

SECTION 4.

HISTORY OF USE / SAFETY EVIDENCE

THE LONG TERM HISTORICAL USE OF (-)-HCA

The following quotations demonstrate the long history of use of (-)-HCA

"Garcinia Cambogia is one of several closely related Garcinia species from the plant family known as Guttiferae. With a thin skin and deep vertical lobes, the fruit of Garcinia Cambogia is about the size of an orange, but looks more like a small yellowish or reddish pumpkin. When the rinds are dried and cured in preparation for storage and extraction, they are dark brown in colour. Another member of the family, Garcinia Mangostana, is cultivated specifically for its fruit and is not a source of HCA. These Garcinia species are native to Southeast Asia and are usually wild-crafted, although they are cultivated in some areas."

AND

"HCA is primarily found in the rind of Garcinia Cambogia, where 10% to (rarely) 30% of the weight of the dried rind is (-)-HCA"

AND

"Along the West coast of Southern India, Garcinia Cambogia is known as "Goroka" or "Kattcha puli" (souring fruit). It is employed commercially in fish curing, especially in Sri Lanka (Colombo curing) and various species of Garcinia are used in food preparation in Thailand, Malaysia and Burma. Garcinia Cambogia is considered to be effective in making meals "more filling". Aside from its use in food preparation and preservation, extracts of Garcinia Cambogia are sometimes used as purgatives in the treatment of intestinal worms and other parasites, for tumours, for dysentery and in the treatment of bilious digestive conditions."

Quoted from: The Diet and Health Benefits of HCA (Hydroxycitric Acid) (New Canaan, CT: Keats Publishing Inc, 1994) Clouatre, Dallas and Michael E. Rosenbaum (1994) in Appendix B

Many observational studies in addition to the above, indicate that Garcinia Cambogia has a long history of use as a food.

Study:

"The acid rinds of the ripe fruit are eaten, and in Ceylon are dried, and eaten as a condiment in curries"

Drury, Heber (1873) The Useful Plants of India, second edition (London: William H Allen & Co., 1873) 220

Study:

"Fruits are edible, but too acidic, also pickled: rind used as a condiment. Seeds yield an edible fat... A decoction of rind is given in rheumatism and bowel complaints."

Publications and Information Directorate, Council of scientific and Industrial Research (1986) The Useful Plants of India (New Dehli: Publications and Information Directorate, 1986) 229.

Study:

"Fruit yellowish or reddish, size of an orange having six or eight deep longitudinal grooves in its fleshy pericarp. Pulp acid is of a pleasant flavour. It is dried among the Singhalese who use it in curries."

Uphof, J. C. Th. (1968) Garcinia Cambogia Desrouss. Dictionary of Economic Plants, second edition. (New York: Verlag von J. Kramer, 1968) 237

**COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION**

SECTION 4 Cont'd

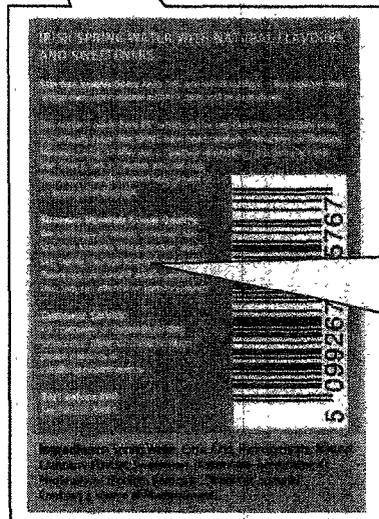
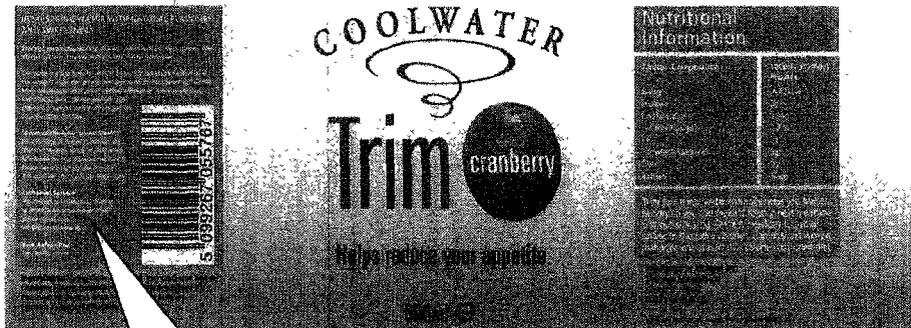
RECENT HISTORY OF USE

Shannon Minerals Ltd. have been marketing products containing Citrin K BG (-)-HCA such as Coolwater Trim in the UK since 1996.

Major food retailers such as ASDA, (a subsidiary of WAL-MART, the largest retailer in the world with 14% of UK grocery market), Tesco (The third largest food retailer in the world and the UK and Irelands largest Supermarket chain, with 28% of UK grocery market) and ALDI (one of Europe's largest supermarket groups), have been selling Coolwater Trim for a number of years. We currently sell in excess of 6 million 500ml bottles of Coolwater Trim per annum, in 24 Countries on 2 Continents, in total since product launch we have sold in excess of 20 million bottles. While there have been reports to us and the supermarkets regarding taste, damaged packaging and fill levels, we have not received any adverse health complaints. (A standard procedure for collecting complaints is in place.)

In addition to this, over 5 billion doses of (-)-HCA have been sold worldwide with no adverse reaction reports from consumers or health professionals, (-)-HCA has proven a very safe product at doses up to 2800mg/day (-)-HCA. Examples of products containing (-)-HCA widely sold in the USA include: SOBE Lean owned by PEPSI, JANA Skinny Water, Natrol CitriMax® Plus, Nature's Plus CitriMate Dual-Action Diet Aid Tablets and many more.

Label for European / UK Coolwater Trim showing how easily consumers may contact the company



SHANNON MINERALS GROUP QUALITY
We are happy to refund or replace any Shannon Minerals Group product which falls below the high standard we expect. Please see our contact details below. This does not affect your statutory rights.

Customer Service
For comments or questions relating to Shannon Minerals Group Products, please email us at: info@shannonminerals.ie

SECTION 4 Cont'd

RECENT HISTORY OF USE

United Kingdoms Adverse Drug Reaction Reporting System (Overview)

 The UK has an extremely comprehensive Adverse Drug Reaction reporting system called the Yellow Card Scheme. The Yellow Card Scheme for spontaneous reporting of suspected adverse drug reactions (ADRs) was introduced in 1964 after the thalidomide tragedy highlighted the urgent need for routine post-marketing surveillance of medicines. Since then more than 500,000 reports of suspected ADRs have been submitted to the Committee on Safety of Medicines (CSM) / MHRA on a voluntary basis by doctors, dentists, pharmacists, coroners, nurses, radiographers, optometrists and by pharmaceutical companies under statutory obligations. Many herbs / herbal extracts are listed in the example.

The Yellow Card Scheme is run by the MHRA, and is used to collect information from health professionals and patients on suspected adverse drug reactions (ADRs). The MHRA (www.mhra.gov.uk) is an Agency of the Department of Health and is responsible for the regulation of medicine.

This scheme reports on the Active Ingredient and NOT the trade name or other identifiers and will report on incidences of adverse reports on products containing just the active ingredient or the active ingredient in COMBINATION with other active ingredients.

We conducted a search for Hydroxycitric Acid, Garcinia Cambogia, Hydroxycitrate, (-)-HCA, derivatives and / or combinations of (-)-HCA. No search results were found, consequently there has never been an Adverse Reaction Report relating to (-)-HCA since 1964. This supports the argument for a long history of safe use.

