



Date: February 10, 2014

Subject: Submission of Petition of substances for Inclusion on the National List of Substances Allowed in Organic Production

The enclosed petition for Triethyl Citrate (TEC), Natural is being submitted by:

Michael Foods, Inc. d/b/a Abbottsford Farms
C/o Denise Ferriman, Regional Quality Manager – Core Eggs
430 Railroad Avenue
Gaylord, MN 55334
507-237-4289
Denise.ferriman@michaelfoods.com

Item A: Indicate on which section the petitioned substance will be included:

- **205.605** - Nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Item B

1. Triethyl Citrate (TEC), Natural (Organic Compliant)
 - Synonyms: Triethyl Ester; Ethyl Citrate; Citroflex 2; CITROFOL® AI
 - Triethyl citrate is an ester of citric acid. It is a colorless, odorless liquid used as a food additive to stabilize foams, especially as whipping aid for egg white.
2. Manufacturer information:
 - Jungbunzlauer Inc,
 - 7 Wells Ave.
 - Newton Centre, MA 02459
 - Phone: 617-614-0223
 - Fax: 617-964-2921
 - Contact: Gretchen Tolson, Technical Service Manager
 - E-Mail: gretchen.tolson@jungbunzlauer.com
3. Current application/ Intended Use
 - Current application is Flavor – Organic
 - Intended use is whipping enhancer for egg whites during processing – Organic
4. List of methods of application for which the substance will be used:
 - Whipping enhancer for organic, Hi Whip egg whites
5. Sources and detailed description of manufacturing procedures
 - This product was not produced from synthetic sources, and without the use of any synthetic solvents, synthetic carrier system or any artificial preservatives.
 - Manufacture procedures are attached (Production of CITROFOL®AI)
6. Summary of any previous reviews by state or private certification programs
 - The product listed above meets the Natural Flavor definition as described in FDA 21 CFR Part 101.22(a)(3), and was produced and handled without the use of GMOs, Irradiation or Sewage Sludge.
 - This product was not produced from synthetic sources, and without the use of any synthetic solvents, synthetic carrier systems, or any artificial preservatives.
7. Information regarding EPA, FDA and State regulatory authority registration
 - 184.1911 Triethyl Citrate
 - 182.1911 describes dried egg whites
8. Chemical Abstract Service (CAS) number

- CAS Number: 77-93-0

9. Physical properties and chemical mode of action

- Molecular formula: C₁₂ H₂₀ O₇
- Molecular weight: 276.2830
- Appearance: Clear colorless liquid
- Purity (by G.C.): >99%
- Specific Gravity @ 25C: 1.1350-1.1390
- Refractive Index @ 20C: 1.4380-1.4460
- Boiling Point/Boiling Point Range (C): 260
- Flash Point (C) (Tag closed Cup): 151
- Density: 1.14 g/ml at 25C
- Vapor Pressure: 1mm @107C
- Solubility in Water (%): Slightly Soluble
- Solubility in Alcohol (%): Soluble
- Triethyl Citrate does not appear on the List of Chemicals Known to Cause Cancer Or Reproductive Toxicity, under section 25249.8 of the CALIFORNIA SAFE WATER AND TOXIC ENFORCEMENT ACT OF 1986 (Chapter 6.6 added by Proposition 65 1986 General Election).
- Stability & Reactivity: No known materials to avoid; no known hazardous decomposition products
- Toxicological Information: None established, not listed as a carcinogen by IARC, ACGIH, NTP or OSHA.
- Ecological Information: No data available
- Disposal Considerations: Nonhazardous; not registered by DOT.
- Grade – Halal, Kosher, NI.
- Allergen: No known allergen

10. Safety information about the substance including a Material Safety Data Sheet and a substance report from the National Institute of Environmental Health Studies.

- Material Safety Data Sheet is attached
- National Institute of Environmental Health Studies substance report is not available.
- ECOCERT Approval

11. Research information for the substance

- Michael Foods, Inc. R & D tested the Organic Egg White with and without TEC per the Technical Request R & D code 13-3227.
- FDA 21CFR 182.1911 in dried egg whites
- Contrasting studies that do not support the use of TEC are not available.

