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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

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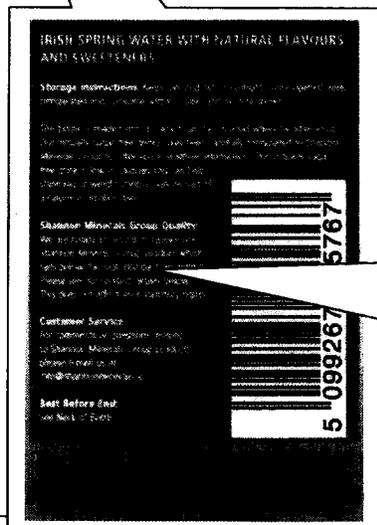
RECENT HISTORY OF USE

Shannon Minerals Ltd. have been marketing products containing (-)-HCA such as Coolwater Trim in the UK since 1996. These products are based on a Potassium salt of (-)-HCA, specifically Citrin K BG ® by Sabinsa Corporation.

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

SHANNON MINERALS LTD.

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.

Back | Forward

- haematoporphyrin
- halcinonide
- halibut liver oil
- halofantrine
- haloperidol
- halothane
- halquinol
- hamamelis virginiana
- harpagophytum procumbens
- helium
- helleborus niger
- hemidesmus indicus
- 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.

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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 both a dietary supplement and a food ingredient.

www.food.gov.uk



Dr Simon Wood
InterHealth Nutraceuticals Inc.
5451 Industrial Way
Benicia
CA94510
USA

04 July 2002

Reference: NFU 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

A handwritten signature in black ink, appearing to read "Mark Boden".

Mark Boden
Novel Foods Division

Room 5162, Aviation House, 125 Kingsway, London WC2B 6NH
Tel: 020 7276 8578 Fax: 020 7276 8684 E-mail: 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>

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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 103.

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 InterHealth Nutraceuticals Inc have classified their product Super CitriMax (HCA-SX) as self affirmed GRAS.

SECTION 4 Cont'd

RELEVANCY OF THIS BURDOCK SAFETY REVIEW TO OUR PRODUCT

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 1166.67mg of SuperCitriMax. SuperCitriMax contains 60% (-)-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 SuperCitriMax® are salts of HCA, the studies of CitriMax® are relevant for the evaluation of SuperCitriMax®."

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

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(-)-HCA SALTS OF EXTRACT OF GARCINIA CAMBOGIA

Many 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; Citrimax® by InterHealth Nutraceuticals™ a Calcium salt, SuperCitrimax® by InterHealth Nutraceuticals™ a Potassium /Calcium Salt, Citrin® by Sabinsa™ a Calcium salt, Citrin K® by Sabinsa,™ a Potassium Salt. All these salts of (-)-HCA are widely sold in the USA.

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

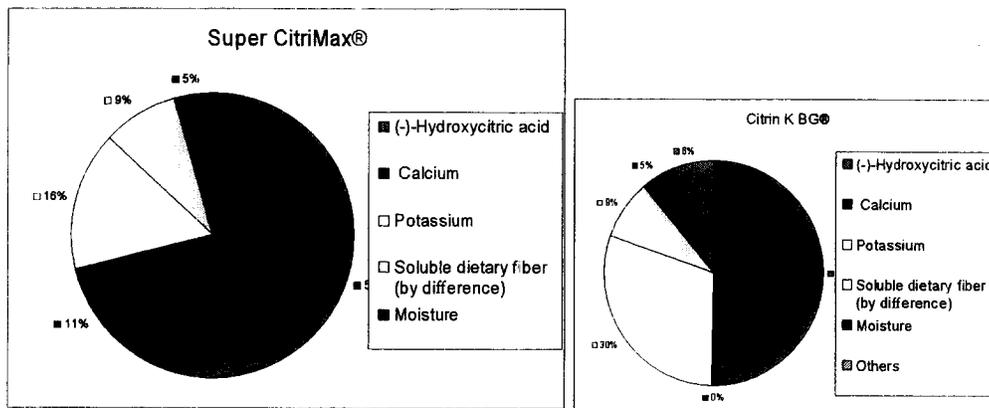


CHART PERCENTAGES ARE ROUNDED FIGURES!
 (For actual values, refer to table below)

	Citrin K BG®	Super CitriMax®
(-)-Hydroxycitric acid	50.0% ± 2%	60.0% ± 5%
Calcium	0.2%	11.0% ± 3%
Potassium	30.0% ± 2%	16.0% ± 4%
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%

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			

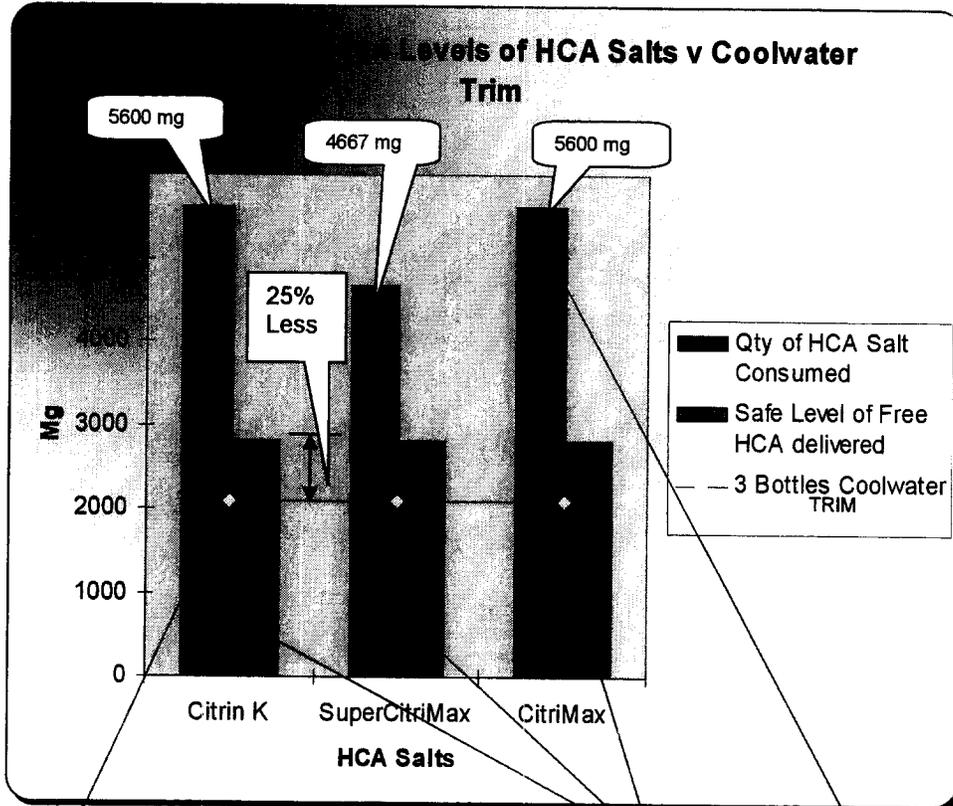
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SAFETY LIMITS

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.