- Page | 10/10/11
- haematopoophyrin
 - halcinonide
 - halibut liver oil
 - halofantrine
 - haloperidol
 - halothane
 - halquinol
 - hamamelis virginiana
 - harpagophytum procumbens
 - helium
 - helleborus niger
 - hemidesmus hindicus
 - hemin
 - heparin
 - herba schizonepeta tennifolia
 - hetastarch
 - hexachlorophane
 - hexamethonium
 - hexamidine
 - hexetidine
 - hexyl nicotinate
 - hexylresorcinol
 - highly purified fish oil
 - histidine
 - homatropine
 - honey
 - house dust mite
 - human clottable protein
 - human hepatitis b immunoglobulin

Screen Shot of UK Yellow Card Database: Nothing is listed for (-)-HCA., derivatives of (-)-HCA or even products containing (-)-HCA.

**COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION**

SECTION 4 Cont'd

RECENT HISTORY OF USE

Link to Adverse reaction Reports from the Yellow Card Scheme

<http://www.yellowcard.gov.uk/daps.html>

Link to Yellow Card Scheme

<http://www.yellowcard.gov.uk/>

UK Food Standards Agency

<http://www.food.gov.uk/>

In addition to the fact that there are no adverse reaction reports listed in the Yellow Card Scheme, the UK Food Standards Agency wrote the following letter.

This letter confirms that in their opinion there is a significant history of use of *Garcinia Cambogia* Extract and it is therefore not subject to novel foods regulations in the European Union (EC 258/97). In turn this means that *Garcinia Cambogia* Extract may be freely used in the European Union as a both dietary supplement and a food ingredient.

www.food.gov.uk



Dr Simon Wood
InterHealth Nutraceuticals Inc
5401 Industrial Way
Berkeley
CA94510
USA

04 July 2002

Reference: NRU 18

Dear Dr Wood

Chromium (poly)nicotinate, Zinc Monomethionine, *Garcinia Cambogia* Extract

Thank you for recently providing the consumption data on the above mentioned products.

Following examination of the data the UK Competent Authority is of the opinion that a significant history of consumption exists for these products. Therefore these ingredients will not fall within the scope of the Novel Food Regulation (EC) 258/97.

I shall copy this letter together with the history of consumption data to the Commission and other Member States for their information but you should be aware that clearance applies to the specified products only.

If I can be of further assistance please do not hesitate to contact me.

Yours sincerely

Mark Boden
Novel Foods Division

Room 5150, Avallon House, 125 Kingsway, London, WC2B 6NH
Tel: 020 7276 8578 Fax: 020 7276 8504 Email: mark.boden@foodstandards.gov.uk

SECTION 4 Cont'd

RECENT HISTORY OF USE

USA FDA Adverse Event Reporting System (AERS)



The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports.

The FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers send reports voluntarily through the MedWatch program. These reports become part of a database. The structure of this database is in compliance with the international safety reporting guidance (ICH E2B) issued by the International Conference on Harmonisation. The guidance describes the content and format for the electronic submission of reports from manufacturers. FDA codes all reported adverse events using a standardized international terminology, MedDRA (the Medical Dictionary for Regulatory Activities). Among AERS system features are: the on-screen review of reports; searching tools; and various output reports. FDA staff use reports from AERS in conducting post-marketing drug surveillance and compliance activities and in responding to outside requests for information.

The reports in AERS are evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to detect safety signals and to monitor drug safety. They form the basis for further epidemiological studies when appropriate. As a result, the FDA may take regulatory actions to improve product safety and protect the public health, such as updating a product's labelling information, sending out a "Dear Health Care Professional" letter, or re-evaluating an approval decision.

No AERS reports can be found in the database files going back over the last 2 years of records relating to the use of (-)-HCA, derivatives of (-)-HCA or (-)-HCA in combination with other substances. This supports the argument for a long history of safe use

Link to FDA Adverse Event Reporting System
<http://www.fda.gov/cder/aers/default.htm>

Adverse Event Report Extracts from Database
<http://www.fda.gov/cder/aers/extract.htm>

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SAFETY EVIDENCE

As well as having a long and safe history of use in food, there are a vast number of research articles outlining the safety of (-)-HCA.

The full text of these articles can be found in Appendix B.

The most comprehensive safety review to date has been published by the Burdock Group, one of the leading experts in toxicology in the United States of America. The title of the study is:

Safety assessment of (-)-hydroxycitric acid and Super CitriMax, a novel calcium/potassium salt.
M. G. Soni, G.A. Burdock, H.G. Preuss, S.J. Stohs, S. E. Ohia, D. Bagchi
Published in Food and Chemical Toxicology 42 (2004) 1513-1529.
See Appendix B starting on page 91.

This study is a review of over 80 published scientific studies conducted primarily on 3 different salts of (-)-HCA. These salts were SuperCitriMax (a Calcium / Potassium Salt referred to in the study as HCA-SX), CitriMax (a Calcium Salt) and an un-branded sodium salt. The study makes clear that safety studies on one salt of (-)-HCA are relevant to other salts of (-)-HCA.

The study concludes the following:

"In several, placebo controlled, double-blind trials employing up to 2800mg/day HCA, no treatment-related adverse effects were reported. There is sufficient qualitative and quantitative scientific evidence, including animal and human data suggesting that intake of HCA or HCA SX at levels up to 2800mg/day or 4,667 mg/day, respectively, is safe for human consumption." Page 1527 of Food and Chemical Toxicology 42 (2004) 1513-1529

And

"In summary, on the basis of scientific procedures, which include human, animal, analytical, and other scientific studies, and history of exposure and use, the consumption of HCA or HCA-SX at dose level of 2800mg/day, or 4,667 mg/day respectively is considered safe."

On the basis of this study Inter-Health Nutraceuticals Inc have classified their product Super CitriMax (HCA-SX) as self affirmed GRAS.

Within the safety review the following point is made in section 2.3.6 Skin Irritation Studies.

"...As both CitriMax® and Super CitriMax® are salts of HCA, the studies of CitriMax® are relevant for the evaluation of Super CitriMax®."

Applying the same logic, the studies of CitriMax® and/or Super CitriMax® are equally relevant to the evaluation of CitriMax K® which is also a salt of (-)-HCA.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

RELEVANCY OF THIS BURDOCK SAFETY REVIEW TO OUR PRODUCT

The study is not confined in scope to just Super CitriMax but was based on studies conducted on 3 different salts of (-)-HCA.

The study declares that there is sufficient evidence to suggest that consumption of (-)-HCA at levels up to 2800 mg/day is considered safe. Our product, Coolwater Trim, will contain 1400mg of Citrin K. Citrin K contains 50% (-)-HCA (w/w). Thus each bottle of Coolwater Trim will contain 700mg of (-)-HCA.

We will recommend on the label that no more than 3 bottles be consumed daily. Therefore we are recommending no more than 2,100mg per day. This is 25% below the safe level of 2,800mg as suggested in the Burdock review.

We recommend this lower dosage to provide an extra safety margin.

Within the safety review the following point is made in section 2.3.6 Skin Irritation Studies.

"...As both CitriMax® and Super CitriMax® are salts of HCA, the studies of CitriMax® are relevant for the evaluation of Super CitriMax®."

Applying the same logic, the studies of CitriMax® and/or Super CitriMax® are equally relevant to the evaluation of Citrin K® which is also a salt of (-)-HCA.

On this basis, together with its history of use, we believe that our product Coolwater Trim when used as recommended on the label will reasonably be expected to be safe.

**COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION**

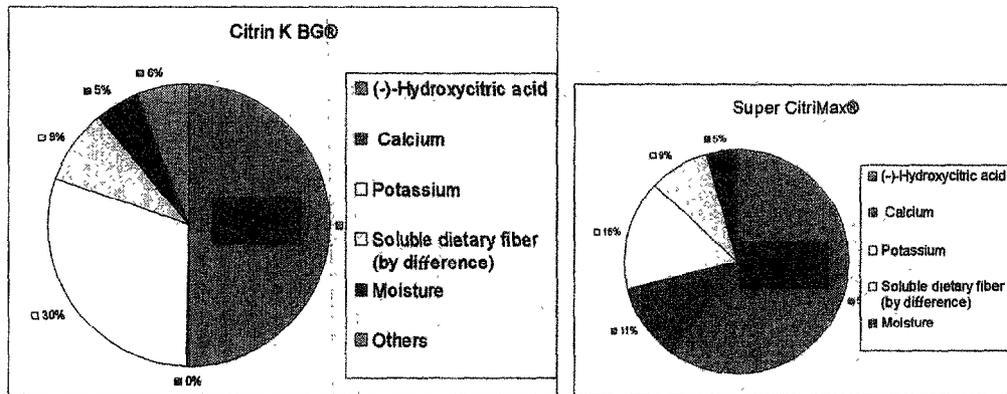
SECTION 4 Cont'd

(-)-HCA SALTS OF EXTRACT OF GARCINIA CAMBOGIA

Many of the scientific studies are identified with one or other proprietary manufacturers of (-)-HCA derived from the fruit rind of Garcinia Cambogia. All manufacturers generate salts of (-)-HCA that are structurally similar but vary in concentration and solubility.

Examples of such salts include, but are not limited to; Citrin® by Sabinsa™ a Calcium salt, Citrin K® by Sabinsa,™ a Potassium Salt, Citrimax® by InterHealth Nutraceuticals™ a Calcium salt, SuperCitrimax® by InterHealth Nutraceuticals™ a Potassium /Calcium Salt. All these salts of (-)-HCA are widely sold in the USA.

Quantitative Comparison Charts of Super CitriMax® v Citrin K BG®



**CHART PERCENTAGES ARE ROUNDED FIGURES!
(For actual values, refer to table below)**

	Citrin K BG®	Super CitriMax®
(-)-Hydroxycitric acid	50.0% ± 2%	60.0% ± 5%
Calcium	0.2%	11.0% ± 3%
Potassium	<u>30.0% ± 2%</u>	<u>16.0% ± 4%</u>
Soluble dietary fiber (by difference)	8.7% ± 2%	8.5%
Moisture	5.0% ± 0.5%	4.5%
Other Minor Constituents: Sodium, Pectin, etc, see Specification for full details	6.1%	n/a
TOTAL	100%	100%

Handwritten notes:
63
140
160/100
84/100
224/100
2

In summary the direct comparison of the Salts of (-)-HCA are as follows.

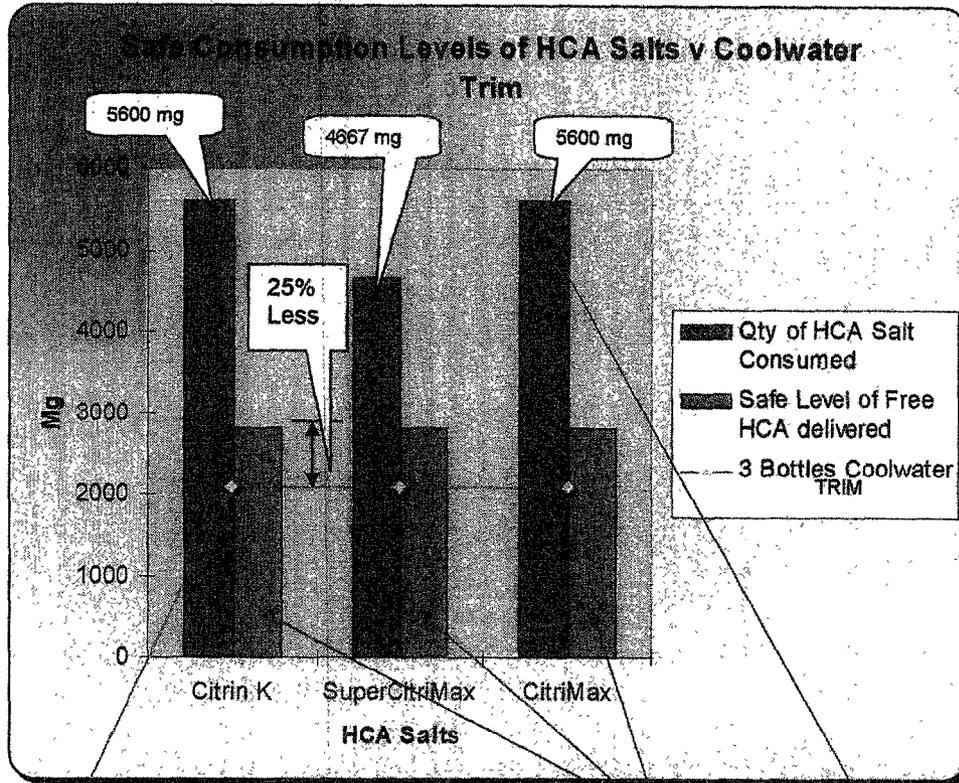
1400Mg Sabinsa Citrin K @ 50% (-)-HCA	}	=	700mg (-)-HCA
OR			
1166.67mg SuperCitriMax @ 60% (-)-HCA			

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SAFETY LIMITS

The following chart illustrates the relationship between the various salts of (-)-HCA, showing their maximum safe daily dose in purple, the level of (-)-HCA delivered (2800mg – same for all salts) in Blue, our recommended daily dosage in Red and Yellow and the additional 25% safety margin in Black.



PURPLE BARS SHOW AMOUNT OF (-)-HCA SALT REQUIRED TO DELIVER 2800 MG (-)-HCA / day

THE RED LINE SHOWS OUR DAILY RECOMMENDED LEVEL (3 X 700 mg = 2100 mg)
 Our label clearly states that NO MORE than 3 bottles of Coolwater Trim be consumed daily.
 This is 25% LESS than the recommended safe daily dose

PURPLE BARS SHOW AMOUNT OF (-)-HCA SALT REQUIRED TO DELIVER 2800 MG (-)-HCA / day

5600 mg of Citrin K @ 50% = 2800 mg (-)-HCA
 4667 mg of SuperCitrinMax @ 60% = 2800 mg (-)-HCA
 5600 mg of Citrinmax @ 50% = 2800 mg (-)-HCA

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SAFETY LIMITS

In addition to our recommended daily dosage of 3 X 500 ml bottles per day yielding 2100 mg / day of (-)-HCA, which is 25% less than the Burdock safety review study, we also recommend that the product is not consumed during pregnancy, lactation or by children. *Clouatre and Rosenbaum*

CAUTIONARY STATEMENT ON ALL USA TRIM PRODUCTS LABELS

EXTRACT OF GARCINIA CAMBOGIA (HCA) IN PURE IRISH WATER WITH NATURAL FLAVORS AND SWEETENERS.

US Label Cautionary Statement for all TRIM® products.

Caution: This product should be avoided during pregnancy, lactation and by children.

Recommended usage of no more than 3 bottles daily.

Storage instructions: Store in a cool, dry place and out of sunlight. Once opened, refrigerate and consume within 14 days and by date shown.

Caution: This product should be avoided during pregnancy, lactation and by children. Recommended usage of no more than 3 bottles daily.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Produced in the USA by
Shannon Minerals Ltd.
10000 1st St.
New York, NY 10001

Manufactured by



COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

TOXICOLOGY

Glossary of Terms :

Term	Explanation
NOAEL	No Observable Adverse Effect Level.
LD50	Lethal Dose Toxicity level at which 50% of the laboratory animals die
Dermal Toxicity	The level at which dermal toxicity reactions occur.

