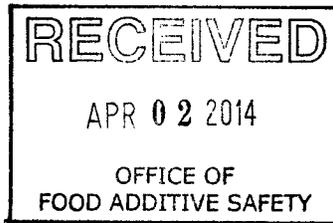


GRAS Notice (GRN) No. 508

<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm>

**ORIGINAL SUBMISSION**



 GRADIENT  
GRN 000508

April 1, 2014

Richard Bonnette  
Consumer Safety Officer  
Division of Biotechnology and GRAS Notice Review  
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway, HFS-255  
College Park, MD 20740

**Re: GRAS Notice for Saltwell Brand Sea Salt, Naturally Reduced Sodium**

Dear Mr. Bonnette:

As we discussed, Gradient is re-submitting the above-referenced GRAS Notice after correcting some administrative errors in Form FDA 3667, and in the original Notice document.

A copy of this submission was provided to USDA on March 31, 2014, and was assigned log# 14-ING-0979-N-A. Your guidance in coordinating with USDA regarding its review of this Notice is greatly appreciated.

As documented in the enclosed Form and GRAS Notice, we have determined that use of this sea salt product is GRAS per 21 CFR 170.30(b) when used as intended in food for flavoring purposes only.

Please do not hesitate to contact me should you have any further questions regarding our submission.

Yours truly,

GRADIENT 

(b) (6)

Eric M. Dubé

Environmental Health Scientist  
Phone: 617-395-5582  
edube@gradientcorp.com

**FDA USE ONLY**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**GENERALLY RECOGNIZED AS SAFE  
(GRAS) NOTICE**

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway (see Instructions); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

**PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION**

1. Type of Submission (Check one)  
 New       Amendment to GRN No. \_\_\_\_\_       Supplement to GRN No. \_\_\_\_\_

2.  All electronic files included in this submission have been checked and found to be virus free. (Check box to verify)

3a. For New Submissions Only: Most recent presubmission meeting (if any) with FDA on the subject substance (yyyy/mm/dd): \_\_\_\_\_

3b. For Amendments or Supplements: Is your (Check one)  
 amendment or supplement submitted in response to a communication from FDA?  
 Yes If yes, enter the date of communication (yyyy/mm/dd): \_\_\_\_\_  
 No

**PART II – INFORMATION ABOUT THE NOTIFIER**

<b>1a. Notifier</b>	Name of Contact Person See Agent or Attorney		Position See Agent or Attorney	
	Company (if applicable) Salinity Food			
	Mailing Address (number and street) AB Hanson & Mohring, Box 222			
City Halmstad		State or Province not applicable	Zip Code/Postal Code 30106	Country Sweden
Telephone Number 011 46 734 484 968		Fax Number 011 46 35 183 290	E-Mail Address edube@gradientcorp.com	
<b>1b. Agent or Attorney (if applicable)</b>	Name of Contact Person Eric Dubé		Position Environmental Health Scientist	
	Company (if applicable) Gradient			
	Mailing Address (number and street) 20 University Road			
City Cambridge		State or Province Massachusetts	Zip Code/Postal Code 02138	Country United States of America
Telephone Number 617-395-5582		Fax Number 617-395-5001	E-Mail Address edube@gradientcorp.com	

**PART III – GENERAL ADMINISTRATIVE INFORMATION**

1. Name of Substance  
Saltwell Brand Sea Salt, Naturally Reduced Sodium

---

2. Submission Format: *(Check appropriate box(es))*

Electronic Submission Gateway       Electronic files on physical media with paper signature page

Paper

If applicable give number and type of physical media  
CD-ROM \_\_\_\_\_

3. For paper submissions only:

Number of volumes \_\_\_\_\_

Total number of pages \_\_\_\_\_

---

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

Yes *(Proceed to Item 5)*       No *(Proceed to Item 6)*

---

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*

a) GRAS Notice No. GRN \_\_\_\_\_

b) GRAS Affirmation Petition No. GRP \_\_\_\_\_

c) Food Additive Petition No. FAP \_\_\_\_\_

d) Food Master File No. FMF \_\_\_\_\_

e) Other or Additional *(describe or enter information as above)* \_\_\_\_\_

---

6. Statutory basis for determination of GRAS status *(Check one)*

Scientific Procedures *(21 CFR 170.30(b))*       Experience based on common use in food *(21 CFR 170.30(c))*

---

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

Yes *(Proceed to Item 8)*

No *(Proceed to Part IV)*

---

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

Yes, see attached Designation of Confidential Information

Yes, information is designated at the place where it occurs in the submission

No

---

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

Yes, a redacted copy of the complete submission

Yes, a redacted copy of part(s) of the submission

No

**PART IV – INTENDED USE**

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population)*.

Saltwell is a sea salt used for food flavoring purposes only as a 1:1 substitute for common table salt (sodium chloride) in food generally, including but not limited to meat and poultry, and bakery products. Saltwell is not for use in infant formula. In salt functionality tests, Saltwell showed no substantial difference in sensory or functional properties compared to table salt for meats, oatmeal, and bakery products. Thus, the limit on its use is based on the preference of the consumer; there are no palatability or functional issues that would restrict its use as a food flavoring additive.