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 SuperCitriMax @ 60% = 2800 mg (-)-HCA
 5600 mg of Citrimax @ 50% = 2800 mg (-)-HCA

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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. *Cloutre 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 30 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.



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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.

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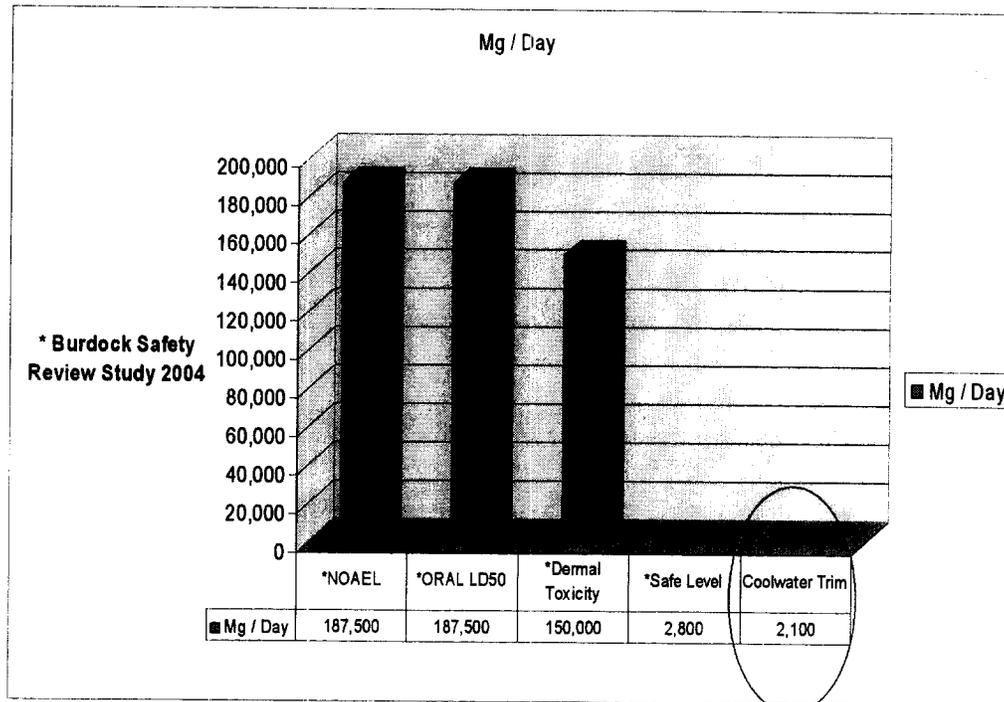
SECTION 4 Cont'd

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 NOAEL amount of (-)HCA. This equates to at least 267.5 litres of Coolwater Trim per day! We recommend only 3 bottles daily.

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TOXICOLOGY

**HOW THESE TRIALS ARE RELEVANT TO OUR
PRODUCT**

All these studies taken together quantify the safety limits of (-)-HCA and salts of (-)-HCA.

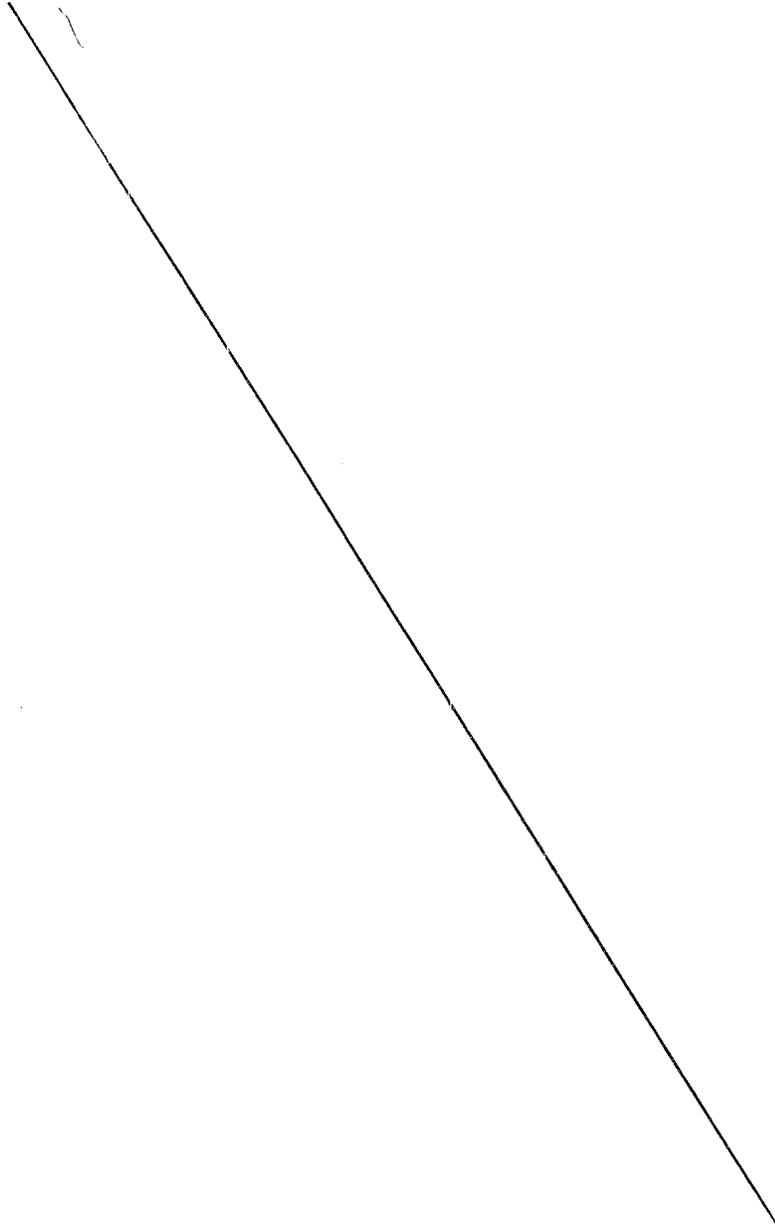
Our product contains 1166.67mg of SuperCitriMax, a Calcium / Potassium salt of (-)-HCA, which is an extract of the rind of the fruit of Garcinia Cambogia. This delivers 700mg of free (-)-HCA. We recommend three bottles daily, which would deliver 2,100mg of (-)-HCA. The Burdock safety review article states 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.