CLINICAL STUDIES AND HUMAN TRIALS

A total of 15 clinical studies involving approximately 914 subjects examining the effects of (-)-HCA have appeared in literature. Of the 15 clinical studies reported, 14 were placebo-controlled, double-blind trials (with 816 participants) and one was a single arm placebo-controlled trial. Double-blind, placebo-controlled studies are considered the least likely to result in bias.

The clinical studies provide an opportunity to assess the safety and 'tolerability' of (-)-HCA intake in fairly diverse populations. Collectively, these studies are of sufficient quality and consistency to draw certain conclusions regarding the safety of (-)-HCA. The placebo-controlled double-blind trials lasted for periods of up to 12 weeks (most studies i.e., 7 of 14, were for eight weeks), and the daily dosage of (-)-HCA in these studies ranged from 110 to 2800 mg.

THE CONCLUSION OF THESE STUDIES ARE AS FOLLOWS

1. In seven, double-blind, placebo-controlled trials, no side effects were noted or reported.
2. In the other studies, although side effects were reported, they were not significantly different from the control group.
3. These studies demonstrate that (-)-HCA did not cause adverse effects and was well-tolerated.
4. The safe daily dosage level of (-)-HCA is 2,800mg. Burdock Safety Study Review . Food and Chemical Toxicology 42 (2004) 1513-1529 or this document Appendix B
5. Our product ONLY delivers 2100mg per day. (25% less than the safe level)
6. Even though a figure > 5000 mg / kg are quoted for the LD50, of critical importance is that no laboratory subjects died at the levels tested. This puts (-)-HCA in a VERY safe category.
7. (-)-HCA (LD50 of > 5000 mg / kg) is at least 14 times greater than Caffeine (LD50 of 355 Mg / Kg)

See Appendix B for supporting documentation.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

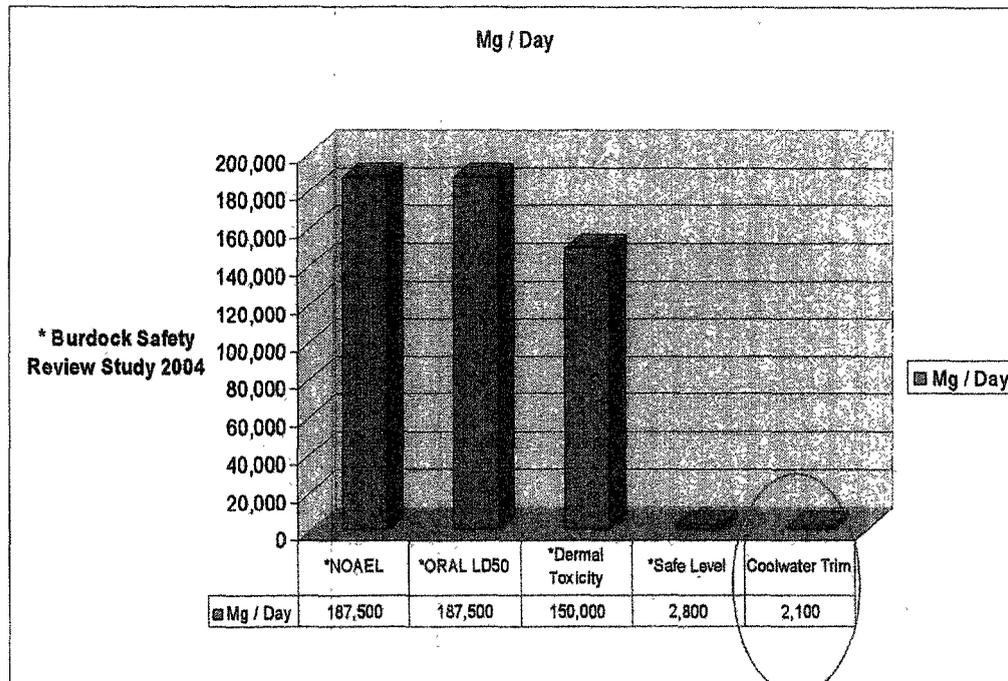
SECTION 4 Cont'd

TOXICOLOGY

See Appendix B for supporting documentation for this chart.

This chart shows the relationship between the LD50, NOAEL, Dermal Toxicity, The Safe Level and our recommended dosage.

NOAEL and ORAL LD50 levels were > 5000 mg / kg bodyweight. Further testing stopped at 5000 mg / kg bodyweight. This resulted in the NOAEL and LD50 levels both being expressed as the same value, although in reality one would expect the LD50 level would be much higher than the NOAEL level.



In Conclusion

1. Our daily-recommended level is 25% less than the safe level as determined by the Burdock Group (Food and Chemical Toxicology 42 (2004) 1513 – 1529)
2. Our daily-recommended level is only 0.56% of the No Observable Adverse Effect Level. (NOAEL)
3. A 75Kg Person would have to consume 535 bottles of Coolwater Trim per day to reach this LD50 amount of (-)HCA. This equates to at least 267.5 litres of Coolwater Trim per day!

recommend three bottles daily, which would deliver 2,100mg of (-)-HCA. The Burdock safety review article states that 2,800mg of (-)-HCA per day is a safe level. By recommending 2100mg per day we are providing a 25% safety margin versus what is recommended in this safety review article.

Additionally the safety study makes clear that the study is relevant to salts of (-)-HCA and not just SuperCitrinMax (-)-HCA. This would include a salt such as Citrin K, a Potassium Salt of (-)-HCA

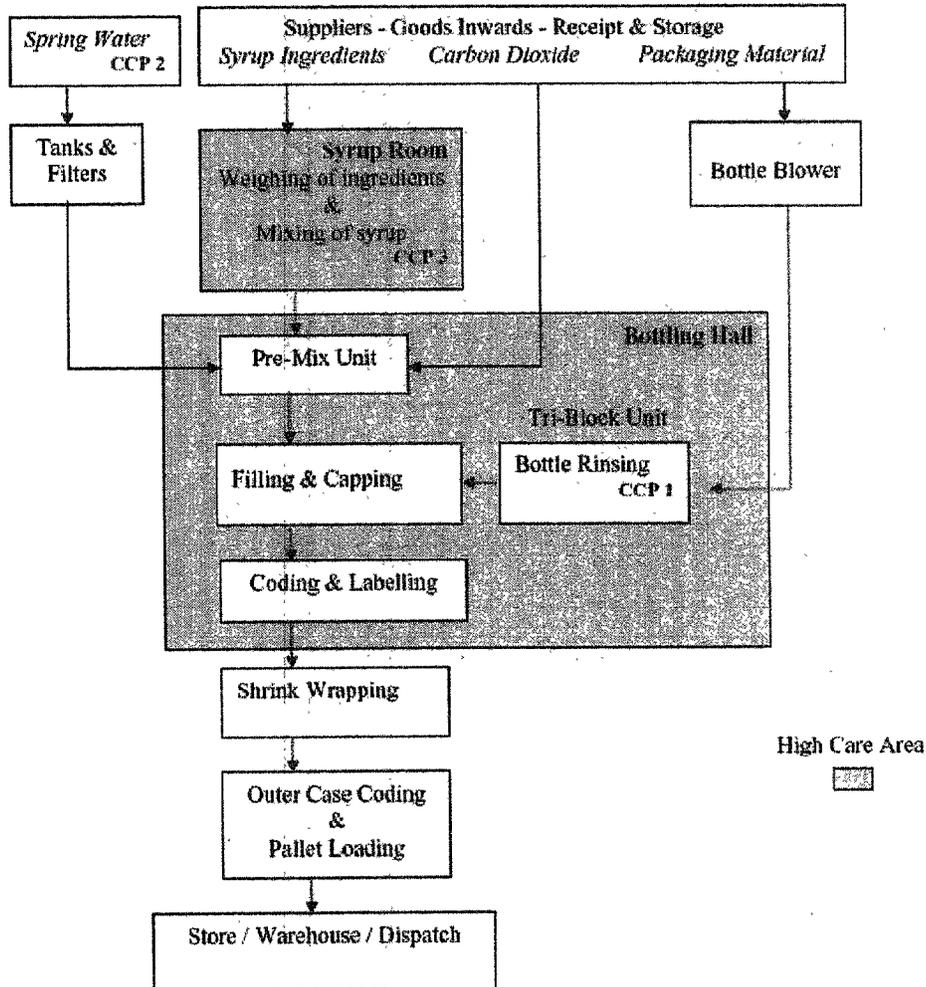
The most likely negative effect from excess intake of the isolate would be bowel intolerance, and this problem would be reversible through a simple reduction in dosage. This problem was not seen in animal or human studies at the recommended safe level of 2800mg.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

