National Seafood Centre

Project No. 92/125.11

Development of a Process to Manufacture Powdered Shark Cartilage

by

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SUMMARY

This project was undertaken in collaboration with Pacific Export Services Queensland Pty Ltd and had the primary objective of developing a powdered shark cartilage product on a pilot commercial scale for the domestic and export markets. The investigations undertaken in this project required several discrete development steps: sourcing of the raw material, removal of excess flesh from the backbone, development of the drying, milling and packaging protocols, establishment of suitable quality manufacturing and testing procedures, and identification of the markets and market requirements. Considerable time and effort was committed to the development of the appropriate techniques and equipment necessary for the production of a quality powdered shark cartilage product. The procedure which is currently employed for shark cartilage powder manufacture involves a heat-pump drying process and a sequence of milling steps. The final product must maintain a low moisture content and produce a fine (<40µm) powder. Additionally, considerable expertise was developed in the handling of the powdered product, and in the further value-adding of the powder into encapsulated and tableted products. Although this project has concluded, the author has a keen interest in the product and in the potential for alternative uses of the shark cartilage. These uses include: treatments of various inflammatory ailments (e.g. arthritis), extraction of collagen or gelatin for the food or pharmaceutical industries, and extraction of chondroitin sulfate for use in corneal transportation media. This project has developed ideas also in the area of total utilisation of the shark, which includes such areas as leather, meat, offal and fin. The project has successfully developed a method for the manufacture of a fine white powder derived from the backbone of the shark. The commercial partner is very satisfied with the results and is keen to continue the development of the process and improvement of the product. Sales of the product in the domestic and international arenas have surpassed expectations.

INTRODUCTION

Shark cartilage powder has been sold for the past 4-5 years for the treatment of patients with advanced (often terminal) cancer. It is not the author's wish to substantiate or refute this inferred claim, but merely to develop a product to fit into a perceived niche market. Shark cartilage has long been thought to have potential cancer preventitive qualities and is commonly available in powdered and capsule/tablet form from health retailers. Chinese folklore has suggested for centuries that the shark fin, as a soup ingredient, has several health benefits. Shark fin is composed of the same basic building blocks as the backbone of the shark, although the backbone is heavily calcified.

A considerable array of literature was amassed in this investigation and a list of relevant references is presented in Appendix 1. This literature collection was largely a compilation of anecdotal evidence in support of the use of shark cartilage as an anti-neoplastic agent. Although it is generally viewed as a cold-blooded killer, the shark is becoming a source of hope in the battle against cancer. The powdered skeleton (composed largely of cartilage) is gaining popularity as a health product, although no one has conclusively proven which agents in the cartilage are active. The suggested mode of action of shark cartilage is as an "anti-angiogenic" compound. In layman terms, an anti-angiogenic compound can inhibit the formation of new blood vessels. Most solid tumours would theoretically be retarded by such agents, resulting in remission of the disease. Although the specific chemical agent in the cartilage has not been isolated, there are several suggestions, including a specific collagenase inhibitor, a hypersulfated mucopolysaccharide and an "anti-angiogenic" compound. There is some peer-reviewed research on the topic, but it is now largely out of date and in need of further investigation. While more recent investigations have apparently been performed by large companies, the results are not freely available. Shark cartilage powder has reportedly reached Phase 2 human clinical trials as an anti-neoplastic agent in the USA (National Institute of Health), but the results with terminal breast and postrate cancer patients have not been made available publicly.

Information regarding the actual methods for the production of cartilage powder was non-existent (i.e. proprietary knowledge). The process outlined in this report was developed for this particular product and manufacturer from first principles. It was a requirement of the process that the capital outlay not be too prohibitive in the first instance.

The project developed from discussions between Dr Davis of the Centre for Food Technology and the commercial partner (Mr Trevor Jordan of Pacific Export Services Queensland) with the support and encouragement of Mr Deon Mahoney of the National Seafood Centre. A significant market demand in Japan and other areas of the Asian region, and a manufacturer in Costa Rica supplying the American needs was sufficient incentive to undertake the project. The author has estimated the current market for dry shark cartilage powder to be in excess of 100 Tonne per year. Dr I. William Lane (the doyen of shark cartilage) had developed a powdered shark cartilage product. This knowledge was not freely available, and it was decided that the potential financial and health rewards warranted the risks involved in the venture. Although small by comparison, the product being produced by the commercial partner represents a niche market in the domestic and international markets and commands a competitive price. Until recently, the majority of domestic shark cartilage powder has been imported from the USA, and the product produced in this project represents a significant import replacement opportunity.

Current trends suggest that the American market for the product is increasing by 25-30% per annum, and the Asian situation is similar (although more difficult to analyse). The product is marketed as a food supplement (any claims as to its efficacy in the treatment of various disease states contravenes many Australian and International regulations). The vast majority of the shark cartilage product sold throughout the world, however, is used as a therapeutic for the treatment of cancer and, to a lesser extent, inflammation (arthritis). The dosage rate suggested by Dr Lane is 1 gm per Kg body weight per day for severe conditions and about 1 gm per 10 Kg of body weight per day for maintenance. The product is taken as either an oral or rectal preparation. This investigation in no way endorses any product, nor does substantiate any of the evidence supporting these anecdotal claims. The primary purpose of this

project was to develop a powdered shark cartilage product for an existing and growing market.