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.

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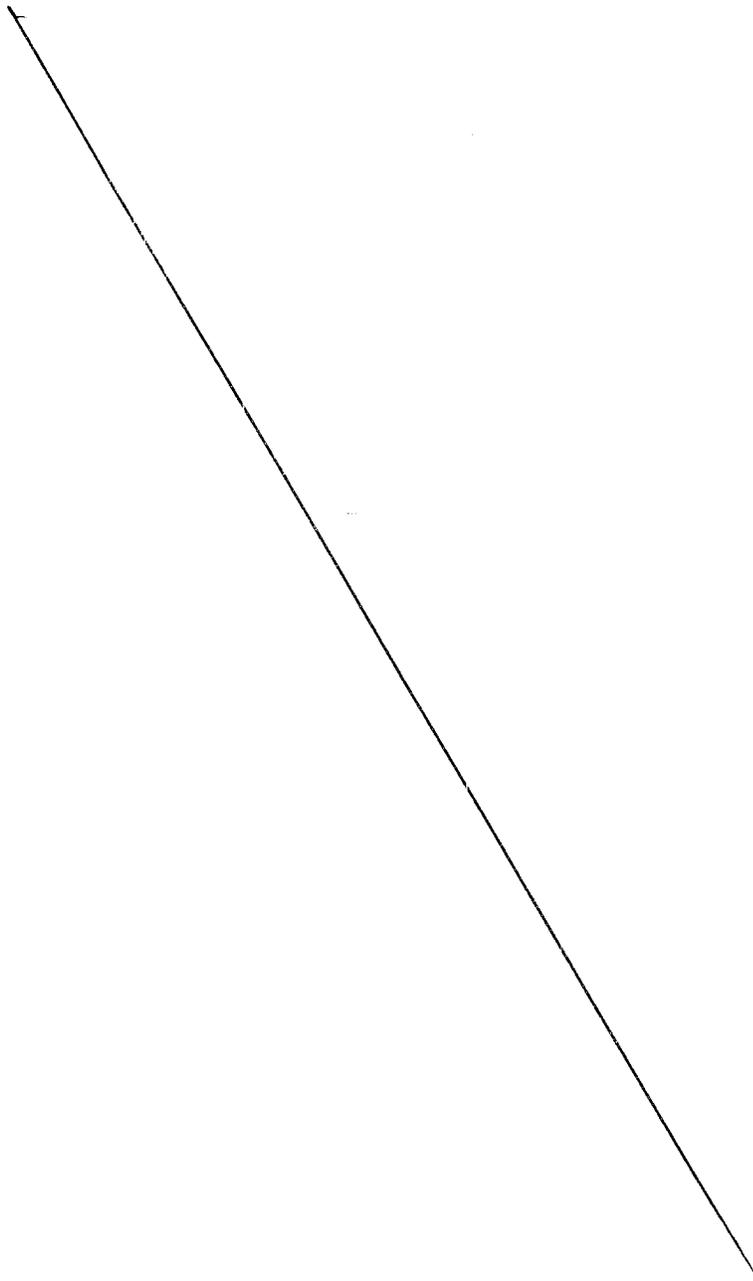


