ORIGINAL SUBMISSION

GRN 000618

TSG

Technology Sciences Group Inc.
1150 18th Street NW Suite 1000
Washington DC
20036

Gary J. Burin, Ph.D., DABT
Senior Managing Toxicologist

December 11, 2015

Dr. Leah Rosenfeld
Consumer Safety Officer
US FDA
CFSAN
5100 Paint Branch Parkway, HFS-255
College Park MD 20740

Dear Dr. Rosenfeld,

Attached please find a CD-ROM with the GRAS Notification for purified seawater. This product was the subject of a teleconference on October 29, 2025 between the notifier and FDA.

As documented in the enclosed Form 3667 and GRAS Notice, TSG has determined that use of this purified sea water is GRAS per 21 CFR 170.30(B) when used as intended for flavoring of food. This notification is being submitted on behalf of Seawater Solutions, Inc.

Please don't hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Gary Burin, Ph.D., MPH, DABT

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER 000618	DATE RECEIVED
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

RECEIVED
DEC 18 2015
OFFICE OF FOOD ADDITIVE SAFETY

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)*: 2015-10-29

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

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person: Joseph Cisneros		Position: Chief Executive Officer	
Company *(if applicable)*: Seawater Solutions, Inc.			
Mailing Address *(number and street)*: 34 Terrace Court			
City: Tiburon	State or Province: California	Zip Code/Postal Code: 94920	Country: United States of America
Telephone Number: 4158028740	Fax Number: 9258293109	E-Mail Address: joe@seawatersolutions.com	

1b. Agent or Attorney *(if applicable)*

Name of Contact Person: Gary Burin		Position: Agent	
Company *(if applicable)*: Technology Sciences Group Inc.			
Mailing Address *(number and street)*: 1150 18th Street NW Suite 1000			
City: Washington	State or Province: District of Columbia	Zip Code/Postal Code: 20036	Country: United States of America
Telephone Number: 2028288980	Fax Number: 2028720745	E-Mail Address: gburin@tsgusa.com	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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1a. Notifier

Name of Contact Person	Position
Joseph Cisneros	Chief Executive Officer

Company *(if applicable)*: Seawater Solutions, Inc.

Mailing Address *(number and street)*: 34 Terrace Court

City	State or Province	Zip Code/Postal Code	Country
Tiburon	California	94920	United States of America

Telephone Number	Fax Number	E-Mail Address
4158028740	9258293109	joe@seawatersolutions.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Gary Burin	Agent

Company *(if applicable)*: Technology Sciences Group Inc.

Mailing Address *(number and street)*: 1150 18th Street NW Suite 1000

City	State or Province	Zip Code/Postal Code	Country
Washington	District of Columbia	20036	United States of America

Telephone Number	Fax Number	E-Mail Address
2028288980	2028720745	gburin@tsgusa.com

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

purified seawater

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

☐ Electronic Submission Gateway

☐ Paper

☒ Electronic files on physical media with paper signature page

If applicable give number and type of physical media

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).*

The notified substance will be used in the same food categories as salt.

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

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	
1	sodium chloride	CAS	7647-14-5	no	
2	potassium chloride	CAS	7444-40-7	no	
3	calcium sulfate	CAS	7778-18-9	no	

[1] 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)*

[2] 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.

The primary components of purified seawater are water, NaCl, KCl, CaSO4 and MgCl. See attachment 1 for specifications and impurity profile.

3. Synonyms

Provide as available or relevant:

1	Mediterranea Agua de Mar
2	
3	

Add Continuation Page

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 Gary Burin
(name of notifier)

has concluded that the intended use*(s)* of purified seawater
(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. ☒ Gary Burin *(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.

Gary Burin *(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.

Technology Sciences Group Inc., 1150 18th Street NW 1000, Washington DC 20036
(address of notifier or other location)

Gary Burin *(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	**Printed Name and Title**	**Date (mm/dd/yyyy)**
Gary Digitally signed by Gary DN: cn=Gary, o, ou, email=gburin@tsgusa.com, c=US Date: 2015.12.14 10:24:00 -05'00'	Gary Burin, Agent	12/14/2015

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)
	Attachment1Manufacturing12102015.pdf	Submission
	GRN dossier 12112015.docx	Submission

mediterranea
AGUA DE MAR

SEA WATER

Production process

Microbiological and chemical criteria

SEA WATER

Production process.
Microbiological and chemical criteria

mediterranea
AGUA DE MAR

1. Applicable law in Europe.

Legislative regulation of seawater for food use comes from the report issued by EFSA on minimum health criteria for clean sea water and sea water bottled for food use. This report makes the following references to European standards:

• Microbiological Criteria - Directive 98/83 / CE of November 3, 1998, concerning the quality of water intended for human consumption.

• Criteria for chemical contaminants - Directive 98/83 / CE of November 3, 1998, concerning the quality of water intended for human consumption.

Analysis of Directive 98/83 / CE of November 3, 1998, concerning the quality of water intended for human consumption and the Report of the EFSA, it appears that:

1. The report of the EFSA determines different levels of use based on the exposure of seawater with food.

a. Under Exposure Level

b. High Exposure Level

c. Maximum Exposure Level.

2. Based on the level of exposure, the EFSA report determines different microbiological and chemical criteria and indicators to monitor parameters. In the case of Maximum Exposure Level they are,

i. Microbiological criteria are set out in Annex I – (D 98/83 CE)

ii. The criteria on chemical contaminants are set out in Annex I – B (D 98/83 CE).

In Spanish law, the EFSA report was reflected in the explanatory note on the health requirements for the marketing of sea water, of the Health Ministry - Spanish Agency for Food and Nutrition security (AECOSAN). Which states that the companies entered in the RGSEAA under the key 27 "packaged water and ice," Activity 10 "seawater", categories 2-5 (packaging, distribution, storage, import). According to the law, when there is direct contact with food (revitalization, seasonings, ingredients) it applies the Maximum Exposure Level. In this sense the requirements of the law are,

• Water treatment required. Annex II.

• Microbiological Criteria. RD 1799/2010, of 30 December, by which the process of developing and marketing packaged prepared waters for human consumption is regulated. Annex I, Part A.

• Additional voluntary criteria on Vibrio spp.

• Additional criteria for turbidity.

• Chemical criteria. Annex III - B. (RD 1799/2010 - Annex I, part B).

• For the specific case of boron, operators must reduce the boron concentration below its parametric value of 1 mg / l in seawater. In that case, we can consider the specific treatment with a selective ion exchange resin for boron (intermediate treatment, Annex II).

Regarding the microbiological parametric values, the EFSA report refers to the provisions of Council Directive 98/83 EC

2. U.S. Strategic Plan

• Seawater Solutions Inc. is the exclusive U.S. Distribution Partner of Maravendis Barcelona, S.L.U. owner of product named Mediterranea Agua de Mar.

• Seawater Solutions, Inc.'s intend is to enter the U.S. Market with importer Mediterranea Agua de Mar product and is seeking U.S. FDA GRAS approval.

• The Mediterranea Agua de Mar purified seawater product's intended use is as an ingredient in food preparation and cooking.

• As the volume of product sold globally exceeds the current Spain-based manufacturing facility's capacity, the two Companies will investigate and seek all needed approvals to build additional manufacturing plants in Spain and potentially other Countries already utilizing the product.

• Seawater Solutions, Inc. would like to bring product to Market in the U.S. in late 2015, provided that all needed food safety approvals have been granted.

3. Production system

MEDITERRANEA SEA WATER has a certified third system (AENOR) which guarantees the quality management system and food security. These certificates correspond to the standards based on the standards UNE-EN-ISO 9001; UNE-EN-ISO 14001 and IFS Food standard V6, in addition to the statutory Health Registry (RGESAA).

ER-0939/2013 GA-2013/0385

These certified, not only compliance with the regulations applicable to our industry, but also ensure the establishment of procedures for monitoring and control of the quality parameters established by law and food safety and established by MEDITERRÁNEA SEA WATER.

Criteria and protocols for monitoring and control are based on the recommendations of the Codex Alimentarius, it means monitoring and control over Prerequisites Food hygiene is performed, as well as Hazard Analysis and Critical Control Points on all stages of the production system. The process diagram that provides the basis for developing the system of critical control points is shown in the margin.