QUALITY SYSTEM OF SHANNON MINERALS LTD

Overall Process Flow Diagram



HACCP – Overall Process Flow
Issue 7
Issue Date: 22/08/03
Authorised by:

CONFIDENTIAL

SECTION 4 Cont'd

QUALITY SYSTEM

KEY PERSONNEL

Brendan O'Mara – Managing Director
Ann O'Mara - Technical Director
Susan Ryan - Quality Services Manager
Gillian O'Shea – Quality Control Manager

QUALITY SYSTEM

It is the policy of Shannon Minerals Ltd. to produce only quality products by implementation of the following:

1. Procedures to manufacture products, which satisfy consumers as to taste, quality and efficacy.
2. Procedures to meet all legal and product safety requirements.
3. Procure only premium quality raw materials.
4. Produce all products in a safe and hazard free environment.
5. Provide continuous training and communication to all employees and management in all aspects of production, product safety and quality and in the importance of meeting statutory, legal and customer requirements.
6. Procedures to test the finished product.

The Mid Western Health Board, an Irish government agency that enforces Irish and EU legislation, inspects Shannon Minerals Ltd. on a regular basis. Shannon Minerals Ltd. has in place a HACCP (Hazard Analysis Critical Control Point) plan. This entails reviewing every step in the production process, and carrying out an assessment of the potential risks at that step. Any identified risks are then monitored and controlled.

Shannon Minerals Ltd. has since the year 2001, had EFSIS (European Food Safety and Inspection Service) accreditation. EFSIS incorporates the requirements of the British Retail Consortium Global Standard-Food (Issue 3, April 2002). In the last 4 audits conducted up to October 2004 Shannon Minerals Ltd. received the highest accreditation. *Our next audit, due in October 2005, will be against BRC Global Standard – Food (Issue 4, July 2005)*

EFSIS

<http://www.efsis.com/>

EFSIS operates in over 70 countries world wide and is currently inspecting 65 per cent of all food products worldwide, which are subject to a third party certificated supplier evaluation. EFSIS has a client base of over 5000 food manufacturers and 25,000 farmers, across all sections of the food industry from fresh produce to fish, poultry, dairy and meat. EFSIS is accredited to EN450, EN45012 and EN45004.

British Retail Consortium Global Standard-Food

<http://www.brc.org.uk/standards/>

Current Standard : Issue 4, 1st July 2005

The objective of the British Retail Consortium Global Standard - Food is to specify food safety and quality criteria which must be in place within the organisation of any manufacturer supplying product to UK retailers. The format and content of the Standard is designed to allow an assessment of the supplier's premises, operational systems and procedures, by a competent third party, thus standardising food criteria and monitoring procedures.

SECTION 4 Cont'd

QUALITY SYSTEM

HACCP SYSTEM

There is a fully documented HACCP system in place with HACCP plans covering the whole range of products manufactured. The HACCP system is conventional and based on the codex alimentarius with a Company Code of Practice used in the formulation of the system. References to legislation and codes of practice used in formulating the HACCP are clearly defined.

There is a detailed HACCP team with two members of the team having undergone HACCP training by an external company and other team members trained in house. HACCP has recently been completely reviewed (July / August 2005) due to the installation of new equipment. The review included using the decision tree approach. CCP's, which include well water extraction, treatment and filtration; bottle rinsing and addition of preservatives are adequately monitored and comprehensive records kept. The requirements of the HACCP plan are incorporated into our quality management and production system.

QUALITY MANAGEMENT SYSTEMS

A documented quality management system is in place with a manual and procedures covering all aspects of production. There is a quality policy, which is signed by the Technical Director and an organisational structure to demonstrate management commitment to quality. Management review meetings are held on a monthly basis.

Documentation, document controls and record keeping are in place and well controlled. Internal audits are scheduled and cover the scope of the EFSIS standard, with corrective actions documented.

PRODUCT DEVELOPMENT

With over 40 years of experience in developing new products, Shannon Minerals Ltd. is industry recognized and highly regarded for new product development, which takes two forms:

New Innovation

Shannon Minerals Ltd. has built a solid reputation for innovation and market leading product development over the last 10 years, focusing on scientific development of new and exciting products. Safety and solid scientific research coupled with investment in modern technology form the basis of our new product development.

Modification of Existing Products

Existing products are constantly monitored for performance, quality and customer feedback. As a result, existing products may be re-engineered, become new products or become variations of a theme.

FACTORY ENVIRONMENT STANDARDS

Premises and plant (walls, floors, ceilings etc) are designed, constructed and maintained to comply with legislation, to reduce potential contamination risks and to provide a clean and safe environment for employees.

Production facilities comprise raw material intake and storage, water filtration systems, syrup room, filling area, bottle blowing area and dispatch area. A state of the art QC lab has been installed.

SECTION 4 Cont'd

QUALITY SYSTEM

Water is supplied from our well and is filtered through a carbon and sand filter; membrane filters to 0.45 micron and is UV treated. Water tests are carried out using the following schedule:

Daily: Total Bacteria Count (TBC), Coliforms, E.Coli and Yeasts / Moulds.
Weekly: Pseudomonas.
Quarterly: Spoiled Sulphate, Faecal Streptococci, Staph Aureus, Salmonella, Campylobacter and Cryptosporidium.

The factory is located on a well-maintained site. High standards of hygiene and housekeeping are observed. Pest control is contracted to a competent pest control company. Waste is recycled / disposed efficiently and safely by a licensed company.

Adequate staff facilities are provided and regularly upgraded. Company vehicles are used to distribute product to local customers. Approved third party hauliers are contracted to transport finished product to major retailers. Risks associated with physical and chemical contamination are well controlled.

EQUIPMENT AND PROCESS VALIDATION

Verification Of Processes & Equipment

The company operates procedures to verify that processes and equipment employed are capable of producing consistently safe and legal products. In the case of equipment failure, procedures are in place to establish the safety status of the product prior to release. Measuring equipment is calibrated to recognized international standards. Scales are checked internally on a daily basis and annually by an external contractor. Refractometers are calibrated in house with known standard solutions. HPLC Calibration is achieved automatically by referencing known standards and there is also a service contract to ensure its optimal performance.

TRAINING

The company ensures that all employees are adequately trained, instructed and supervised. The company has a documented training procedure commencing with induction training for new staff and extending to Food Hygiene Training and work specific training undertaken by an external company.

Those staff responsible for monitoring CCP's have also been adequately trained and training records are kept.

PERSONNEL

Personal hygiene standards are appropriate and adopted by all members of staff. Protective clothing is laundered by an outside contractor. Medical screening of staff is undertaken at the start of employment and on return to work after illness; visitors undergo a self-audit screening procedure. Training procedures and records are in place.