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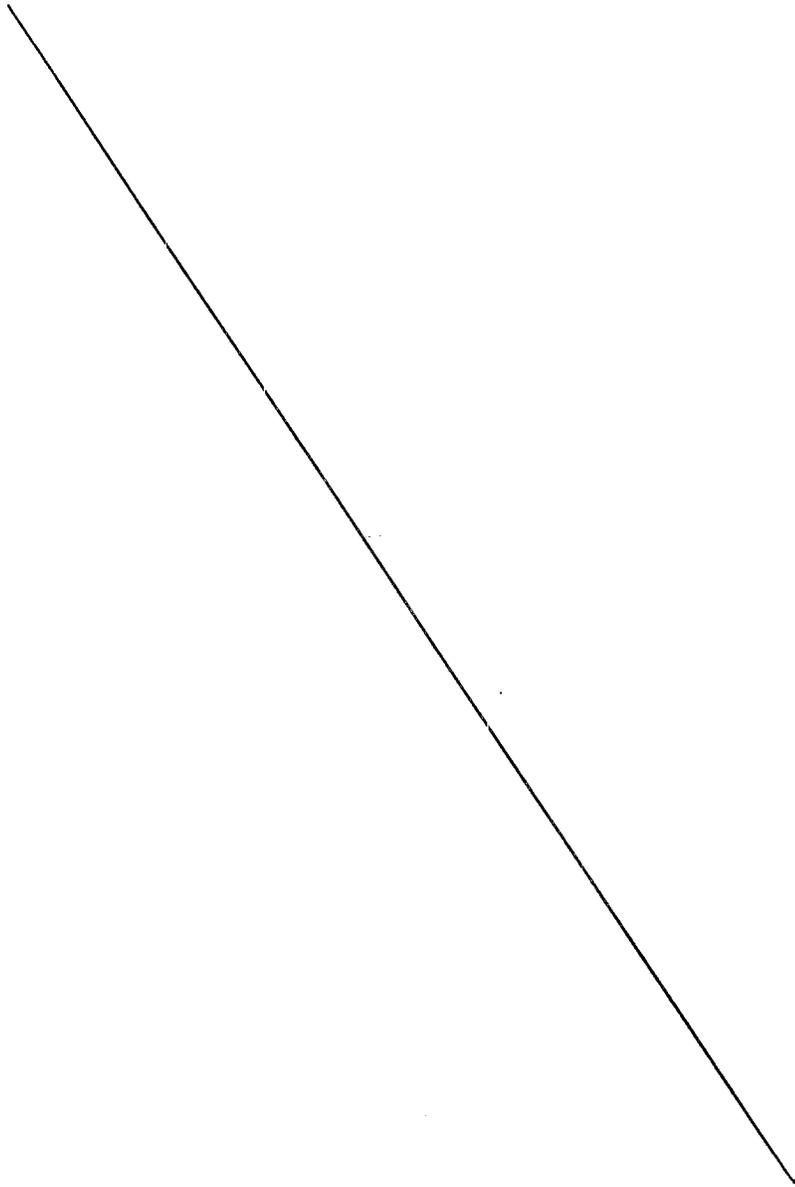
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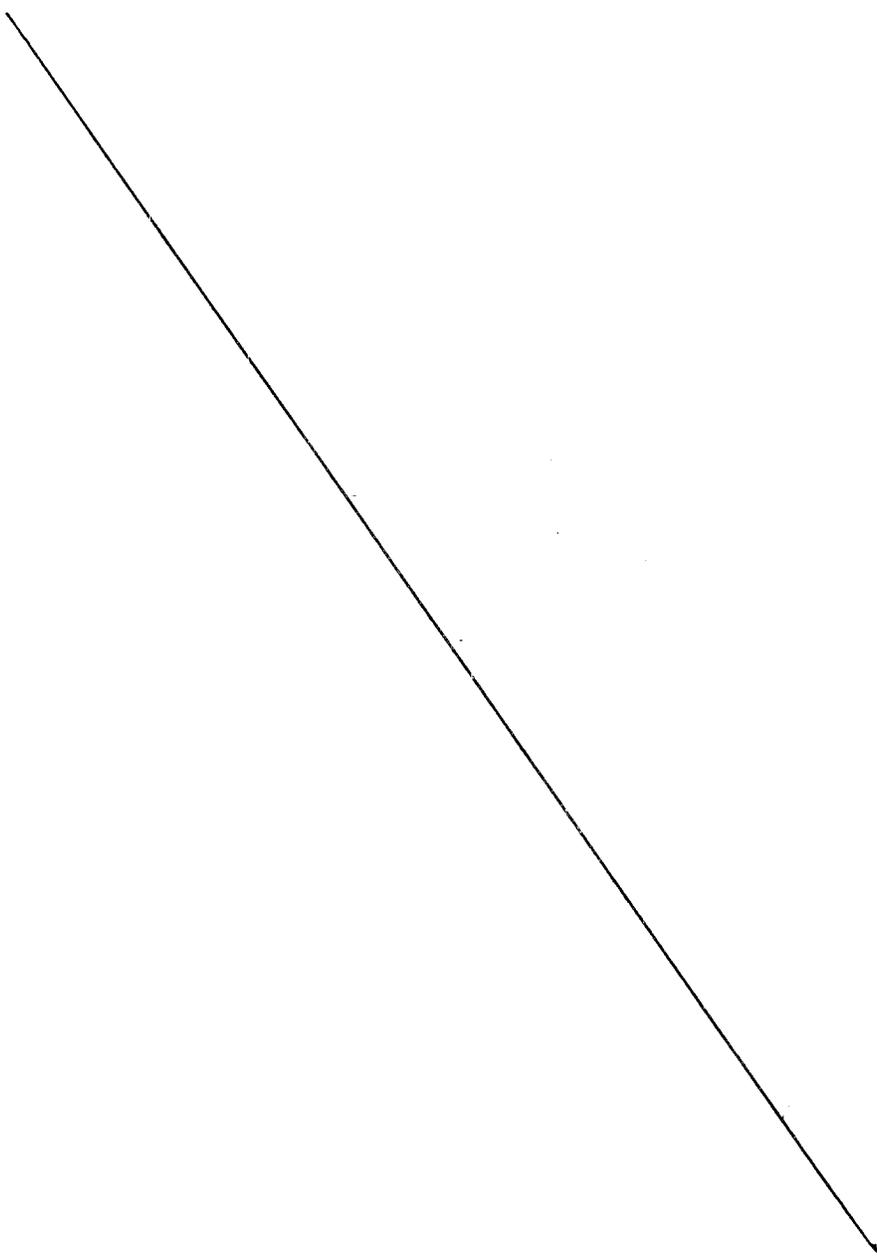
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