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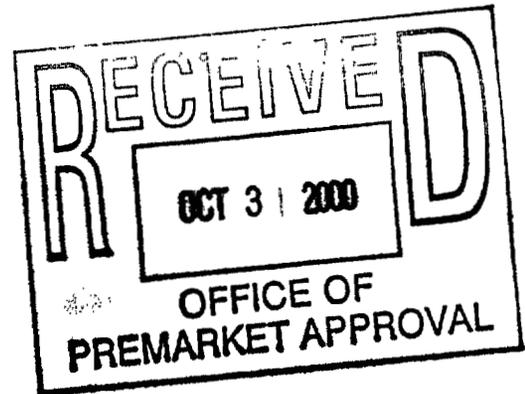
**ORIGINAL SUBMISSION**

000001

BETTY J. PENDLETON  
15505 COUNTRY RIDGE DRIVE  
CHESTERFIELD, MISSOURI 63017-7455  
(636) 532-5687  
FAX (636) 537-3953

October 12, 2000

Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204



Dear Sir,

The attached information is being submitted on behalf of Jones-Hamilton Co., 30354 Tracy Road, Walbridge, Ohio, as a GRAS notification on the use of potassium bisulfate for use as (1) a pH control agent and leavening agent in cake mixes at a level of 0.1% to 1.0% by weight and (2) a pH control agent and processing aid in food at levels not to exceed good manufacturing practices. It would be used in food for its clean flavor profile and acid value.

In 1998, FDA designated the sodium bisulfate notice as GRAS Notice No. GRN 000003. This notice states that Jones-Hamilton Company has determined that sodium bisulfate ( $\text{NaHSO}_4$ ) is generally recognized as safe (GRAS). At that time, FDA had no questions regarding that conclusion. That conclusion was based on scientific procedures. Jones-Hamilton believes the basis for GRAS determination of potassium bisulfate should also be on scientific procedures. Sodium and potassium bisulfate are the acid salts of sulfuric acid which is recognized as GRAS (21 CFR 582.1095) and (21CFR 184.1095). Sodium and potassium bisulfate are very similar chemicals. The bisulfate ion ( $\text{HSO}_4$ ) is what generates their acid properties. These mild acids are neither more nor less dangerous than any other food acid of the same concentration.

Potassium bisulfate is a permitted food additive by the European Scientific Committee for Food, Reference number E515 (see attached document).

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**Potassium Bisulfate:**

**Synonyms: potassium acid sulfate, potassium hydrogen sulfate, and sulfuric acid monopotassium salt.**

**Chemical formula: KHSO<sub>4</sub>**

**CAS Registry Number: 7646-93-7**

**Molecular Weight: 136.17**

**The following pages provide information on manufacturing, characteristic properties, specifications, self-limiting levels of use, and food additives in the European Union.**

**Jones-Hamilton has common knowledge of safety within the export community relating to the chemical identity or characteristic properties of the substance, as well as methods of manufacturer; reasonable certainly that the substance is not harmful under the intended conditions of use. The substance is neither more safe nor less safe than the approved food additive sulfuric acid or sodium bisulfate.**

**If you have any questions concerning this notification, please do not hesitate to contact me.**

**~~Sincerely,~~**

**Betty Perdleton**

**000003**

**Name and address of the notifier:** Jones-Hamilton  
30354 Tracy Road  
Walbridge, Ohio 43465

**Common or usual name :** Potassium Bisulfate

**Conditions of use:** General food additive, for leavening cake mixes

**Levels of use:**  
1. 0.1% to 1.0% by weight  
2. levels not to exceed good manufacturing practices

**Purpose:**  
1. pH control agent and leavening agent in cake mixes  
2. pH control agent and processing aid in food

**Basis for determination:** Experience based on common use in food

**Statement of Availability:** The data and information that are the basis for the GRAS notification are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at 30354 Tracy Road, Walbridge, Ohio or will be sent to FDA upon request.

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The use of potassium bisulfate is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because Jones Hamilton has determined that such use is GRAS.

Signed \_\_\_\_\_

Date

10/13/00

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**Description of Manufacturing Process:**

Food grade potassium chloride (KCl) and sulfuric acid are mixed together in a reaction vessel at 600 'F. Molten Potassium bisulfate and hydrogen chloride gas are produced from this reaction.



The molten potassium bisulfate is transferred to the spray chamber, where it is sprayed and cooled to form a solid bead. The solid potassium bisulfate is then screened for size and transferred to bulk storage bins or packaged off into containers.