Natural medicine suggests that only intact (unfractionated) cartilage preparations are able to control the formation of new blood vessels. From a scientific view point, it would be interesting to focus on the active ingredient and market this as a medicine. There are two distinct schools of thought in this area. The first proposes that a protein agent (possibly up to four proteins) is the functional agent. The second proposes that complex carbohydrates or mucopolysaccharides (particularly chondroitin sulphate) are responsible for the effects. The aim of this project was to develop and optimise the processes for the production of a powdered shark cartilage product for domestic use from local raw materials. The project focused primarily on developing a process to manufacture a 100% pure shark cartilage product. The product was required to have comparable or superior characteristics to the imported material, namely:

- a) low moisture (<5%)
- b) fine particle size (<40 μ m)
- c) minimal flesh contamination (reduces the smell and taste)
- d) white colour
- e) high protein content
- f) low microbiological levels
- g) food standard-acceptable proximate values (heavy metals, etc)

Additionally, relevant proximate and microbiological analyses were developed for the product to compete in the marketplace. A pilot scale preparation was trialled in the domestic and international markets, and the costs of full scale production were determined.

Further value-adding initiatives (e.g. packaging, tableting, encapsulation, characterisation of efficacy, etc.) were investigated and experiments to develop assay procedures for the determination and characterisation of "activity" were undertaken.

AIM

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MATERIALS AND METHODS

The commercial partner expressed a preference for Queensland shark purpose caught for shark meat or derived from the by-catch of prawn trawlers. The decision to use this larger bone was proven to be a sensible and valid choice. The protein and mucopolysaccharide contents of this material were comparable to the product of competitors and to trial runs with smaller southern shark cartilage. The drying technology (i.e. heat-pump drying) was already owned by the commercial partner and was shown to be an economically sensible choice. Financial considerations placed important restrictions on the level of size reduction which was able to be performed on-site in the early stages of the production. These considerations, along with the final product requirements, were important contributors to the process which was developed for the manufacture of shark cartilage powder for the commercial partner. The flow diagram (Figure 1) below outlines to major steps necessary for the production of such a product. Each of these steps required some level of process development which will be outlined in as much detail as possible.

Raw material (clean frozen shark backbone)

 \downarrow

Defleshing (to reduce odour and taste)

 \downarrow

Sanitisation (reduction and maintenance of microbiological count)

 \downarrow

Drying (<5% moisture)

 \downarrow

Milling (to produce a fine white powder)

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Packaging (to meet market requirements)

Figure 1. A flow diagram representing the process developed for the preparation of shark cartilage powder.

(i) Raw material

The commercial partner expressed a desire that (wherever possible) the raw material be derived from local (Queensland or Australian) fisheries and that (if practical) this be a by-product or waste stream of an existing industry. This desire was partly driven by financial concerns, but also by an interest in the conservation of our marine resources and the more total utilisation of the catch. For the purposes of cleanliness and sterility of the final product, the raw bone was preferably sourced from export registered fish processing premises. Cartilage suppliers process their shark post-rigour in order to maximise the quality of their meat. To facilitate the later steps in the processing, the backbone was purchased in a "knife-clean" form. Storage of this material in a frozen state until processing is important for the production of a quality final product. Material should be as free as possible of blood, flesh and other debris, and packed into clean poly bags or boxes (Figure 2).



Figure 2. Clean, frozen shark cartilage as received from the supplier.

These procedures are necessary to minimise the potential for enzymatic or bacterial spoilage of the cartilage. Comparisons between larger northern shark backbone and the backbones of smaller domestically consumed shark suggest that the larger product has some superior characteristics (proximate composition and yield). Availability, accessibility and price were also contributing factors in the decision to use cartilage from larger shark. The cartilage sourced for the production of this cartilage powder product is *derived* from shark species which are caught primarily for their meat. These species include: *Carcharodon carcharias, Carcharhinus limbatus, Isurus oxyrinchus, Galeorhinus australis, Sphyrna zygaena, Mustelus antacticus*.

(ii) Defleshing and Sanitisation

The defleshing and sanitisation steps are undertaken as quickly as possible. The material is thawed and the flesh removed. A variety of defleshing techniques were These included enzymatic digestion, chemical digestion, heating, high trialled. pressure water and abrasion. Ultimately, a system using high pressure water in a purpose-designed cabinet was chosen as the most appropriate system for defleshing. Some ligamentous material remained attached to the backbone, but a large proportion of the typical "shark" odour (which is water-soluble) is removed. The basis of the method involved the use of washing protocols for maximal flesh removal and odour Complete flesh (non-cartilage protein) removal is important if the reduction. undesirable odour and flavour characteristics of the product are to be minimised. Additionally, the potential for bacterial contamination will be reduced, and the protein content of the final product will be represented almost entirely by cartilage protein (and not protein derived from the flesh of the shark). The use of harsh chemicals (such as bleach and peroxide) was avoided. Similarly, denaturation of "active" compounds was minimised by avoiding the use of heat in the defleshing procedures. Microbial contamination is best avoided through careful processing in sterile conditions from catch to the final product.

