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ORIGINAL SUBMISSION

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BETTY J. PENDLETON
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1998 FEB 26 A 8: 30

February 11, 1998

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 sodium bisulfate as an general acidifier and leavening agent in cake mixes or general food additive. Sodium bisulfate would replace the use of other acids.

Sodium Bisulfate is sodium salt of sulfuric acid generally expressed as NaHSO_4 .

Sodium bisulfate is exempted from tolerance requirements when used as an acidifying/buffering agent in pesticide formulations applied to growing crops; cleared as an adhesive; and cleared by USDA as a cooling and retort water treatment agent to inhibit corrosion on exteriors of canned goods.

While sodium bisulfate is an unapproved additive for use in animal feed, CVM reviewed the same information provided under an informal opinion basis and ruled that sodium bisulfate is similar to that of sulfuric acid when used in feed. Sodium bisulfate was accepted by CVM as a general purpose food additive based on sulfuric acid being recognized as GRAS (21 CFR 582.1095) for use in animals as a general purpose food additive.

Sulfuric acid is considered GRAS under 21 184.1095 for use in alcoholic beverages and cheeses. Jones Hamilton is notifying the Agency that based on the GRAS approval of sulfuric acid and the similarity of sodium bisulfate, that sodium bisulfate is being used as a general purpose food additive.

Jones Hamilton has common knowledge of safety within the expert 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.

If you have questions concerning this notification, please let me know.

Sincerely,

Betty Pendleton

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The use of sodium 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

2/11/98

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GENERAL

GENERAL

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GRN # 000003

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

Common **or usual** name : Sodium Bisulfate

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

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

Purpose: **General** food additive, for leavening cake mixes

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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Detailed information: SODIUM BISULFATE is listed in **Food Chemicals Codex**. Sodium Bisulfate is sodium salt of sulfuric acid generally expressed as NaHSO₄. **Minimum sodium** bisulfate (NaHSO₄) must be specified.

CFR 21 184.1095 **Sulfuric acid**

(a) Sulfuric acid (H_2SO_4 , **CAS Reg. No.** 7664-93-9), also known as oil of vitriol, is a clear, colorless, **oily** liquid. It is prepared by reacting **sulfur** dioxide (SO_2) with **oxygen** and **mixing** the resultant sulfur trioxide (SO_3) with water, **or by** reacting nitric oxide (NO) with **sulfur** dioxide and water.

(b) The ingredient **meets** the specifications of the "Food Chemicals **Codex**," 3d Ed. (1981), pp. 317-318, which is incorporated by reference.....

© The ingredient is **used as a** pH control agent **as** defined in 170.3(o)(23) of this chapter and processing **aid as** defined in 170.3(o)(24) of **this** chapter.

(d) The ingredient is used **in** food at levels not to exceed good manufacturing practice in accordance with 184.1(b)(1). Current **good manufacturing** practice results in a **maximum** level, **as** served, **of** 0.014 percent for alcoholic beverages **as** defined in 170.3(n)(2) of **this** chapter **and** 0.0003 percent **for** cheeses **as** defined in 170.3(n)(5) of **this** chapter.

(e) Prior sanctions **for** this ingredient different **from** the uses established in **this section do not exist or have been waived.**

Sodium bisulfate is exempted from tolerance requirements when **used as an** acidifying/buffering agent in pesticide formulations applied to growing crops; cleared **as** an adhesive; and cleared by **USDA as a cooling** and retort water treatment agent to inhibit corrosion **on** exteriors of **canned goods.**

While **sodium** bisulfate is **an** unapproved additive for **use** in **animal** feed, CVM reviewed the same information provided **under** an informal **opinion** basis and ruled that sodium bisulfate **is** similar to that **of sulfuric** acid when **used** in feed. It was accepted by CVM **as** a general purpose **food** additive. **Sulfuric** acid is recognized **as GRAS** (21 CFR 582.1095) **for use** in **animals** **as a general purpose food** additive.

Method of manufacture: Food **grade** sodium chloride (salt) and sulfuric acid **are mixed** together in a reaction vessel **at** 600 **°F**. Molten sodium bisulfate and hydrogen chloride gas are produced from this reaction.



The molten **sodium** bisulfate is transferred to the spray chamber, where it is sprayed and cooled **to form** a solid bead. The solid sodium 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.

Potential human toxicants: The potential **human** toxicant associated with sodium bisulfate is its acidic nature. Sodium bisulfate **is a milk** 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 in use.

Self-limiting levels of use: **Sodium** 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 **mix** to rise). **Sodium** bisulfate (acid) reacts with **sodium** bicarbonate (**base**) to **produce** sodium sulfate (salt), water, and carbon dioxide **gas**. The amount of sodium bisulfate and **sodium** bicarbonate in the mixture are **such** that after **the** reaction **takes place** very **little** acid or **base** remains.

Basis for determination: Jones-Hamilton has experience based **on** common use in food. Reasonable **certainly** that the substance is not harmful under the **intended** conditions of use. Substance is neither more safe **nor** less safe for this use than the approved food additive sulfuric acid.

SPECIFICATIONS

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DATA SHEET
SODIUM BISULFATE ANHYDROUS
GLOBULAR TECHNICAL

PROPERTIES:

Formula	-	NaHSO ₄ ; molecular weight 120
Common Names	-	Sodium Bisulfate, Sodium Hydrogen Sulfate, Sodium Acid Sulfate, Nitre Cake
Physical Form	-	Dry (Anhydrous), crystalline solid; spherical shape (bead) approx. 0.75 mm diameter (1/32 in.)
Solubility	-	Material is readily soluble in water.
pH of a 5% Aqueous Solution	-	1.0 pH

TYPICAL ANALYSIS:

	<u>Typical</u>	<u>Range</u>
Assay, as NaHSO ₄ , Wt. %	93.2	90.5 to 95.5
Sodium Sulfate, as Na ₂ SO ₄ , Wt. %	6.5	9.3 to 4.0
Moisture, as H ₂ O, Wt. %	0.2	0.2 to 0.5
Iron, as Fe, Wt. %	0.002	0.001 to 0.075
Free Acid, as H ₂ SO ₄	Nil	Nil
Acidity, as H ₂ SO ₄ , Wt. %	38.1	37.0 to 39.0
Color	Off-white	Off-white to light yellow
Bulk Density, Loose	82 to 84 lbs./cu. ft. 1.318-1.35 kg/l	80 to 85 lbs./cu. ft. 1.28 to 1.37 kg/l

Particle Size:

1. Non-cumulative

<u>USS Screen</u>	<u>Opening in Microns</u>		<u>Typical</u>	<u>Range</u>
On 10	On 2000,	Wt. %	0.0	0.0 to 0.1
Through 10, on 20	Through 2000, on 841,	Wt. %	39.0	30 to 80
Through 20, on 40	Through 841, on 420,	Wt. %	55.0	10 to 60
Through 40, on 60	Through 420, on 250,	Wt. %	5.0	1 to 9
Through 60, on 100	Through 250, on 149,	Wt. %	0.8	0.2 to 1
Through 100	Through 149,	Wt. %	0.2	0 to 0.3

2. Cumulative

<u>USS Screen</u>	<u>Opening in Microns</u>		<u>Typical</u>	<u>Range</u>
On 10	On 2000,	Wt. %	0.0	0.0 to 0.1
On 20	On 841,	Wt. %	39.0	30 to 80
On 40	On 420,	Wt. %	94.0	85 to 95.8
On 60	On 250,	Wt. %	99.0	90 to 99.8
On 100	On 149,	Wt. %	99.8	98.7 to 100
Through 100	Through 149,	Wt. %	0.2	0 to 0.3

JONES-HAMILTON CO.