Furthermore, MEDITERRANEA SEA WATER has established some additional control plans:

- Prerequisites control plan commensurate with the Codex Alimentarius.
- Analytics of raw materials and finished product plans.
- Verification and Monitoring Plan HACCP.
- Food Defense Plan

The present method for improve features of seawater comprising the following phases or steps:

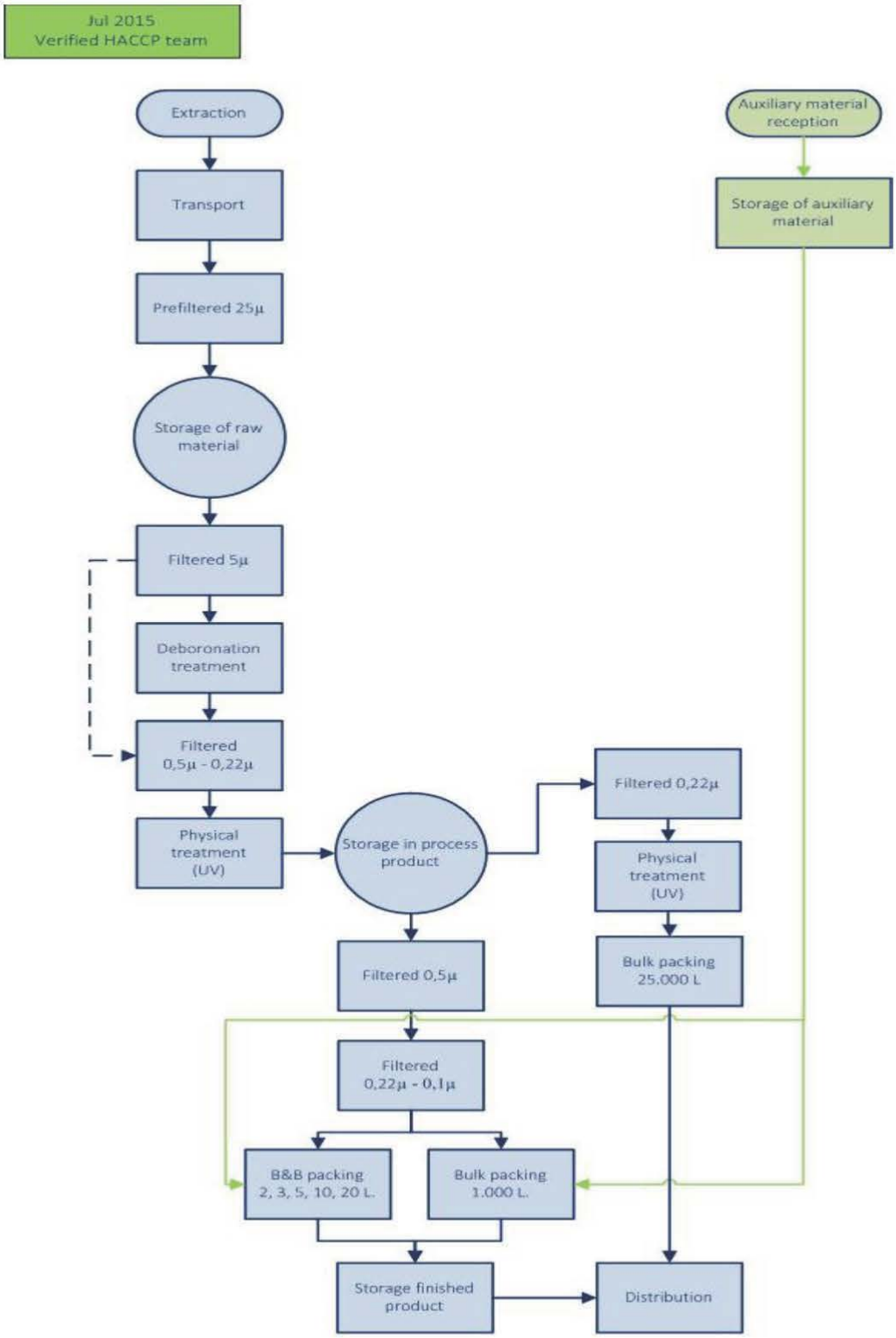
- Seawater extraction
- Purity analysis
- Microfiltration
- Deboronation treatment
- Microbiological analysis
- Packaging

An object of the present method is therefore a method far obtaining a seawater with a minimal boron content, less than 1 mg/L, free of organic matter, macromolecules and bacteria, which maintains the mineral load and composition of natural seawater, has a higher alkalinity and an improved molecular structure.

Seawater extraction

Seawater extraction is performed from fixed points,by tankers duly equipped with extraction pumps and tanks approved for use in food.

Before extraction, determinations of at least salinity, turbidity, chlorophyll (phytoplankton) and dissolved oxygen are taken by means of a multiparametric probe capable of measuring the entire water column in real time.


Jul 2015
Verified HACCP team
Extraction
Transport
Prefiltered 25µ
Storage of raw material
Filtered 5µ
Deboronation treatment
Filtered 0,5µ - 0,22µ
Physical treatment (UV)
Storage in process product
Filtered 0,5µ
Filtered 0,22µ - 0,1µ
B&B packing 2, 3, 5, 10, 20 L.
Bulk packing 1.000 L.
Storage finished product
Distribution
Auxiliary material reception
Storage of auxiliary material
Filtered 0,22µ
Physical treatment (UV)
Bulk packing 25.000 L

FILTRATION STEP

FILTRATION STEP	FILTER	FILTER SIZE	FILTERED ELEMENTS
1 STEP (MAIN)	FILTER Nº1	25 µm	Sands
			Algae
	FILTER Nº2	5 µm	Suspended Solids
	BORON FILTER Nº3	-	Boron
	FILTER Nº4	0,5 µm	Clostridium perfingens
			Coliforms
	FILTER Nº5	0,22 µm	Enterococci
			Pseudomona aeruginosa
			Vibrio spp
	UV	-	Aerobic microrganism 22/37 °C
2 STEP (SECURITY)	FILTER Nº6	0,5 µm	Clostridium perfingens
			Coliforms
	FILTER Nº7	0,22 µm	Enterococci
	FILTER Nº8	0,1 µm	Vibrio spp
			Pseudomona aeruginosa
	UV	-	Aerobic microrganism 22/37 °C

PURITY ANALYSIS

For that purpose, standard physicochemical and microbiological analyses known by the person skilled in the art are performed following normalized methods (see the attached table) to verify that it is free of pollutants and complies with the parameters established by specific regulations, treatment and use of seawater, it must also comply with the recommendation of the EFSA (European Food Safety Authority) in the EFSA Scientific Evaluation (EFSA Journal 2012;10(3):26139), which includes some of the parameters comprised in Royal Decree 140/2003, limiting the concentration of possible chemical and biological pollutants. These determinations and the criteria followed for validating extracted seawater will be broadened and/or modified provided it is necessary in order to comply with the regulations in force at all times and with the recommendations established by renowned organiza-tions such as EFSA.

Parameter	Testing method/Protocol
Organoleptic analysis	PNTM3087 (UNE-EN 1622)
Conductivity	B.O.E. 0. 1.7.1987
pH	B.O.E. 0.15.9.1985
Turbidity	ISO 7027
Sulfates, oxidizability, nitrites	B.O.E. 0.1.7.1987
Nitrates	B.O.E. 0. 1.7.1998
Aluminum, boron, cadmium, copper, chromium, iron, manganese, nickel, sodium	PNTA0141 (ICP-AES)
Arsenic, mercury, lead, selenium, antimony	PNTQ1032/AAS/GF)
Cyanides	APHA 4500-CN E
Chlorides	PNTA0078
Aerobic microorganisms (22oC)	PNTM3000
Total coliforms	PNTM3045
Clostridium perfringens	PNTM3086
Escherichia co/i	EN ISO 9308
Enterococcus	EN ISO 7899
Vibrio spp	ISO/TS 21872:2007
Halogenated and non halogenated solvents, aromatic polycyclic hydrocarbons, pesticides	GC/MS

Maximum levels of chemical pollutants are established in Directive 98/83/EC on the quality of water intended for human consumption, and additionally the maximum limits of barium and manganese are established in Directive 2003/04/EC.
Based on these parameters contemplated in EFSA's report, the boron content is the only parameter with which natural extracted seawater does not comply. Seawater contains about 5 mg/I of boron, whereas the limit recommended by EFSA is 1 mg/I. As a result, the process for obtaining the seawater contemplates a deboronation step or treatment which will be explained in detail below.

FIRST MICROFILTRATION

The extracted seawater must be subjected to a microfiltration that allows removing the organic and macromolecular components from the water without modifying the original mineral composition thereof, i.e., neither the concentration nor the form of the mineral elements in seawater are affected in any way by this water treatment.