RAW MATERIAL CONTROL

Specifications

Appropriate specifications are maintained for all raw materials, packaging and finished products. Specifications are formally agreed with relevant parties with product specifications being reviewed every two years and raw materials annually.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

QUALITY SYSTEM

HPLC Test Method

Raw materials are regularly tested using HPLC.



Upper Clare Street
Limerick, Ireland
T: +353 (0)61 418068
F: +353 (0)61 418179
E: info@shannonminerals.ie
W: www.shannonminerals.ie

HPLC Method for Estimation of (-)-HCA

Equipment

1. Analytical Balance with 4 decimal place accuracy
2. Agilent 11 HPLC system with:
 - a. Standard Auto sampler
 - b. Isocratic Quaternary Pump
 - c. Thermostatically controlled Column Compartment
 - d. Variable Wavelength Detector
 - e. Chem-Station Software
3. 100 ml volumetric flask
4. pH meter

Reagents:

1. HPLC Grade Water
2. Sodium Sulphate (Na_2SO_4)
3. Sulphuric Acid (H_2SO_4)
4. (-) Hydroxycitric Acid Calcium Salt Standard (Wako with Catalogue No 084-07621)

HPLC Conditions:

1. Injection Volume: 10 μ L
2. Flowrate: 1 ml / min
3. Column: Nucleosil 10C8-5 μ m-4.6X250mm
4. Run Time: 20 mins
5. Temperature: 25° C \pm 2°C
6. Detector: 210nm

Mobile Phase

1. 14.2g of sodium sulphate is weighed out using the analytical balance and dissolved in 1L of HPLC grade water.
2. The pH is adjusted to 2.1 using sulphuric acid

Standard Preparation

1. 140mg of (-)-HCA Calcium Salt Standard is weighed out using the analytical balance and made up to 100ml using HPLC grade water

Sample Preparation

2. 14.2g Na_2SO_4 is weighed out using the analytical balance and dissolved in 1L of HPLC grade water.
3. The pH is adjusted to 1.75 using Sulphuric Acid.
4. 1.5ml of the sample is added to 1.5ml of buffer in a 3ml cuvette.

Procedure

1. 10 μ L of both the standard and the sample are injected separately and ran for 20mins.
2. All calculations are done automatically using the Chem-Station software.

Document xxiv
HPLC Method Rev 2
HPLC05052005
Authorized by GOS / AOM

SHANNON MINERALS LTD
Private & Confidential

SHANNON MINERALS LTD
Private & Confidential

CONFIDENTIAL

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

QUALITY SYSTEM

Tests and Testing Frequency

A fully documented raw material control procedure is in place. For new suppliers, we test the first 6 batches of raw material. Thereafter, once approved, Random Skip Lot testing of all incoming raw materials is performed.

Any nonconforming product is identified and controlled, the supplier is contacted and full explanations of any non-conformances are required before any further product can be accepted. They are automatically removed from the approved list and immediately return to 100% testing.

PRODUCTION CONTROL

Recipe and Specification Information

Recipe and Product specifications are maintained in a database, with the current authorized copy printed and signed by the Technical Director. This copy is photocopied for use in the production plant. No modifications or alterations are possible to the specification until authorized by the Technical Director. Product conformance to specification is verified through HPLC analysis.

On-Line testing

On-Line automatic BRUX testing ensures that out of specification product is controlled and that production is stopped immediately.

Off Line Testing of Product Specifications

Brix, pH, acidities and torque measurements are controlled, monitored and recorded on an hourly basis. Preservative, sweetener, and active ingredient addition is verified through HPLC analysis.

Metal Detection/Foreign Body Detection

The company ensures that all necessary steps are taken to identify, avoid, eliminate or minimise the risks of metal or other foreign body contamination. Water undergoes filter treatments through sand and carbon filters, membrane filters down to 0.45 microns and then UV treatment. In addition, checks are undertaken every 30 minutes to ensure that bottle rinse jets are working effectively during production. Metal detection is carried out on finished product.

Product Analysis

A dedicated Quality Control lab is on site, which undertakes routine analysis and covers all micro and chemical analysis, including Acesulfame K, Aspartame, Caffeine, Sodium Benzoate, Potassium Sorbate and (-)-HCA. Procedures are in place to ensure reliability of test results and personnel undertaking analysis are suitably qualified and trained.

Pathogen testing is sent off site as required by law. The main sub contract lab – Microchem Laboratories Ltd. is able to demonstrate operation in accordance with ISO17025.

Shelf Life Testing

Shelf life has been established taking into account product formulation, packaging, factory environment and subsequent storage conditions. Shelf life is established by microbiological, chemical, HPLC and organoleptic testing.

CONFIDENTIAL

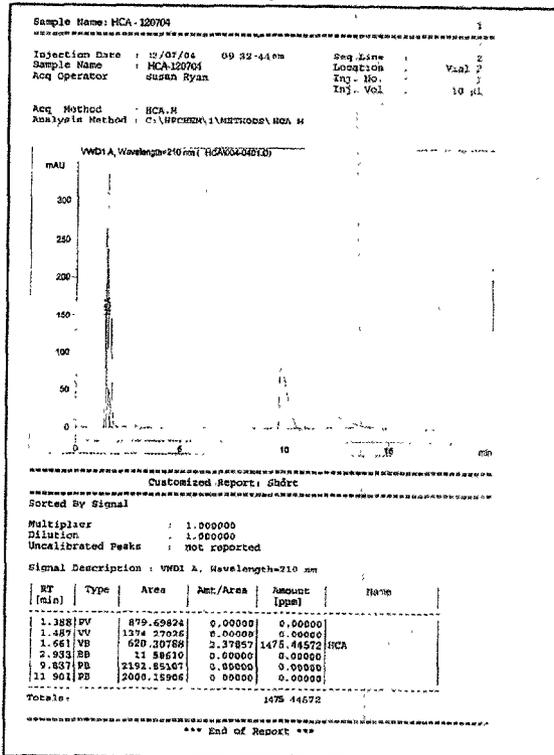
COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

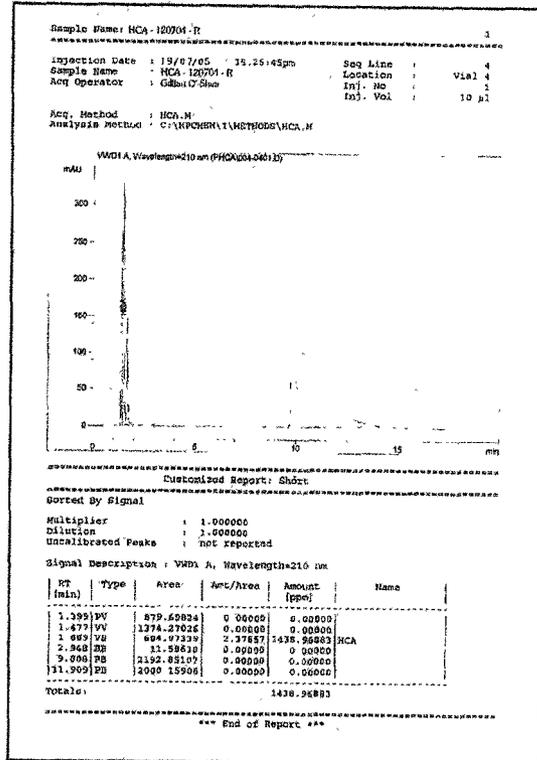
HPLC Shelf Life Testing

2 Tests on same batch shown below for (-)-HCA concentration after 1 year approx.

Test A



Test B



Microbiology Tests results:

Date of Analysis	Batch Number 4189	
	July 12, 2004	July 19, 2005
TVC's @ 37 degrees Celsius for 3 Days	<10cfu/ml	<50cfu/ml
Coliforms @ 37 degrees Celsius for 2 days	<1cfu/ml	<1cfu/ml
E.Coli @ 37 degrees Celsius for 2 days	<1cfu/ml	<1cfu/ml
Yeasts & Moulds @ 28 degrees Celsius for 3 days	1cfu/ml	10cfu/ml

CONFIDENTIAL

SECTION 4 Cont'd

QUALITY SYSTEM

CONTROL OF NON-CONFORMING/SURPLUS PRODUCT

The company ensures that all out of specification product is clearly identified with a green rejected label and quarantined. Procedures are in place and corrective actions are maintained to avoid recurrence.