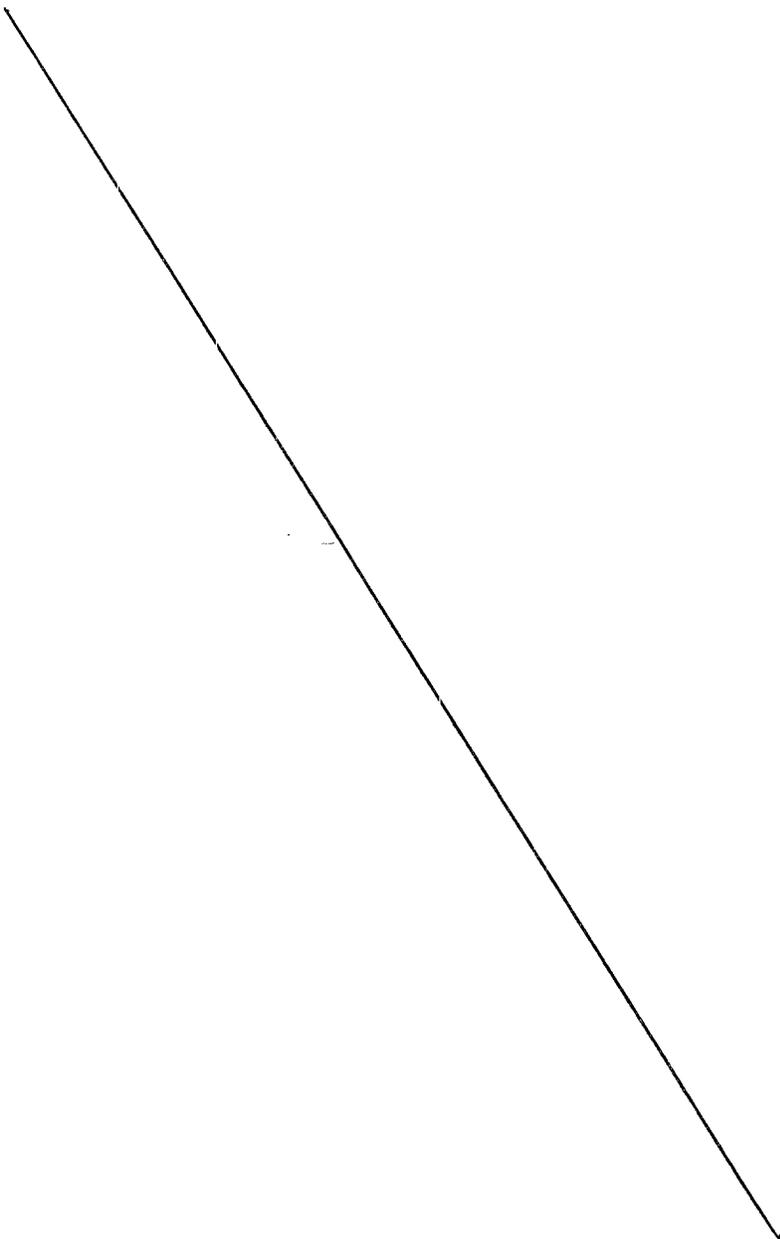
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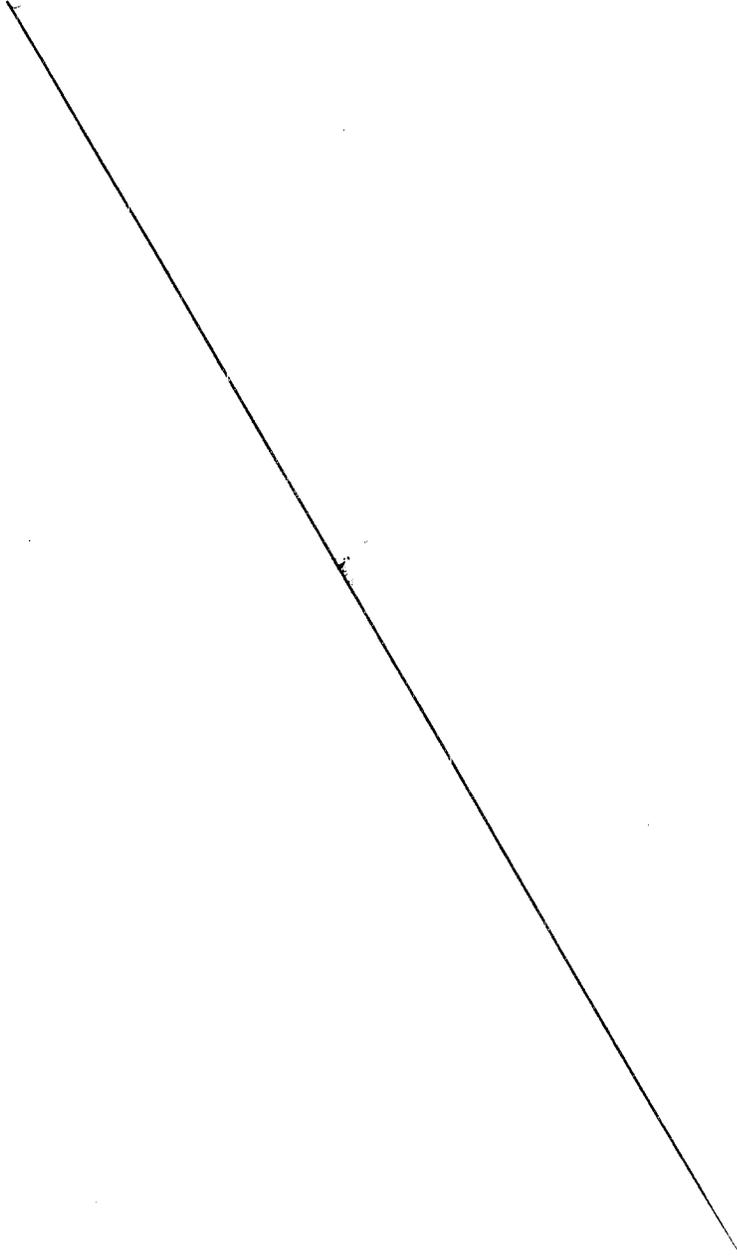
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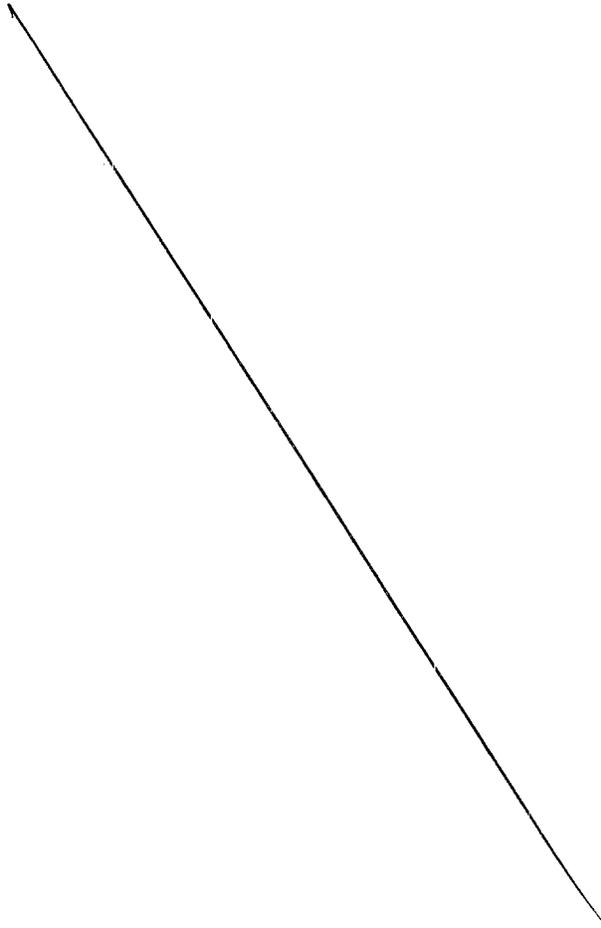