Microfiltration is performed in two steps: in the first step, the water passes through a membrane pre-filter. with a pore size of 0.5 µ, and in the second step it passes through a membrane filter with a pare size of 0.22 µ, both steps being capable of removing from the seawater substantially all the components larger than 0.22 µ without compromising the mineral composition and concentration of the original seawater.

The filters used are pleated hydrophilic Durapore CBR cartridge filters with a PVDF membrane and extractable polypropylene components providing high flow rates and low outputs with broad chemical compatibility.

DEBORONATION TREATMENT

The most important and essential aspect of this step is, however, to perform the selective removal of boron, thus maintaining the remaining mineral concentration and composition of seawater in its natural state.

To that end a selective ion exchange demineralization system which allows separating the boron from the water without affecting either the concentration or the form of the remaining mineral elements present in the water by means of using a specific solid matrix (resin).

The type of specific resins to be used are conventionally strong base anion resins (tertiary amino functional group bound to a polyamide base matrix), with very high selectivity for boron and approved for use in water for consumption or water that come into contact with foods.

SECOND MICROFILTRATION

Before packaging the end product, the seawater obtained in the preceding step is subjected to final 0.5µ-0.22µ-0.1 µ microfiltration. This second microfiltration is also performed by means of using Hydrophilic Durapore CBR filters, and it additionally allows assuring complete sterilization (removal of bacteria), removing a large amount of viruses, particularly viruses associated with bacteria.

Any bacterium of a size greater than 0.1 µ that may have contaminated the product during processing is removed with this microfiltration, assuring end product food safety.

MICROBIOLOGICAL ANALYSIS

Once the water is processed and before being used far packaging ar bulk sale, it is re-analyzed to check process reliability and assure the complete absence of bacteria in each of the batches produced. To that end, of each batch is processed following all the steps described above, they are stored in tanks, a minimum storage period of 48 hours starting at that time, and this is the time used to take microbiological determinations that are needed to validate the quality of the water and market it.

If a colony farming unit is obtained in any of the analyses performed, the batch is discarded and the causes of the contamination are studied, checking the production process and the operation of the equipment involved in said process.

The microbiological determinations to be taken are: mesophilic aerobic bacteria at 22ºC (PNTM 3000 method), total coliforms (PNTM 3045 method), Escherichia coli (EN ISO 9308 method), Entero-coccus (EN ISO 7899), Clostridium perfringens (PNTM 3086), Vibrio spp (ISO-ITS 21872:2007).

PACKAGING

In the packaging process it is performed using a sterile over pressured air chamber minimizing the risk of product contamination.

After at least 48 hours have passed and the microbiological quality of the seawater has been validated with the analytical confirmation of the absence of bacteria, the product can be packaged for loaded into vats far bulk transport to later be sold.

4. Control Program Test

Test	Frequency	Parameters
Raw Material – Sea Water (Internal Test)	**Each batch**	Temperature
		pH
		Salinity
		Turbidity
		Dissolved Oxygen
Microbiological criteria Raw Material	**July - August**	E. Coli
		Enterococci
		Vibrio
Physical Criteria Post filtration seawater	**Each batch**	Turbidity
		pH
		Conductivity
		Smell, color, flavor
		Boron
Microbiological criteria Post filtration seawater	**Each batch**	Total Coliforms
		E. Coli
		Mesofilos at 22ºC
		Mesofilos at 37ºC
		Pseudomonas aeruginosa
		Clostridium perfringens
		Vibrio sp
		Enterococci
Metal Test Post filtration seawater	**Each batch**	Cadmium
		Lead
		Nickel
		Mercury
		Copper
		Iron

Chemical Criteria Post filtration seawater	**Biannual**	Antimony
		Ammonium
		Aluminum
		Arsenic
		Benzene
		Benzopyrene
		Trichloroethane + Tetrachloroethane
		1.2- Dichloroethane
		Chlorides
		Chrome
		Cyanide
		Fluorides
		Nitrates
		Pesticides
		Total pesticides
		Polycyclic aromatic hydrocarbons
		Selenium
		Total trihalomethanes
		Barium
		Manganese
		Total Organic Carbon (Oxi-disability)
		Sulfates
		Sodium

Aerobic test – B&B Packaged Seawater	**Monthly**	Mesofilos a 22ºC
		Mesofilos a 37ºC

Other Criteria	**As required**	Bromate
		Acrylamide
		Epichlorohydrin
		Vinyl chloride
		Nitrites
		Legionella

5. Test for shelf life stability.

Shelf life test was made by an outside laboratory. The report studied some microbiological criteria en organoleptic determinations.

The outcome of the test was that the seawater has a useful life of 2 years. Attached the report.

6. Relevant Documents.

· Scientific Opinion on the minimum hygiene criteria to be applied to clean seawater and on the public health risks and hygiene criteria for bottled seawater intended for domestic use. http://www.efsa.europa.eu/en/efsajournal/pub/2613.htm

· Interpretative note on health requirements for the marketing of seawater. http://aesan.msssi.gob.es/AESAN/web/cadena_alimentaria/subseccion/lista_no tas_interpretativas_II.shtml

· Royal Decree 140/2003 of 7 February, establishing health criteria for the quality of water for human consumption. http://www.boe.es/buscar/- doc.php?id=BOE-A-2003-3596

· Royal Decree 1799/2010 of 30 December, by which the process of developing and marketing packaged, prepared waters for human consumption is regulated. http://www.boe.es/buscar/doc.php?id=BOE-A-2011-1011

mediterranea
AGUA DE MAR

SEA WATER

Control Analysis

ENAC
ENSAYOS
Nº 109/LE285

LABAQUA

Informe de análisis

* Los ensayos marcados no están amparados por la acreditación de ENAC.

DATOS GENERALES

INFORME Nº: 1670211
ANÁLISIS Nº: 2607729
MUESTRA REMITIDA POR: MAREVENDIS BARCELONA, S.L.U.
DOMICILIO: C/ Aragó, 208-210, 5º 2ª puerta
POBLACION: 08011-Barcelona
DENOMINACIÓN MUESTRA: L-15240. (AGUA DE MAR) ENVASES PRODUCTO ACABADO
DESCRIPCIÓN MUESTRA: Plástico 1L(1), conteniendo agua mar
FECHA RECEPCIÓN: 2/09/2015
FECHA FINALIZACIÓN Y EMISIÓN: 2/09/2015

Análisis realizado por LABAQUA Alicante. Acreditado por ENAC nº 109/LE285; C/ Dracma,16-18- Pol. Ind. Las Atalayas 03114 ALICANTE - Tel. 965 10 60 70 - Fax 965 10 60 80:
Fecha inicio análisis 2/09/2015.

PARÁMETROS	MÉTODOS	Límites	RESULTADOS	UNIDADES
Caracteres organolépticos				
Color	A-C-PE-0028 Fotometría		< 1.0 ±12%	mg/L Pt/Co
* Olor	A-A-PE-0014 Dilución		1	Ind. de dil.
* Sabor	A-A-PE-0015 Dilución		10	Ind. de dil.
Turbidez	A-A-PE-0021 Nefelometría	<1	0.20 ±10%	UNF
Caracteres Físico-Químicos				
Conductividad a 20ºC	A-A-PE-0004 Electrometría		50400 ±6%	µS/cm
pH	A-A-PE-0010 Electrometría		7.9 ±0.1	U. pH.
Metales				
Boro	A-D-PE-0025 ICP-OES	<1	< 0.20 ±12%	mg/L

INTERPRETACIONES

Las interpretaciones que se indican seguidamente están fuera del alcance de ENAC.
Se sube el límite de cuantificación del B por interferencias con la matriz.

Aprobado en Labaqua Alicante por Técnico Superior: Jose Gallardo Armengot, Director Técnico: Francisco García Andreu.

Documento firmado electrónicamente. Autenticidad verificable mediante código seguro 5b7cb2d88c568113da3d6e31aece9755f0665059 en www.fnmt.es.

Emitido en ALICANTE, 2 de Septiembre de 2015

ENAC
ENSAYOS
Nº109/LE285

LABAQUA

Informe de análisis

* Los ensayos marcados no están amparados por la acreditación de ENAC.