---

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

Yes       No

**PART V – IDENTITY**

**1. Information about the Identity of the Substance**

	<b>Name of Substance<sup>1</sup></b>	<b>Registry Used (CAS, EC)</b>	<b>Registry No.<sup>2</sup></b>	<b>Biological Source (if applicable)</b>	<b>Substance Category (FOR FDA USE ONLY)</b>
1	Sodium Chloride	CAS	7647-14-5	Not applicable	
2	Potassium Chloride	CAS	7447-40-7	Not applicable	
3	Calcium Sulphate	CAS	7778-18-9	Not applicable	

<sup>1</sup> Include chemical name or common name. Put synonyms (*whether chemical name, other scientific name, or common name*) for each respective item (1 - 3) in Item 3 of Part V (*synonyms*)

<sup>2</sup> Registry used e.g., CAS (*Chemical Abstracts Service*) and EC (*Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB)*)

**2. Description**

Provide additional information to identify the notified substance(s), which may include chemical formula(s), empirical formula(s), structural formula(s), quantitative composition, characteristic properties (*such as molecular weight(s)*), and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source (*e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source*), and include any known toxicants that could be in the source.

Chemical Formula of Primary Constituents in Saltwell

NaCl

KCl

CaSO<sub>4</sub>

MgCl<sub>2</sub>

**3. Synonyms**

Provide as available or relevant:

1	Table Salt
2	
3	

**PART V – IDENTITY (Continued)**

**1. Information about the Identity of the Substance**

	<b>Name of Substance<sup>1</sup></b>	<b>Registry Used (CAS, EC)</b>	<b>Registry No.<sup>2</sup></b>	<b>Biological Source (if applicable)</b>	<b>Substance Category (FOR FDA USE ONLY)</b>
4	Magnesium Chloride	CAS	7786-30-3	Not applicable	
5					
6					

<sup>1</sup> Include chemical name or common name. Put synonyms (*whether chemical name, other scientific name, or common name*) for each respective item (4 - 6) in Item 3 of Part V (*synonyms*)

<sup>2</sup> Registry used e.g., CAS (*Chemical Abstracts Service*) and EC (*Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB)*)

**2. Description**

Provide additional information to identify the notified substance(s), which may include chemical formula(s), empirical formula(s), structural formula(s), quantitative composition, characteristic properties (*such as molecular weight(s)*), and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source (*e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source*), and include any known toxicants that could be in the source.

**3. Synonyms**

Provide as available or relevant:

4	
5	
6	

**PART V – IDENTITY**

**1. Information about the Identity of the Substance**

	<b>Name of Substance<sup>1</sup></b>	<b>Registry Used (CAS, EC)</b>	<b>Registry No.<sup>2</sup></b>	<b>Biological Source (if applicable)</b>	<b>Substance Category (FOR FDA USE ONLY)</b>
7					
8					

<sup>1</sup> Include chemical name or common name. Put synonyms (*whether chemical name, other scientific name, or common name*) for each respective item (7 - 9) in Item 3 of Part V (*synonyms*)

<sup>2</sup> Registry used e.g., CAS (*Chemical Abstracts Service*) and EC (*Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB)*)

**2. Description**

Provide additional information to identify the notified substance(s), which may include chemical formula(s), empirical formula(s), structural formula(s), quantitative composition, characteristic properties (*such as molecular weight(s)*), and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source (*e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source*), and include any known toxicants that could be in the source.

**3. Synonyms**

Provide as available or relevant:

7	
8	

**PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE**

*(check list to help ensure your submission is complete – check all that apply)*

- Any additional information about identity not covered in Part V of this form
- Method of Manufacture
- Specifications for food-grade material
- Information about dietary exposure
- Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- Comprehensive discussion of the basis for the determination of GRAS status
- Bibliography

**Other Information**

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

Yes     No

Did you include this other information in the list of attachments?

Yes     No

**PART VII – SIGNATURE**

1. The undersigned is informing FDA that Salinity Food  
(name of notifier)  
 has concluded that the intended use(s) of Saltwell Brand Sea Salt, Naturally Reduced Sodium  
(name of notified substance)  
 described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2.  Salinity Food  
(name of notifier) agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

Salinity Food  
(name of notifier) agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

Salinity Food, AB Hanson & Mohring, Box 222, 30106 Halmstad, Sweden  
(address of notifier or other location)

Salinity Food  
(name of notifier) agrees to send these data and information to FDA if FDA asks to do so.

OR

The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No.

-----  
(GRAS Affirmation Petition No.)

**3. Signature of Responsible Official,  
Agent or Attorney**

(b) (6)

**Printed Name and Title**

Eric Dubé, Environmental Health Scientist

**Date (mm/dd/yyyy)**

03/31/2014

**PART VIII – LIST OF ATTACHMENTS**

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	GRAS Exemption Claim for Saltwell Brand Sea Salt, Naturally Reduced Sodium	1-18 (including title page)

**OMB Statement:** Public reporting burden for this collection of information is estimated to average 150 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

## **GRAS Exemption Claim for Saltwell Brand *Sea Salt, Naturally Reduced Sodium***

Prepared for:  
Salinity Food  
AB Hanson & Möhring  
Box 222  
301 06 Halmstad  
Sweden

March 31, 2014



**GRADIENT**

[www.gradientcorp.com](http://www.gradientcorp.com)  
20 University Road  
Cambridge, MA 02138  
617-395-5000