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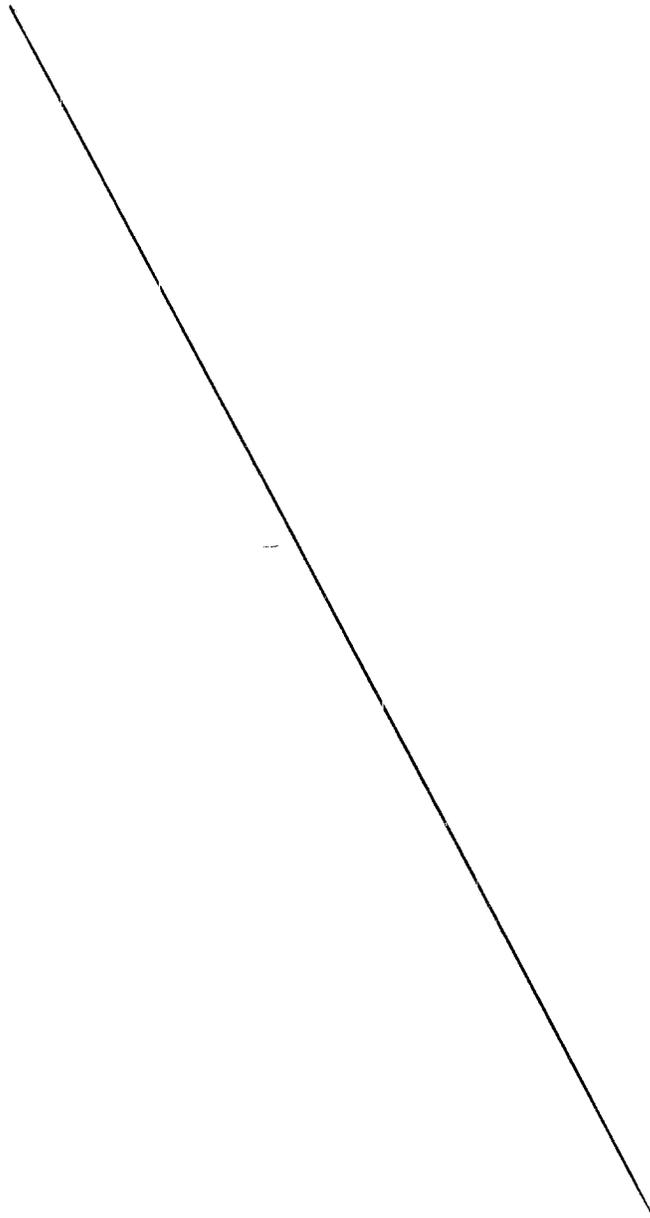
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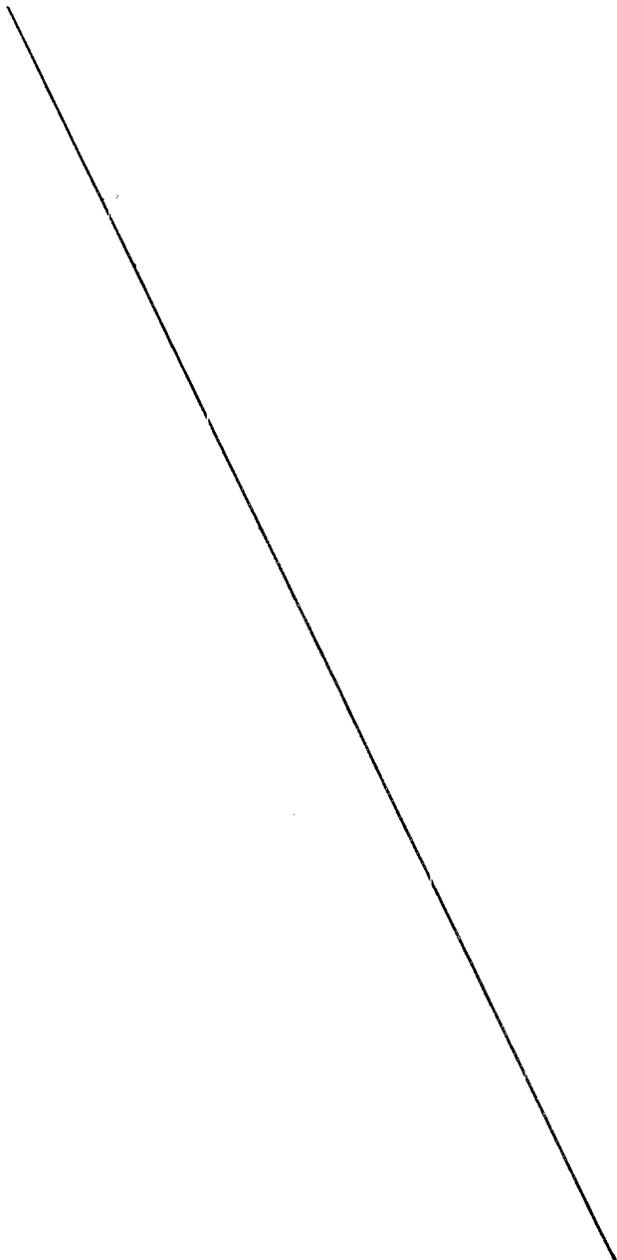