The hydrogen chloride gas produced from the reaction is absorbed in water to produce hydrochloric acid.

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Levels of use: 1 to 10 grams of potassium bisulfate per 1000 grams of total mix (0.1% to 1.0% by weight).

Potential Human Toxicants: The potential human toxicant associated with potassium bisulfate is its acidic nature. Potassium bisulfate is a mild acid with a strength similar to phosphoric acid. When used in foods for its acid value, its toxicity would be similar to the acids already used in foods.

Self-limiting levels of use: Potassium bisulfate is a mild acid with a strength similar to acids currently being used in foods.

Most leavening systems are a mixture of an acid with sodium bicarbonate (a base). When water is added to this mixture, the acid reacts with the base to produce water, salt and carbon dioxide gas (which causes the batter to rise). Potassium bisulfate (acid) reacts with sodium bicarbonate (base) to produce potassium sulfate (salt), water, and carbon dioxide gas. The amount of potassium bisulfate and sodium bicarbonate in the mixture are such that after the reaction takes place very little acid or base remains.

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## POTASSIUM BISULFATE FOOD GRADE

### PROPERTIES:

Formula	-	KHSO <sub>4</sub> ; Molecular Weight 136.17
Physical Form	-	Dry crystalline solid: Spherical shape bead.
Solubility	-	56g in 100g of water
Melting Point		197C (387F)
<b>ANALYSIS:</b>		
Assay, as KHSO <sub>4</sub> wt %	-	90.5 – 95.2
Moisture as H <sub>2</sub> O wt %	-	0.6 % Max
Heavy Metals (as Pb)	-	< 0.003%
Lead	-	< 5 mg/Kg
Selenium	-	<0.003%
Water-Insoluble Substances	-	< 0.05%
Color	-	Off White

### Particle Size: Cumulative (Percent retained on screen)

<u>USS Screen</u>	<u>Typical</u>	<u>Range</u>
10mesh	0.0	0.0 to 0.1
20 mesh	39.0	30 to 80
40 mesh	94.0	85 to 99
60 mesh	99.0	90 to 99.9
100 mesh	99.8	98.0 to 100
Through 100 mesh	0.2	0.0 to 0.3

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**JONES-HAMILTON CO.**

8400 Enterprise Drive, Newark, CA 94560-3310

(510) 797-2471

**MATERIAL SAFETY DATA SHEET****SECTION 1 IDENTIFICATION**

**MANUFACTURER'S NAME / ADDRESS:** JONES-HAMILTON CO.  
8400 ENTERPRISE DRIVE  
NEWARK, CA 94560  
OR  
30354 TRACY ROAD  
WALBRIDGE, OHIO 43465

**EMERGENCY PHONE NUMBERS:**  
(510) 797-2471 OR  
(510) 792-4500  
OR  
(419) 666-9838  
(419) 666-6337  
CHEMTREC: (800) 424-9300

**PRODUCT NAME:** POTASSIUM BISULFATE

**SECTION 2 PRODUCT INGREDIENTS**

**CHEMICAL FORMULA:** KHSO<sub>4</sub>  
**COMPONENTS:**

<u>INGREDIENT</u>	<u>PERCENT (BY WEIGHT)</u>	<u>PEL</u>	<u>TLV</u>
POTASSIUM BISULFATE	93.2	NONE ESTABLISHED	NONE ESTABLISHED
POTASSIUM SULFATE	6.5	NONE ESTABLISHED	NONE ESTABLISHED

**SECTION 3 HAZARDOUS HEALTH DATA**

PRINCIPLE HEALTH HAZARDS, INCLUDING SIGNIFICANT ROUTES, EFFECTS, AND SYMPTOMS OF OVEREXPOSURE AND MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE MAY BE:

**EYE:** MILD TO SEVERE IRRITANT. MAY CAUSE BURNS IF NOT FLUSHED WITH WATER.

**SKIN:** MODERATE IRRITANT. MAY CAUSE BURNS IF NOT FLUSHED WITH WATER.

**INHALATION:** IRRITANT. MAY IRRITATE OR BURN NOSE, THROAT AND LUNGS. NO EXPOSURE LIMITS ESTABLISHED.

**INGESTION:** IRRITANT. MAY IRRITATE OR BURN MOUTH, ESOPHAGUS OR STOMACH.

**CARCINOGENICITY:** NOT LISTED AS CARCINOGEN BY NTP, IARC OR OSHA.

**SECTION 4 FIRST AID**

**IN EYES:** IMMEDIATELY FLUSH WITH WATER FOR FIFTEEN (15) MINUTES, LIFTING EYELIDS TO THOROUGHLY FLUSH. GET PROMPT MEDICAL ATTENTION.