# Table of Contents

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	<u>Page</u>
1	Generally Recognized As Safe Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) ..... 4
1.1	Name and Address of Notifier ..... 4
1.2	Common or Usual Name and Identity of Notified Substance ..... 4
1.3	Conditions of Use ..... 4
1.4	Summary of Basis for GRAS Determination..... 4
1.5	Availability of Information for FDA Supporting GRAS Notification ..... 5
2	Detailed Information Regarding Identity of Notified Substance ..... 6
2.1	Description and Identification ..... 6
2.2	Chemical Formula and Chemical Abstract Service Registry Number ..... 6
2.3	Substance Composition and Characteristic Properties ..... 6
2.4	Manufacturing Method ..... 7
2.5	Substance Specifications..... 8
3	Self-limiting Levels of Use ..... 9
4	Detailed Summary of Basis for GRAS Use of Notified Substance ..... 10
4.1	Estimate of Intake ..... 10
4.1.1	Intake of Sodium Chloride and Saltwell..... 10
4.1.2	Estimated Intake of Constituents in Saltwell ..... 11
4.2	Expert Scientific Consensus Supporting GRAS Use of Notified Substance ..... 12
4.2.1	Sodium Chloride..... 13
4.2.2	Potassium Chloride ..... 13
4.2.3	Calcium Sulphate ..... 14
4.2.4	Magnesium Chloride..... 14
5	Conclusion Regarding GRAS Determination for Saltwell ..... 16
	References ..... 17

## **List of Tables**

---

Table 1	Saltwell Composition and Characteristic Properties of Its Constituents
Table 2	Saltwell Product Specifications
Table 3	Intake of Sodium, Potassium, Sulphate, Magnesium, and Calcium in Notified Substance and Comparison to Recommended Intakes

## **Figure**

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Figure 1	Saltwell Manufacturing Method
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## **Abbreviations**

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ADI	Acceptable Daily Intake
AI	Adequate Intake
ANS	Additives and Nutrient Sources
EFSA	European Food Safety Authority
EU	European Union
FDA	US Food and Drug Administration
GRAS	Generally Recognized As Safe
JECFA	Joint Food and Agriculture Organization/WHO Expert Committee on Food Additives
NHANES	National Health and Nutrition Examination Survey
SCOGS	Select Committee on GRAS Substances

# 1 Generally Recognized As Safe Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.30(b)

---

## 1.1 Name and Address of Notifier

Salinity Food  
AB Hanson & Möhring  
Box 222  
30106 Halmstad  
Sweden

## 1.2 Common or Usual Name and Identity of Notified Substance

The common name of the notified substance is sea salt. This sea salt product is obtained from ancient, underground salt lakes in the Atacama Desert in South America. Any grain of the salt contains a natural, homogeneous combination of sodium chloride, potassium chloride, calcium sulphate, and magnesium chloride. This product is produced by Salinity Food under the brand name Saltwell. To differentiate the unique composition and grain structure of this sea salt product from others on the market, its statement of identity is *Sea Salt, Naturally Reduced Sodium*, but is referred to as "Saltwell" in this document for convenience.

## 1.3 Conditions of Use

Saltwell is used for food flavoring purposes as a 1:1 substitute for common table salt (sodium chloride) in food generally, including but not limited to meat and poultry. Saltwell is not for use in infant formula.

## 1.4 Summary of Basis for GRAS Determination

Pursuant to 21 CFR 170.30, Saltwell has been determined to be Generally Recognized As Safe (GRAS) by scientific procedures, including published expert evaluations of the safety of its constituents when used as intended in food. Other than sodium chloride, each of the naturally occurring constituents in Saltwell has been affirmed as GRAS by the US Food and Drug Administration (FDA), as summarized here:

Saltwell Constituent	FDA Regulation - Direct Food Substances Affirmed as GRAS
Potassium chloride	21 CFR 184.1622
Calcium sulphate	21 CFR 184.1230
Magnesium chloride	21 CFR 184.1426

For sodium chloride, language in FDA regulations indicates that it is GRAS, although, there is no specific regulation indicating its GRAS status. Instead, the narrative at the beginning of 21 CFR 182.1 – *Substances that are generally recognized – as safe* indicates that salt and several other common food ingredients are GRAS.

## **1.5 Availability of Information for FDA Supporting GRAS Notification**

The information and data that provide the basis for this GRAS determination will be sent to the FDA upon its request during normal business hours, by contacting Eric Dubé, Environmental Health Scientist, Gradient, 20 University Road, Cambridge, MA 02138. Mr. Dubé is an Agent for the Notifier.

## 2 Detailed Information Regarding Identity of Notified Substance

### 2.1 Description and Identification

Saltwell is food-grade sea salt that can be used to replace traditional table salt (sodium chloride). Saltwell is obtained from ancient, underground salt lakes in the Atacama Desert in South America. Any grain of Saltwell contains a natural, homogeneous combination of sodium chloride, potassium chloride, calcium sulphate, and magnesium chloride.