12. Petition justification statement

Michael Foods, Inc. is requesting that Triethyl Citrate be approved for organic use ingredient in the function of enhancing the whipping factor in pasteurized egg whites – Hi Whip.

- Triethyl Citrate is a natural, organic compliant ingredient flavor and is also used by the egg industry as a pasteurized egg white whipping enhancer in baking, i.e. angel food cakes.
- The substance is essential for organic productions:
 - Michael Foods, Inc. Research and Development Department has done extensive research to find an organic substitute to serve the same purpose and has found that there is no alternative substance.
 - Comparative research was completed with and without the use of Triethyl Citrate, and the research demonstrates that in order to meet customer egg white whipping requirements the substance is necessary.
- The substance is compatible with organic production practice:
 - The product was produced and handled without the use of GMO, Irradiation or Sewage Sludge. GMO position attached. The product was not produced from synthetic sources, and without the use of any synthetic solvents, synthetic carrier systems or any artificial preservatives.
 - Triethyl Citrate, having been designed as containing no artificial flavor, does not - to the best of our knowledge and belief and the manufacturer's knowledge and belief – contain any artificial flavor and has not had any artificial flavor added.

13. CBI STATEMENT

- This petition does not contain any confidential business information.

14. ATTACHMENTS

- Production on CITROFOL®Al (triethyl citrate)
- Product Label(s) for Triethyl citrate or products containing Triethyl citrate (Information on Standard Packaging CITROFOL®AL)
- MSDS for Triethyl citrate
- GMO Position
- Natural Status CITROFOL®Al
- ECOCERT Approval

Natural Status CITROFOL®AI

Jungbunzlauer

Ladenburg, Thursday, 06 June 2013

Dear customers

Jungbunzlauer CITROFOL® AI (Triethyl Citrate; TEC) is manufactured by the natural derived raw materials citric acid and ethanol, both based on the process of fermentation. Therefore CITROFOL® AI can be considered as based 100 % on natural raw materials.

Citric acid and ethanol are fermented, using the naturally derived raw materials glucose syrup from maize as well as molasses and sugar from sugar beet or sugar cane.

The strains used for the manufacturing of the raw materials are not genetically modified according to the directive 90/219/EC and as amended in directive 2001/18/EC.

CITROFOL® AI itself is produced by esterification with additional purification and distillation steps and is finally obtained in its highly pure form.

There is no particular law that defines the requirements for "natural" food ingredients or products. As esterification is a chemical reaction and certain chemicals are used during the purification step of the ester, we do not approve the "natural" status of CITROFOL® AI.

We leave it up to our customers, if they indicate their end product as natural.

With best regards,
Technical Service Manager

Production of CITROFOL[®] AI (Triethyl Citrate)