**ON SKIN:** IMMEDIATELY FLUSH WITH WATER FOR FIFTEEN (15) MINUTES. IF BURN OCCURS, OBTAIN MEDICAL HELP.

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**IF INHALED:** MOVE TO FRESH AIR LOCATION. IF IRRITATION OR DISCOMFORT PERSISTS, SEEK MEDICAL ATTENTION.

**IF SWALLOWED:** DRINK LARGE QUANTITIES OF MILK OR WATER. FOLLOW WITH MILK OF MAGNESIA, BEATEN EGGS OR VEGETABLE OIL. DO NOT INDUCE VOMITING. CONTACT PHYSICIAN IMMEDIATELY.

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**SECTION 5 FIRE AND EXPLOSION HAZARD DATA**

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**FLASH POINT:** NOT APPLICABLE, WILL NOT BURN.

**EXPLOSIVE LIMITS:**  
(UPPER): NOT APPLICABLE

(LOWER): NOT APPLICABLE

**EXTINGUISHING MEDIA:** WATER OR DRY CHEMICAL AS APPROPRIATE FOR COMBUSTIBLES IN AREA. AVOID WATER CONTACT TO MATERIAL IF POSSIBLE.

**HAZARDOUS THERMAL DECOMPOSITION PRODUCTS:** AT TEMPERATURES OVER 806° F, PRODUCT WILL DECOMPOSE, GENERATING OXIDES OF SULFUR.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** PRODUCT READILY DISSOLVES IN WATER TO FORM AN ACID SOLUTION. NO GASES OR TOXIC FUMES ARE EMITTED FROM THIS REACTION, BUT PRECAUTIONS FOR EXPOSURE TO ACID SHOULD BE FOLLOWED.

**SPECIAL FIRE FIGHTING PROCEDURES:** IF WATER IS USED TO EXTINGUISH COMBUSTIBLES AND PRODUCT IS DISSOLVED IN WATER IT WILL FORM AN ACID, WEAR ACID PROTECTIVE EQUIPMENT. IF ELEVATED TEMPERATURES (> 806° F) ARE REACHED, SELF-CONTAINED BREATHING APPARATUS SHOULD BE WORN.

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**SECTION 6 SPILL OR LEAK PROCEDURES**

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**SMALL SPILLS:** MATERIAL IS GRANULAR PRODUCT AND CAN BE SWEEPED UP FROM SURFACES.

**LARGE SPILLS:** PICK UP AS MUCH MATERIAL AS POSSIBLE WITH SHOVEL OR OTHER TOOL. NEUTRALIZE BALANCE OF SPILL WITH WEAK ALKALINE SOLUTION AND WASH DOWN TO SEWER IF FEDERAL, STATE OR LOCAL REGULATIONS PERMIT.

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**SECTION 7 SAFE HANDLING AND STORAGE**

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- AVOID CONTACT WITH SKIN, EYES OR CLOTHING.
- DO NOT STORE WHERE EXPOSED TO MOIST CONDITIONS OR NEAR STRONG ALKALIS.
- KEEP CONTAINERS TIGHTLY CLOSED.
- WEAR ALL RECOMMENDED PROTECTIVE EQUIPMENT WHEN HANDLING.

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**SECTION 8** **PERSONAL PROTECTION DATA**

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**VENTILATION:** LOCAL VENTILATION TO A DUST COLLECTOR IS RECOMMENDED.

**RESPIRATORY PROTECTION:** NIOSH OR MSA CERTIFIED DUST MASK SHOULD BE WORN WHILE HANDLING PRODUCT TO CONTROL EXPOSURE BELOW NUISANCE DUST LIMITS OF 10 MG/M<sup>3</sup>.

**PROTECTIVE GLOVES:** WEAR ACID RESISTANT GLOVES SUCH AS RUBBER OR NEOPRENE.

**EYE PROTECTION:** SAFETY GLASSES OR GOGGLES.

**OTHER PROTECTIVE EQUIPMENT:** CLOTHES SHOULD COMPLETELY COVER SKIN TO AVOID SKIN CONTACT. COATS, COVERALLS OR APRONS ARE RECOMMENDED.