30354 Tracy Road, Walbridge, OH 43465 • Day (419)666-9838 • Night (419)666-6337 • Fax (419) 666-1817

Issued 1996

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LABORATORY REPORT

SODIUM BISULFATE

FOOD CHEMICALS CODEX SPECIFICATION GRADE

Date Manufactured: THIRD QUARTER, 1996

This is to certify that a representative sample was obtained and analyzed in our laboratory according to the test methods required in Food Chemicals Codex, Third Edition. Results obtained were as follows:

<u>ITEM</u>	<u>FOOD CHEMICALS CODEX LIMITS</u>	<u>ANALYSIS Result</u>
Assay:		
As available H ₂ SO ₄	35.0 to 39.0	38.4
As NaHSO ₄ , %	85.4 to 95.2	93.7
Arsenic as As, p.p.m.	3 max	e3
Heavy Metals as Pb, p.p.m.	30 max	e30
Lead as Pb, p.p.m.	10 max	<10
Loss on Drying, %	0.8 max	<0.2
Selenium, (p.p.m. Se)	30 max	e30
Water-Insolubles Substance, %	0.05 max	eo.05

Signed: _____

Date: 10/29/96

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JONES-HAMILTON CO

30354 TRACY ROAD, WALBRIDGE, OHIO 43465 (419) 666-3910 TWX 810-442 1673 JONES HAM WABC
FAX (419) 666-1817

SALES SPECIFICATIONS FOR SULFURIC ACID 98-99%,

STRENGTH	98.0 H ₂ SO ₄ MINIMUM
COLOR, APHA	40 MAXIMUM
SULFUR DIOXIDE	50 PPM MAXIMUM
IRON	50 PPM MAXIMUM
ORGANICS	50 PPM MAXIMUM
SELENIUM	0.5 PPM MAXIMUM



morton salt product data



Purex® And TFC Purex® Salts

Silver Springs, NY; Rittman, OH Production

Description

Purex® Salt is food grade, unscreened granulated sodium chloride produced in the vacuum pan evaporating system from raw, untreated brine. The salt crystals are cubic in structure. There are no additives.

TFC Purex® Salt is prepared by treating Purex® Salt with a minute concentration of Yellow Prussiate of Soda (sodium ferrocyanide), a water soluble anticaking agent used in accordance with 21CFR Sec. 172.490.

Yellow Prussiate of Soda, as an incidental, nonfunctional additive under 21CFR Sec. 101.100 (a) (3), is exempt from label declaration on foods incorporating the salt.

Chemical Analysis

	Typical	Range
Sodium Chloride (b ²)	99.85	99.7 - 99.9
Calcium Sulfate (%)	0.12	0.08 - 0.20
Calcium Chloride (%)	3.32	0.01 - 0.07
Magnesium Chloride (%)	0.006	0.00 - 0.01
Moisture (%)	0.05	<0.1
Water Insolubles (ppm)	—	<20
Copper (ppm)	0.2	0.1 - 0.7
Iron (ppm)		
Free	1	u.4 - 2.0
Complexed	3.9	0.5 - 2.3
Sodium Ferrocyanide (ppm)	5	3 - 13 ¹¹

- (1) By difference of impurities, moisture-free basis (ASTM).
 (2) Contributed by sodium ferrocyanide (18% Fe).
 (3) Used in TFC Purex® Salt only.

Producing Plants

Silver Springs, NY and Rittman, OH. For data concerning production at other plants refer to PDS 105.2 - Manistee, MI; PDS No. 105.3 - Hutchinson, KS; PDS NO. 105.4 Grand Saline, TX. Weeks, LA.

Commodity Codes

	Purex ¹ Salt	TFC Purex ² Salt
50 lb. bags	1514	—
80 lb. bags	1522	1518
Bulk	1519	1517

Packaging

Multiwall, polyethylene-lined kraft paper bags.

Unit Dimensions			
Net Wt (lb)	Gross Wt (lb)	LxWxH (in)	Cube (ft ³)
50	50.5	24x13x3	0.5
80	80.9	28x16x3.5	0.9
Palletized*			
Units	Cube (ft ³)	Gross Wt (lb)	
49	43	2545	
30	46	2497	

*Includes 48" x 40" standard wood pallet.

Physical Properties

Pour (loose) bulk density is 1.17 - 1.28 g/ml (73 - 80 lbs/ft³)

Production is unscreened, receiving a coarse scalping of 10-14 mesh. Screening analysis within 90% confidence is:

U.S.S. Mesh	Opening Microns*	Percent Retained**			
		Silver Springs Typical Range		Rittman Typical Range	
20	850	1	Tr - 4	Tr	0 - 4
30	600	6	1 - 19	11	2 - 27
40	425	22	12 - 42	42	12 - 55
50	300	40	30 - 57	37	20 - 58
70	210	23	10 - 37	9	2 - 29
Pan	—	8	1 - 15	1	0 - 8

- * 25.400 Microns (micrometers) per inch
 **On individual screens.

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For further information

Industrial/Chemical • Morton Salt Division of Morton Thiokol, Inc. • 110 North Wacker Drive, Chicago, Illinois 60606

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HAZARD CLASSIFICATION
OF VARIOUS ACIDS

<u>Acid</u>	<u>DOT Hazard Classification</u>	<u>NFPA Hazard Rating</u>			
		<u>Health</u>	<u>Flamability</u>	<u>Reactivity</u>	
SBS	Non-regulated	1	0	1	Least Hazardous  Most Hazardous
Citric	Non-regulated	1	1	0	
Propionic	Corrosive	1	2	1	
Phosphoric	Corrosive	2	0	0	
Acetic	Corrosive	2	2	1	
HCl	Corrosive	3	0	0	
Sulfamic	Corrosive	3	1	0	
Sulfuric	Corrosive	3	0	2	

DOT - Department Of Transportation:

NFPA - National Fire Protection Association:

SBS - Sodium Bisulfate

~~MSDS~~

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JONES-HAMILTON CO.

8400 Enterprise Drive, Newark, CA 94560-33 10

(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: SODIUM BISULFATE, ANHYDROUS GLOBULAR, TECHNICAL

GENERAL OR GENERIC IDENTIFICATION: SODIUM ACID SULFATE, NITRE CAKE, SODIUM HYDROGEN SULFATE

SECTION 2 PRODUCT INGREDIENTS

CHEMICAL FORMULA: NaHSO₄

HAZARDOUS COMPONENTS:

INGREDIENT	PERCENT (BY WEIGHT)	PEL	TLV
SODIUM BISULFATE	93.2	NONE ESTABLISHED	NONE ESTABLISHED
SODIUM 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.

- 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.

SECTION 5 FIRE AND EXPLOSION HAZARD DATA

- 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 A WEAK SULFURIC ACID SOLUTION. NO GASES OR TOXIC FUMES ARE EMITTED FROM THIS REACTION, BUT PRECAUTIONS FOR EXPOSURE TO SULFURIC ACID SHOULD BE FOLLOWED.
- SPECIAL FIRE FIGHTING PROCEDURES:** IF WATER IS USED TO EXTINGUISH COMBUSTIBLES AND PRODUCT IS DISSOLVED IN WATER FORMING SULFURIC ACID, WEAR ACID PROTECTIVE EQUIPMENT. IF ELNATED TEMPERATURES (> 570°F) ARE REACHED, SELF-CONTAINED BREATHING APPARATUS SHOULD BE WORN.

SECTION 6 SPILL OR LEAK PROCEDURES

- 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.

SECTION 7 SAFE HANDLING AND STORAGE

- 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.

SECTION 8 **PERSONAL PROTECTION DATA**

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 10MG/M³.
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.

SECTION 9 **PHYSICAL AND CHEMICAL PROPERTIES**

<u>PROPERTY.</u>	<u>VALUE</u>
MELTING POINT	350° F
BULK DENSITY	83 LB / CU FT
SOLUBILITY	100%
PERCENT VOLATILE	NON-VOLATILE

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

SECTION 10 **REACTIVITY DATA**

STABILITY: STABLE
INCOMPATIBILITY: AVOID CONTACT WITH STRONG ALKALINE MATERIALS SUCH AS CAUSTIC. REACTS WITH WATER TO FORM WEAK SULFURIC 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° F, AT WHICH SULFUR DIOXIDE AND SULFUR TRIOXIDE ARE FORMED.

SECTION 11 **TOXICOLOGICAL INFORMATION**

NOTES TO PHYSICIAN:

EYES: NATURAL WATERING OF EYES WILL DISSOLVE SODIUM BISULFATE, FORMING A WEAK SULFURIC-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.

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

SECTION 12 ECOLOGICAL INFORMATION

ANIMAL TEST DATA: 1) LD RAT 2800 MG / KG

2) THIS MATERIAL IS NEITHER CORROSIVE NOR DESTRUCTIVE TO THE SKIN OF NEW ZEALAND RABBITS. OCCASIONALLY, A VERY SLIGHT RASH MAY APPEAR.