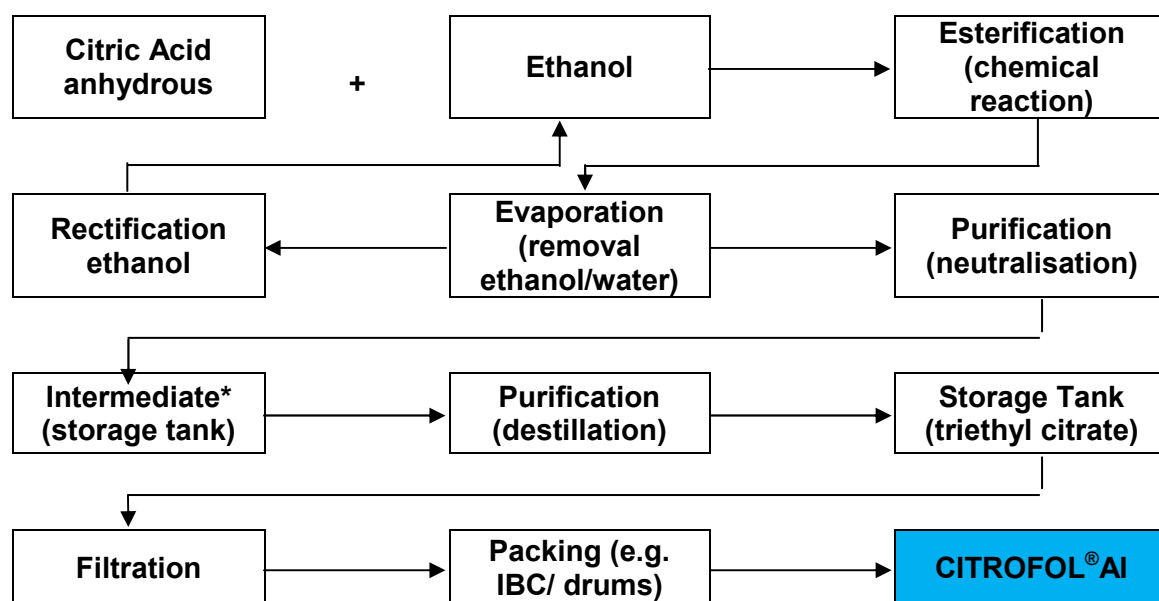
CITROFOL[®] AI is the Jungbunzlauer trade name of triethyl citrate which is chemically, according to the IUPAC nomenclature, a 1,2,3-propane tricarboxylic acid, 2-hydroxy, triethyl ester.

Esterification process

CITROFOL[®] AI is produced by acidic esterification. As starting material citric acid and ethanol, both based on fermentation of carbohydrates raw materials, are dissolved in a reaction vessel. After the reaction the ethanol and water are removed by evaporation and is undergoing a rectification process to further usage in the process. Purification follows by neutralization and washing processes. In an intermediate step material it stored. This material can be additionally used for a second esterification by acetylation process (CITROFOL[®] AII). After the purification by distillation the triethyl citrate is filled in a storage tank. During the processing, the citrate ester passes through several filters and, before final filling into containers or trucks, passing a final safety filter of 25 µm.

Process flow chart

The following flowchart covers the single steps of our CITROFOL[®] AI:



*Raw material for acetylation

CITROFOL[®] AI is supplied in canisters with a net content of 25 kg, iron drums of 225 kg, ecobulk containers (IBC) of 1.000 kg and truckloads. In a cool, dry place and in original closed containers CITROFOL[®] AI can be stored for at least 3 years. A retest is recommended after the above mentioned time.

The given information reflects the current status. Jungbunzlauer will not automatically inform about updated information or minor changes. All sales of the described products are subject to our general conditions of sale.

MATERIAL SAFETY DATA SHEET

JUNGBUNZLAUER INC.
Product: CITROFOL® AI

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMERCIAL PRODUCT NAME	CITROFOL® AI
COMPANY/SUPPLIER	Jungbunzlauer Inc. 7 Wells Avenue Newton Centre, MA 02459
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	Plasticizer, solvent, egg white whipping aid, fixative, deodorant active ingredient

2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical name	Triethyl Citrate
Chemical characterization	$C_{12}H_{20}O_7$ 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, triethyl ester
Chemical family	organic Acid Ester
Synonyms	Triethyl citrate, TEC, TEC plasticizer
COMPOSITION	CAS Reg. No. %
Triethyl Citrate	77-93-0 100
Hazardous impurities	None
EINECS-No.	201-070-7
E-No.	E 1505

3. HAZARDS IDENTIFICATION

Most important Hazard	None
Emergency Overview	Colorless, slightly oily liquid
Inhalation	No data available
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 you	No hazards which require special first aid measures. If 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: CITROFOL® AI

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5. FIRE FIGHTING MEASURES

Flash point	151°C
Flammable limits	Not available
Autoignition temperature	Not available
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 equipmt. Avoid dust formation.
Environmental precautions	Do not allow material to contaminate ground water system.
Methods for cleaning up gel,	Soak up with inert absorbent material (e.g. sand, silica acid binder, universal binder, sawdust).