DATOS GENERALES

INFORME Nº: 1669934
ANÁLISIS Nº: 2607738
MUESTRA REMITIDA POR: MAREVENDIS BARCELONA, S.L.U.
DOMICILIO: C/ Aragó, 208-210, 5º 2ª puerta
POBLACION: 08011-Barcelona
DENOMINACIÓN MUESTRA: L-15240. (AGUA DE MAR) ENVASES PRODUCTO ACABADO
DESCRIPCIÓN MUESTRA: Plástico estéril 1 L (Tiosulfato sódico)(2), conteniendo agua mar
FECHA RECEPCIÓN: 29/08/2015
FECHA FINALIZACIÓN Y EMISIÓN: 2/09/2015

Análisis realizado por LABAQUA Alicante. Acreditado por ENAC nº 109/LE285; C/ Dracma,16-18- Pol. Ind. Las Atalayas 03114 ALICANTE - Tel. 965 10 60 70 - Fax 965 10 60 80:
Fecha inicio análisis 29/08/2015.

PARÁMETROS	MÉTODOS	Límites	RESULTADOS	UNIDADES
Caracteres microbiológicos				
Clostridium perfringens	A-E-PE-0048. Filtr. Membrana.	0	0	u.f.c./100 mL
Coliformes totales	A-E-PE-0061. Aislamiento en cultivo	0	0	u.f.c./250 mL
Enterococos	A-E-PE-0013. Aislamiento en cultivo	0	0	u.f.c./250 mL
Escherichia coli	A-E-PE-0061. Aislamiento en cultivo	0	0	u.f.c./250 mL
Microorganismos aerobios a 22ºC	ISO 6222. Aislamiento en cultivo.	100	8	u.f.c./mL
Microorganismos aerobios a 37ºC	ISO 6222. Aislamiento en cultivo.	20	0	u.f.c./mL
Pseudomonas aeruginosa	A-E-PE-007. Aislamiento en cultivo	0	0	u.f.c./250 mL
* *Vibrio spp.*	A-E-PE-0024. Filtr. y Enriquec.	0	Ausencia	/L

OBSERVACIONES

Resultados en microbiología: de 1 a 3 ufc se interpreta como organismo presente y de 4 a 9 ufc como recuento estimado.

Este informe sólo afecta a la muestra analizada. Sólo podrá reproducirse parcialmente con la autorización por escrito del laboratorio.

Aprobado en Labaqua Alicante por Técnico Superior: Jose Gallardo Armengot, Director Técnico: Francisco García Andreu.

Documento firmado electrónicamente. Autenticidad verificable mediante código seguro 5b7cb2d88c568113da3d6e31aece9755f0665059 en www.fnmt.es.

Emitido en ALICANTE, 2 de Septiembre de 2015

ENAC
ENSAYOS
Nº109/LE285

LABAQUA

Informe de análisis

DATOS GENERALES
INFORME Nº: 1671890
ANÁLISIS Nº: 2607745
MUESTRA REMITIDA POR: MAREVENDIS BARCELONA, S.L.U.
DOMICILIO: C/ Aragó, 208-210, 5º 2ª puerta
POBLACION: 08011-Barcelona
DENOMINACIÓN MUESTRA: L-15240. (AGUA DE MAR) ENVASES PRODUCTO ACABADO
DESCRIPCIÓN MUESTRA: Plástico 1L(1), conteniendo agua mar
FECHA RECEPCIÓN: 2/09/2015
FECHA FINALIZACIÓN Y EMISIÓN: 4/09/2015

Análisis realizado por LABAQUA Alicante. Acreditado por ENAC nº 109/LE285; C/ Dracma,16-18- Pol. Ind. Las Atalayas 03114 ALICANTE - Tel. 965 10 60 70 - Fax 965 10 60 80:
Fecha inicio análisis 2/09/2015.

PARÁMETROS	MÉTODOS	Límites	RESULTADOS	UNIDADES
Metales				
Cadmio	A-D-PE-0026-1 Metales ICP-MS	5	< 1 ±13%	µg/L
Cobre	A-D-PE-0026-1 Metales ICP-MS	2	< 0.002 ±13%	mg/L
Hierro	A-D-PE-0026-1 Metales ICP-MS	200	< 10 ±15%	µg/L
Mercurio	A-D-PE-0005 Fluorescencia atómica	1	< 0.10 ±18%	µg/L
Niquel	A-D-PE-0026-1 Metales ICP-MS	20	< 2 ±15%	µg/L
Plomo	A-D-PE-0026-1 Metales ICP-MS	10	< 2 ±13%	µg/L

Este informe sólo afecta a la muestra analizada. Sólo podrá reproducirse parcialmente con la autorización por escrito del laboratorio.

Aprobado en Labaqua Alicante por Técnico Superior: Jose Gallardo Armengot, Director Técnico: Francisco García Andreu.

Documento firmado electrónicamente. Autenticidad verificable mediante código seguro 5b7cb2d88c568113da3d6e31aece9755f0665059 en www.fnmt.es.

Emitido en ALICANTE, 4 de Septiembre de 2015

mediterranea
AGUA DE MAR

Seawater

Ion Exchange Resins
Boron Removal

PRACTICAL GUIDE

Boron Removal

Using Amberlite™ IRA743 and Amberlite™ PWA10

INTRODUCTION

With Amberlite IRA743 or Amberlite PWA10, borate can be removed very effectively from water.
This ion exchange resin is so selective for boric acid that practically any salt background is tolerable. There are different fields of application:

- Removal of boron for drinking water
- Removal of boron in ultra-pure water
- Treatment of magnesium brines containing boron
- Removal of boron from water for irrigation

We will focus here on the drinking water application, although most of the following information is valid for all fields.

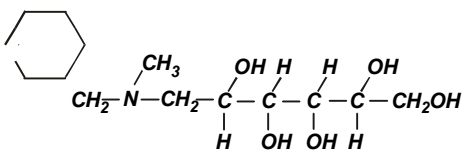
BORON

Boron in water is always present as some form of boric acid, which is a very weak acid, similar to silicic acid ("silica") with a pK value of 9.1. At a pH lower than 7, boric acid is undissociated as H_3BO_3 or $B(OH)_3$. Boric acid is a Lewis acid, i.e. an OH^- acceptor rather than an H^+ donor. At a pH higher than 11.5, boron occurs as dissociated
borate $[B(OH)_4]^-$.

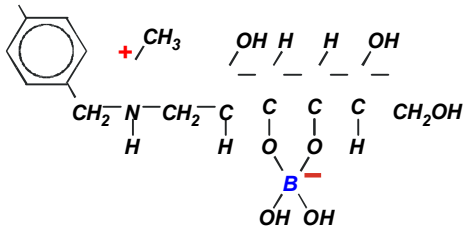
$$B(OH)_3 + NaOH \text{ -7 } [B(OH)_4]^- + Na^+$$

ION EXCHANGE REACTION

Amberlite IRA743 and PWA10 are macroporous styrenic resins with methyl glucamine functionality. The active group is essentially a weak base (tertiary amine) with a "sugar tail". A developed formula is shown here:



The uptake of boron as borate $[B(OH)_4]^-$ is a curious mechanism, as it involves protonation of the amine, de-protonation of the polyol sugar tail, shedding of water and formation of an ester. The next picture is believed to be the final result:



The uptake of borate by Amberlite IRA743 can in principle be done with the resin in acidic form (e.g. HCl) as a true substitution combined with complex formation. However it has been demonstrated experimentally that the capacity was higher with the resin in free base form.

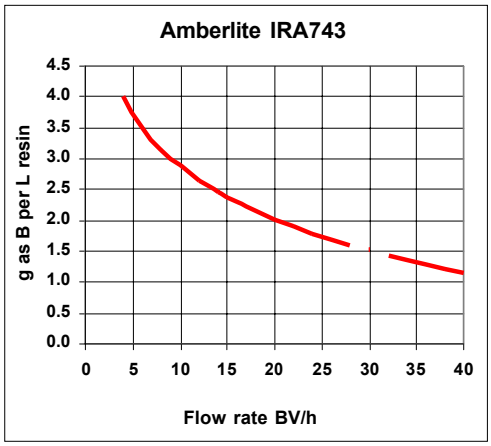
RESINS USED

For general use: Amberlite IRA743.
For drinking water: Amberlite PWA10, specially prepared to meet potable water regulations.

OPERATING CAPACITY

As this is a weakly basic resin, it is usually regenerated in co-flow. The most important parameter is flow rate as shown in the graph.

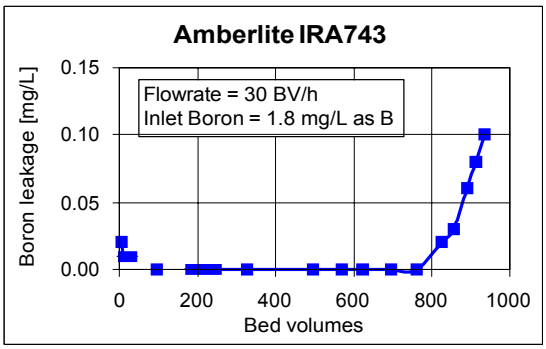
Boron concentration and salt background have little effect on operating capacity.