SECTION 13 DISPOSAL CONSIDERATIONS

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

SECTION 14 TRANSPORTATION INFORMATION

HAZARD CLASSIFICATION (DOT): NOT CLASSIFIED AS HAZARDOUS

SECTION 15 REGULATORY INFORMATION

CAS NUMBER: 7681-38-1

NIOSH REGISTRY NO.: UNKNOWN

OTHER REGISTRIES: ANABSTR, APILIT, APILIT2, APIPAT, APIPAT2, BEILSTEIN, BIOBUSINESS, BIOSIS, CA, CAOLD, CAPREVIEWS, CASREACT, CEN, CHEMINFORMRX, CHEMLIST, CBNB, CIN, CJACS, CSHEM, CSNB, DETHERM, DIPPR, DSL, EINECS, EMBASE, GMELIN, HSDS, IFICDB, IFIPAT, IFIUDB, IPA, JANAF, MEDLINE, MRCK, MSDS-OHS, MSDS-PEST, MSDS-SUM, PDLCOM, PIRA, PNI, PROMT, RTECS, TOXLINE, TOXLIT, TRCTHERMO, TSCA, USAN, VTB.

OSHA HAZARD COMMUNICATIONS HEALTH HAZARD CLASSIFICATION: IRRITANT

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	1	NONE

SECTION 16

MISCELLANEOUS INFORMATION

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 1996

SIGNATURE / TITLE OF PREPARER: _____

COLBY LAMBERT
EXECUTIVE DIRECTOR OF COMPLIANCE AND ENGINEERING

METHODOLOGY

SODIUM BISULFATE ANALYSIS

Assay, as $\% \text{NaHSO}_4$

ACIDITY AND ASSAY

Equipment

1. 200ml Beaker or Erlenmeyer Flask
2. 50 or 100ml total capacity burette
3. Magnetic stirrer and stir bar
4. Balance with the readability of at least 0.01g

Reagents

1. 1.0 Normal sodium hydroxide solution
2. Phenolphthalein indicator
3. Distilled water

Procedure

1. Weigh out a 3.0g sample of Sodium Bisulfate into a weighing boat.
2. Transfer Sodium Bisulfate to beaker or flask, add 50 to 100mls distilled water, 2 to 5 drops phenolphthalein indicator, and stir bar
3. Place beaker or flask on magnetic stirrer and dissolve Sodium Bisulfate.
4. Fill burette with 1.0N NaOH
5. Titrate sample with 1.0N NaOH to a faint trace of pink which persists for about 2 minutes.

Calculations

$$\% \text{NaHSO}_4 = \frac{\text{mls} \times N \times 12.006}{\text{grams sample}}$$

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~~UTILITY~~

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JWS

J. S. Williams, Inc.
Food Technology Consulting
11865 26th Avenue North
Plymouth, M N 55441

PH: 612-557-9763 FAX: 612-557-9794

Attention: Carl Knueven
Jones-Hamilton Co.
30354 Tracy Road
Walbridge, Ohio 43465

Objective: To determine the feasibility of using Sodium Bisulfate as the acidulant in the leavening system for a basic yellow cake.

Procedure: In the control cakes, baking powder was used as the leavening system. In the variable cakes, sodium bisulfate and sodium bicarbonate were used as the leavening system. Cakes were observed for height, texture, crumb structure and tasted for flavor. (Tests were done only for feasibility, no specific measurements were taken.)

Basic Yellow Cake (Control)

cake flour (Softasilk)	293 grams
sugar (granulated)	346 grams
baking powder (Calumet)	12 grams
salt	6 grams
milk (skim)	188 grams
shortening (Crisco)	151 grams
eggs (mixed)	156 grams
milk (skim)	117 grams
vanilla extract (single fold)	3 grams

In mixing bowl, combine flour, sugar, baking powder and salt. Add 188 grams of milk and shortening. **Mix**, using paddle and Hobart Kitchen Aid mixer at speed 2 for 2 minutes. Add eggs, 117 grams of milk and vanilla extract. **Mix** for 2 minutes more on speed 3. Pour batter (1 145 grams) into a greased and floured (13 x 9 x 2-inch) pan and bake in a preheated oven of 350 degrees F for 35 minutes.

Basic Yellow Cake (Variable)

cake flour (Softasilk)	293 grams
sugar (granulated)	346 grams
sodium bisulfate	7 grams
sodium bicarbonate	5 grams
salt	6 grams
milk (skim)	188 grams
shortening (Crisco)	75.5 grams
water	55.9 grams
eggs (mixed)	156 grams
milk (skim)	117 grams
vanilla extract (single fold)	3 grams

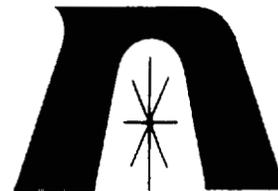
In **mixing** bowl, combine flour, sugar, sodium bisulfate, sodium bicarbonate and salt. Add 188 grams of **milk**, and shortening. **Mix**, using paddle and Hobart Kitchen Aid mixer at speed 2 for 2 minutes. Add eggs, 117 grams of milk and vanilla extract. **Mix** for 2 minutes more on speed 3. Pour batter (1 145 grams) into a greased and floured (13 x 9 x 2-inch) pan and bake in a preheated oven of 350 degrees **F** for 35 minutes.

Results: Both the control and variable cakes were of equal height, texture and crumb structure. Sensory testing concluded that the flavor was acceptable in both the control and the variable cakes. The flavor of the variable cake was thought to have a lighter, cleaner and slightly citrus-like taste with no off flavors when it was compared to the control cake.

Notes: Variable cakes baked with fine grind leavening components produced acceptable results in terms of surface appearance. Coarse grind leavening components produced black specks (sodium bisulfate) and brown surface flock (sodium bicarbonate). Coarse grind leavening components should be avoided.

Conclusion: **As** a result of our **preliminary** bake tests, sodium bisulfate functions as a suitable acidulant in a leavening system with sodium bicarbonate. Additional bake testing will be necessary to determine specific cake measurements along with further uses for sodium bisulfate in other chemically leavened bakery systems. **FDA** approval will need to be pursued.

~~TOXICITY~~



CORRECTED

REPORT TO:

JONES HAMILTON CO.

ACUTE ORAL TOXICITY
PRIMARY SKIN IRRITATION

NVP REPORT NO. X8G081G

March 15, 1990

Respectfully submitted,

M. J. Deenihan, Manager
Toxicology Laboratory Services

TEST SPONSOR:

Mr. Daniel Gilbert
President
Jones Hamilton Co.
8400 Enterprise Drive
Newark, CA 94560

REPORT DATE: March 15, 1990

STUDY AUTHORIZATION: Signed Protocol

NVP REPORT NO: X8G081G

DATE STARTED: 07-27-88

DATE COMPLETED: 03-15-90

DATE RECEIVED: 06-30-88

SAMPLE IDENTIFICATION:

Sodium Bisulfate

TESTS PERFORMED:

Acute Oral Toxicity
Primary Skin Irritation

Objectives:

A. Acute Oral Toxicity Test

This test *is* designed to investigate the toxicity *of* an orally administered compound and the possible correlation between any observed symptoms and the rats' exposure to the test substance.

B. Primary Skin Irritation Test

This test is designed to show to what degree the test compound under evaluation causes skin irritation.



A. ACUTE ORAL TOXICITY

Procedure:

Sixty-four healthy male and female Sprague-Dawley rats weighing approximately 150 to 300 grams each were used to determine the oral toxicity of the test compound at six doses of 1750, 2000, 2250, 2500, 3000 and 3500 mg/kg of body weight. These rats were obtained from Bantin & Kingman, Fremont, CA.

The animals were housed in groups of no more than five to a cage by sex. Each animal was identified by tail marking. Food was withheld from all the animals for sixteen hours prior to dosing. Four hours after dosing, until they died or were killed fourteen days later, Purina Rodent Chow and water were available to all the animals *ad libitum*.

Doses were administered by means of a metal intubation needle attached to a hypodermic syringe. The test compound was administered diluted in deionized water. A dosing volume of 10 ml/kg of body weight was used. Additional rats, males and females, were similarly dosed with deionized water (10 ml/kg of body weight) to serve as vehicle controls.

All animals were weighed on days 0, 7, 14 or at death. All of the animals were observed for toxic symptoms (severity, onset and duration) several times on the day of dosing and daily until they died or were killed fourteen days later at the end of the test.

Results:

Toxic symptoms observed during the study included weight loss, dehydration, scruffy coats, lethargy and death.

Upon necropsy gross abnormalities observed in the animals that died on test included: mottled red lungs and livers mottled with pale areas. Several of these animals were also observed to have either lesions on their stomachs or stomachs ruptured with contents emptied into the peritoneal cavity.



Conclusion:

In male Sprague-Dawley rats, the oral LD₅₀ of this compound was 2800 mg/kg of body weight. The 95% confidence limits for the LD₅₀ was 2393 - 3276 mg/kg.