7. HANDLING AND STORAGE

HANDLING

Technical measures/Precautions	Use only in area provided with appropriate exhaust ventilation.
Safe handling advice	Use personal protective equipment.
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	Intermediate Bulk Container (IBC), Iron drums

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering measures	Ensure adequate ventilation, especially in confined areas.
Exposure limit(s)	None established for this ingredient,
Personal protection equipment	
Respiratory protection	No personal respiratory protective equipment normally required
Hand protection	Impervious gloves, break through time >8 hours
Eye Protection	Safety glasses with side shields
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: CITROFOL® AI

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9. PHYSICAL AND CHEMICAL PROPERTIES

Form	liquid
Color	colorless/translucent
Odor	slight
pH	not available
Vapor pressure (25°C)	1.89 x 10 ⁻³ mm Hg
Vapor density	9.7
Boiling point	294°C
Boiling point range (1mmHg)	127°C
Pour point	-45.5°C
Decomposition temperature	>200°C
Evaporation rate	< 1 vs. butyl acetate
Coefficient of water/oil distribution	not available
Melting point/range	not available
Relative density	1.135 g/cm ³
Explosive properties	None when properly stored
Water solubility (25°C)	65 g/kg
Solubility in other solvents	
Alcohol	soluble
Acetone	soluble
Viscosity (25°C)	35.2 mPa.s

10. STABILITY AND REACTIVITY

Stability	Stable at normal conditions
Conditions to avoid	none under normal use. Hydrolyses in presence of aqueous solution of alkali salts
Materials to avoid	Incompatible with strong bases and oxidizing agents.
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/p.o./rat >32 g/kg bw(1) LD50/i.p./mouse = 1.75 g/kg bw(2)
Local effects	No skin irritation and no eye irritation (rabbit) (3)
Chronic toxicity	Did not show carcinogenic effects in animal experiments. NOEL (no-observed-effect-level) =100 mg/kg bw (3)
Reproductive toxicity	Did not show mutagenic effects in animal experiments (3) Not mutagenic in AMES Test (4)
Human experience	Health injuries are not known or expected under normal use. Patch test on human volunteers did not demonstrate sensitization properties. (5)

MATERIAL SAFETY DATA SHEET

JUNGBUNZLAUER INC.
Product: CITROFOL® AI

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12. ECOLOGICAL INFORMATION

Mobility	No information available
Persistence and degradability	Readily biodegradable, according to OECD test. ⁽⁶⁾
Ecotoxicity	This product has no known eco-toxicological effects. EC50/72h/algae = G _a 1 ⁽⁶⁾ LC50/96h/golden orfe = 450 mg/l ⁽⁷⁾ EC10/18h/bacteria => 100,000 mg/L ⁽⁹⁾

13. DISPOSAL CONSIDERATIONS

Waste from residues/unused products	Can be landfilled or incinerated when in compliance with local, state and federal laws and regulations (contact local or state environmental agency for specific rules).
Contaminated packaging recycling	Empty containers should be transported/delivered for local or waste disposal

14. TRANSPORT INFORMATION

Not a Hazardous Material for DOT shipping.

15. REGULATORY INFORMATION

is generally regarded as safe (GRAS) by USA FDA. 21 CFR 182.1911
The ingredient is listed on the TSCA Inventory List.
European Food Additive, E 1505
CERCLA (Comprehensive Response Compensation, and Liability Act): Not hazardous
SARA Title III (Superfund Amendments and Reauthorization Bill): Not Considered Hazardous
USP-NG listed; Ph.Eur. Listed, FEMA (3083), JECFA Flavoring agent 629
Foreign Inventory Status: Canadian DSL (Domestic Substance List)