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(iii) Drying

The use of heat-pump drying was found to be the most efficient and effective drying method available (Figure 3). The choice of the method of drying used for shark cartilage becomes very important in the entire procedure when one considers the potential heat lability of the active agents in shark cartilage. Research suggests that few methods are able to dry shark cartilage without the incorporation of a heating step in the process. Even the often highly recommended freeze drying methods have been shown to generate temperatures of 60-70°C where the water molecules are volatilised from the product. In the process of drying products using heat-pump drying, a flow of dehumidified air is passed over the product. The temperature of this dehumidified air can be carefully controlled. Water is removed continually until the moisture level approaches 3-4%. The maximum drying temperature of 38°C was chosen because at this temperature, the labile materials in the cartilage would be compromised no more than they would when they were ingested by the purchaser. Other methods of drying (e.g. microwave, desiccant and freeze drying) were shown to have shortcomings (e.g. cost, temperature) which affected their appropriateness for the production of dried shark cartilage. The profiles in Appendix 2 represent the shark cartilage drying curves which were used to optimise the drying process in the commercial heat-pump drier assembly. These conditions represent the maximum drying rate at 38-40°C, but will need to be determined for each individual heat pump drier. Dehydration of the whole backbone (>5% moisture) was achieved in these experiments in about 14 hours. The air flow system and rate were set to minimise the energy consumption while maximising the energy efficiency of the drying process.



Figure 3. Cleaned shark cartilage was loaded onto metal trays and dried in a heat pump drier.

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(iv) Milling

In dealing with large shark cartilage (up to 6 cm in diameter), it is particularly important that the milling technology be able to reduce product size in a number of discrete steps. Primary size reduction is achieved using a wood chipper powered by an electric motor. In order for this apparatus to meet food production specifications, all components which had contact with the product were replaced with stainless steel materials. Initial investigations compared the efficiency and ease of coarse milling before and after the drying step. From a time and a handling point of view, drying prior to milling appears to be the most appropriate technique. With this decision, the milling steps could be consolidated to some degree. The coarse mill was mounted on top of a stainless steel hammer mill (Figure 4).



Figure 4. Shark cartilage was milled to a coarse powder using a stainless-steel hammer mill.

The primary milling step produced material of 2-3 cm in diameter. The secondary milling step (in the hammer mill) reduced the cartilage to a particle size of less than 1 mm in diameter. While the hammer mill was capable of producing a finer product, it was found to be counter-productive to mill the cartilage any finer than this. Subsequent milling procedures have (until recently) been undertaken interstate using several distinct milling procedures. Mills used in the final stages of the size reduction included pin mills, super micron mills and jet mills. Optimisation of the milling process is on-going. One of the major problems in the preparation of shark cartilage powder is the generation of "fluff". This material can contribute as much as 20% of the final dry weight of the dried powder. Improvements in the entire processing procedure can minimise the loss of valuable material in the form of "fluff". This material now contributes less than 5% of the total powder weight. Important considerations in the processing which may contribute to the maximisation of the quality and yield of powder are careful temperature control and gentle milling procedures.

(v) Product specifications

Considerable time was spent in developing appropriate tests to substantiate the quality of this shark cartilage product in the marketplace. The tests which were ultimately performed on each batch of shark cartilageand a selection of analyses are presented in Appendix 3. These analyses can be broadly divided into four main groups: general proximate analyses, microbiological analyses, heavy metal analyses, and specialised analyses.

The marketing profile used by the commercial partner is presented in Appendix 4. It contains some indicative levels for the more important elements of these analyses.

General proximate analyses include determinations of the protein, fat, moisture, carbohydrate and ash components of any given batch of shark cartilage. These analyses are very useful to prospective purchasers of the final product as they give some useful information of the product source and method of processing. The inclusion of cartilage other than that derived from shark (e.g. from bovine sources) can usually be determined from the fat value. Shark cartilage will routinely have a fat level

of less than 2% while bovine cartilage usually has a fat level of greater than 4%. The moisture content is another important determination. The moisture content should be less than 7% (preferably less than 4%) in order to minimise the likelihood of unwanted bacterial growth. The bottles should always be closed tightly after use as the product is highly hygroscopic (water absorbing). It is probably wise to also store cartilage powder (particularly after opening) in the refrigerator. The ash content is usually less than 50%, comprising mainly calcium and phosphorus. Some shark cartilage manufacturers are removing a portion of the ash component, which severely alters these interpretations. The demand, however, is for 100% pure (unadulterated) shark cartilage powder. The protein content would generally be expected to be at least 40%. This parameter is a difficult one to interpret as a high protein value (55% or greater) would generally suggest the presence of flesh proteins in the final product. The simple carbohydrate (sugar) determination should be negligible, indicating that the product has not been "cut" with a filler (e.g. dextrose).