### 2.2 Chemical Formula and Chemical Abstract Service Registry Number

Empirical Formula: NaCl · KCl · CaSO<sub>4</sub> · MgCl<sub>2</sub>

Chemical Formula: NaCl · KCl · CaSO<sub>4</sub> · MgCl<sub>2</sub>

Chemical Abstract Service# 7647-14-5 7447-40-7 7778-18-9 7786-30-3

### 2.3 Substance Composition and Characteristic Properties

**Table 1 Saltwell Composition and Characteristic Properties of Its Constituents**

Substance Constituent	Approximate Percent (dry weight)	Characteristic Property
Sodium Chloride	65	White or colorless crystalline solid Solubility = 359 g/L; salty taste
Potassium Chloride	30	White crystalline solid Solubility = 344 g/L; salty taste
Sulfate (SO <sub>4</sub> )	1.5	White/yellow-white powder <sup>1</sup> Solubility = 2.1 g/L
Magnesium (Mg)	0.4	White or colorless crystalline solid <sup>2</sup> Solubility > 540 g/L
Calcium (Ca)	0.6	Refer to sulphate entry above
Moisture (H <sub>2</sub> O)	1.0	Not applicable

Notes:

(1) Based on characteristics of calcium sulfate, which is the predominant form of calcium and sulfate in Saltwell.

(2) Based on characteristics of magnesium chloride, which is the predominant form of magnesium in Saltwell.

## 2.4 Manufacturing Method

Saltwell originates as a mineral-rich sea water approximately 30 meters below the surface of the Atacama Desert in Chile, South America. The sea water that forms the Saltwell crystal is pumped up to the surface into large ponds from several pumping stations. The sun's heat slowly evaporates the water as it is transferred in steps from one pond to the next (refer to Figure 1, below). The unique Saltwell crystals form naturally in the final pond. Once it has dried in the sun, Saltwell is gathered into stock piles for further drying. Saltwell is then packed into bags and placed in storage. An anti-caking agent, such as silicon dioxide, can be added to Saltwell in storage.

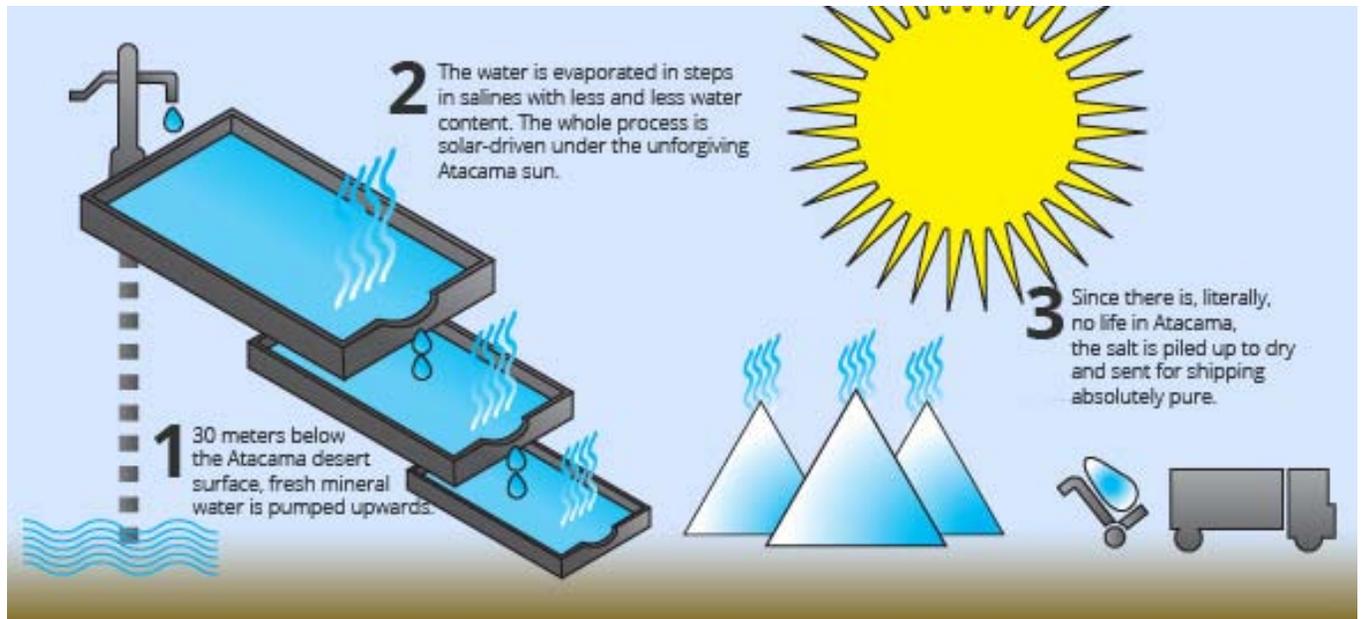


Figure 1 Saltwell Manufacturing Method

## 2.5 Substance Specifications

**Table 2 Saltwell Product Specifications**

<b>Chemical Specifications</b> <sup>1</sup>	Sodium as sodium chloride (NaCl) <sup>2</sup>	65%
	Potassium as potassium chloride (KCl) <sup>3</sup>	30%
	Sulphur as sulphate (SO <sub>4</sub> ) <sup>4</sup>	1.5%
	Magnesium (Mg)	0.4%
	Calcium (Ca)	0.6%
	Moisture (H <sub>2</sub> O)	1.0%
	Anti-caking agent as silicon dioxide (SiO <sub>2</sub> ) <sup>5</sup>	0.3%
	Arsenic (As)**	<0.5 mg/kg
	Copper (Cu)**	<2 mg/kg
	Lead (Pb)**	<2 mg/kg
	Cadmium (Cd)**	<0.5 mg/kg
Mercury (Hg)**	<0.1 mg/kg	
Lithium (Li)***	<0.035%	
<b>Sodium Content</b>	25.5 g Na/100 g SALTWELL™	
<b>Typical Sieve Analysis</b>	>0.85 mm	10%
	0.85-0.18 mm	80%
	<0.18 mm	10%
<b>Country of Origin</b>	The Atacama Desert, Chile	
<b>Bulk Density</b>	1,000-1,250 kg/m <sup>3</sup>	
<b>Storage</b>	Dry conditions and room temperature. Storage indoors.	
<b>Date of Specification</b>	01-04-2013	

Notes:

(1) The concentrations of the salt constituents in Saltwell can vary by 1-3%.