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**SECTION 9** **PHYSICAL AND CHEMICAL PROPERTIES**

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<u>PROPERTY</u>	<u>VALUE</u>
MELTING POINT	387 <sup>o</sup> F
BULK DENSITY	83 LB / CU FT
SOLUBILITY	56Gg in 100g water
PERCENT VOLATILE	NON-VOLATILE

**DESCRIPTION:** OFF-WHITE, BEAD-LIKE, GRANULAR DRY MATERIAL.

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**SECTION 10** **REACTIVITY DATA**

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**STABILITY:** STABLE

**INCOMPATIBILITY:** AVOID CONTACT WITH STRONG ALKALINE MATERIALS SUCH AS CAUSTIC. REACTS WITH WATER TO FORM AN ACID SOLUTION. **DO NOT MIX** WITH LIQUID CHLORINE BLEACH, AMMONIA CLEANSERS OR SIMILAR PRODUCTS.

**CONDITIONS TO AVOID:** STORE IN DRY AREA TO AVOID MOISTURE CONTACT.

**HAZARDOUS DECOMPOSITION:** NONE, UNLESS HEATED OVER 806<sup>o</sup> F, AT WHICH SULFUR DIOXIDE AND SULFUR TRIOXIDE ARE FORMED.

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**SECTION 11** **TOXICOLOGICAL INFORMATION**

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**NOTES TO PHYSICIAN:**

**EYES:** NATURAL WATERING OF EYES WILL DISSOLVE POTASSIUM BISULFATE, FORMING A WEAK ACID SOLUTION WHICH MAY CAUSE BURNS. FLUSH EFFECTED AREA THOROUGHLY WITH WATER. **DO NOT USE** CHEMICAL ANTIDOTES OR NEUTRALIZING SOLUTIONS.

**SKIN:** MILD BURNS MAY OCCUR IF NOT THOROUGHLY FLUSHED PREVIOUSLY.

**INHALATION:** MILD BURNING SENSATIONS MAY OCCUR TO MUCOUS MEMBRANES AND UPPER RESPIRATORY TRACT.

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**INGESTION:** BODY WATER CONTENT WILL REACT WITH POTASSIUM BISULFATE TO FORM A WEAK ACID SOLUTION, WHICH MAY BURN TISSUES IN MOUTH, ESOPHAGUS OR STOMACH. SOLUTION SHOULD BE DILUTED TO REDUCE BURNING EFFECT.

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**SECTION 12 ECOLOGICAL INFORMATION**

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**SECTION 13 DISPOSAL CONSIDERATIONS**

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**WASTE DISPOSAL METHODS:** COMPLY WITH ALL FEDERAL, STATE AND LOCAL REGULATIONS.

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**SECTION 14 TRANSPORTATION INFORMATION**

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**HAZARD CLASSIFICATION (DOT):** Hazard Class: 8  
UN/NA: UN2509  
Packing Group: II

**PROPER D.O.T. SHIPPING NAME:** POTASSIUM HYDROGEN SULFATE

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**SECTION 15 REGULATORY INFORMATION**

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**CAS NUMBER:** 7646-93-7

**NIOSH REGISTRY NO.:** UNKNOWN

**OTHER REGISTRIES:**

**OSHA HAZARD COMMUNICATIONS HEALTH HAZARD CLASSIFICATION:**

**SECTION 312 OR SARA TITLE III HAZARD CATEGORY:** ACUTE

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM (HMIS) RATING:**

<u>HEALTH</u>	<u>FLAMMABILITY</u>	<u>REACTIVITY</u>	<u>PROTECTIVE EQUIPMENT</u>
1	0	1	F

**NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATING:**

<u>HEALTH</u>	<u>FLAMMABILITY</u>	<u>REACTIVITY</u>	<u>SPECIAL NOTICE</u>
1	0	0	NONE

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**SECTION 16**

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**MISCELLANEOUS INFORMATION**