In females, the oral LD₅₀ of this compound is greater than 2500 mg/kg of body weight. Due to the nature of this material we were not able to establish good confidence limits for the LD₅₀ in females. As the test progressed and higher doses were administered, the animals exhibited the same toxic symptoms as those at the lower doses, but few animals died. To obtain good confidence limits it would have been necessary to dose many more animals. At the discretion of the Study Director and for humane reasons it was decided to stop dosing as it was quite clear that the LD₅₀ of this material was above 2500 mg/kg of body weight in female Sprague-Dawley rats.

Mortality Summary Table

<u>Dose Number</u>	<u>ml/kg</u>	<u>NO. Dead/ No. Dosed</u>		<u>% Mortality</u>	
		<u>Males</u>	<u>Females</u>	<u>Males</u>	<u>Females</u>
1	1750	-	1/5	-	20
2	2000	0/5	2/5	0	40
3	2250	1/5	1/5	20	20
4	2500	0/5	4/5	0	80
5	3000	3/5	1/10	60	10
6	3500	4/5	-	80	-

LD50 DETERMINATION BY THE LITCHFIELD-WILCOXON METHOD

Route of Administration: Oral Species: Rat, Male

Dose (mg/kg)	# Dead/ # Treated	Observed % Effect	Expected % Effect	(Obs. - Exu.)	Contr. to Chi ² $\left[\frac{(O - E)^2}{(100 - E)(E)} \right]$
2000	0/5	0 (2.9)	9.0	6.1	0.045
2250	1/5	20.0	20.0	0	0
2500	0/5	0 (8.3)	30.0	21.7	0.224
3000	3/5	60.0	60.0	0	0
3500	4/5	80.0	80.0	0	0

of doses = K = 5

TOTAL = 0.269

n = K-2 = 3

total # animals treated = 25

Chi² of line = TOTAL x avg. # animals =
 (0.269)x(5.0) = 1.35

Avg. # animals/dose =
 total #/K = 5.0

Chi' from table 2 for $\frac{3}{(n)}$ deg. of
 freedom = 7.82

R = largest/smallest dose plotted = 1.75

(N.B. If Chi² of the line is less
 than Chi" in table 2, the
 line is a good fit).

N' = 20; N'^{1/2} = 4.5

LD₀₁ = 2200

LD₀₅ = 2800

LD₅₀ = 3600

S = 1.28

A = 1.14

f_{LD} = 1.17

f_A = 1.26

PO

95% confidence limits for LD₀₁ = 95% confidence limits for S= 1.02 - 1.61
 2393 - 3276 mg/kg

Litchfield, J. Jr., and Wilcoxon, F., J. Pharm. Exp. Therap. 96:99-115 (1949)

LD50 DETERMINATION BY THE LITCHFIELD-WILCOXON METHOD

Route of Administration: **Oral** Species: Rat, Female

Dose (mg/kg)	# Dead/ # Treated	Observed % Effect	Expected % Effect	(Obs. - Exp.)	Contr. to Chi ² [$\frac{(O - E)^2}{(100 - E)(E)}$]
1750	1/5	20.0	30.0	10.0	0.05
2000	2/5	40.0	35.0	5.0	0.01
2250	1/5	20.0	40.0	20.0	0.16
2500	4/5	80.0	44.0	36.0	0.50
3000	1/10	10.0	50.0	40.0	0.60

of doses = K = 5

TOTAL = 1.32

n = K-2 = 3

Chi² of line = TOTAL x avg. # animals =
(1.3)x(6.0) = 7.8

total # animals treated = 30

Avg. # animals/dose =
total #/K = 6.0

Chi² from table 2 for $\frac{3}{(n)}$ deg. of

freedom = 7.82

R = largest/smallest dose plotted = 1.7

(N.B. If Chi² of the line is less than Chi² in table 2, the line is a good fit).

N' = 30; N'^{1/2} = 5.5

LD₁₀ = 1050

LD₅₀ = 3000

LD₉₀ = 7000

S = 2.6

A = 7.5

f_{LD} = 1.6

f_s = 18.7

ao

95% confidence limits for LD₅₀ =
1875 - 4800 mg/kg

95% confidence limits for S = 0.14-48.62

Litchfield, J. Jr., and Wilcoxon, F., J. Pharm. Exp. Therap. 96:99-115 (1949)



TABLE 1
ACUTE ORAL TOXICITY
1750 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
1	F	151	179	220
2	F	157	201	220
3	F	154	127 ¹	---
4	F	152	197	205
5	F	151	182	195
<u>Control</u>				
1	F	158	209	224

¹ Animal's weight at death, five days after dosing.

TABLE 2
ACUTE ORAL TOXICITY

2000 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
Dose A				
1	M	170	246	283
2	M	178	229	279
3	M	177	241	267
1	F	163	157 ¹	---
2	F	165	161 ¹	---
3	F	164	195	218
<u>Controls</u>				
1	M	178	266	297
2	F	169	204	221
Dose B				
1	M	176	230	259
2	M	172	181	229
1	F	161	186	207
2	F	158	157	155
<u>Controls</u>				
1	M	170	226	251
2	F	158	209	224

¹ Animal's weight at death, one day after dosing.



TABLE 3
ACUTE ORAL TOXICITY

2250 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
1	M	175	174 ¹	---
2	M	183	232	269
3	M	161	182	214
4	M	171	238	272
5	M	175	163	176
1	F	173	185	218
2	F	164	192	208
3	F	167	162 ¹	---
4	F	183	188	212
5	F	182	175	154
<u>Controls'</u>				
1	M	170	226	251
2	F	171	208	231

¹ Animal's weight at death, one day after dosing.

TABLE 4
ACUTE ORAL TOXICITY
2500 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
1	M	185	207	138
2	M	180	233	281
3	M	177	151	157
4	M	175	161	227
5	M	172	200	237
1	F	218	212 ¹	---
2	F	162	156	198
3	F	165	142 ¹	---
4	F	182	174 ¹	---
5	F	170	146 ²	---
<u>Controls</u>				
1	M	165	239	278
2	F	158	198	230

¹ Animal's weight at death, two days after dosing.

² Animal's weight at death, four days after dosing.

TABLE 5
ACUTE ORAL TOXICITY

3000 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
Dose A				
1	M	199	185 ¹	---
2	M	211	202 ¹	---
3	M	196	190	174
4	M	199	194 ¹	---
5	M	183	168	166 ²
1	F	163	159	157
2	F	161	145	132
3	F	152	138	152
4	F	156	178	149
5	F	161	169	209
<u>Controls</u>				
1	M	165	242	288
2	F	158	198	230

¹ Animal's weight at death, one day after dosing.

² Animal's weight at death, eleven days after dosing.

TABLE 5

ACUTE ORAL TOXICITY

3000 mg/kg (continued)

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
Dose B				
1	F	187	152	174
2	F	207	209	198
3	F	162	122 ¹	---
4	F	185	173	159
5	F	163	192	224
<u>Control</u>				
1	F	159	195	218

¹ Animal's weight at death, nine days after dosing

TABLE 6

ACUTE ORAL TOXICITY

3500 mg/kg

Animal Weights During Test Period

<u>Animal No.</u>	<u>Sex</u>	<u>Initial Wt/gram</u>	<u>7 Day Wt/gram</u>	<u>14 Day Wt/gram</u>
1	M	179	168 ¹	---
2	M	188	202	182
3	M	193	188 ¹	---
4	M	186	185 ¹	---
5	M	173	156 ¹	---
<u>Control</u>				
1	M		242	288



TABLE 7

Observations at Necropsy

1750 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
1	F	No abnormalities observed
2	F	No abnormalities observed
3	F	Stomach had large lesions (1 1/2 x 1 1/2 cm); peritoneal cavity filled with reddish brown fluid: advanced autolysis: no other abnormalities observed
4	F	No abnormalities observed
5	F	No abnormalities observed

Control

1	F	No abnormalities observed
---	---	---------------------------

TABLE 8

Observations at Necropsy

2000 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
Dose A		
1	M	Liver has white area approx. 2 cm ² on underside of lobe: brown-white areas approx. 2 cm ² on lungs: no other abnormalities observed
2	M	Peritoneal cavity filled with brown fluid: no other abnormalities observed
3	M	No abnormalities observed
1	F	Lungs mottled red; no other abnormalities observed
2	F	No abnormalities observed
3	F	No abnormalities observed
<u>Controls-</u>		
1	M	No abnormalities observed
2	F	No abnormalities observed
Dose B		
1	M	No abnormalities observed
2	M	No abnormalities observed
1	F	No abnormalities observed
2	F	Stomach enlarged and filled with gas and liquid: no other abnormalities observed
<u>Controls</u>		
1	M	No abnormalities observed
2	F	No abnormalities observed