(2) Sodium chloride is present in Saltwell at approximately 65%.

(3) Potassium chloride is present in Saltwell at approximately 30%.

(4) Sulphate is present in Saltwell at approximately 1.5%.

(5) The addition of silicon dioxide to Saltwell is optional. However, its use as an anti-caking agent is considered GRAS by FDA; refer to 21 CFR 172.480 – *Food Additives Permitted for Direct Addition to Food for Human Consumption*.

\*\*These contaminant levels are below limits specified in the current edition of the Food Chemicals Codex, Fifth Edition (IOM, 2003).

\*\*\*A Recommended Dietary Allowance for lithium of 1 mg/day for an adult has been proposed (Schrauzer, 2002).

### 3 Self-limiting Levels of Use

---

Saltwell is used for food flavoring purposes only as a 1:1 substitute for table salt (sodium chloride). In salt functionality tests, Saltwell showed no substantial difference in sensory or functional properties compared to table salt for meats, oatmeal, and bakery products (Ipsos, 2012). Thus, the limit on its use is based on the preference of the consumer; there are no palatability or functional issues that would restrict its use as a food flavoring additive.

## 4 Detailed Summary of Basis for GRAS Use of Notified Substance

---

This section provides a discussion of the generally available and accepted scientific data, information, and methods that establish the safe use of Saltwell as a substitute for traditional table salt.

### 4.1 Estimate of Intake

Saltwell is a highly pure, food-grade sea salt intended to be used as a 1:1 substitute for traditional salt (NaCl). As discussed in Section 3, Saltwell has been successfully tested in a number of different foods, and there are no palatability or functional issues that would restrict its use as a food flavoring additive. The actual use level for Saltwell will vary by food category and consumer taste preferences.

Currently, Saltwell is used by food manufacturers to reduce the sodium content of processed foods by up to 35% while still maintaining the salty flavor and desired texture in most foods, because the natural presence of potassium chloride and other minerals in the substance largely compensate for the reduced concentration of sodium chloride. Salt functionality tests conducted by Ipsos demonstrated that Saltwell was successfully used in foods as a substitute for traditional table salt (Ipsos, 2012). However, the amount of Saltwell added to food will not exceed the amount reasonably required to accomplish its intended technical effect, as required by FDA regulation.<sup>1</sup>

#### 4.1.1 Intake of Sodium Chloride and Saltwell

Saltwell is intended as a 1:1 replacement for sodium chloride in the diet, therefore, potential exposure to this substance may be estimated using current sodium chloride consumption data for the US population. Gradient relied on dietary interview data collected over 2009-2010 as part of the National Health and Nutrition Examination Survey regarding the intake of sodium and other minerals in Saltwell (*e.g.*, potassium, calcium, and magnesium), for US population groups (CDC, 2013). NHANES provides a comprehensive and validated estimate of sodium intakes at the group level (*e.g.*, children and adults), including discretionary table salt use (*e.g.*, using salt at home) and naturally-occurring sodium in food (CDC, 2013). Using the most recent NHANES data, Gradient calculated the mean and 90<sup>th</sup> percentile intakes of sodium for consumers aged 2-69 years old as 3,550 mg/day<sup>2</sup> and 5,810 mg/day, respectively. Because sodium accounts for approximately 40% of the mass of sodium chloride, the mean and 90<sup>th</sup> percentile intake estimates for the compound, sodium chloride, are increased to 8,875 mg/day and 14,525 mg/day, respectively.

Sodium chloride is present in Saltwell at approximately 65%, thus the average daily intake of sodium chloride from Saltwell is approximately 5,769 mg/day (*i.e.*, 0.65 x 8,875 mg/day). The average daily intake of sodium only from Saltwell is approximately 2,308 mg/day (0.65 x 3,550 mg/day), and the 90<sup>th</sup> percentile intake is approximately 3,777 mg/day (*i.e.*, 0.65 x 5,810 mg/day).

---

<sup>1</sup> Refer to 21 CFR 182.1(b)(1).

<sup>2</sup> This value is comparable to the average sodium intake estimate of 3,400 mg/day for Americans 2 years and older, as reported in Dietary Guidelines for Americans (USDA, 2010).

Gradient based the estimated intake of potassium chloride from Saltwell on the intake of traditional table salt (sodium chloride). Potassium chloride is present in Saltwell at approximately 30%, therefore its average daily intake from Saltwell is about 2,663 mg/day (*i.e.*, 0.30 x 8,875 mg/day). About 52% of the mass of potassium chloride is potassium, thus the average daily intake of potassium only from Saltwell is 1,385 mg/day (*i.e.*, 0.52 x 2,663 mg/day), and the 90<sup>th</sup> percentile intake is approximately 2,266 mg/day (*i.e.*, 0.30 x 14,525 mg/day x 0.52).