Operating capacity vs. flow rate

EXPECTED LEAKAGE

A very low leakage can be obtained when the endpoint is kept low. In UPW, references mention leakage values of 20 ng/L (ppt) for inlet values of 50 to 100 µg/L (ppb). Here is a typical leakage profile:



Typical leakage profile

With an endpoint set at 0.1 mg/L, a part of the stream can often be by-passed, which reduces the plant size by a factor of 20 to 40%.

REGENERATION

It is done in two steps: first the borate is displaced with sulphuric or hydrochloric acid, then the resin is converted back to the free base form. Initial work showed regeneration with acid only, but studies have shown that the conversion step gives a much higher performance. The regeneration procedure does not depend on capacity or any other parameter, and involves complete conversion of the active groups. The optimum flow rate is 15 to 30 BV/h when the inlet boron value is in the single ppm range.

EFFICIENCY

The extreme selectivity of Amberlite IRA743 and PWA10 makes this ion exchange process highly efficient: unlike with other processes such as reverse osmosis, only the targeted contaminant, boron, is removed from the water. The other ions such as sodium, calcium, bicarbonate, chloride and sulphate are not affected. Ion exchange with Amberlite IRA743 or PWA10 is the only process to remove boron ***selectively*** from water.

RECOMMENDED OPERATING CONDITIONS

Temperature	5 to 100°C
Bed depth	> 1000 mm (40 in) Preferably about 1400 mm (56 in)
Specific flow rate	5 to 30 BV/h
Regenerant	H_2SO_4 or HCl
Regenerant concentration	3.5 to 5% so that the regenerant volume is 1 BV
Regenerant quantity	HCl : 35 g/L (as HCl 100 %) i.e. 2.2 lb/ft^3 H_2SO_4 : 50 g/L i.e. 3.2 lb/ft^3
Regenerant contact time	25 to 40 minutes
Regenerant flow rate	1.5 to 2 BV/h
Slow rinse (displacement)	About 3 bed volumes in 60 minutes
Conversion step	NaOH (ammonia is possible)
Caustic soda quantity	28 g/L (as NaOH 100 %) i.e. 1.8 lb/ft^3
NaOH concentration	2.5%
Contact time	25 to 40 minutes, i.e. 1.5 to 2 BV/h
NaOH displacement and rinse	2 BV only in about 40 minutes
Quality of water for regeneration	For acid dilution, acid displacement, caustic dilution and displacement: demineralized or soft water

Rohm and Haas/Ion Exchange Resins - Philadelphia, PA - Tel. (800) RH AMBER - Fax: (215) 409-4534
Rohm and Haas/Ion Exchange Resins - 75579 Paris Cedex 12 - Tel. (33) 1 40 02 50 00 - Fax : 1 43 45 28 19
http://www.amberlite.com

AMBERLITE PWA10 Resin

Drinking Water Grade

Introduction

Boron Selective

AMBERLITE PWA10 resin is a unique drinking water grade ion exchange resin designed for the removal of boron from drinking water. The resin can be regenerated using a two-step process consisting of a regeneration step to displace the boron followed by a conversion step.

AMBERLITE PWA10 resin has been shown to be nearly universal in its high selectivity for boron. Salts, including bases, do not interfere significantly. The concentration of boric acid or the salt background in water also has little effect upon the selectivity. This high selectivity for boron and low risk of interference makes AMBERLITE PWA10 resin highly suitable for removal of boron from water derived from desalination.

Properties

Matrix	Macroporouspolystyrene
Physical form	Opaque beige beads
Total exchange capacity	≥ 0.7 eq/L
Moisture holding capacity	48 54%
Shipping weight	700 kg/m^3 (44 lb/ft^3)
Particle size	
Screen grading	0.3 - 1.2 mm (16 to 50 mesh US Std Screens)
Fines content	<0.300 mm: 1% max

Suggested Operating Conditions

Maximum operating temperature	45°C (110°F)
Minimum bed depth	800 mm, recommended 1400 mm (32 in / 56 in)
Typical service flow rate	5 to 35 BV/h* (0.6 4.5 gpm/ft^3)
Regeneration	Please contact a representative for details

Commissioning and limits of use

AMBERLITE PWA10 resin is suitable for use in potable water applications after an initial commissioning soak in water for 24 hrs followed by a rinse of 5 bed volumes (35 gal/ft3) of potable water at ambient temperature.

The operating capacity of AMBERLITE PWA10 resin depends on the operating conditions.

Regulatory

Please contact Dow Water & Process Solutions for certification information.

Resin products are manufacturing in ISO 9001 certified facilities.

Hydraulic Characteristics

Figure 1 and Figure 2 show the pressure drop data for AMBERLITE PWA10 resin as a function of flow rate and water temperature. Pressure drop data are valid at the start of the service run with clean water and a correctly classified bed. Figure 3 and Figure 4 show the bed expansion of AMBERLITE PWA10 resin as a function of backwash flow rate and water temperature.

Figure 1 Pressure Drop (metric)

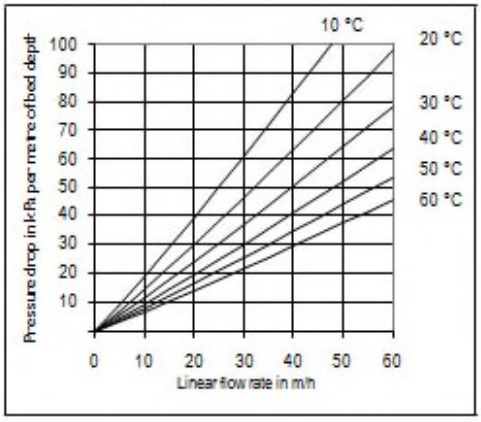


Figure 2 Pressure Drop (US units)

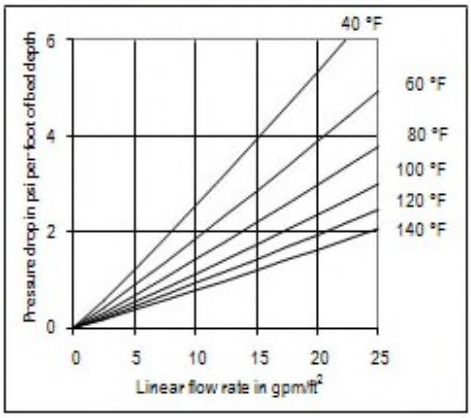


Figure 3 Bed Expansion (metric)

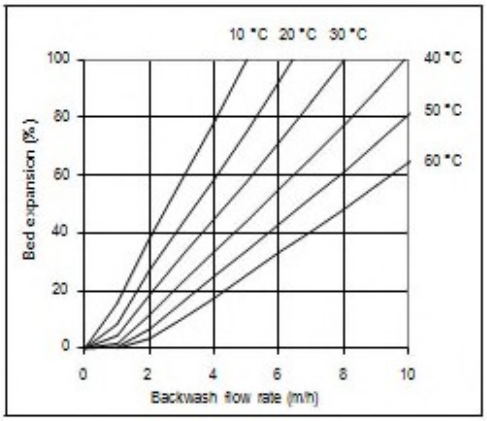
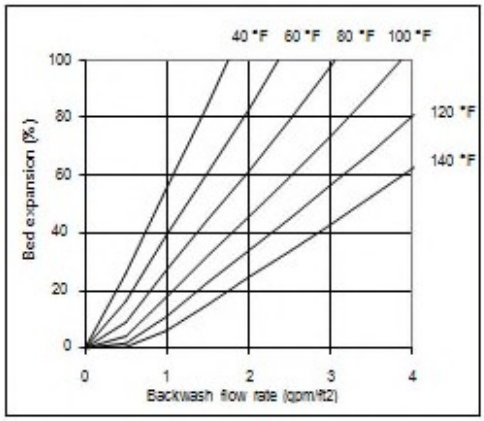


Figure 4 Bed Expansion (US units)



For more information about DOW ™ resins, call the Dow Water & Process Solutions business:
North America: 1-800-447-4369
Latin America: (+55) 11-5188-9222
Europe: +800-3-694-6367
Italy: +800-783-825
South Africa: +0800 99 5078
Pacific: +8007776 7776
China: +400 889-0789
http://www.dowwaterandprocess.com

mediterranea
AGUA DE MAR

SEA WATER

European Certifications

1FS Certificate

1FS-2013/0046

Herewith the certification body AENOR, being an accredited certification body for IFS certification, and having signed an agreement with the IFS owners, confirms that the processing activit