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THE DATA IN THIS MATERIAL SAFETY DATA SHEET RELATES ONLY TO THE SPECIFIC MATERIAL DESIGNATED HEREIN AND DOES NOT RELATE TO USE IN COMBINATION WITH ANY OTHER MATERIAL IN ANY PROCESS. THE INFORMATION SET FORTH HEREIN IS FURNISHED FREE OF CHARGE AND IS BASED ON TECHNICAL DATA THAT JONES-HAMILTON CO. BELIEVES TO BE RELIABLE. IT IS INTENDED FOR USE BY PERSONS HAVING TECHNICAL SKILL AND AT THEIR OWN DISCRETION AND RISK. SINCE CONDITIONS OF USE ARE OUTSIDE OUR CONTROL, WE MAKE NO WARRANTIES, EXPLICIT OR IMPLIED, AND ASSUME NO LIABILITY IN CONNECTION WITH ANY USE OF THIS INFORMATION. NOTHING HEREIN IS TO BE TAKEN AS A LICENSE TO OPERATE UNDER OR A RECOMMENDATION TO INFRINGE ANY PATENTS.

DATE OF LAST REVISION: AUGUST 2000

SIGNATURE / TITLE OF PREPARER:

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COLBY LA PLACE  
EXECUTIVE DIRECTOR OF COMPLIANCE AND ENGINEERING

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## ASSAY DETERMINATION OF POTASSIUM BISULFATE

This procedure documents the steps required to determine the %potassium bisulfate by titration.

### RESOURCES

The following materials are required to perform this procedure:

Beaker, 100 ml buret, magnetic stirrer and stir bar, top loading balance (with readability of 0.01 g), 1.00 N sodium hydroxide solution, Phenolphthalein indicator,

### GENERAL HYGIENE AND SAFETY

The following personal protective equipment must be worn when performing this procedure:

Safety glasses

### PROCEDURE

- 1 Add approximately 100 mls of water to a clean beaker.
- 2 Weight out a 3.00 g sample of potassium bisulfate.
- 3 Transfer potassium bisulfate to the beaker, and add 3 to 5 drops of phenolphthalein indicator and stir bar.
- 4 Place the beaker on the magnetic stirrer and dissolve the potassium bisulfate.
- 5 Fill the buret with 1 N sodium hydroxide
- 6 Titrate until a pink end point appears and remains.
- 7 Note the final level of sodium hydroxide in the buret to the nearest 0.1 ml.
- 8 Determine the %  $\text{KHSO}_4$  using the following formula:

$$\% \text{KHSO}_4 = \frac{\text{mls} \times \text{N}(\text{NaOH}) \times 13.617}{\text{Grams of sample}}$$

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The Department of Food Science and Technology  
The University of Reading, UK

# Food Law

## Food Additives in the European Union

*(compiled by Dr David Jukes)*

To go to main Food Law Index page, [click here](#).

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As part of the moves to create the Internal Market, the Community agreed that the control of food additives should be harmonised throughout the Community. Earlier attempts had only be partially successful and for the purposes of the Internal Market, full agreement was needed.

In late 1988 (but published in 1989), the Community adopted a framework directive which set out the criteria by which additives would be assessed and provided for the adoption of more specific technical directives establishing the list of additives which could be used, the foods in which they could be used and any maximum levels. The Directive is:

- Council Directive of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (89/107/EEC).

This Directive requires that all permitted food additives are assessed by the European Scientific Committee for Food (SCF) for their safety against the criteria which are stated in the Annex to the Directive.

The specific Directives were eventually adopted. 3 Directives now provide the requirements for additive legislation within the whole of the European Community. They are:

- **Sweeteners:** European Parliament and Council Directive (94/35/EC) of 30 June 1994 on sweeteners for use in foodstuffs (OJ L237, 10.09.1994, page 3)
- **Colours:** European Parliament and Council Directive (94/36/EC) of 30 June 1994 on colours for use in foodstuffs (OJ L237, 10.09.1994, page 13)
- **Food additives other than colours and sweeteners:** European Parliament and Council Directive (95/2/EC) of 20 February 1995 on food additives other than colours and sweeteners (OJ L61, 18.03.1995, page 1)

The framework Directive was amended in 1994 by:

- European Parliament and Council Directive of 30 June 1994 amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorised for use in foodstuffs intended for human consumption (94/34/EC)

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The amendment provided that countries can nominate certain foods which have traditional characteristics and which, in the territory of the Member State, have not been permitted to contain certain additives. If it is subsequently agreed, the Member States concerned can continue to restrict the use of additives in these foods within their territory. This has resulted in the adoption of a Decision providing approved national derogations:

- Decision No 292/97/EC of the European Parliament and of the Council of 19 December 1996 on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs (OJ L48, 19.02.1997, p.3)

In addition, there are amending directives which have amended 2 of the 3 specific Directives. These are:

