.
References:	(1) Evaluation of the Health Aspects of Sodium, Potassium, Magnesium and Zinc Gluconates as Food Ingredients, SGOGS-78, Life Sc. Res. Office, Rockville, 1977

## 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 mgO2/g
DIN EN 29888 (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

# MATERIAL SAFETY DATA SHEET

JUNGBUNZLAUER INC.

Product: Sodium Gluconate

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Review Date: 5/4/2005

## 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 E576

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

\*Hazardous Materials Information System of the National Paint and Coating Association.

MSDS Status: Revised 7/2/2004 to incorporate Ca Prop65 Statement. Reviewed 5/4/2004.

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.



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 West Warwick, Rhode Island 02893

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www.bradfordsoap.com

## 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):**

Code	IC#	Component	Supplier	INCI	Abbreviation	%
<b>POSITIVE CONTROL</b>						
519992-2967	816810	Unchelated vegetable soap base	Bradford			99.60
	290379	Dissolvine D-40/C-Quest H21 Mix	Dewolf			0.40
	028787	Dissolvine D-40	Akzo Nobel	Pentasodium Peritrate	DPTANa5	
	028790	C-Quest H21 Mix	Compass Chemical	Tetrasodium Etidronate	HEDPNa4	

<b>NEGATIVE CONTROL</b>						
519992-2968	816810	Unchelated vegetable soap base	Bradford			100.00
						0.00

519992-2973	816810	Unchelated vegetable soap base	Bradford			99.60
	020493	Sodium Citrate	Jungbunzlauer	Trisodium Citrate	NaCit	0.40

519992-2972	816810	Unchelated vegetable soap base	Bradford			99.60
	021224	Sodium Gluconate	Jungbunzlauer	Sodium Gluconate	NaGluc	0.40





BRADFORD SOAP WORKS, INC.  
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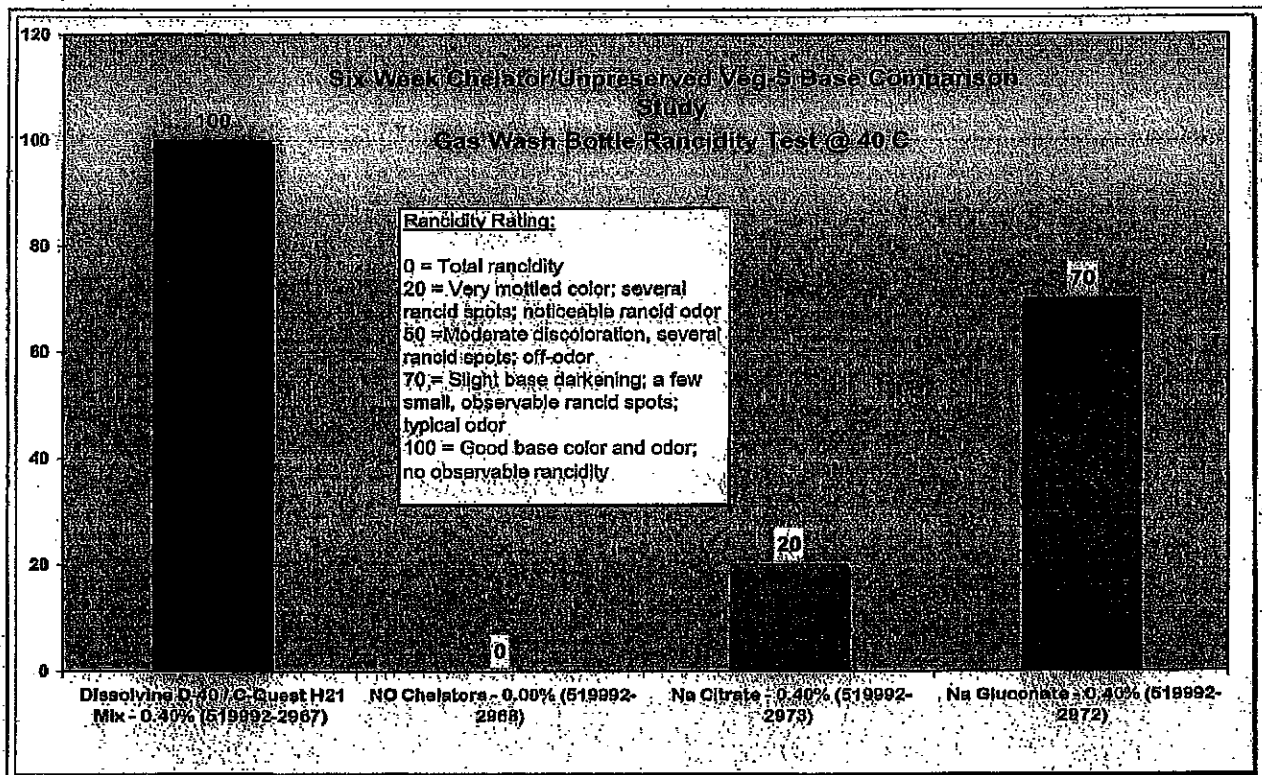
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www.bradfordsoap.com

### 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 (O<sub>2</sub>), 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:



**Chart 1**  
**Test Results**



BRADFORD SOAP WORKS, INC.  
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### Discussion

Each sample was exposed to moisture, heat and oxygen ( $O_2$ ) 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 Pentasodium Pentetate/ Tetrasodium Etidronate 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  $Fe^{2+}$ ,  $Al^{3+}$  and other heavy metals (so-called pro-oxidant metals), as well as  $Ca^{2+}$  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.