16. OTHER INFORMATION

HMIS* Rating	Health	= 1
	Fire	= 1
	Reactivity	= 0

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

Sources of key data used to compile the datasheet

- (1) M.Finklestein&H.Gold, Toxic. Appl. Pharmac. (1959))1, 283
- (2) D.B. Meyers et all, J. pharm. Sci. (1964) 53, 774
- (3) CSTE (1999) 11th Plenary meeting on 28.9.99
- (4) J.L.Heath&M.Reilly, Poult. Sci. (1982) 61, 2517
- (5) Hill Top Research Report 77-1035A-71 for Pfizer Inc. (1978)
- (6) Jungbunzlauer 1994, DIN 38 412 L 25
- (7) Universität des Saarlandes for Jungbunzlauer 3/95, DIN 38412 L 33
- (8) Universität des Saarlandes for Jungbunzlauer 3/95, DIN 38412 L 15
- (9) Universität des Saarlandes for Jungbunzlauer 3/95, Cell inhibition test DIN 38412 L8

MSDS Status: Reviewed 11/16/2009.

The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

ECOCERT Approval

Jungbunzlauer "From nature to ingredients[®]" approved for personal care

With the mission "From nature to ingredients[®]" the company commits itself to the security of man and the environment. Jungbunzlauer is a responsible and sustainable leader in naturally derived biodegradable ingredients. The ECOCERT approval of Jungbunzlauer products is important for all our customers seeking ingredients to formulate natural personal care products.

With the attached approval Jungbunzlauer products have been classified as 100% natural origin and can be used in the formulation of personal care products certified according to the ECOCERT Natural and Organic Cosmetic Standard.

The approval was granted for the following products and production plants:

JUNGBUNZLAUER AUSTRIA AG (Austria)

- Citric Acid Anhydrous
- CITROCOAT[®] N
- Trisodium Citrate Anhydrous
- Xanthan Gum FFPC
- Xanthan Gum FFCS-PC
- Xanthan Gum FFCSP-PC
- Xanthan Gum FEDCS-PC
- Citric Acid Monohydrate
- LIQUINAT[®] (Citric Acid Solution)
- Trisodium Citrate Dihydrate
- Xanthan Gum FNPC
- Xanthan Gum FNCS-PC
- Xanthan Gum FNCSP-PC
- Zinc Citrate

JUNGBUNZLAUER LADENBURG GMBH (Germany)

- Calcium Lactate Gluconate
- CITROFOL[®] AI (Triethyl Citrate)
- Monosodium Citrate
- Citric Acid DC
- LIQUINAT[®] (Citric Acid Solution)
- Tripotassium Citrate

JUNGBUNZLAUER S.A. (France)

- ERYLITE[®]
- L(+)-Lactic Acid 50%
- L(+)-Lactic Acid 80%
- L(+)-Lactic Acid 88%
- L(+)-Lactic Acid 90%
- Glucono-delta-Lactone
- Potassium-L(+)-Lactate 60%
- Sodium-L(+)-Lactate 50%
- Sodium-L(+)-Lactate 60%
- Sodium Gluconate

Please find enclosed the ECOCERT approval showing the INCI names and the most common functions in their use in personal care applications.

Jungbunzlauer
Technical Service

Information on Standard Packaging CITROFOL® AI

Standard Canister:

Construction:	HDPE (blue coloured)
Filling weight:	25 kg
Canister weight:	ca. 1.4 kg
Dimension:	358 mm x 293 mm x 418 mm
Volume	30 litres
Closure:	lock closure



Example canister as used for all CITROFOL® products

Standard Drums:

Construction:	mild steel drum
Filling weight:	225 kg
Drum weight:	ca.18 kg
Dimension:	571.5 mm x 585 mm x 882 mm
Volume:	216.5litres
Drums diameter:	585 mm
Drums heights:	882 mm
Closures:	a) ¾ " b) 2"
Sealant:	EPDM



Example steel drums as used for all CITROFOL® products

Standard Bulk Container (IBC):

Construction:	HDPE with UV protection
Filling weight:	1000 kg
IBC weight:	ca. 60 kg
Dimension:	120 x 100 cm
Filling opening:	150 mm
Steelcase:	Galvanised steel tubes (18x18 mm)