TRACEABILITY

A system is in place to identify all raw materials, work in progress and finished products at all stages during manufacture, storage and dispatch. Effective traceability enables our recall procedure to operate effectively. Complaints can be traced to a defined production run.

COMPLAINT HANDLING

The company has a documented system for the management of product complaints. A complaint log is maintained with trend analysis undertaken to implement improvements to product safety to help avoid recurrence. A database is maintained of complaints received for further analysis. Extract from customer complaints register follows.

CONFIDENTIAL

**COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION**

SECTION 4 Cont'd

QUALITY SYSTEM



CUSTOMER COMPLAINTS REGISTER

Customer Reference	Date Received	Cause of Customer Complaint	Date Actioned
MK1	10/Nov/2004	No Gas in Cola	15/Nov/2004
648764	11/Nov/2004	Odour Contamination from another product	03/Dec/2004
6488092	15/Nov/2004	Lo Brix and weak taste	16/Nov/2004
M BROWNE 9704	24/Nov/2004	Piece of Outer Packing in Bottle	05/Dec/2004
6528942	12/Dec/2004	Customer may be caffeine sensitive	19/Jan/2005
PEARL CONROY	15/Dec/2004	Not known. No bottle returned to us	21/Dec/2004
6530189	21/Dec/2004	Tiny foreign body - piece of paper	14/Feb/2005
6536821	04/Jan/2005	Contamination from mouth, backwash	23/Feb/2005
1087592028	14/Jan/2005	No complaint, bottle returned	22/Feb/2005
6550871	17/Jan/2005	Customer not satisfied with product. Full refund given. Nothing wrong with product. BOOST 330 ml.	29/Jan/2005
6556179	17/Jan/2005	Empty bottle in Six Pack 330 ml	28/Jan/2005
MRS O DEA	24/Jan/2005	No bottle returned. No action could be taken.	24/Feb/2005
656621	24/Jan/2005	No bottle returned. Bottle apparently lost in post.	22/Feb/2005
SABDIE EVANS	07/Feb/2005	Customer did not like taste of Coolwater Detox. returned for full refund.	14/Feb/2005
6587375	17/Feb/2005	Carelessness. No adult supervision	22/Mar/2005

DOC X Customer Complaints Register
Revision 1
Issue Date 11/09/01
Authorised by ACM

CONFIDENTIAL

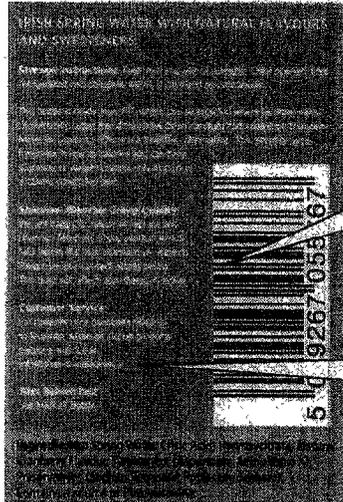
**COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION**

SECTION 4 Cont'd

QUALITY SYSTEM

In addition, the label has the following complaints contact information.

Screen shot of European Label



SHANNON MINERALS GROUP QUALITY
We are happy to refund or replace any Shannon Minerals Group product which falls below the high standard we expect. Please see our contact details below. This does not affect your statutory rights.

CUSTOMER SERVICE
For comments or questions relating to Shannon Minerals Group Products please email us at: info@shannonminerals.ie

The contact details for any customer service and complaints are clearly listed on the bottle. info@shannonminerals.ie

INTERNAL AUDITS

Internal audits are undertaken of systems and procedures, which are critical to product safety, legality and quality. Audits are undertaken to a schedule and cover the scope of the EFSIS standard. Results of internal audits are brought to the attention of the personnel responsible with corrective actions and timescales being agreed. A record of corrective actions is maintained and verified to ensure satisfactory completion.

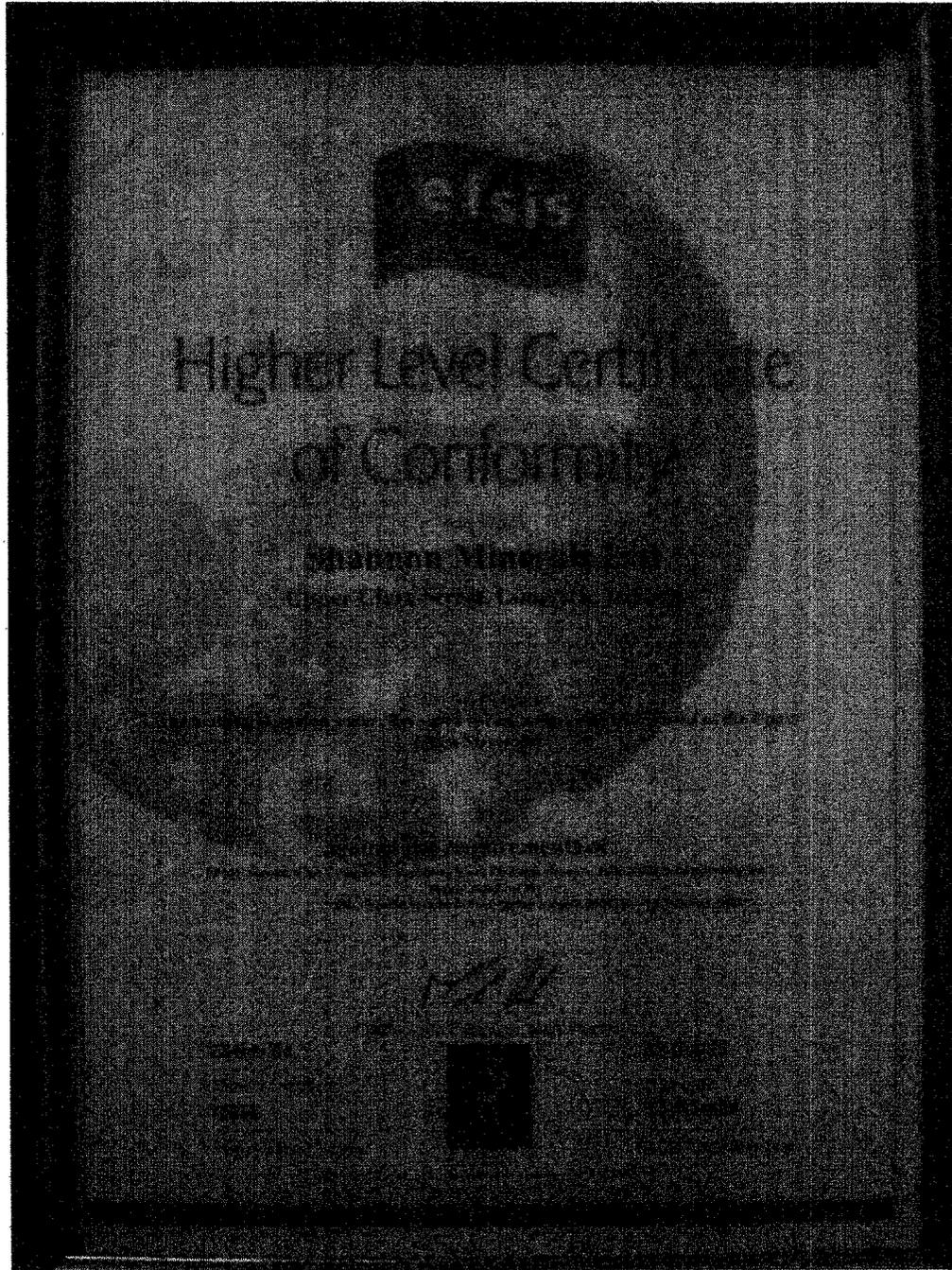
CORRECTIVE ACTION

Where significant non-conformities against standards, specifications and procedures have occurred the company has systems in place to investigate and implement timely corrective actions to prevent reoccurrence. All corrective actions are accurately documented assigning appropriate responsibility and accountability.