#### 4.1.2 Estimated Intake of Constituents in Saltwell

**Table 3 Intake of Sodium, Potassium, Sulphate, Magnesium, and Calcium in Notified Substance and Comparison to Recommended Intakes**

Substance Constituent	Estimated Intake <sup>a</sup> (mg/day)		Recommended Intake (mg/day)	Source for Recommended Intake	Source Notes
	Mean	90 <sup>th</sup> Percentile			
Sodium	2,308	3,777	2,300	IOM, 2013	b
Potassium	1,385	2,266	4,700	IOM, 2005	c
Sulphate	133	218	--	Not applicable	d
Magnesium	36	58	240-420	IOM, 1997	e
Calcium	53	87	1,000-1,300	IOM, 2010	e

Notes:

(a) Based on mean (8,875 mg/day) and 90<sup>th</sup> percentile (14,525 mg/day) intake estimates of table salt (sodium chloride) for consumers ages 2-69 in the US, and adjusted for the specified concentration of the constituent in Saltwell, and the mass of the mineral of interest (*e.g.*, sodium, potassium, sulphate, magnesium, and calcium).

(b) This value represents the federal guideline for dietary sodium intake for the general US population.

(c) This value represents an Adequate Intake (AI) for potassium for all adults.

(d) The Institute of Medicine (IOM) reported that sulfate requirements are met when intakes include recommended levels of sulfur amino acids, which is why an Estimated Average Requirement, Recommended Dietary Allowance (RDA) or an AI has not been established for sulphate (IOM, 2005). Furthermore, there is insufficient information available to set an Upper Intake Level for sulphate.

(e) These values represent RDAs. The range in RDAs for magnesium and calcium are based on different age requirements.

The average estimated intake of sodium from Saltwell is nearly equivalent to the federal guideline<sup>3</sup> for sodium intake of 2,300 mg/day (IOM, 2013). In addition to reducing sodium intake, Saltwell also increases potassium intake, which is important because the average dietary intake of potassium by all groups in the United States (and Canada) is considerably lower than its AI of 4,700 mg/day (IOM, 2005). For example, the NHANES dietary interview data discussed in Section 4.1.1 indicates a mean potassium intake of 2,640 mg/day for consumers aged 2-69 years old, and a 90<sup>th</sup> percentile intake of 4,180 mg/day (CDC, 2013). If Saltwell were used as a 1:1 replacement for table salt it would contribute an average daily intake of potassium of about 1,385 mg/day; adding this value to the existing average intake of potassium yields a total average intake 4,025 mg/day, which is just below the AI for potassium. If the intake of potassium were to exceed the AI as a result of the use of Saltwell, it would not pose a health concern because the IOM indicates that exceeding the AI for potassium poses no increased risk because it is readily excreted in the urine (IOM, 2005). Finally, the contribution of sulphate, magnesium and calcium from Saltwell, even at their 90<sup>th</sup> percentile intake levels, represent insignificant additions of these minerals to the diet, and therefore, are unlikely to pose any health effects.

<sup>3</sup> Based on extensive research linking excessive sodium intake to high blood pressure, which is an accepted biological risk predictor for cardiovascular disease and stroke, the US Department of Health and Human Services, and the US Department of Agriculture developed a goal of reducing dietary sodium intake to less than 2,300 mg/day for the general population (IOM, 2013).

## 4.2 Expert Scientific Consensus Supporting GRAS Use of Notified Substance

This section provides a summary of the basis for concluding that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food, and that there is reasonable certainty that the notified substance is not harmful under the intended conditions of use. As discussed previously in Section 1.4, the main components of Saltwell, including sodium chloride, potassium chloride, calcium sulfate, and magnesium chloride, are already considered GRAS by FDA for their intended food uses. Therefore, this section only briefly discusses the safety of these principal constituents.

Following are summaries from three independent expert committees regarding the food safety of the constituents in Saltwell. The first expert committee is the Select Committee on GRAS Substances (SCOGS), which was a group of qualified scientists who evaluated the available information on each of the GRAS substances first published by FDA in the Federal Register on December 9, 1958 (US FDA, 2013). The SCOGS members were chosen for their experience, judgment, and breadth in the appropriate professional disciplines. The SCOGS retained the services of *ad hoc* consultants in specialized areas to supplement the expertise of the Committee, as needed. The Select Committee's evaluations were made independently of FDA or any other group, governmental or non-governmental. The SCOGS provided opinions on the safety of sodium chloride, potassium chloride, and magnesium chloride.

The second expert committee cited is the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA), which is administered jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization. JECFA has been meeting since 1956, initially to evaluate the safety of food additives (FAO/WHO, 2006). Its work also includes the evaluation of contaminants, naturally-occurring toxicants, and residues of veterinary drugs in food. JECFA normally meets twice a year and the membership of its meetings varies according to its agenda, with different experts being used depending on the subject matter. JECFA evaluated the food safety of each of the constituents in Saltwell.