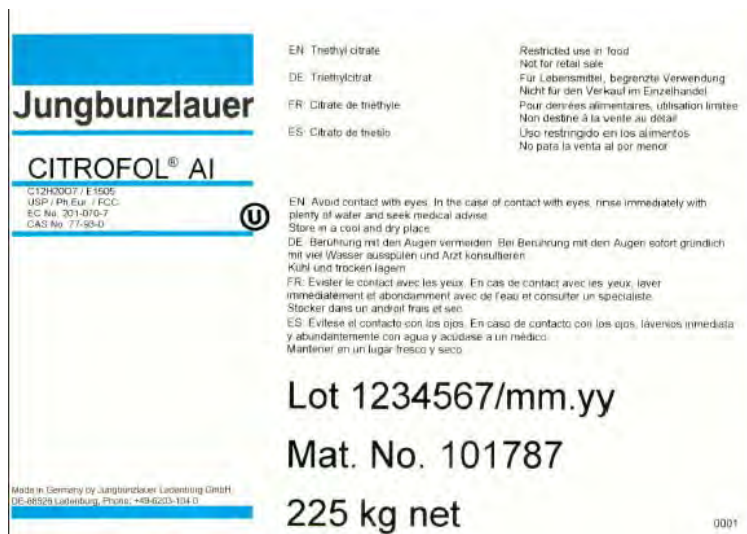


Example IBC as used for all CITROFOL® products

Standard markings on labels:

(Difference only in net weight)

- Product name
- Chemical formula
- Specified Grade
- CAS / EC number
- Symbol kosher OU
- Country of Origin /Production
- Name and address of the manufacturer
- Chemical name and uses
- Safe handling instruction
- Lot number and expiry date
- Material code number
- Net weight
- Number of the label within the lot



Standard Pallets:

Heat treated wood in compliance with ICCP Standard

CP-1 Pallet

Dimension: 120 x 100 x 14 cm

Weight: approx. 20 kg

CP- 3 Pallet

Dimension: 114 x114 x 14 cm

Weight: approx. 20 kg



Loading details:

Numbers of units	Weight	Height	Remark
27 canister	675 kg	ca. 140 cm	CP-1
4 drums	900 kg	ca. 100 cm	CP-3
1 IBC	1000 kg	ca. 120 cm	CP-1

The given information reflects the current status. Jungbunzlauer will not automatically inform about updated information or minor changes.

GMO Position European Manufacturing Sites

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

The following Jungbunzlauer products

Citrics	Citric Acid LIQUINAT [®] Citric Acid Solution Trisodium Citrate
Gluconates	Gluconic Acid Glucono-delta-Lactone Sodium Gluconate
Lactics	L(+)-Lactic Acid L(+)-Lactic Acid Buffered Potassium-L(+)-Lactate Potassium-L(+)-Lactate / Sodium Diacetate Potassium-L(+)-Lactate / Potassium Diacetate Sodium-L(+)-Lactate Sodium-L(+)-Lactate / Sodium Diacetate
Specialities	Citric Acid DC CITROCOAT [®] N CITROFOL [®] ESSICCUM [®] sub4salt [®]
Special Salts	Calcium Lactate Gluconate CITROMA [®] (CITRATE MA in the USA) Monosodium Citrate Potassium Gluconate Tricalcium Citrate Trimagnesium Citrate Tripotassium Citrate Zinc Citrate
Sweeteners	ERYLITE [®] ERYLITE [®] Stevia
Xanthan Gum	Xanthan Gum Xanthan Gum Blends

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

Micro-organisms - Production Strains

Jungbunzlauer does not use genetically modified production strains* for the manufacture of above mentioned food additives.

*no GMO in the meaning of the European Directive 2009/41/EC which replaces Directive 90/219/EEC and its successive amendments.

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).

For the glucose syrup production at the Jungbunzlauer plant in Pernhofen we purchase maize from farmers upon non-GMO agreement.

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 is not applicable to above-mentioned Jungbunzlauer food additives.

Regulation on GMO Traceability

The regulation (EC) No **1830/2003** 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 1830/2003.