TABLE 9

Observations at Necropsy

2250 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
1	M	Peritoneal cavity filled with fluid; stomach ruptured; no other abnormalities observed
2	M	No abnormalities observed
3	M	Lung mottled red; no other abnormalities observed
4	M	No abnormalities observed
5	M	Pale areas on liver; no other abnormalities observed
1	F	No abnormalities observed
2	F	No abnormalities observed
3	F	Stomach filled with blue-green liquid; no other abnormalities observed
4	F	No abnormalities observed
5	F	Stomach grossly enlarged and filled with gas and liquid; no other abnormalities observed
<u>Controls</u>		
1	M	No abnormalities observed
2	F	No abnormalities observed

TABLE 10

Observations at Necropsy

2500 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
1	M	Stomach filled with gas: no other abnormalities observed
2	M	No abnormalities observed
3	M	Liver pale; gas in stomach; no other abnormalities observed
4	M	No abnormalities observed
5	M	No abnormalities observed
1	F	Stomach filled with blue liquid: peritoneal cavity filled with fluid: blood around nose: no other abnormalities observed
2	F	No abnormalities observed
3	F	Stomach filled with red fluid: intestines filled with blue-green fluid: no other abnormalities observed
4	F	Peritoneal cavity filled with fluid: stomach filled with blue-green liquid: liver has white areas; no other abnormalities observed
5	F	Peritoneal cavity filled with red fluid; intestines filled with gas: no other abnormalities observed
<u>Controls</u>		
1	M	No abnormalities observed
2	F	No abnormalities observed

TABLE 11

Observations at Necropsy

3000 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
Dose A		
1	M	Peritoneal cavity filled with yellow-red transparent fluid: stomach filled with blue-green liquid: no other abnormalities observed
2	M	Peritoneal cavity filled with yellow-red transparent fluid: stomach filled with blue-green liquid: fatty tissue dark yellow: blood around nose: no other abnormalities observed
3	M	Stomach grossly enlarged and disfigured: no other abnormalities observed
4	M	Peritoneal cavity filled with yellow-red transparent fluid: stomach filled with blue-green liquid: fatty tissue dark yellow: no other abnormalities observed
5	M	Peritoneal cavity bloated and filled with fluid; advanced autolysis: no other abnormalities observed
<u>Control</u>		
1	M	No abnormalities observed

TABLE 11

Observations at Necropsy

3000 mg/kg (continued)

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
Dose A		
1	F	Stomach grossly enlarged and filled with gas; no other abnormalities observed
2	F	Stomach grossly enlarged and filled with gas ; no other abnormalities observed
3	F	No abnormalities observed
4	F	Stomach grossly enlarged and filled with gas: no other abnormalities observed
5	F	No abnormalities observed
Dose B		
1	F	No abnormalities observed
2	F	No abnormalities observed
3	F	Liver dark: lungs red; no other abnormalities observed
4	F	Stomach grossly enlarged and filled with gas: no other abnormalities observed
5	F	No abnormalities observed
<u>Control</u>		
1	F	No abnormalities observed

TABLE 12

Observations at Necropsy

3500 mg/kg

<u>Animal No.</u>	<u>Sex</u>	<u>Observations</u>
1	M	Peritoneal cavity filled with yellow-red transparent fluid: white areas on liver: stomach filled with blue-green liquid: no other abnormalities observed
2	M	Stomach grossly enlarged and filled with gas ; no other abnormalities observed
3	M	Peritoneal cavity filled with yellow-red transparent fluid; stomach filled with blue-green liquid: no other abnormalities observed
4	M	Peritoneal cavity filled with yellow-red transparent fluid: stomach filled with blue-green liquid: no other abnormalities observed
5	M	Stomach and intestines filled with dark blue-green liquid; underside of liver has yellow areas: no other abnormalities observed
<u>Control</u>		
1	M	No abnormalities observed

B. PRIMARY SKIN IRRITATION

Procedure:

Six healthy, young New Zealand rabbits weighing 2.0 or more each were used to determine the degree, if any, of skin irritation produced by the administration of 0.5 g of the test compound. Prior to dosing the undiluted test compound was moistened with a few drops of deionized water. These rabbits were obtained from Elkhorn Rabbitry, Watsonville, CA.

The animals were housed individually in suspended cages. Tap water was available *ad libitum*, and the animals were fed approximately 200 g of Purina Complete Blend Rabbit Chow per day.

One day prior to testing, all six rabbits were weighed, and a portion of their dorsal surfaces were clipped free of hair. Only animals with healthy, intact skin were used.

A 0.5 g portion of the test material was applied to two sites, one intact and one abraded, on the back of each animal. The material was applied under two layer thick cotton gauze patches measuring one inch square.

The entire trunks of the animals were wrapped in a non-occlusive manner to prevent the animals from disturbing the test sites for the twenty-four hour exposure period. After the animals were unwrapped, all residual test material was gently rinsed off with water. The animals were observed and scored for skin irritation according to Draize (See Tables 13 and 14) at 24 and 72 hours after application of the test material.

Results:

Mild to moderate erythema was observed on all of the animals during the study. More severe irritation with some necrotic areas was observed at the abraded test sites.

Conclusion:

The Mean Primary Irritation score of this material was 1.66. Therefore, according to the Federal Hazardous Substance Act it is a mild skin irritant. However as necrosis was observed the Study Director considers this a potentially severe irritant.



TABLE 13

EVALUATION OF SKIN REACTIONS (DRAIZE)*

<u>Erythema and Eschar Formation</u>	<u>Value</u>
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet-redness) to slight eschar formation (injuries in depth)	4

<u>Edema Formation</u>	<u>Value</u>
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised about 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

DESCRIPTIVE RATING
Mean Primary Irritation Score

<u>Range of Value</u>	<u>Descriptive Value</u>
0	Non-irritating
0 - 1.9	Mildly irritating
2 - 5.9	Moderately irritating
6 - 8.0	Severely irritating

* Draize, J.H., "The Appraisal of Chemicals in Food, Drugs, and Cosmetics". Dermal Toxicity, pp. 45-59. Association of Food and Drug Officials of the United States, Topeka, Kansas (1965).

TABLE 14
PRIMARY SKIN IRRITATION SCORES

<u>Rabbit Number</u>	<u>Time</u>	<u>Erythema</u>		<u>Edema</u>	
		<u>Intact</u>	<u>Abraded</u>	<u>Intact</u>	<u>Abraded</u>
9316	24 hours	0	1	0	1
9317		0	1	0	0
9318		1	2	0	1
9352		0	1	0	1
9353		1	2	1	2
9354		1	2	1	2
9316	72 hours	0	2	0	2
9317		0	1	0	0
9318		0	2	0	2
9352		0	1	0	0
9353		0	3	0	2
9354		0	3	0	1

Protocol:

These tests were conducted according to Protocol Nos: NVX-121, and 123 which are on file at Northview Pacific Laboratories, Inc., under File No. X8G081G. These protocols satisfy the requirements of the Consumer Product Safety Commission (CPSC); 16 CFR Part 2500, January 1, 1980; Federal Hazardous Substance Act Regulations.

Deviations from Protocol:

There were none.

Data Disposition:

Raw data and retained samples from these studies are archived at Northview Pacific Laboratories, Inc., 2800 Seventh Street, Berkeley, CA 94710, under File No. X8G081G.

QUALITY ASSURANCE UNIT
GLP INSPECTION & AUDIT SUMMARY

Comparisons of the raw data and laboratory operations with the protocol for NVP Report No. X8G081G were conducted by the Quality Assurance Unit on the following dates:

<u>NVP Protocol No.</u>	<u>Phase of Study</u>	<u>Date</u>
NVX-121	Dosing	7/21/88
	Weighing - Day 14	8/04/88
	Dosing	8/09/88
	Dosing	8/30/88
	Necropsy	9/27/88
NVX-123	Dosing	7/21/88

QAU inspection findings are routinely reviewed by the management of Northview Pacific Laboratories. Management is notified immediately if there are any deviations which might affect the integrity of the study data.

Final Report Audit

NVP Report No. X8G081G represents an accurate description of the conduct and final results of this study. To the best of my knowledge and ability, this study has been conducted in compliance with applicable Good Laboratory Practices Regulations.