Microbiological analyses are necessary to ensure that the product meets the relevant health regulations. A standard plate count (SPC) and an enterobacteriaciae count are the standard tests performed on each batch of cartilage powder for the domestic and export markets. The SPC should be less than 500 colonies/gm and the *E.coli* count should be less than 1 colony/gm.

The heavy metal analyses are important to ensure that product with unacceptable levels of heavy metals (e.g. arsenic, cadmium, lead, etc.) is not sold for human consumption. The levels of heavy metals deemed to be acceptable by the National Food Authority (NFA) are presented in Appendix 5.

Specialist analyses are performed in order to get an indication of the levels of compounds which are not routinely analysed for. The most important of these is mucopolysaccharide which is undertaken by determining the uronic acid content of the product. A conversion factor enables the calculation of the chondroitin sulphate concentration in a given batch of shark cartilage. This analysis is undertaken interstate (at Monash University) and a representative analysis is presented in Appendix 6.

Developmental analysis of the contribution of flesh proteins to the total protein content of a shark cartilage batch is being undertaken using High Performance Liquid Chromatography (HPLC). This procedure has the potential to separate and possibly quantitate the relative contribution of flesh proteins, cartilage collagen and chondroitin sulphate in the product. This analysis will give an indication of the care taken with flesh removal, and the extent of thermal denaturation of the various heat labile components in shark cartilage.

(vi) Packaging

The initial requirement for packaging was for bulk transportation. This was achieved using 25 Kg cardboard kegs lined with sealed double plastic bags (Figure 5). These containers were used for the transportation of product interstate (e.g. for final milling) and for the transport of bulk finished material to final destinations (largely overseas).



Figure 5. Shark cartilage was transported in bulk in plastic-lined 25 Kg cardboard kegs.

A selection of commercial plastic bottles were sourced, and appropriate seals and moisture/odour absorbent sachets were tested. Bottles containing various weights of powdered shark cartilage (1000, 500, and 250 gm) were developed (Figure 6).



Figure 6. A selection of final products produced from the shark cartilage powder.

Discussions were also held with numerous pharmaceutical companies with regard to the development of encapsulated and tableted shark cartilage products. Ultimately, these products were produced by Herron Pharmaceuticals in a Therapeutic Goods Administration (TGA) approved premises. These products were also packaged into similar plastic bottles. It should be noted here that at the current time, the sale of shark cartilage (and other products) in capsule and tablet form is close to compromising TGA regulations. Consequently, the commercial partner has decided to sell these products in the international arena where the demand for the product is greater and the regulatory controls less severe.

(vii) Labelling

A considerable amount of time was committed to the preparation of labels for the powder, tablets and capsules. The commercial partner contributed the design of the label. The final content of the label was achieved following much discussion. Strict adherence to the various governmental regulations (e.g. the State and Federal Health Departments, the Australian Quarantine and Inspection Service, the Customs Department, the Therapeutic Goods Administration, the National Food Authority, etc.) was of particular concern. A range of examples of current labels is presented in Appendix 7.

RESULTS/OUTCOMES

The result of this project was the development of a fine dry white powder derived from the backbone of the shark. This product has a market acceptance in Asia, America and more recently, Australia. The commercial partner is a small-scale shark cartilage producer compared to some of the larger (predominantly American) companies. The market penetration of the final product is the main constraint of the expansion of the current business. The product has been developed to a niche market and is undergoing continuous change. The US market demand for shark cartilage powder is of the order of US\$30M per year. The success of this project was dependent upon the resolution of many problems at all stages of production. These included suitable supply of the raw material, appropriate defleshing, drying and milling technologies, and extensive discussions with the many governmental regulatory bodies. All of the components which contribute to the cost of full-scale production of this shark cartilage product are summarised in Appendix 8. Ultimately, the product quality is assessed by customer acceptance and the comparative chemical and microbiological analyses. This product is certainly considered satisfactory by consumers because they are continuing to purchase product.

Dr Davis has more recently been analysing the powdered shark cartilage to identify and determine the quantities of active ingredient it contains. He has developed the methodologies necessary for the testing of anti-angiogenic activity using the Chorio-Allantoic Membrane (CAM) assay system. This *in vivo* system was not satisfactory since it was difficult to standadise and was prone to operator error. More recently, we have developed an animal model to assess the level of acute and chronic relief from inflammatory pain (e.g. arthritis). Further research in these areas is entirely dependent upon securing further financial support.

Future developments will be market driven. Currently, the market demands a 100% pure shark cartilage powder. The consumer, however, is becoming increasingly concerned about the undesirable odour and flavour of the product. This is an example of how the market can drive change in the presentation of the final product. Improvement in these characteristics can only be achieved through improved

processing techniques, extraction of the undesirable agents and/or the addition of an absorbent. The potential also exists for the development of shark cartilage extracts for smaller niche markets (e.g. chondroitin sulphate for corneal transportation), and for the investigation of the potential of shark cartilage as an anti-inflammatory (anti-arthritic) agent.