MAREVENDIS BARCELONA, S.L.U.

meets the requirements set out in the
IFS FOOD Version 6, April 2014
and other associated normative documents

address:	CL ARAGÓN, 208 5º - 2ª. 08011 - BARCELONA
COID:	41652
scope:	The filtration, purification by ion exchange resin and packing in bag in box format and in tanks of seawater. la filtración, purificación mediante resina de intercambio iónico y envasado en formato bag in box y en cisternas de agua de mar.
exclusions from scope:	None. Ninguna.
product scope:	8. Beverages
technology scope:	C.P5, E.P10, F.P12
level:	Higher Level
Date of the audit:	2014-11-20
Date of issue of the certificate:	2014-12-30
Certificate valid until:	2016-01-06
Next audit to be performed:	from 2015-09-17 to 2015-11-26

(b) (6)

AE (b) (6)

Avelino BRITO MARQUINA
Chief Executive Officer

Certificado del Sistema de Gestión de la Calidad

AENOR ER Empresa Registrada UNE-EN ISO 9001

ER-0939/2013

AENOR, Asociación Española de Normalización y Certificación, certifica que la organización

MAREVENDIS AGUA DE MAR, S.L.

dispone de un sistema de gestión de la calidad conforme con la Norma UNE-EN ISO 9001:2008

para las adividades: La comercialización de agua de mar envasada a granel. El envasado de agua de mar en formato Bag in Box.

que se realizan *en:* MAREVENDIS AGUA DE MAR, S.L.
CL REYES CATÓLICOS, 315º B. 03005 - ALICANTE
MAREVENDIS BARCELONA, S.L.U.
CARRER ARAGó, 208-210. 08011 - BARCELONA
CARRER REC DELS TEMPLARIS, 4. 08460 - SANTA MARIA DE PALAUTORDERA (BARCELONA)

Fecha de primera emisión: 2013-12-23
Fecha de expiración: 2016-12-23

(b) (6)

Avelino BRITO MARQUINA
Diredor General de AENOR

AENOR Asociación Española de Normalización y Certificación
Génova, 6. 280() {¡ Madrid. España
Tel. 902 102 201 - www.aenor.es

IAF ENAC CERTIFICACIÓN IQNet

Certificado del Sistema de Gestión Ambiental

AENOR

Gestión Ambiental

UNE-EN ISO 14001

GA-2013/0385

AENOR, Asociación Española de Normalización y Certificación, certifica que la organización

MAREVENDIS AGUA DE MAR, S.L.

dispone de un sistema de gestión ambiental conforme con la norma UNE-EN ISO 14001:2004

para las adividades: La comercialización de agua de mar envasada a granel. El envasado de agua de mar en formato Bag in Box.

que se realiza/n en: MAREVENDIS AGUA DE MAR, S.L.
CL REYES CATÓLICOS, 315º B. 03005 - ALICANTE
MAREVENDIS BARCELONA, S.L.U.
CARRER ARAGó, 208-210. 08011 - BARCELONA
CARRER REC DELS TEMPLARIS, 4. 08460 - SANTA MARIA DE PALAUTORDERA (BARCELONA)

(b) (6)

Fecha de primera emisión: 2013-12-23
Fecha de expiración: 2016-12-23

Avelino BRITO MARQUINA
Diredor General de AENOR

AENOR Asociación Española de Normalización y Certificación
Génova, 6. 280() {¡ Madrid. España
Tel. 902 102 201 - www.aenor.es

GRAS NOTIFICATION OF THE USE OF PURIFIED SEAWATER AS A FLAVORING SUBSTANCE

Submitted to:
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration
5100 Paint Branch Parkway
College Park MD
20740-3835

Applicant:
Seawater Solutions, Inc.
34 Terrace Court
Tiburon CA 94920

Table Of Contents

Generally Recognized as Safe Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.30(b) Seawater Solution's Purified Seawater

1. GRAS Exemption Claim

Seawater Solutions Inc. has determined that its sea water product, purified seawater which meets the specifications as described in this document, is Generally Recognized As Safe (GRAS) in accordance with Section 201(s) of the FFDCA. This determination is made by an appropriately trained expert who is qualified by scientific training and experience. The GRAS determination is based on scientific procedures. A GRAS determination requires common knowledge that the substance for the intended use. The data and information used to establish safety must be generally available. There must be a basis upon which to conclude that there is a consensus among qualified scientists about the safety of the substance for its intended use; this is established by relying upon published, peer-reviewed scientific journals or secondary scientific literature such as published review articles, textbooks or compendia, or the opinions of expert panels or authoritative bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the National Academy of Sciences.

1.1 Name and Address of Notifier

Seawater Solutions, Inc.
34 Terrace Court
Tiburon CA 94920

1.2 Common Name and Identity of the Notified Substance

The common name of the substance is purified seawater. It consists of water and naturally occurring components of seawater including sodium, potassium and magnesium cations and chloride and sulfate anions in solution. Impurities include other naturally occurring components of sea water. Some sea water ingredients such as boron and microbes are removed from the final product.

1.3 Conditions of Intended Use in Food

Purified seawater preparations are intended to be used as a substitute for sodium chloride (table salt) in various food categories such as vegetables and fish. Use levels will be self-limiting and should not exceed the respective amounts required to accomplish the intended technical effect.

1.4 Basis for the GRAS Determination

Pursuant to 21 CFR 170.30, purified seawater has been determined to be GRAS on the basis of scientific procedures as detailed below. In addition, salts that constitute a major portion of the non-aqueous composition of the product are potassium, sodium and magnesium chlorides, and calcium sulfates. These salts have already been determined to be GRAS through regulation.

1.5 Availability of Information

The data and information that serve as the basis for this notification will be sent to the US FDA upon request or will be available at Technology Sciences Group Inc. (TSG) by appointment. Technology Sciences Group Inc. is located at 1150 18th Street NW, Washington DC 20036.

Introduction

At the request of Seawater Solutions, an independent safety evaluation of purified seawater was carried out for its use as a substance to be added to food as a salt substitute. The purpose of the review is to determine whether or not the intended food uses of purified seawater can be considered as GRAS when used in food products for technical effects as a flavor enhancer (21 CFR 170.3 (o)(11), flavoring agent (21 CFR 170.3 (o)(12) and a nutrient (21 CFR 170.3 (o)(20)). A search of the scientific and regulatory literature through December 10, 2015 was conducted. The summary of safety information in this document relies primarily on scientific evaluations conducted by other expert and authoritative bodies to reach a determination of safety for the intended use.

2. Detailed Information Regarding Identity of Notified Substance

2.1 Description and Identification

Seawater Solutions' product is a food-grade solution that is purified sea salt solution that is used to replace sodium chloride for food flavoring purposes in raw and processed foods.

2.2 Chemical Formula and Chemical Abstract Service Registry Number

The product consists primarily of water and sea salts including sodium chloride (NaCl), potassium chloride (KCl), calcium sulfate ($CaSO_4$), and magnesium chloride ($MgCl_2$). The empirical and chemical formulas and Chemical Abstract Services Numbers are shown below for the salts that constitute the primary components:

Table 1: Identification of Primary Components of Purified Seawater

Chemical name	sodium chloride	Potassium chloride	Calcium sulfate	Magnesium chloride
Empirical formula	NaCl	KCl	CaSO	MgCl
Chemical formula	NaCl	KCl	$CaSO_4$	$MgCl_2$
Chemical abstracts services number	7647-14-5	7447-40-7	7778-18-9	7786-30-3

2.3 Substance Composition and Characteristic Properties

Table 2. Composition of Purified Seawater (Major Components of Product of 250 ml container)

Component	Amount	Properties
Sodium (chloride)	965 mg	Colorless or white crystal, solubility = 359 g/L (as sodium chloride)
Potassium (chloride)	37.5 mg	White crystal, solubility = 334 g/L
Calcium (sulfate)	33.8 mg	White or yellow powder, solubility = 2.1 g/L
Magnesium (chloride)	106.7 mg	Colorless or white solid, solubility > 540 g/L
Total salt	2.3 g	N.A.

2.4 Manufacturing Method

The sea water is collected by tankers equipped with extraction pumps and tanks approved for food use. Salinity, turbidity, chlorophyll and dissolved oxygen are measured in real time prior to collecting sea water. The first microfiltration removes organic and large components from the water without modifying the mineral composition of the seawater. The first microfiltration step first uses a pore size of 0.5 microns and is followed by a second filtration with pore size of 0.22 microns.