Quality Assurance Unit

Date

3/16/90



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SIGNATURES

Study Director

Date

3/16/90

Quality Assurance Unit

Date

3/16/90

Management

Date

3/16/90

Test Sponsor

Date

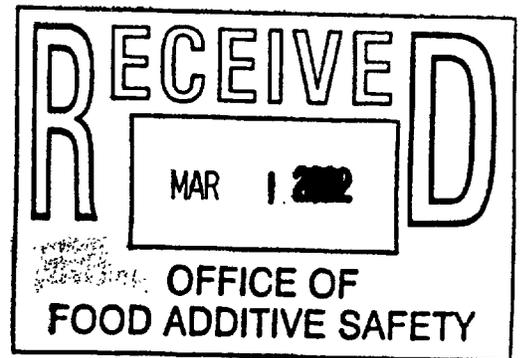
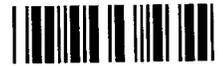


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Information Submitted to the Division of Biotech and GRAS

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

In support of

An application for the use of Sodium Bisulfate as a pH control agent and
processing aid in meat and poultry production plants

Submitted by:

Jones-Hamilton Co.
Agricultural Division
1 Plaza East, Suite 702
Salisbury, Maryland 21801

000063

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6	FDA letter to B. Murphy, January 18, 2002
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9	Chart: pH and Chlorine
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JONES-HAMILTON CO.

Poultry Litter Treatment - PLT®

1 PLAZA EAST, SUITE 505
SALISBURY, MARYLAND 21801

PLT® HOTLINE 1-800-379-2243
410-548-9422
PLT® FAX 410-548-2840

February 28, 2002

Dr. Rudolph Harris
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition – HFF 200
200 C Street SW
Washington, DC 20204

Ref: GRAS Notice No. GRN 000003 dated June 5, 1998 (Attached)
Letter from FDA to C. Knueven dated May 22, 2000 (Attached)
Letter from FDA to B. Murphy dated January 18, 2002 (Attached)

Dear Dr. Harris:

On February 20, 2002 I contacted Dr. Robert Post to follow up on the letter to B. Murphy dated January 18, 2002. During the phone conversation I learned that more information is needed by FSIS in order for FSIS to determine the suitability of sodium bisulfate as a processing aid and for use as a pH control agent in both chill tanks and scalders in poultry and meat processing plants.

During a subsequent call to Dr. Post's office on February 25, 2002 I learned that according to the MOU between The FSIS USDA and The FDA USDHH, Regarding the Listing and Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products, the additional information should be sent to your office for review and forwarding onto Dr. Post's office at OPPDE FSIS USDA for review and comments from FSIS.

In an effort to expedite this review, I have included Attachment 1, entitled Sodium Bisulfate – for use as a pH Control Agent and Processing Aid, that describes the intended use of sodium bisulfate in meat and poultry product production, a protocol for in plant testing and the results of two in plant tests.

Your urgent handling of this submission would be greatly appreciated. Based on the FDA letters of May 22, 2000 and January 18, 2002, Jones-Hamilton Co. has proceeded with the belief that FSIS had no comments or questions regarding the use of sodium bisulfate as a pH control agent in chillers and scalders in meat and poultry products plants. We have initiated efforts to market sodium bisulfate to the meat and poultry industry but are now faced with a dilemma on how to proceed.

In addition it is our opinion that a processing plant's water supply is used throughout the plant and therefore it is expected that the pH control effect of sodium bisulfate would be similar throughout the plant water system. Jones-Hamilton Co. expects the use of sodium bisulfate would be suited for use in water for final bird washers and equipment surface rinse water. Jones-Hamilton Co. therefore requests that your reply be written to include meat and poultry plant processing water.

As far as the use of sodium bisulfate in chiller water, Jones-Hamilton Co. has no basis to expect that a decrease in water pH would affect water uptake or retention in immersion chilled meat or poultry.

Please review this packet and forward to the office of Dr. Robert C. Post for review and comments.

Thank you for your help in this matter. Please contact me if there are any questions.

Regards,

Bernard D. Murphy, Ph.D.
General Manager, Agricultural Division
Jones-Hamilton Company
812-376-6070

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U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Washington, DC 20204

June 5, 1998

Ms. Betty J. Pendleton
Jones-Hamilton Co.
15505 Country Ridge Drive
Chesterfield, MO 63017

Re: GRAS Notice No. GRN 000003
Docket No. 98S-0104

Dear Ms. Pendleton:

This is in response to your GRAS notice dated February 11, 1998, which was received by the Food and Drug Administration (FDA) on February 26, 1998. This request was submitted to FDA on behalf of Jones-Hamilton Co. in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997). FDA designated your notice as GRAS Notice No. GRN 000003.

Your notice states that Jones-Hamilton Co. has determined that sodium bisulfate (NaHSO_4 ; CAS Reg. No. 7681-38-1) is generally recognized as safe (GRAS) for use as (1) a pH control agent and leavening agent in cake mixes at a level of 1 to 10 grams sodium bisulfate per 1000 grams of total mix (0.1 per cent to 1.0 per cent by weight) and (2) a pH control agent and a processing aid

in food at levels not to exceed good manufacturing practice. Your notice refers to the provision in 21 CFR 184.1095 (sulfuric acid) that current good manufacturing practice results in a maximum level, as served, of 0.014 per cent for alcoholic beverages and 0.0003 per cent for cheeses. Your notice describes the manufacturing process for sodium bisulfate, which is the sodium salt of sulfuric acid. The manufactured sodium bisulfate meets the specifications for this ingredient in the Food Chemicals Codex, Fourth Edition (1996). Its main characteristic is its acidity in water solutions.

Your notice states that the basis for the GRAS determination is through experience based on common use in food - i.e., that Jones-Hamilton Co. has experience based on common use in food. However, as we discussed by telephone on April 27, 1998, FDA considered your notice under scientific procedures (§ 170.30(b)). Based on the information provided by Jones-Hamilton Co., as well as other information available to FDA, the agency has no questions at this time regarding the conclusion of Jones-Hamilton Co. that sodium bisulfate is GRAS under the proposed conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of sodium bisulfate. As always, it is your continuing responsibility to ensure that food ingredients that you market are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of this letter has been made available for public review and copying at the agency's Dockets Management Branch (Docket No. 98S-0104). As mentioned in our letter dated March 5, 1998, which acknowledged receipt of your GRAS notice, a copy of the information in your notice that conforms to the information in proposed § 170.36(c)(1) is likewise available in Docket No. 98S-0103.

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket
Approval
Center for Food Safety
and Applied Nutrition

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	Summary Table			

Content last updated by lsk on 1999-MAR-24
Hypertext last updated by rdb on 1999-JUN-04

000068

MAY 22 2000

Carl Knueven
Manager Product Development
Jones-Hamilton Co.
30354 Tracy Road
Walbridge, Ohio 43465-9797

Dear Mr. Knueven:

This is in response to your request concerning the use of sodium bisulfate as a pH control agent in chill tanks of poultry processing plants. Your letter indicated that USDA's FSIS needed a specific response from FDA before they would allow this use.

You submitted a GRAS notice that sodium bisulfate is generally recognized as safe for use as a pH control agent and a processing aid in food at levels not to exceed good manufacturing practice which was filed by FDA on June 5, 1998. Based on the information submitted, FDA had no questions regarding the conclusion of Jones-Hamilton Co. that sodium bisulfate is GRAS under the proposed conditions of use. Therefore, we would not object to your determination that the use of sodium bisulfate is GRAS for the use in chill tanks.

We are forwarding a copy of this response to Dr. Robert Post, FSIS.

Sincerely yours,

Rudolph Harris, Ph.D.
Division of Product Policy, HFS-206
Center for Food Safety
and Applied Nutrition

000069



January 18, 2002

Dr. Bernard D. Murphy
General Manager
PLT Division
Jones-Hamilton Company
1 Plaza East, Suite 505
Salisbury, Maryland 21801

Dear Dr. Murphy:

This is in response to your e-mail and our conversation of December 6, 2001, regarding the use of sodium bisulfate as a pH control agent in poultry plant scalders and scalding systems. FDA filed a GRAS notice on June 5, 1998 that sodium bisulfate is generally recognized as safe for use as a pH control agent and a processing aid in food at levels not to exceed good manufacturing practice. You referenced the notice and our May 22, 2000- letter to Mr. Carl Knueven of the Jones-Hamilton Company wherein we stated that: "Based on the information submitted, FDA had no questions regarding the conclusion of Jones-Hamilton Co. that sodium bisulfate is GRAS under the proposed conditions of use. Therefore, we would not object to your determination that the use of sodium bisulfate is GRAS for the use in chill tanks."

Based on the available information, we still have no questions regarding the conclusion that use of sodium bisulfate is GRAS in poultry plant scalders and scalding systems. We are forwarding a copy of this response to Dr. Robert Post, FSIS.

Sincerely yours.