While the current market for shark cartilage is in the treatment of cancer, the potential of the product as an anti-inflammatory agent (e.g. in arthritis) is receiving more and more attention. Although not relevant to this report, the author is undertaking considerable work in this area.

APPENDICES

Appendix 1. A review of some of the relevant literature relating to the use of shark cartilage as a natural medicinal.

Structural studies on sulfated oligosaccharides derived from the carbohydrateprotein linkage region of chondroitin 6-sulfate proteoglycans of shark cartilage.

Sugahara,-K.; Ohi,-Y.; Harada,-T.; de-Waard,-P.; Vliegenthart,-J.F.G.

1992

Shark cartilage proteoglycans bear predominantly chondroitin 6-sulfate. After exhaustive protease digestion, reductive beta -elimination, and subsequent chondroitinase ABC digestion, 13 hexasaccharide alditols, which are nonsulfated, sulfated, and/or phosphorylated, were obtained from the carbohydrate-protein linkage region. Six compounds, containing 0 or 1 sulfate and/or phosphate residue, represent approximately 40% of the isolated linkage hexasaccharide alditols. They were analyzed by chondroitinase ACII or alkaline phosphatase digestion in conjunction with high performance liquid chromatography, and by 500 MHz one- and two-dimensional super(1)H NMR spectroscopy. All six compounds have the conventional structure in common.

Distribution of different molecular species of collagen in the vertebral cartilage of shark (Carcharinus acutus).

Rama,-S.; Chandrakasan,-G.\

1984

It is known that cartilage collagen in higher vertebrates conforms to Type II collagen but very little is known of the nature of shark cartilage. This study was undertaken to determine the differences, if any, between shark cartilage collagen and that of higher vertebrates. Collagen was obtained from shark (Carcharinus acutus) cartilage by pepsin solubilization and characterized by amino acid analysis and determination of chain composition by SDS-polyacrylamide gel electrophoresis and CM-cellulose chromatography. Results indicated the presence not only of Type II collagen but also of Type I collagen. Type I collagen accounted for about one third of the total collagen content of shark cartilage.

Inhibitors, enzymes and growth factors from shark cartilage.

Lee,-A.K.; Beuzekom,-M.-van; Glowacki,-J.; Langer,-R.

1984

Shark cartilages were extracted with different dissociating agents such as guanidine. The cartilage matrix of sharks is more tightly bound than that of calves and more resistant to guanidine dissolution. Extracts of shark cartilage contain lysozyme, inhibitors of trypsin, chymotrypsin, plasmin, and collagenase and a stimulator of cell proliferation. The collagenase inhibitor and cell growth factor had activity maxima at 35,000 and between 5000 and 25,000 molecular weight respectively. The large size of sharks and, in particular, the fact that the entire endoskelton of sharks is composed of cartilage suggests that sharks may be an excellent source of such bioactive agents. Determination of the distribution of constituent disaccharide units within the chain near the linkage region of shark-cartilage chondroitin sulfate C.

Uchiyama,-H.; Kikuchi,-K.; Ogamo,-A.; Nagasawa,-K.

1987

A method for analyzing the distribution of constituent disaccharide units within the chain near the linkage region of chondroitin sulfate has been developed. The method consists of (a) chemical modification of the reducing terminal residue in the polysaccharide by a 2-(2,4-dinitrophenylamino)ethylamino (DNP-AEA) group, (b) controlled fragmentation of the DNP-AEA-labeled polysaccharide with chondroitinase AC-I.

Isolation of bioactive compounds from sharks.

Langer,-R.

1989

Most solid tumors start as a small mass of avascular tissues which must be nourished by the host's vascular network in order to grow and later metastasize. Thus an inhibition of neovascularization, or anti-angiogenesis, is a possible therapeutic approach to controlling the growth of tumors. Cartilage, a source of this inhibitor, is vascular and rarely invaded by neoplastic tissues. An abundant source of cartilage or anti-angiogenic factor was sought in sharks, because their skeletal tissue is entirely cartilage. When basking shark (Cetorhinus maximus) fin cartilage was extracted for 41 days in 1 M guanidine solution and tested for anti-angiogenic activity against V2 carcinoma in the rabbit cornea, the vascular growth of the treated animals was 25% that of the control. In addition, shark cartilage contains inhibitors of many proteases including trypsin, plasmin and chymotrypsin. (Grant NA86AA-D-SG/89. Sponsored by National Sea Grant Coll. Program, Rockville, MD (USA).) Proteoglycans from the cartilage of young hammerhead shark Sphyrna lewini .

1989

The majority of proteoglycans were extracted from shark (Sphyrna lewini) fin cartilage with 3 M GuHCl. Conventional methods with either 4 M GuHCl or 8 M urea extracted only 36% and 12%, respectively. The proteoglycans have shown higher hydrodynamic sizes than those observed for mammalian hyaline cartilages. These data suggest that the proteoglycans in shark fin cartilage present a structural organization which is different from that of mammalian cartilages.