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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

# Attachment 7

## Sodium Gluconate



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### 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):**

<u>Lot Code</u>	<u>IC#</u>	<u>Component</u>	<u>Supplier</u>	<u>INCI</u>	<u>Abbreviation</u>	<u>%</u>
<b>NEGATIVE CONTROL</b>						
20735	816783	Unchelated vegetable soap base	Bradford			100
20731	816783	Unchelated vegetable soap base	Bradford			99.65
	021224	Sodium Gluconate added to kettle soap	Jungbunzlauer	Sodium Gluconate	NaGlu	0.35
<b>POSITIVE CONTROL</b>						
20722	22073	Standard Veg-S chelated with pentasodium pentetate/tetrasodium etidronate	Bradford			99.7
						0.3

**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 etidronate 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 (O<sub>2</sub>), sealed and placed in a 45°C



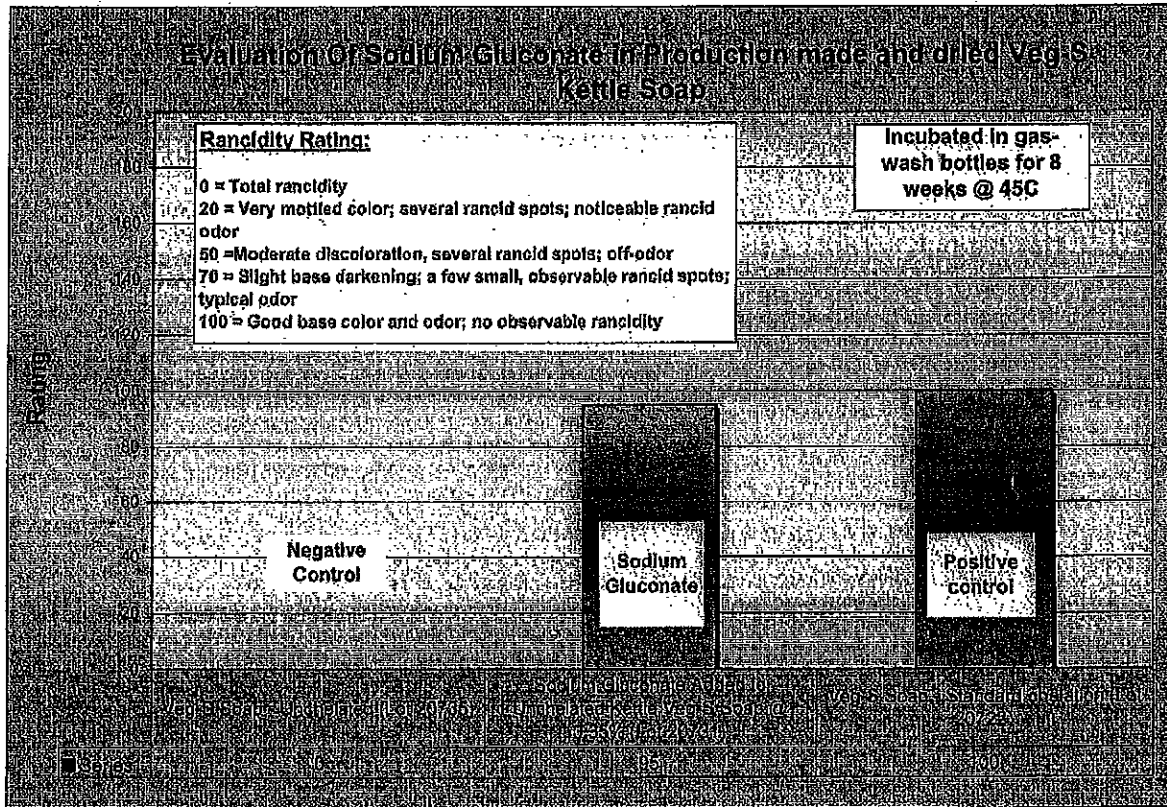
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oven. The bottles were periodically observed for soap discoloration and poor odor indicative of rancidity.

## Results



**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.



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**Conclusions:**

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

E. George  
3/6/2009

**Bradford Soap Works**  
Retail Sales Potential for Organic Soap

**Attachment 8**  
**Sodium Gluconate**

STORE BRAND	NUMBER OF PRODUCTS	NUMBER OF STORES	ANNUAL VOLUME (1 UNIT PER STORE PER MONTH)	AVERAGE UNIT SELLING PRICE TO RETAILER	TOTAL EXTENDED BRADFORD SALES
[CBI]	8	1200	499,200	[CBI]	[CBI]
[CBI]	8	500	208,000	[CBI]	[CBI]
[CBI]	4	1500	312,000	[CBI]	[CBI]
[CBI]	6	3000	936,000	[CBI]	[CBI]
[CBI]	6	800	249,600	[CBI]	[CBI]
[CBI]	4	100	20,800	[CBI]	[CBI]
[CBI]	10	2500	1,300,000	[CBI]	[CBI]
				<b>TOTAL ANNUAL SALES</b>	[CBI]

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