Rudolph Harris, Ph.D.
Division of Biotech & GRAS
Notification Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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Attachment 1

Sodium Bisulfate –for use as a pH Control Agent and Processing Aid in Food

Chemical formula: NaHSO_4

CAS Reg. No.: 7681-38-1

Food grade - Food Chemicals Codex, Fourth Edition, page 356 (Attached)

Sodium bisulfate is also referred to sodium acid sulfate

Background:

Municipalities, poultry and meat processing plants may add chlorine to processing plant water. The effectiveness of chlorine depends on the pH of the water. The most effective form of chlorine, chlorous acid (HOCl) is preferentially formed when water pH is below 7.4. (See attached Chart: pH and Chlorine) In locations where the pH of the processing plant water supply is higher a pH control agent is needed to lower the pH.

Intended Use:

Sodium bisulfate will be added to processing water used in the production of meat and poultry products. The amount of sodium bisulfate used will be determined by the characteristics of the plant water supply, the desired pH level and will be determined on an individual plant basis. Use of the appropriate amount of sodium bisulfate will result in the lowering of the water pH. This effect in water is desirable in order to maximize the potential effectiveness of chlorine.

Procedure:

Pre In plant test

A water sample from a processing plant will be collected. The pH will be measured and recorded. One hundred milliliters (100 mls) of the sample will be titrated with sodium bisulfate. The titration result will be used to calculate the amount of sodium bisulfate required to adjust the pH to the target level.

Results of water sample titrations are included in Table 1.

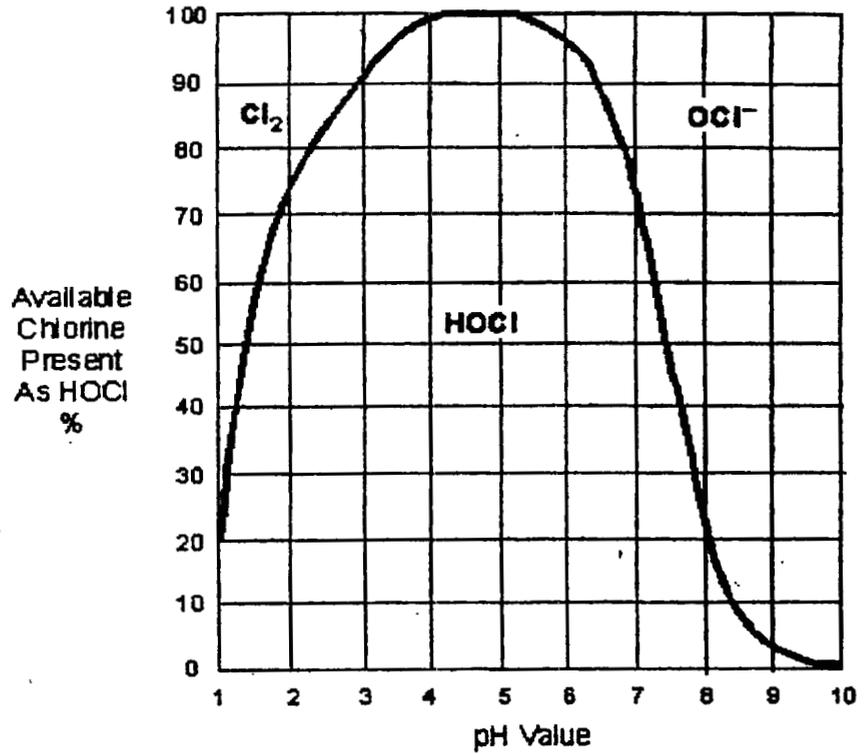
In plant test

Based on the sample titration results, sodium bisulfate will be added to the plant processing water at a rate adequate to adjust pH to the target level. Water samples will be collected during the addition and pH measured in order to confirm that an adequate amount of sodium bisulfate is being added.

In plant test results are reported in Tables 2 and 3 and demonstrate that the use of sodium bisulfate adjusts pH in processing plant water.

Pages 000072 - 000072 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Chart: pH and Chlorine



The table above shows the effect of pH value on the form of Free Chlorine in water at 25°C.

As the pH falls below 2, the predominant form is Cl_2 . Between pH 2 and 7 the equilibrium is in favor of HOCl. At pH 7.4 HOCl and OCl^- are about equal, while above this increasing proportions of OCl^- are present.

A test kit which measures free chlorine will indicate the combined concentrations of HOCl, OCl^- , and Cl_2 .

000073

Attachment 2

The following Tables 1, 2 and 3 contain data that demonstrates the pH control effect of sodium bisulfate in plant processing water.

Table 1 is included to show that water from different sources require different amounts of sodium bisulfate to attain a similar pH. The amount of sodium bisulfate cannot be predicted or standardized due to water source characteristic differences. The water supply of each meat and poultry processing plant is titrated to estimate the amount of sodium bisulfate needed. The actual amount required to attain a specific pH range will be determined by an evaluation in the plant during production.

Table 2 describes a poultry plant that has two, 2-stage immersion chiller systems. This plant uses tri sodium phosphate as a pre chill antimicrobial intervention. Tri sodium phosphate is a basic compound. Because some of the tri sodium phosphate enters the chiller it causes the pH of the chiller water to be higher than the plant water supply. This higher pH water requires more sodium bisulfate to be used than estimated by the lab analysis of the plant supply water. This is an example of a process that can affect the amount of sodium bisulfate required to adjust the chiller water pH to a target level.

NOTE: The opposite situation may occur in a plant that uses acidified sodium chlorite as a pre chill antimicrobial intervention. The carcass associated carry over into the chiller would be expected to lower the chill water pH and therefore less sodium bisulfate may be required to attain the target pH range.

Table 3 describes a poultry plant that has a single 4-stage immersion chiller system. This plant does not use a pre chill antimicrobial intervention. As a result, the amount of sodium bisulfate required to attain the target pH range is more accurately estimated by the lab titration results.

Figure 1 provides a schematic representation of a chiller. One means of sodium bisulfate addition is presented. An aqueous solution of sodium bisulfate is metered into the rechilled red water line. The treated rechilled red water is added back to the chiller at the end where carcasses leave the chiller. Water sample locations are noted and those results are reported in Tables 2 and 3. This schematic is general but adequately represents the addition of sodium bisulfate to a chiller. Similar set ups would be designed for uses such as scalders, final bird washers and equipment rinse water.

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Table 1 - Examples of Variation in the Amount of Sodium Bisulfate Required to Adjust pH Among Water Samples from Different Sources

Initial pH of Water Sample	Water Sample A			Water Sample B			Water Sample C			Water Sample D		
	A	B	C	A	B	C	A	B	C	A	B	C
	SBS**	SBS	SBS	SBS	SBS	SBS	SBS	SBS	SBS	SBS	SBS	SBS
	gm/100ml	lbs/1000gal	% (w/w)									
	pH			pH			pH			pH		
9.2	-	-	-	9.1	-	-	8.7	-	-	8.6	-	-
8.5	0.004	0.3	0.002	0.2	0.004	0.3	0.004	0.3	0.004	0.005	0.4	0.005
8	0.007	0.8	0.004	0.3	0.011	0.9	0.011	0.9	0.011	0.013	1.1	0.013
7.5	0.015	1.2	0.01	0.8	0.017	1.4	0.017	1.3	0.016	0.028	2.2	0.026
7	0.028	2.3	0.028%	2.3	0.022	1.8	0.022%	1.8	0.022%	0.041	3.4	0.041%
6.5	0.042	3.5	0.042%	3.5	0.024	2.0	0.024%	2.0	0.028%	0.052	4.3	0.052%
6	0.054	4.5	0.054%	4.5	0.027	2.2	0.027	2.2	0.03	0.058	4.8	0.052%
5.5	-	-	-	-	0.028	2.3	0.028	2.3	0.031	0.06	5.0	0.06
5	0.058	4.8	-	4.8	0.029	2.4	0.029	2.4	0.032	0.061	5.1	0.061
4.5	0.063	5.2	-	5.2	0.03	2.5	0.03	2.5	0.033	0.063	5.2	0.063
4	0.065	5.4	-	5.4	-	-	-	-	-	-	-	-

Initial pH of Water Sample

Titration pH Points

** SBS is used to abbreviate sodium bisulfate

Columns A - The amount of sodium bisulfate (gms) required to be added to 100 mls of water sample to achieve the noted pH point
 Columns B - The calculated amount of sodium bisulfate (lbs) required to be added to 1000 gallons of water to achieve the noted pH point
 $\text{Lbs/1000 gallons} = (\text{SBS gms/100ml}) / 454 \text{ gm/lb} \times 10 \text{ (to convert 100mls to 1 liter)} \times 3.78 \text{ (to convert liters to gallons)} \times 1000$
 Columns C - The concentration of SBS expressed as a %