Deboronation follows the first microfiltration step. Selective ion exchange demineralization separates boron from water through the use of specific solid matrix. The ion exchange resin has a high selectivity for boron and is food grade.

The second microfiltration step occurs after deboronation and removes bacteria and viruses. This step uses hydrophilic microfilters of 0.5, 0.22 and 0.1 micron pore size. After this filtration step, the seawater product is stored in tanks for 48 hours and analyzed for the presence of microbes. If colony forming units are found in any batch it is discarded. The microbes that are specifically identified are mesophilic aerobic bacteria, total coliforms, *Escherichia coli*, enterococcus, *Clostridium perfringens* and *Vibrio* spp. The product is packaged only after confirmation of the absence of unacceptable concentrations of bacteria.

2.5 Product Analytical Data

Product specifications are shown in the following table and analytical data confirming compliance with these specifications is shown in Appendix A.

Table 3. Specifications of Purified Seawater

Parameter	Result	Unit
Color	<1.0 ± 12%	Mg/L Pt/Co
Turbidity	<1	UNF
pH	7.9 ± 0.1	pH units
Boron	<1	mg/L
Cadmium	<5	Microgram/l
Copper	<2	Mg/l
Iron	<200	Microgram/l

Mercury	<20	Microgram/L
Nickel	<20	Microgram/L
Lead	<10	Microgram/L

2.6 Impurities

The impurities present in purified seawater are those that may be found in water collected in the Mediterranean Sea. Boron, microbes, sand and plankton are removed and the resulting product meets the standards for bacterial counts specified in 21 CFR 165.110. Soluble elements remain after filtration and the ion exchange used to reduce boron concentrations. Some of these elements are essential (copper, zinc and iron) and all are within applicable drinking water standards of the US EPA. Concentrations of these elements are less than those specified for sodium chloride in the Food Chemicals Codex (2014) when assessed on a dry weight basis. The FCC specifications for sodium chloride are shown below.

Table 4. Food Chemical Codex Specifications for Sodium Chloride

Impurity	Limit
Arsenic	≤ 1 mg/kg
Cadmium	≤ 2 mg/kg
Copper	≤ 2 mg/kg
Lead	≤ 2 mg/kg
Mercury	≤ 2 mg/kg

3. Self-limiting levels of use

This product will be used as a salt replacement for flavoring purposes and as a nutrient in a limited number of product cat0egories. Because of the increased cost of the product compared to table salt the product is expected to substitute for salt only in certain high end applications. The product will be used at similar use levels as sodium chloride but, in many cases, may be needed in smaller amounts due to the competing flavors of other components of the mixture such as potassium chloride and calcium sulfate. Functionality tests with this product are now being performed to quantify the amount of sodium chloride reduction that should be expected from standard recipes. In addition, the large aqueous component of this product will limit the amounts to be used on dry foods such as meats, fish and butter. The practical self-limit of use will be determined by individual preferences and the specific food to which the product is added as a flavoring ingredient.

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

4.1 Dietary Exposure

Based on the intended food uses as a salt substitute and the specialty nature of the product, dietary intake of the product can be assumed to average no more than one 30 gram serving per day. Dietary exposures to the components and impurities of the product can be estimated based on this intake level. In the case of this product, a single serving is estimated to be approximately 30 grams and it is not likely that the frequency will be more than one time per day. Daily intakes of the primary components of the product based on the daily consumption of a single serving are shown in the table below and compared to the estimated daily intakes for adult males in the United States.

Table 5. Major Components of Purified Seawater in a Single Serving (30 gram)

Component	Amount	Dietary Intake from All Sources
Sodium	115.8 mg	3.4 g
Potassium	4.5 mg	2.9-3.2 g
Calcium	33.8 mg	728-942 mg
Magnesium	4.06 mg	328 mg
Total salt	0.276 g	Unknown

Exposure from these primary components of the product represent only a small fraction of the total dietary intake of sodium, potassium, calcium and magnesium. Exposures are clearly within recommended Upper Tolerable Limits and are, in fact, below levels of Adequate Intake that have been established for the beneficial effects of these essential elements. Tolerable Upper Limits for these essential elements and relevant anions are discussed in the following section of this GRAS Notification.

4.2 REVIEW OF SAFETY DATA

Studies are available in the scientific literature on the biological effects of the primary components of this purified sea water product. The major components of the product have been frequently and extensively reviewed for their safety by national and international regulatory agencies and organizations including the Food and Nutrition Board of the Institute of Medicine (IOM) of the National Academy of Sciences, Food and Drug Administration (FDA), and the World Health Organization (WHO). Sodium chloride, potassium chloride, calcium sulfate and magnesium chloride are already considered to be GRAS for their intended food uses. These salts have been intensively reviewed over the course of several decades and are only briefly discussed in this section. Based on the evaluations of these expert groups and authoritative bodies it can be concluded that the notified substance is not harmful under the intended conditions of u se.

A. Potassium Chloride (KCI)

1. Dietary Intake

An Institute of Medicine Panel reported that the median intake of potassium by adults in the United States was 2.9 to 3.2 g/day for men and 2.1 to 2.3 g/day for women (IOM, 2005).

2. Scientific & Medical Community Opinions Regarding the Safety of Potassium Chloride

KCI is GRAS for use as a flavor enhancer, a flavoring agent, a nutrient supplement, a pH control agent, and a stabilizer or thickener. The SCOGS (Select Committee on GRAS Substances) (1979) states that potassium chloride is an essential constituent of the body and a major constituent of plant and animal cells. Potassium can be adjusted to homeostatic levels following ingestion in amounts that can be tolerated without causing nausea and vomiting. Serious toxic reactions to potassium chloride rarely occur.

Potassium chloride is well tolerated and metabolism quickly and efficiently adjusts potassium in the body to narrow homeostatic levels. JECFA did not specify an Acceptable Daily Intake for potassium chloride (JECFA, 1986). This signifies that the total daily intake of the substance from background levels and the amount necessary to achieve the desired effect does not represent a hazard to health.

The IOM Panel (IOM, 2005) has set 4700 mg potassium/day as an Adequate Intake (AI) for all adults. It concluded that intake of potassium at this level from foods should maintain lower blood pressure levels, reduce the adverse effects of sodium chloride intake on blood pressure, reduce the risk of recurrent kidney stones, and possibly decrease bone loss. A Tolerable Upper Intake Level (UL) was not set.

B. Magnesium Chloride

1. Dietary Intake

The Center for Disease Control (CDC) reports that the mean dietary intake of magnesium in the US is 290 mg/day (Ford and Mokdad, 2003). The 1999-2000 NHANES survey indicates that a substantial number of US adults consume less than the recommended daily allowance of magnesium (King et al., 2005). The daily average intake of magnesium (including magnesium from dietary supplements) was 328 mg and 68% of adults consumed less than the RDA of magnesium, which is 310-420 mg/day. Intake of magnesium appears to be low in the United States.

2. Summary of Opinions in the Scientific & Medical Community about Safety of Magnesium Chloride

The SCOGS noted that magnesium is an essential dietary ingredient. The Committee determined that there is no information on magnesium carbonate, magnesium chloride, magnesium sulfate, magnesium hydroxide, magnesium oxide, magnesium stearate or magnesium phosphate that suggests a hazard to the public when used at the current levels or those which might be reasonably expected in the future (SCOGS, 1979).

JECFA did not specify an ADI for magnesium chloride (JECFA, 2006). This indicates that JECFA concludes that the total intake of the substance from use levels and background levels in food does not represent a hazard to health. JECFA did not consider it necessary to specify a quantitative restriction.

$MgCl_2$ is affirmed as GRAS in 21 CFR 184.1426 for use as a flavoring agent, an adjuvant and a nutritional supplement. Magnesium is an essential element that is involved in metabolic reactions. Magnesium is also important in electrolyte balance. The Food and Nutrition Board recommended that cereal grain products should be fortified with magnesium based on the potential risk of deficiency among significant segments of the population.

An Institute of Medicine Panel (IOM, 1997) set the Upper Tolerable Limit for supplemental magnesium at 350 mg/day for individuals 9 years and older. Although limited to magnesium obtained from dietary supplements, no upper limit was set on intake of magnesium from food sources. When ingested in foods, no adverse effects have been found. High levels of magnesium salts used for therapeutic purposes have been found to cause osmotic effects in the gastrointestinal tract.