A comparative study of elasmobranch corneal and scleral collagens.

Conrad,-G.W.; Kelly,-P.T.; von-der-Mark,-K.; Edelhauser,-H.F.

1980

In the present study the authors used collagen type-specific antibodies, together with indirect immunofluorescence, to localize the types of collagen within and surrounding the shark (Squalus acenthias) cornea and have used peptide fingerprint analysis to characterize the predominant collagen alpha -and beta -chains in shark cornea and cartilage.

Shark cartilage contains an inhibitor of tumor neovascularization.

Lee,-A.; Langer,-R.

Cartilage is a source of potentially useful biochemicals, including a substance proven extremely effective at inhibiting vascular proliferation in tumors. Because sharks have a large endoskeleton composed almost entirely of cartilage, they may be a unique source of the inhibitor. Efforts to test the efficacy of these substances have been constrained by the small yield of inhibitor from mammalian cartilage. The purpose of this paper is to explore the possibility that (a) substances exist which inhibit neovascularization, (b) these substances can be used to restrict the growth of solid tumors, and, finally, (c) marine organisms, in particular sharks, are a source of such chemicals. Distribution of different molecular species of collagen in the vertebral cartilage of shark (Carcharius acutus).

Rama,-S.; Chandrakasan,-G.

1984

It is known that cartilage collagen in higher vertebrates conforms to Type II collagen but very little is known of the nature of shark cartilage. This study was undertaken to determine the differences, if any, between shark cartilage collagen and that of higher vertebrates. Collagen was obtained form shark cartilage by pepsin solubilization and characterized by amino acid analysis and determination of chain composition by SDSpolyacrylamide gel electrophoresis and CM-cellulose chromatography. Results indicated the presence not only of Type II collagen but also of Type I collagen. Type I collagen accounted for about one third of the total collagen content of shark cartilage.

Shark cartilage contains inhibitors of tumor angiogenesis.

Lee,-A.; Langer,-R.

1983

Shark (Cetorhinus maximus) cartilage contains a substance that strongly inhibits the growth of new blood vessels toward solid tumors, thereby restricting tumor growth. The abundance of this factor in shark cartilage, in contrast to cartilage from mammalian sources, may make sharks an ideal source of the inhibitor and may help to explain the rarity of neoplasms in these animals.

Extraction of the P-SCH complex from shark cartilage.

Rodriguez,-D.; Cabrera,-I.; Henriquez,-R.D.

1982

Chondroitine sulphate is an acid mucopolysaccharide, and high quantities of it can be found in the connective tissues of animals, forming a P-SCH complex with proteins by means of ester-like bonds. This mucoploysaccharide was extracted in the laboratory by enzymatic treatment. By using a proteolytic enzyme (papain) it was possible to obtain a product with a purity higher than commercial standards, although with a low yield. Three extracting methods were compared by factorial design: using water, calcium chloride solution 10%, and potassium chloride solution 25% (pH 10), with 2 stirring systems. The parameters analyzed were: yield, protein and hexosamine content. In addition, pH can be estimated by the determination of (n). A preliminary study on the anti-thrombosic effect of acidic mucopolysaccharide from shark Cetorhinus maximus

Fu,-Dehua; He,-Zhijian; Li,-Linghua; Chen,-Shumei

1993

The acidic mucopolysaccharide from shark Cetorhinus maximus (Gunner) (CMAMP) showed significant inhibitive effects on thrombosis in vitro of rats by ip (12.5, 25.0, 50.0 mg/kg) and in vivo of rabbits by iv (12.0, 24.0 mg/kg). These effects were dose-dependent.

Primary structure of a protein isolated from reef shark (Carcharhinus springeri) cartilage that is similar to the mammalian C-type lectin homolog, tetranectin.

Neame,-P.J.; Young,-C.N.; Treep,-J.T.

1992

During the course of characterization of low molecular weight proteins in cartilage, we have isolated a protein from reef shark (Carcharhinus springeri) cartilage that bears a striking resemblance to the tetranectin monomer originally described by Clemmensen et al. The amino acid sequence had 166 amino acids and a calculated molecular weight of 18,430. The function of tetranectin is unknown; it was originally isolated by virtue of its affinity for the kringle-4 domain of plasminogen. Sequence comparison of human tetranectin and the shark-derived protein gives clues to potentially important regions of the molecule.

Structural studies on sulfate oligosaccharides derived from the carbohydrateprotein linkage region of chondroitin 6-sulfate proteoglycans of shark cartilage. 2. Seven compounds containing 2 or 3 sulfate residues.

de-Waard,-P.; Vliegenthart,-J.F.G.; Harada,-T.; Sugahara,-K.