The third expert committee cited is the European Food Safety Authority (EFSA), which conducts risk assessments on food and feed safety for the European Union in close collaboration with national authorities and in open consultation with its stakeholders (EFSA, 2014). EFSA is an independent European agency funded by the European Union (EU) budget that operates separately from the European Commission, European Parliament, and EU Member States. EFSA provided an opinion regarding the safe use of calcium sulphate as a nutritional supplement.

## 4.2.1 Sodium Chloride

### Summary of SCOGS Opinion

The Select Committee commented that a reduction in sodium chloride consumption by the US population would reduce the frequency of hypertension, which it identified as the primary health concern regarding the use of sodium chloride as a food additive. The Select Committee concluded that the available data at the time (1979) on sodium chloride was insufficient to determine that hypertension is not deleterious to the health of a significant proportion of the public when sodium chloride is used at levels current and in practice at the time.

It has long been recognized that excessive consumption of sodium chloride contributes to hypertension/high blood pressure and that this condition can pose health risks. However, these risks can be managed by reducing the intake of sodium, as noted by the Select Committee, which did not identify any other significant health concerns with sodium chloride other than hypertension (US FDA, 1979a).

### JECFA Evaluation

JECFA did not specify an Acceptable Daily Intake (ADI) for sodium chloride (JECFA, 1986). When an ADI is not specified it means that based on the chemical, biochemical, toxicological, and other data/information available to the Committee, the total daily intake of the substance from use levels necessary to achieve the desired effect, and from background levels in food, does not represent a hazard to health. For this reason, JECFA did not judge it necessary to specify a quantitative restriction on daily intake of certain substances (JECFA, 1986).

## 4.2.2 Potassium Chloride

### Summary of SCOGS Opinion

The Select Committee commented that potassium chloride is a major constituent of plant and animal cells, an essential constituent of the body, is metabolized quickly and efficiently, and is readily adjusted in the body to narrow homeostatic levels. The Select Committee concluded that there is no evidence that demonstrates or suggests reasonable grounds to suspect a hazard to the public when potassium chloride is used at current levels or levels that might reasonably be expected in the future (US FDA, 1979b).

### JECFA Evaluation

JECFA did not specify an ADI for potassium chloride (JECFA, 1986). When an ADI is not specified it means that based on the chemical, biochemical, toxicological, and other data/information available to the Committee, the total daily intake of the substance from use levels necessary to achieve the desired effect, and from background levels in food, does not represent a hazard to health. For this reason, JECFA did not judge it necessary to specify a quantitative restriction on daily intake of certain substances (JECFA, 1986).

### 4.2.3 Calcium Sulphate

#### Summary of EFSA Opinion

The European Commission asked EFSA to provide a scientific opinion regarding the safety and bioavailability of calcium sulphate added for nutritional purposes to food supplements. This charge was taken up by EFSA's Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS), which noted that the safety of calcium sulphate when used as a food additive had been evaluated by JECFA, which assigned an ADI not specified for the respective calcium and sulphate ions (EFSA, 2008). Calcium sulphate is permitted as a food additive in most foods with no other restriction other than good manufacturing practice. Consuming up to the tolerable upper intake level of 2,500 mg calcium per day as calcium sulphate as a "worst case" scenario would correspond to an intake of 8.5 g of calcium sulphate (anhydrous) per day. This calcium sulphate intake would result in a daily intake of 6 g of sulphate ion. JECFA reported that the few available studies in experimental animals do not raise concern about the toxicity of the sulphate ion in sodium sulphate. Sodium sulphate is used clinically (orally) as a laxative. In clinical trials using 2-4 oral doses of up to 4.5 g sodium sulphate decahydrate per person (9-18 g/person) only occasional loose stools were reported. These doses corresponded to 2.7-5.4 g sulphate ion. On the basis of available studies, the ANS Panel considered that the bioavailability of calcium from calcium sulphate is comparable to other inorganic calcium salts and that the use of calcium sulphate as a source of calcium in food supplements is of no safety concern assuming the total dietary exposure to calcium remains within the defined tolerable upper intake level indicated above (EFSA, 2008). It should be noted that the daily tolerable upper intake level for calcium sulphate is orders of magnitude greater than the amount of calcium sulphate potentially ingested from Saltwell on a daily basis.

#### JECFA Evaluation

JECFA did not specify an ADI for calcium sulphate (JECFA, 1986). When an ADI is not specified it means that based on the chemical, biochemical, toxicological, and other data/information available to the Committee, the total daily intake of the substance from use levels necessary to achieve the desired effect, and from background levels in food, does not represent a hazard to health. For this reason, JECFA did not judge it necessary to specify a quantitative restriction on daily intake of certain substances (JECFA, 1986).

### 4.2.4 Magnesium Chloride

#### Summary of SCOGS Opinion

The Select Committee noted that magnesium is an essential dietary ingredient involved in a number of metabolic reactions, it is necessary for the activity of many intracellular enzymes, and is important in electrolyte balance. The Select Committee concluded that there is no evidence in the available information on magnesium carbonate, magnesium chloride, magnesium sulfate, magnesium hydroxide, magnesium oxide, magnesium stearate, dibasic magnesium phosphate, and tribasic magnesium phosphate that demonstrates or suggests reasonable grounds to suspect a hazard to the public when they are used at current levels and in the manner practiced or which might reasonably be expected in the future (US FDA, 1979c).