C. Sodium Chloride

1. Dietary Intake

Sodium chloride intake was calculated using the Dietary Guidelines for Americans (USDA, 2010). The estimated average intake of sodium except for table salt is approximately 3.4 g/person/day. Assuming 100% of the 3.4 grams per day of elemental sodium is in the form of sodium chloride (table salt), the average per person intake of sodium chloride is 8.5 grams/day. Assuming twice the average for consumption by a high user at the 90th percentile consumption level, the high user consumption level of

sodium chloride is estimated to be 17 g/person/day. This estimate does not include sodium chloride from discretionary use of table salt. Mattes and Donnelly (1991) reported that discretionary table salt use is about 11% of dietary sodium intake. Including discretionary table salt use would increase the estimated 90th percentile consumption levels to 18.9 g/person/day.

Sodium added to foods in processing from all sources, including food additives (Mattes and Donnelly, 1991) contributes 77% of total intake, while the background sodium content of food accounts for 12% of total intake. The 18.9 g/person/day estimate should therefore be reduced by 12% to 16.6 g/person/day. It is not likely the Seawater Solutions product will replace all sodium chloride used in food processing. The US Geological Service estimates that 50 million metric tons of sodium chloride was used in the United States in 2013 and that no more than 5% is used in food processing (USGS, 2014).

The median dietary intake of sodium, not including that added at the table, ranged from 3.1 to 4.7 g for men and 2.3 to 3.1 g for women in the US according to NHANES 1999-2000. These intake ranges are equivalent to 7.8 to 11.8 g/day of sodium chloride for men and 5.8 to 7.8 g/day of sodium chloride for women. The 90th percentile user is estimated to use 14,525 mg/day of sodium chloride based on an intake of 5,810 mg/day of sodium and the fact that sodium constitutes 40% of sodium chloride.

2. Summary of Opinions in the Scientific & Medical Community about the Safety of Sodium Chloride

While not specifically listed on the formal GRAS list for use as a direct food ingredient, except for its specific use as a substance that migrates to food from paper and paperboard products and cotton and cotton fabrics used in food packaging (21 CFR 182.70, 21 CFR.182.90), sodium chloride was cited as an example of a GRAS chemical in 21 CFR 182.1. This regulation notes that "…the Commissioner regards such common food items as salt, pepper, vinegar, baking powder and monosodium glutamate as safe for their intended use."

The Joint FAO/WHO Expert Committee on Food Additives and Contaminants did not specify an Acceptable Daily Intake for sodium chloride (JECFA, 2006). This signifies that JECFA did not consider it to be necessary to specify a quantitative limit on the dietary intake of the substance. The SCOGS evaluation noted that a reduction in sodium chloride consumption would reduce the frequency of hypertension but it did not identify a specific level that would not be considered to be excessive (SCOGS, 1979).

The Institute of Medicine Panel (I0M, 2005) established a Tolerable Upper Intake Level (UL) for sodium chloride as 2.3 g sodium/day (5.8 g sodium chloride) based on the increased risk of cardiovascular outcomes, particularly cardiovascular disease and stroke and the adverse effects of higher levels of sodium intake on blood pressure.

D. Calcium Sulfate

1. Summary of Opinions in the Scientific & Medical Community about the Safety of Calcium Sulfate

Median calcium intake for males in the United States is estimated to range from 942 mg in young men to 728 mg in older men (Mangano et al., 2014).

Calcium sulfate is permitted to be used as a food additive for many applications (see 21 CFR 184.1230). The European Food Safety Authority (EFSA) concluded that calcium sulfate in dietary supplements is of no safety concern if the dietary exposure to calcium remains below the Tolerable Upper Intake Level for calcium of 2,500 mg calcium per day (EFSA, 2008). The Tolerable Upper Intake Level for calcium is equivalent to 8.5 g of calcium sulfate per day.

The recommended intake of calcium is 1,000 to 1,300 mg/day for an adult (IOM, 2010). Calcium sulfate is used as a laxative. Doses of 9-18 g/person resulted in occasional loose stools (EFSA, 2008).

E. Safety of Impurities in the Product

The product is purified sea water and because it is derived from the marine environment it will have levels of impurities that are characteristic of that environment. The concentrations of the impurities will vary but will be less than the product specifications. These specifications are compared to the health-based drinking water guideline values of the World Health Organization (WHO, 2011) in Table 6 below. The drinking water guideline values, with the exception of iron, are derived from the Tolerable Daily Intake (TDI) which is defined as the amount of a substance in food and drinking water that can be ingested over the course of a lifetime without appreciable health risk and with a margin of safety. In the case of iron the guideline value is based on taste and odor considerations. WHO notes that the TDI is not so precise that it cannot be exceeded for short periods of time and that the large uncertainty factors

generally involved in setting the TDI provide assurance that exceeding the TDI for short periods of time is unlikely to have an adverse health effect.

The WHO guideline values are set with the assumption that an adult consumes two liters of drinking water and that a child consumes 1 liter of water per day. Consumption of the purified sea water product is expected to be no greater than 30 grams per day and the product will be rarely consumed by children. The WHO guideline values represent a benchmark for comparison of the purified drinking water specifications but not a concentration that should not be exceeded in the purified seawater product. In the case of cadmium the US maximum limit in bottled water is the same as the product specification of 5 microgram/liter. In the case of mercury, the specified concentration is much than the Tolerable Intake of 120 microgram/kg for a 60 kg human (WHO, 2011). Analytical data show that typical concentrations in purified seawater are well below the specified concentrations.

Table 6: Comparison of Specifications in Product to WHO Drinking Water Guideline Values

Impurity	Specified Concentration	WHO Drinking Water Guideline Value	Unit
Boron	<1	2.4	mg/L
Cadmium	<5	3	Microgram/L
Copper	<2	2	mg/L
Iron	<200	300	Microgram/L
Mercury	<20	6	Microgram/L
Nickel	<20	Not applicable	Microgram/L
Lead	<10	10	Microgram/L

5. Conclusions

Use of the purified sea water product will result in lower sodium chloride intake than the equivalent amount of table salt when compared to table salt on a dry weight basis. Gourmet salts, the sector that the product will be sold in, can be assumed to constitute less than 10% of the dietary salt intake. The intakes of major components of this product are much less than Tolerable Intakes established by the NAS IOM. Impurity concentrations in this aqueous solution are generally less than those recommended in the World Health Organization Drinking Water Guidelines (2011) and are lower than levels that would pose a health concern.

Purified seawater that is produced in accordance with FDA Good Manufacturing Practices and which meets the specifications described in this document is Generally Recognized As Safe when consumed in foods at the intended levels.

(b) (6)

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6. References

EFSA, 2008. European Food Safety Authority "Scientific opinion: calcium sulfate for use as a source of calcium in food supplements." EFSA J 814:1-9.

Ford ES and Mokdad AH , 2003. Dietary Magnesium Intake in National Sample of US Adults. J Nutrition 133:2979-2882.

JECFA, 2006. Joint FAO/WHO Expert Committee on Food Additives. Combined Compendium of Food Additive Specifications. Food and Agriculture Organization, Rome Italy.

IOM, 1997. Institute of Medicine Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Flouride. Available at http://books.nap.edu/openbook.php?record id=5776&page=1

IOM, 2005. Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride and Sulfate. Available at http://books.nap.edu/openbook.php?record id=10925&page=1

IOM, 2010. Institute of Medicine. Committee on Strategies to Reduce Sodium Intake in the United States.

King DE, Mainous AG, Geesey ME and FW Woolson, 2015. Dietary magnesium and C-reactive protein levels. J Am Coll Nutr 24:166-171.

Mangano KM, SJ Walsh, KL Insogna, AM Kenny and JE Kerstetter, 2014. Calcium intakes in the United States from Dietary and supplemental sources: New estimates for the National Health and Nutrition Examination Survey 2003-2006. J Am Diet Assoc 111(5): 687-695.

Mattes RD and D Donnelly, 1991. Relative contributions of dietary sodium sources. J Am Coll Nutrit 10(4):383-93.

SCOGS, 1976. Select Committee on GRAS Substances. Evaluation of the Health Aspects of Magnesium Salts as Food Ingredients. Report 60.

SCOGS, 1979. Select Committee on GRAS Substances. Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients. Report 102.

USDA, 2010. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans 2010. Washington DC

USGS (2015). Salt- Statistical Compendium. http://minerals.usgs.gov/minerals/pubs/commodity/salt/stat/. Accessed December 10, 2015.

WHO, 2011. WHO Guidelines for Drinking Water Quality, Fourth Edition, Geneva Switzerland.

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