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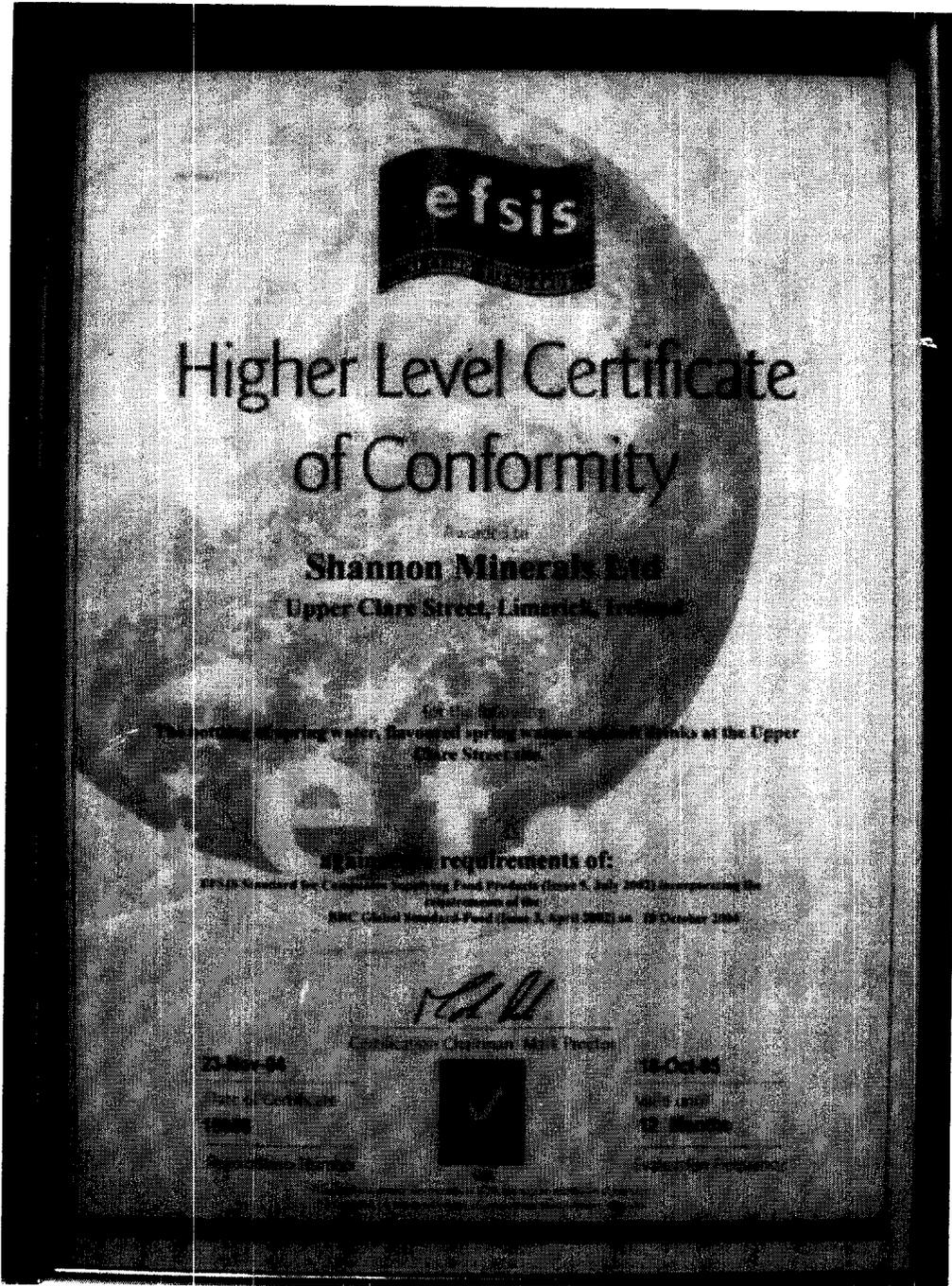
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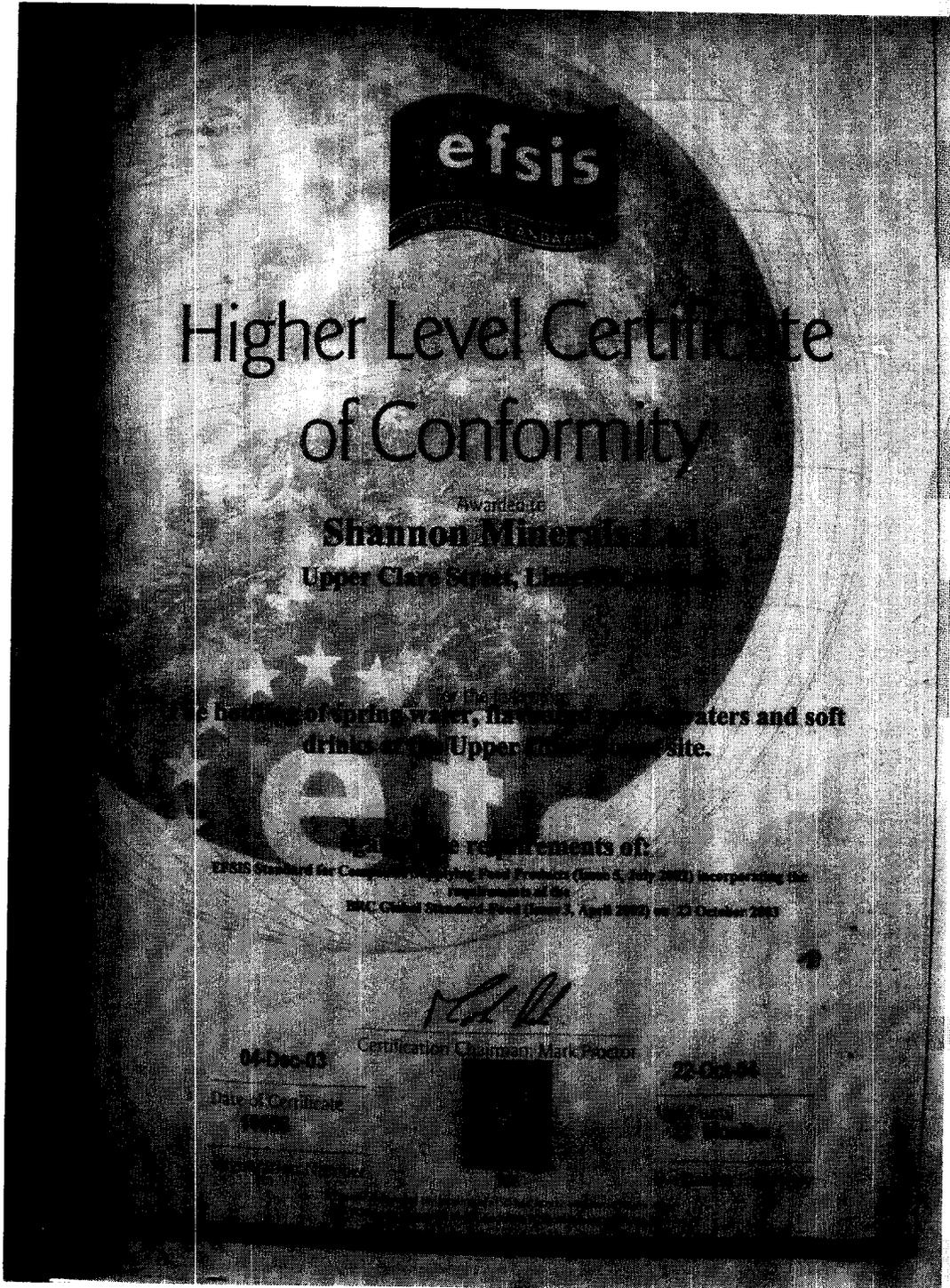
QUALITY CERTIFICATES