CONFIDENTIAL

SECTION 4 Cont'd

QUALITY CERTIFICATES

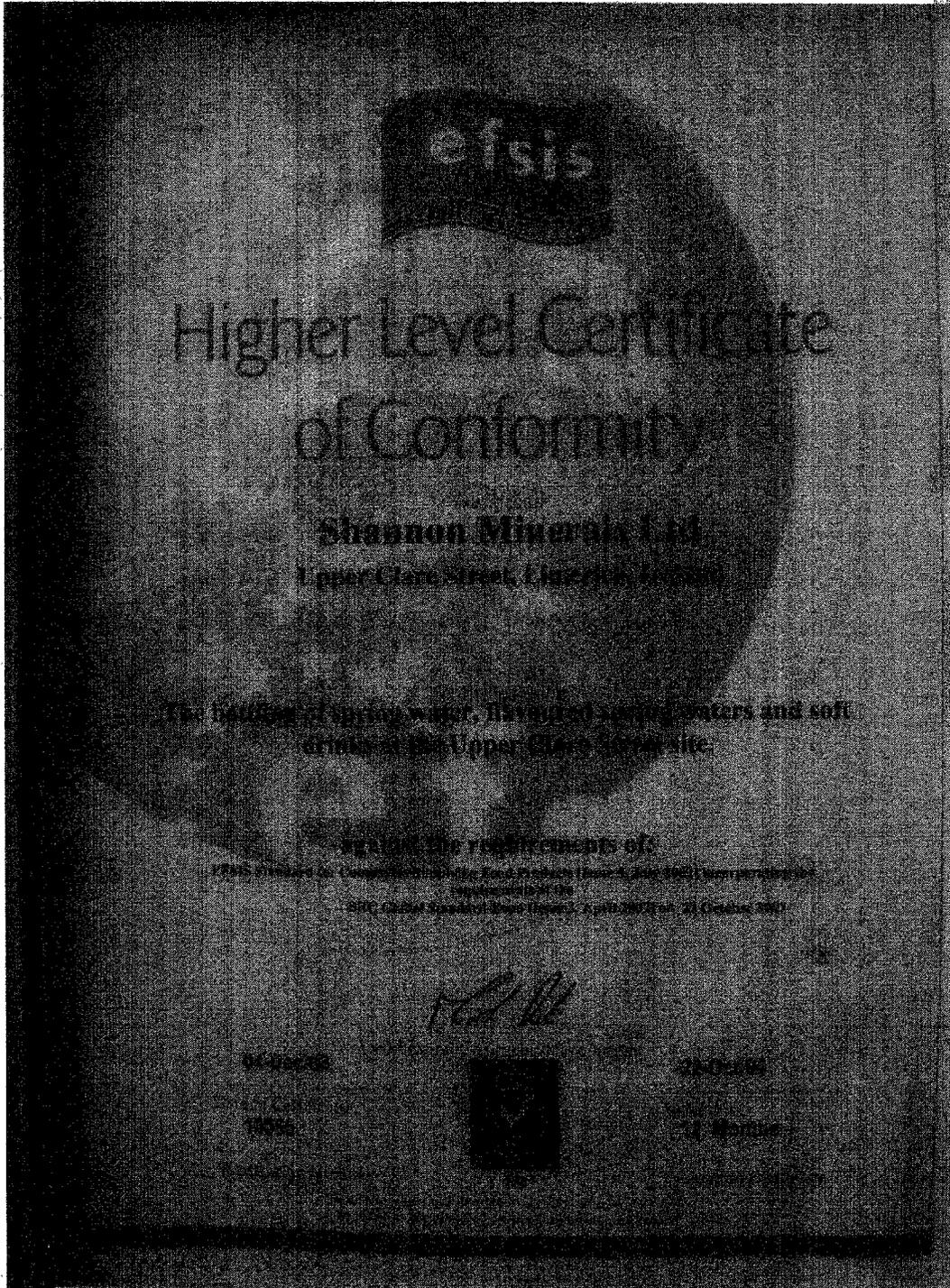


Current Certificate is Valid until 18/October/2005

Q
U
A
L
I
T
Y

SECTION 4 Cont'd

QUALITY CERTIFICATES



COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

QUALITY CERTIFICATES



C
O
O
L
W
A
T
E
R
T
R
I
M

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SUMMARY OF HISTORY OF USE / SAFETY INFORMATION

(See also appendices A and B)

1. 15 human clinical studies involving 914 subjects examined the effects of (-)-HCA. These studies demonstrate that (-)-HCA did not cause adverse effects and was well-tolerated at up to 2800 mg / day.
2. A Potassium / Calcium Salt of (-)-HCA has been Self Affirmed GRAS, however, the studies on which the Self Affirmed GRAS status were based, are relevant to all salts of (-)-HCA.
3. At least 5 billion doses of (-)-HCA have been sold in the last 10 years worldwide with no adverse reaction reports.
4. Shannon Minerals Ltd. has sold more than 6 million bottles of Coolwater Trim containing Sabinsa Citrin K (-)-HCA, with NO reports of adverse effects, either to the company or to the UK Adverse Drug Reaction reporting scheme. (Yellow Card Scheme).
5. No adverse event reports regarding (-)-HCA have been filed with the FDA AERS (Adverse Event Reporting System) database.
6. No adverse reaction reports regarding (-)-HCA or (+)-HCA in combination with other substances have been reported to the UK's Yellow Card scheme going back to 1964.
7. European Union (EC 258/97). Garcinia Cambogia Extract may be freely used in the European Union as a both dietary supplement and a food ingredient.
8. No adverse events have been reported to the Irish Food Safety Authority regarding (-)-HCA.
9. Coolwater Trim will be labelled for use with an extra 25% Safety Margin less than the recognized safe dose, as determined by the Burdock Group (*Food and Chemical Toxicology 42 (2004) 1513-1529*) Burdock Study.
10. Shannon Minerals laboratory shelf tests prove that Trim products are stable and that the quantity of (-)-HCA does not alter significantly over time.
11. (-)-HCA has a long history of use without any reports of adverse effects.
12. Garcinia Cambogia, the main source of naturally- occurring (-)-HCA, has a long history of common use as a flavouring, preservative and herbal tonic. A typical daily dose of (-)-HCA in humans for the purpose of suppressing appetite is roughly the equivalent to the rind of half a fruit, which is not out of proportion of its common use.
13. Reports of toxicity do not appear in the literature regarding the traditional use of the extract, so it is highly unlikely that there is any danger from regular consumption.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SUMMATION

In summation, we believe that Coolwater Trim containing the New Dietary Ingredient, Extract of *Garcinia Cambogia*, will be a safe and efficacious dietary supplement when used according to the label instructions.

We base this on the information provided in our application, which includes:

- The identity and specification of the New Dietary Ingredient
- The long and safe history of use of (-)-HCA.
- Our ability to produce a safe product
- Our History of producing safe products
- The many scientific studies supporting the safety of (-)-HCA

S

U

M

M

A

T

I

O

N