1992

Shark cartilage proteoglycans bear predominantly chondroitin 6-sulfate. After exhaustive protease digestion, reductive beta -elimination and subsequent chondroitinase ABC digestion, 13 hexasaccharide alditols were obtained from the carbohydrate-protein linkage region. Seven compounds, which represent approximately 60% of the isolated linkage hexasaccharides, were analyzed by chondroitinase ACII digestion in conjunction with high performance liquid chromatography and by 500-MHz one- and two dimensional super(1)H NMR spectroscopy.

Age, growth, and structure of vertebra in the school shark Galeorhinus galeus (Linnaeus, 1758) from southern Brazil.

Ferreira,-B.P.; Vooren,-C.M.

1991

Age and growth of the school shark Galeorhinus galeus was studied from rings in the vertebra and length-frequency data. Samples were collected by trawling off the southern Brazilian coast from Jun 1980 to Sep 1986. Histological studies were also conducted on the characteristics of the vertebra. Standard histological techniques and microradiography were used to determine the pattern of vertebral calcification. The vertebra presents a pattern of alternating heavily and less heavily mineralized zones, narrow and wide, respectively. These rings are probably laid down yearly in a slow-growing phase extending throughout the four winter months of Jun to Sep.

Multiple prismatic calcium phosphate layers in the jaws of present-day sharks (Chondrichthyes; Selachii).

Dingerkus,-G.; Seret,-B.; Guilbert,-E.

1991

Jaws of large individuals, over 2 m in total length, of the shark species Carcharodon carcharias (great white shark) and Isurus oxyrinchus (mako shark) of the family Lamnidae, and Galeocerdo cuvieri (tiger shark) and Carcharhinus leucas (bull shark) of the family Carcharhinidae were found to have multiple, up to five, layers of prismatic calcium phosphate surrounding the cartilages. Smaller individuals of these species and other known species of living chondrichthyans have only one layer of prismatic calcium phosphate surrounding the cartilages, as also do most species of fossil chondrichthyans. Two exceptions are the fossil shark genera Xenacanthus and Tamiobatis .

Vertebral deformities in a school shark, Galeorhinus galeus: Circumstantial evidence for endoskeletal resorption?

Officer,-R.A.; Clement,-J.G.; Rowler,-D.K.

1995

The appearance of deformed vertebrae from a single mature female school shark, Galeorhinus galeus, are described. Two unusual, pronounced bumps were noticed in the caudal region of this shark. There were no scars in the skin over these protrusions, suggesting that the lesions had arisen internally. Radiographic and histologic investigation of these lesions showed that mineralized tissue had probably been lost following an injury to the tail. Histological observations provided circumstantial evidence that mineralized tissue had been removed by internal processes, but did not reveal the agency by which skeletal tissue had been resorbed. Since the capacity to resorb mineralized tissue is characteristic of animals possessing bone, the apparent loss of mineralized tissue seen in this shark provides circumstantial evidence for the existence of bone cell lineages in school sharks. This evidence is discussed in relation to the possible implications for evolutionary and fisheries biology.

Production and characterization of monoclonal antibodies to shark cartilage proteoglycan

Alves, -M.L.M.; Straus, -A.H.; Takahashi, -H.K.; Michelacci, -Y.M.*

1994

Two proteoglycans, PG1 and PG2, have been isolated from shark cartilage. Both are highly polydisperse and large (molecular mass: 1-10 X 10 super(6) Daltons) and contain chondroitin sulfate and keratan sulfate side chains, but PG2 is somewhat smaller than PG1 and contains less keratan sulfate. Monoclonal antibodies were raised against PG1. Many antibodies were obtained and one of them, MST1, was subcloned and further characterized. This monoclonal antibody reacts with PG1 and PG2 from shark cartilage and also with aggrecan from bovine trachea cartilage. Chondroitinase AC-treated proteoglycans react with MST1, indicating that the antibody does not recognize chondroitin sulfate. MST1 also recognizes aggrecan from human cartilage and a proteoglycan from bovine brain (neurocan) but it does not recognize proteoglycans from rat Walker tumor, fetal calf muscle and decorin from human myoma. Using MST1 we were able to demonstrate that both PG1 and PG2 aggregate with hyaluronic acid.

Ultrastructure of calcified cartilage in the endoskeletal tesserae of sharks.

Kemp,N.E.; Westrin,S.K.-(Div.-Biol.-Sci.,-Dep.-Exp.-Biol.,-Univ.-Michigan,-Ann-Arbor,-MI-48109,-USA)

1979

The tesserate pattern of endoskeletal calcification has been investigated in jaws, gill arches, vertebral arches and fins of the sharks Carcharhinus menisorrah, Triaenodon obesus- and Negaprion brevirostris- by light and electron microscopy. Calcified cartilage as a tissue type in the endoskeleton of sharks is a primitive vertebrate characteristic. Calcification in the tesserate pattern occurring in modern Chondrichthyes may be derived from an ancestral pattern of a continuous bed of calcified cartilage underlying a layer of perichondral bone, as theorized by Orvig (1951); or the tesserate pattern in these fish may itself be primitive,