Current Certificate is Valid until 18/October/2005
(Our next audit is scheduled on 10th October 2005.)

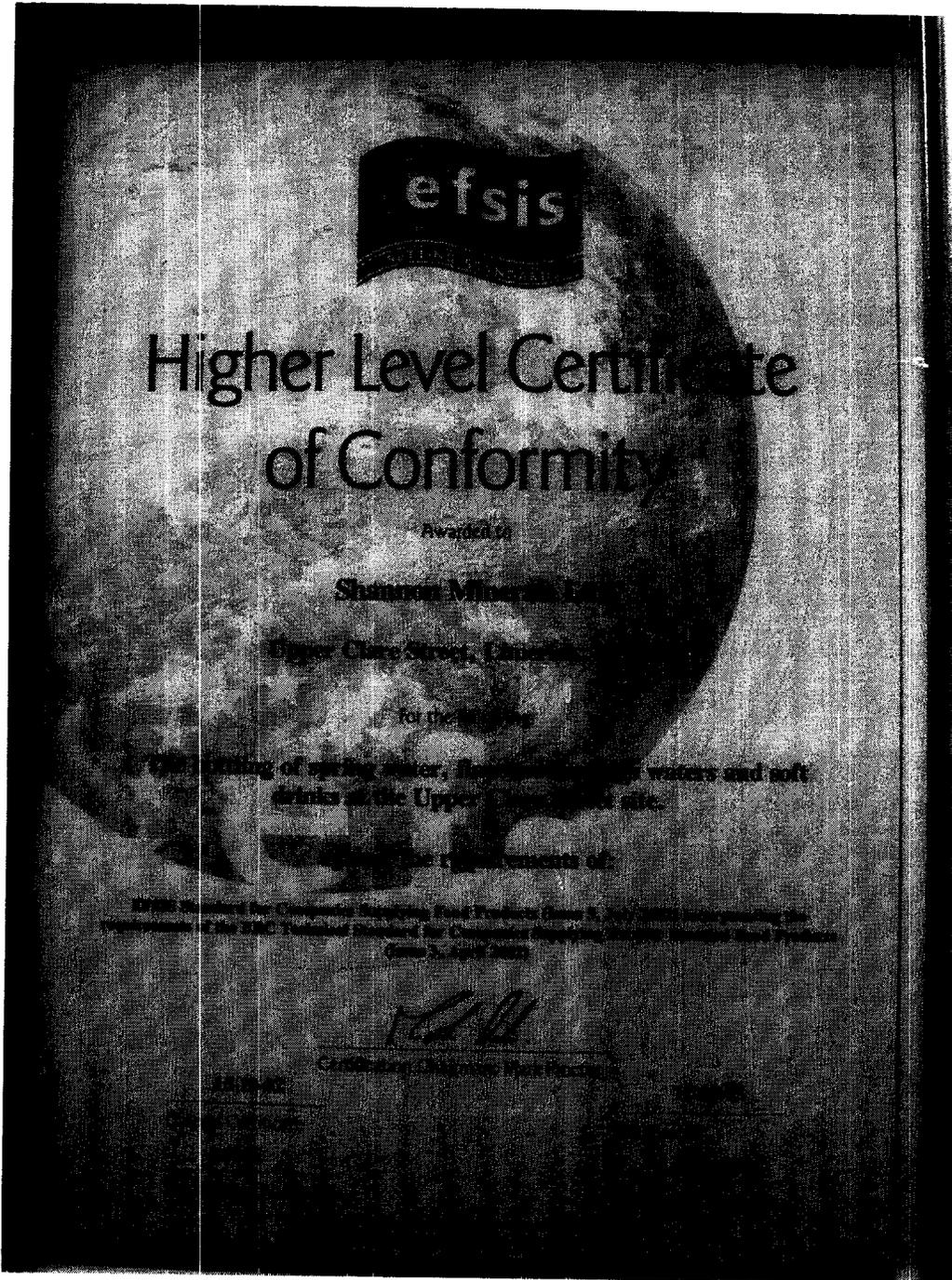
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QUALITY CERTIFICATES



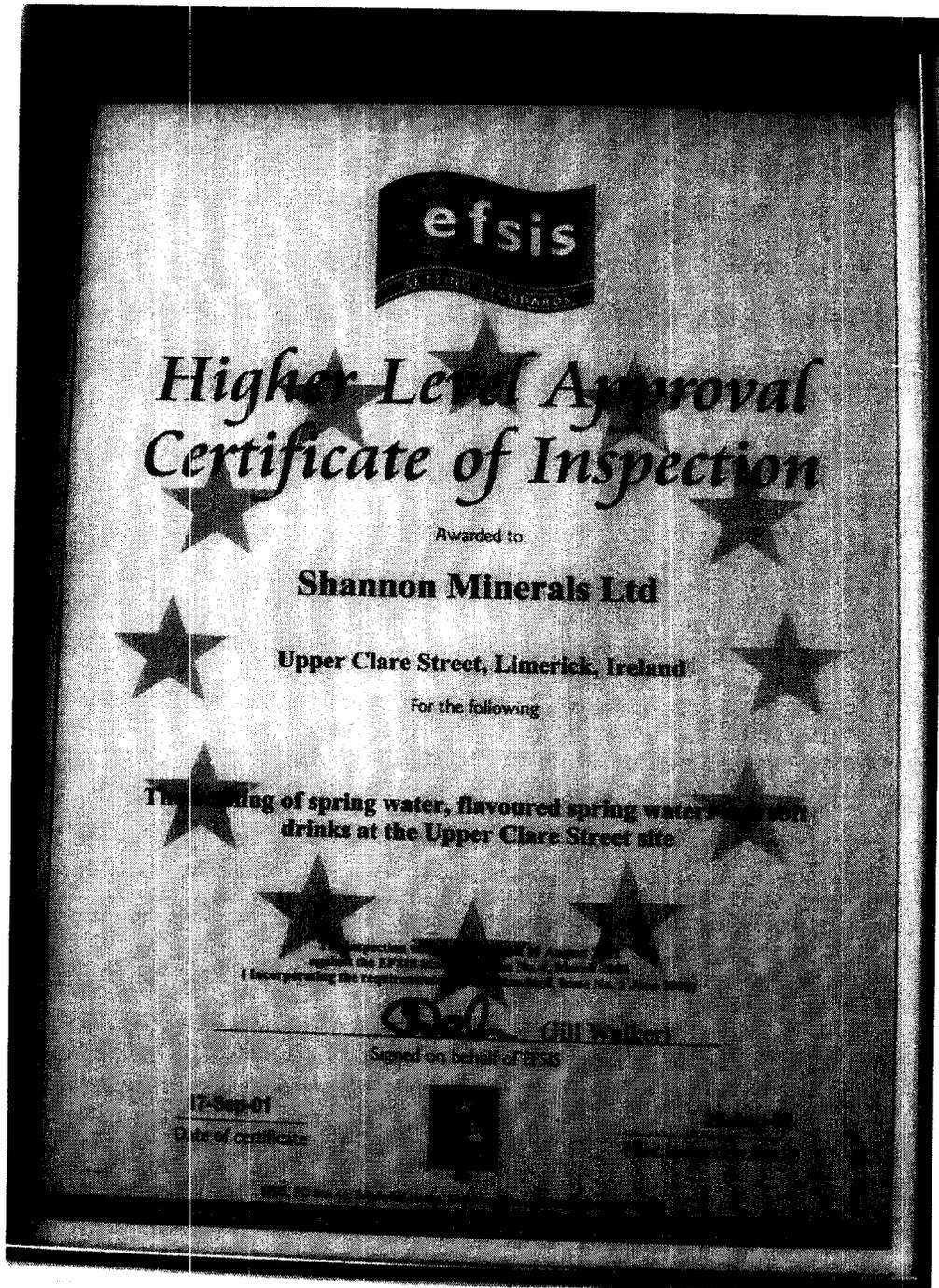
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QUALITY CERTIFICATES



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QUALITY CERTIFICATES



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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. SuperCitriMax, 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 other 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 (-)-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 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™
SuperCitriMax®
75 DAY PRE-MARKET NOTIFICATION

SECTION 4 Cont'd

SUMMATION

In summation, we believe that Coolwater Trim containing the New Dietary Ingredient, SuperCitriMax, 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

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