- Directive 96/83/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 94/35/EC on sweeteners for use in foodstuffs (OJ L48, 19.02.1997, page 4)
- Directive 96/85/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 95/2/EC on food additives other than colours and sweeteners (OJ L86, 28.03.1997, page 1)
- Directive 98/72/EC of the European Parliament and of the Council of 15 October 1998 amending Directive 95/2/EC on food additives other than colours and sweeteners (OJ L295, 4.11.1998, page 18)

Work has progressed on defining specific purity criteria for the additives. These are adopted by additional Directives:

- Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs (OJ L178, 28.07.1995, page 1)
- Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs (OJ L226, 22.09.1995, page 1)

The following amendments have also been adopted:

- Commission Directive 98/66/EC of 4 September 1998 amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs (OJ L257, 19.09.1998, page 35)
- Commission Directive 98/86/EC of 11 November 1998 amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L334, 9.12.1998, page 1)

For the United Kingdom, the Directives have been implemented into UK legislation by the following Regulations which came into effect on the 1st January 1996

- Colours in Food Regulations 1995 (SI 1995 No 3124)
- Sweeteners in Food Regulations 1995 (SI 1995 No 3123)
- Miscellaneous Food Additives Regulations 1995 (SI 1995 No 3187)

## **Adding Additives to the List**

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The procedure for requesting a new additive to be listed is to contact the EU Commission. The address to

write to is:

Directorate General III / E1  
European Commission  
Rue de la Loi 200,  
1049 Bruxelles  
Belgium.

If DGIII believes that the substance is appropriate, it will request the necessary scientific data from the applicant. Once submitted, the data will be forwarded to the EU Scientific Committee for Food for safety evaluation. Evaluation may take several months. If approved by the SCF, the Commission will then initiate the process to amend the legislation so as to add the substance to the appropriate directive. This can take a further 12 - 18 months. Only when the legislation has been passed will the substance then be permitted.

The directives allow a Member State to grant temporary authorisation for products marketed on their territory. The maximum authorisation is 2 years after which, if the substance has not been added to the directive, sales must cease.

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The list below gives the reference number (the "E number") and the English name of all those additives listed in the 3 specific directives. It should be noted that some additives are restricted to a very limited number of foods whereas others may be permitted at the level necessary to achieve the desired technical effect ("quantum satis") with no numerical limit stated. The Directives or the implementing legislation in the Member States should be consulted for actual details.

The numbering system is being adapted for international use by the Codex Alimentarius Commission who are developing an International Numbering System (INS). This will largely use the same numbers (but without the E).

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### E Number List

- E100 Curcumin
- E101 (i) Riboflavin (ii) Riboflavin-5'-phosphate
- E102 Tartrazine
- E104 Quinoline Yellow
- E110 Sunset Yellow FCF, Orange Yellow S
- E120 Cochineal, Carminic acid, Carmines
- E122 Azorubine, Carmoisine
- E123 Amaranth
- E124 Ponceau 4R, Cochineal Red A
- E127 Erythrosine
- E128 Red 2G
- E129 Allura Red AC
- E131 Patent Blue V
- E132 Indigotine, Indigo carmine
- E133 Brilliant Blue FCF

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- E494 Sorbitan monooleate
- E495 Sorbitan monopalmitate
- E500 Sodium carbonates (i) Sodium carbonate (ii) Sodium hydrogen carbonate (iii) Sodium sesquicarbonate
- E501 Potassium carbonates (i) Potassium carbonate (ii) Potassium hydrogen carbonate
- E503 Ammonium carbonates (i) Ammonium carbonate (ii) Ammonium hydrogen carbonate
- E504 Magnesium carbonates (i) Magnesium carbonate (ii) Magnesium hydroxide carbonate (syn. Magnesium hydrogen carbonate)
- E507 Hydrochloric acid
- E508 Potassium chloride
- E509 Calcium chloride
- E511 Magnesium chloride
- E512 Stannous chloride
- E513 Sulphuric acid
- E514 Sodium sulphates (i) Sodium sulphate (ii) Sodium hydrogen sulphate
- E515 Potassium sulphates (i) Potassium sulphate (ii) Potassium hydrogen sulphate
- E516 Calcium sulphate
- E517 Ammonium sulphate
- E520 Aluminium sulphate
- E521 Aluminium sodium sulphate
- E522 Aluminium potassium sulphate
- E523 Aluminium ammonium sulphate
- E524 Sodium hydroxide
- E525 Potassium hydroxide
- E526 Calcium hydroxide
- E527 Ammonium hydroxide
- E528 Magnesium hydroxide
- E529 Calcium oxide
- E530 Magnesium oxide
- E535 Sodium ferrocyanide
- E536 Potassium ferrocyanide
- E538 Calcium ferrocyanide
- E541 Sodium aluminium phosphate, acidic
- E551 Silicon dioxide
- E552 Calcium silicate
- E553a (i) Magnesium silicate (ii) Magnesium trisilicate
- E553b Talc
- E554 Sodium aluminium silicate
- E555 Potassium aluminium silicate
- E556 Calcium aluminium silicate
- E558 Bentonite
- E559 Aluminium silicate (Kaolin)
- E570 Fatty acids
- E574 Gluconic acid
- E575 Glucono-delta-lactone
- E576 Sodium gluconate
- E577 Potassium gluconate
- E578 Calcium gluconate
- E579 Ferrous gluconate