## **JECFA Evaluation**

JECFA did not specify an ADI for magnesium chloride (JECFA, 1980). When an ADI is not specified it means that based on the chemical, biochemical, toxicological, and other data/information available to the Committee, the total daily intake of the substance from use levels necessary to achieve the desired effect, and from background levels in food, does not represent a hazard to health. For this reason, JECFA did not judge it necessary to specify a quantitative restriction on daily intake of certain substances (JECFA, 1986).

## 5 Conclusion Regarding GRAS Determination for Saltwell

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Pursuant to 21 CFR 170.30 and as documented here, Saltwell has been determined to be GRAS by scientific procedures, including comparison of the estimated intake of the principal constituents in Saltwell to available recommended intake levels established by the IOM, and based on published expert evaluation of the safety of its constituents when used as intended in food.

## References

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- Centers for Disease Control and Prevention (CDC). 2013. "National Health and Nutrition Examination Survey: Dietary Interview: Total Nutrient Intakes -- First Day (DR1TOT\_F)." Accessed on January 24, 2014 at [http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/DR1TOT\\_F.htm](http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/DR1TOT_F.htm), May.
- European Food Safety Authority (EFSA). 2008. "Scientific opinion: Calcium sulphate for use as a source of calcium in food supplements." *EFSA J.* 814:1-9.
- European Food Safety Authority (EFSA). 2014. "About EFSA." Accessed on February 20, 2014 at <http://www.efsa.europa.eu/en/aboutefsa.htm> 2p.
- Food and Agriculture Organization of the United Nations (FAO); World Health Organization (WHO) September 2, 2006. "Fact Sheet - What is JECFA?" Accessed on February 20, 2014 at [http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/jecfa\\_2006-02.pdf](http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/jecfa_2006-02.pdf)4p.
- Institute of Medicine (IOM). 1997. "Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride." Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board. Accessed on January 6, 2014 at [http://www.nal.usda.gov/fnic/DRI//DRI\\_Calcium/calcium\\_full\\_doc.pdf](http://www.nal.usda.gov/fnic/DRI//DRI_Calcium/calcium_full_doc.pdf),
- Institute of Medicine (IOM). 2003. "Sodium chloride." In *Food Chemicals Codex (Fifth Edition)*. National Academies Press, Washington, DC, p407-408.
- Institute of Medicine (IOM). 2005. "Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate." Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board. Accessed on January 6, 2014 at [http://www.nal.usda.gov/fnic/DRI//DRI\\_Water/water\\_full\\_report.pdf](http://www.nal.usda.gov/fnic/DRI//DRI_Water/water_full_report.pdf), 638p.
- Institute of Medicine (IOM). 2010. "Dietary Reference Intakes for Calcium and Vitamin D." Accessed on January 2, 2014 at <http://www.iom.edu/~media/Files/Report%20Files/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D/Vitamin%20D%20and%20Calcium%202010%20Report%20Brief.pdf>, 4p., November.
- Institute of Medicine (IOM). 2013. "Sodium Intake in Populations: Assessment of Evidence." Accessed on January 2, 2014 at [http://www.iom.edu/~media/Files/Report%20Files/2013/Sodium-Intake-Populations/SodiumIntakeinPopulations\\_RB.pdf](http://www.iom.edu/~media/Files/Report%20Files/2013/Sodium-Intake-Populations/SodiumIntakeinPopulations_RB.pdf), 4p., May.
- Ipsos Marketing (Ipsos). 2012. "Salt Functionality Test." Stockholm, Sweden, 9p., April 5.
- Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1980. "Evaluation of Certain Food Additives: Report of the Twenty-Third Joint FAO/WHO Expert Committee on Food Additives (JECFA)." World Health Organization (WHO), Geneva, Switzerland, WHO Technical Report Series 648. Accessed on January 6, 2014 at [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_648.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_648.pdf), 48p.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1986. "Evaluation of Certain Food Additives and Contaminants: Report of the Twenty-Ninth Joint FAO/WHO Expert Committee on Food Additives (JECFA)." World Health Organization (WHO), Geneva, Switzerland, WHO Technical Report Series 733. Accessed on January 6, 2014 at [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_733.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_733.pdf), 60p.

Schrauzer, GN. 2002. "Lithium: Occurrence, dietary intakes, nutritional essentiality." *J. Am. Coll. Nutr.* 21(1):14-21.

US Dept. of Agriculture (USDA). 2010. "Dietary Guidelines for Americans 2010." US Dept. of Health and Human Services. Accessed on January 2, 2014 at <http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm>, 112p.

US Food and Drug Administration (US FDA). 1979a. "Database of Select Committee on GRAS Substances (SCOGS) Reviews: Sodium Chloride." Report No. 102. Accessed on January 6, 2014 at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=291>, 3p.

US Food and Drug Administration (US FDA). 1979b. "Database of Select Committee on GRAS Substances (SCOGS) Reviews: Potassium Chloride." Report No. 102. Accessed on January 6, 2014 at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=240>, 2p.

US Food and Drug Administration (US FDA). 1979c. "Database of Select Committee on GRAS Substances (SCOGS) Reviews: Magnesium Chloride." Report No. 60. Accessed on January 6, 2014 at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=193>, 2p.

US Food and Drug Administration (US FDA). April 18, 2013. "History of the GRAS List and SCOGS Reviews." Accessed on February 20, 2014 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm084142.htm> 3p.

**SUBMISSION END**