000075

Table 2 - The Use of Sodium Bisulfate as a pH Control Agent in Processing Plant Water

Plant Test - 7-2001-A

Plant water pH - 8.4

2 stage chill system

Tri sodium phosphate used pre chill as an antimicrobial intervention

Target pH range - less than 7.0

	pH of Water in Chiller A				pH of Water in Chiller B			
	Sample Time	Sampling site			Red Water Return	Sampling site		
		Red Water Return*		Middle*		Red Water Return		Middle
***	500 AM	-		8.5	-		8.4	
	600 AM	7.0		-	7.4		-	
**	615 AM	6.3		-	6.6		-	
	710 AM	5.9		6.2	6.4		6.6	
	745 AM	6.7		6.4	6.4		6.5	
	845 AM	6.7		6.6	6.6		6.6	
	945 AM	6.6		6.6	6.3		6.2	
	1030 AM	6.8		6.8	6.6		6.8	
	1100 AM	6.6		6.8	6.8		6.8	
	600 PM	6.2		6.6	6.2		6.5	

*** This is the pH of water being used to fill the chillers

** Time when first carcass entered chiller

- Water samples taken at point where rechilled redwater enters chiller
- Water samples taken from mid point of chiller

In plant procedure:

Water pH was measured upon arrival at the plant and noted. The objective was to reduce the pH in the chiller to below 7.0. Based on the lab titration, 100 pounds of sodium bisulfate was added to the water used to fill each chiller. Sodium bisulfate was added to the redwater rechilling system prior to going back into the chiller. The addition rate of sodium bisulfate was set based on the pH of water samples collected from the chiller. For this plant set up, approximately 200 pounds of sodium bisulfate will be used during a 16 hour production cycle per chiller. This is in addition to the 100 pounds added to the chiller as it was being filled with 35,000 gallons of water.

The pH measurements in the above table demonstrate the effectiveness of sodium bisulfate as a pH control agent in processing plant water.

Table 3 - The Use of Sodium Bisulfate as a pH Control Agent in Processing Plant Water

Plant Test - 1-2002-A

Plant water pH - 7.3

Four stage chill system

No prechill antimicrobial intervention

Target pH range - less than 7.0

Water pH in Chiller 4 - Day 1				Water pH in Chiller 4 - Day 2			
		Sampling Site				Sampling Site	
		Red Water				Red Water	
		Return*	Middle*			Return*	Middle*
***	550 AM		7.2	***	445 AM		7.4
	630 AM	6.8	-		650 AM	7.0	-
	700 AM	6.8	-		700 AM	6.5	-
	715 AM	6.9	7.1		720 AM	6.9	6.9
	730 AM	6.6	6.9				
**	755 AM	6.2	6.4	**	800 AM	6.9	6.9
	830 AM	5.6	6.1		830 AM	6.4	6.8
	910 AM	5.6	5.7		900 AM	6.2	6.6
	930 AM	6.7	6.5		930 AM	6.7	6.7
	945 AM	6.2	6.4		1000 AM	7.0	6.9
	1015 AM	6.0	6.2		1030 AM	7.0	7.1
	1115 AM	6.3	6.4				
	1145 AM	6.8	6.7		1200 PM	6.8	6.9
	1230 PM	6.6	6.8				
	130 PM	6.8	6.9		130 PM	6.9	7.0
	230 PM	7.1	7.0				
	300 PM	6.9	7.0				

- *** This is the pH of water being used to fill the chillers
- ** Time when first carcass entered chiller
- * Water samples taken at point where rechilled redwater enters chiller
- ° Water samples taken from mid point of chiller

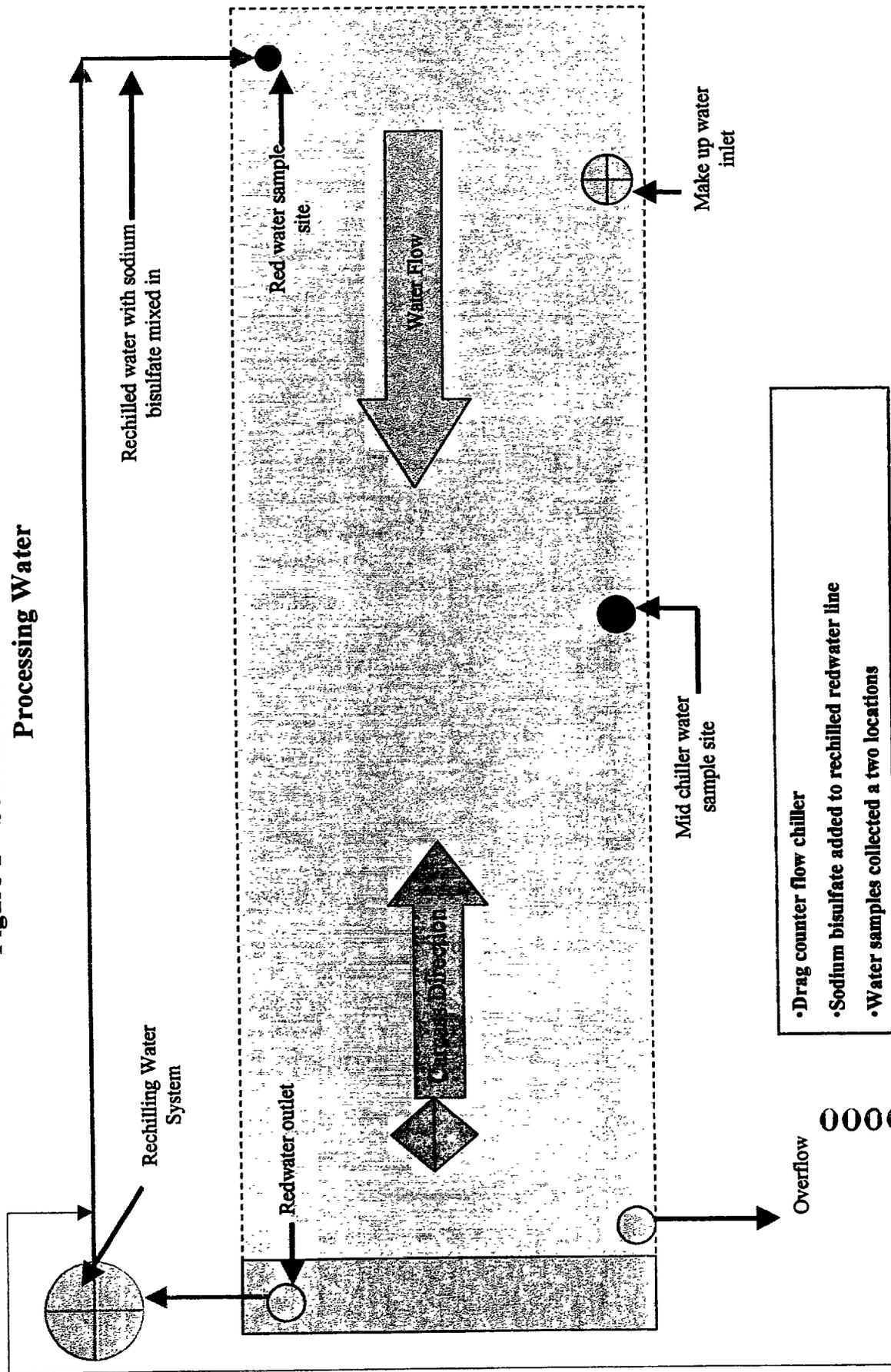
In plant procedure:

Water pH was measured upon arrival at the plant and noted. The objective was to reduce the pH in the chiller to below 7.0. Based on the lab titration, 125 pounds of sodium bisulfate was added to the water used to fill chiller # 4. Sodium bisulfate was added to the redwater rechilling system prior to going back into the chiller. The addition rate of sodium bisulfate was set based on the pH of water samples collected from the chiller. For this plant set up, approximately 250 pounds of sodium bisulfate will be used during a 16 hour production cycle. This is in addition to the 125 pounds used when the chiller was being filled with 36,500 gallons of water.

The pH measurements in the above table demonstrate the effectiveness of sodium bisulfate as a pH control agent in processing plant water.

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Figure 1 – Schematic of Sodium Bisulfate Addition to Processing Water



000078

Sodium Bisulfate
Sodium Acid Sulfate

Reference List for Industry Submission, GRN 000003

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Publisher</i>	<i>BIB_Info</i>
000072 - 000072	NA	Sodium Bisulfate	1996	Food Chemicals Codex	Fourth Edition, pg 356

NA- Not applicable