SUBMISSION END

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BETTY J. PENDLETON  
15505 COUNTRY RIDGE DRIVE  
CHESTERFIELD, MISSOURI 63017-7455  
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FAX (636) 537-3953

November 3, 2000

Dr. Linda Kahl  
Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

VIA FAX 202-418-3131

Dear Dr. Kahl,

GRAS Notification  
Potassium Bisulfate  
Jones-Hamilton Co.

This is to confirm our telephone conversation of today in which I realized that there was an inconsistency in my cover letter dated October 12, 2000 and the attached revised GRAS Exemption Claim.

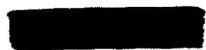
I have revised the attachment to list the Basis for determination to be: Based on scientific procedures.

If you have any questions, please do not hesitate to contact me. Thank you for your help in this matter.

Sincerely, \_\_\_\_\_

Betty Pendleton

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**Name and address of the notifier:** Jones-Hamilton  
30354 Tracy Road  
Walbridge, Ohio 43465

**Common or usual name :** Potassium Bisulfate

**Conditions of use:** General food additive, for leavening cake mixes

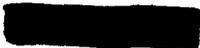
**Levels of use:** 1. 0.1% to 1.0% by weight  
2. levels not to exceed good manufacturing practices

**Purpose:** 1. pH control agent and leavening agent in cake mixes  
2. pH control agent and processing aid in food

**Basis for determination:** Scientific Procedures

**Statement of Availability:** The data and information that are the basis for the GRAS notification are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at 30354 Tracy Road, Walbridge, Ohio or will be sent to FDA upon request.

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JONES-HAMILTON CO.  
30354 TRACY ROAD  
WALBRIDGE, OH 43465

TEL: (419) 666-9838  
TEL: (419) 666-5910  
FAX: (419) 666-1817

**FAX TRANSMITTAL**

TO: Parvin Yasaei  
DATE: 1/8/00  
COMPANY: \_\_\_\_\_  
FAX NUMBER: \_\_\_\_\_  
FROM: Carl Kneevern  
**Jones-Hamilton Co.**

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**ASSAY DETERMINATION OF POTASSIUM BISULFATE**

This procedure documents the steps required to determine the %potassium bisulfate by titration.

**RESOURCES**

The following materials are required to perform this procedure:

Beaker, 100 ml buret, magnetic stirrer and stir bar, top loading balance (with readability of 0.01 g), 1.00 N sodium hydroxide solution, Phenolphthalein indicator,

**GENERAL HYGIENE AND SAFETY**

The following personal protective equipment must be worn when performing this procedure:

Safety glasses

**PROCEDURE**

- 1 Add approximately 100 mls of water to a clean beaker.
- 2 Weight out a 3.00 g sample of potassium bisulfate.
- 3 Transfer potassium bisulfate to the beaker, and add 3 to 5 drops of phenolphthalein indicator and stir bar.
- 4 Place the beaker on the magnetic stirrer and dissolve the potassium bisulfate.
- 5 Fill the buret with 1 N sodium hydroxide
- 6 Titrate until a pink end point appears and remains.
- 7 Note the final level of sodium hydroxide in the buret to the nearest 0.1 ml.
- 8 Determine the %  $\text{KHSO}_4$  using the following formula:

$$\% \text{KHSO}_4 = \frac{\text{mls} \times \text{N}(\text{NaOH}) \times 13.617}{\text{Grams of sample}}$$

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