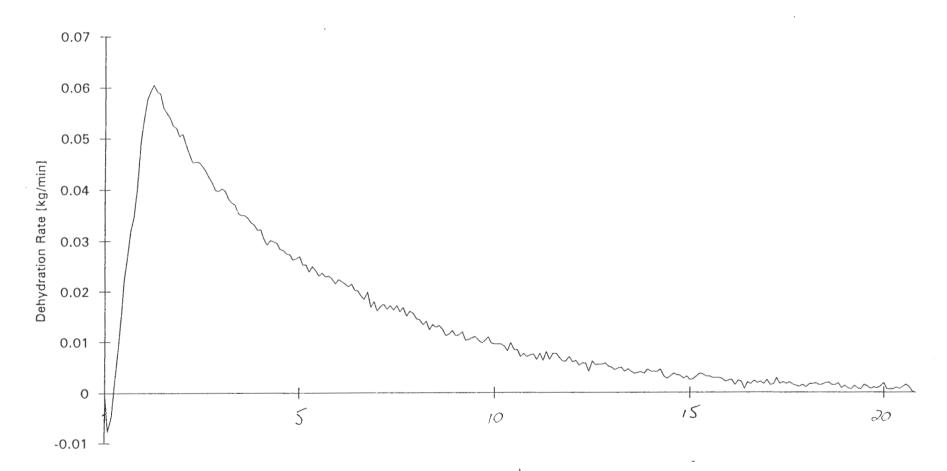
Appendix 2. Representitive drying profiles of shark cartilage using a heat-pump drying system.

Dehydration Rate Mass Cumulative Power Consumption Relative Humidity Dewpoint Temperature Temperature

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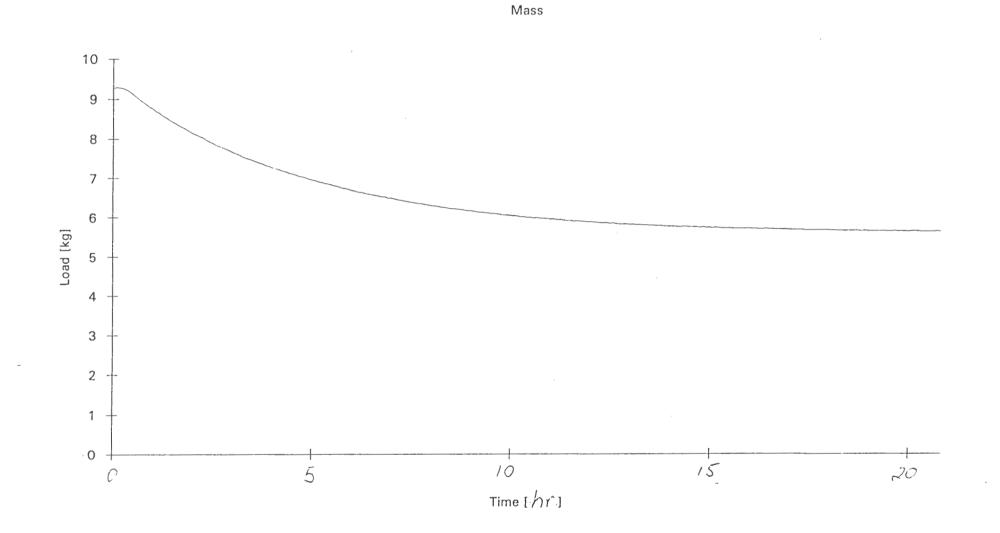


Dehydration Rate

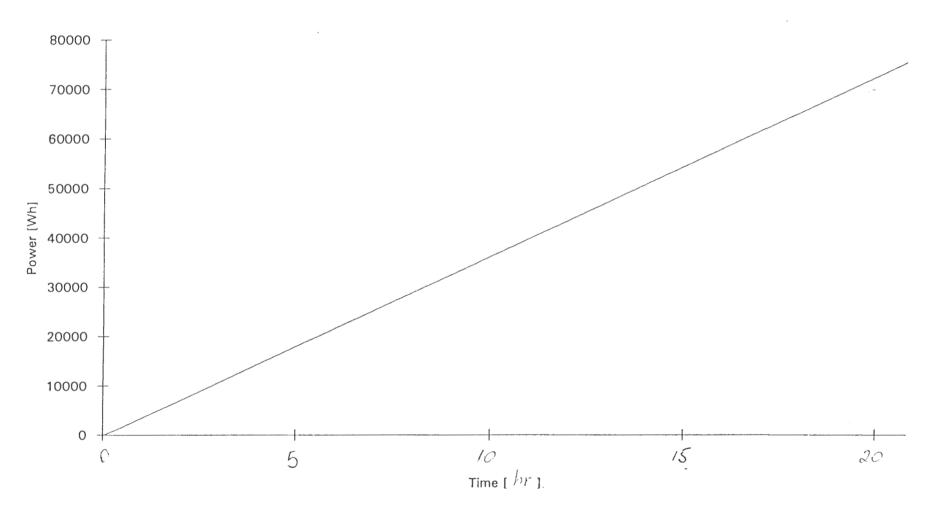
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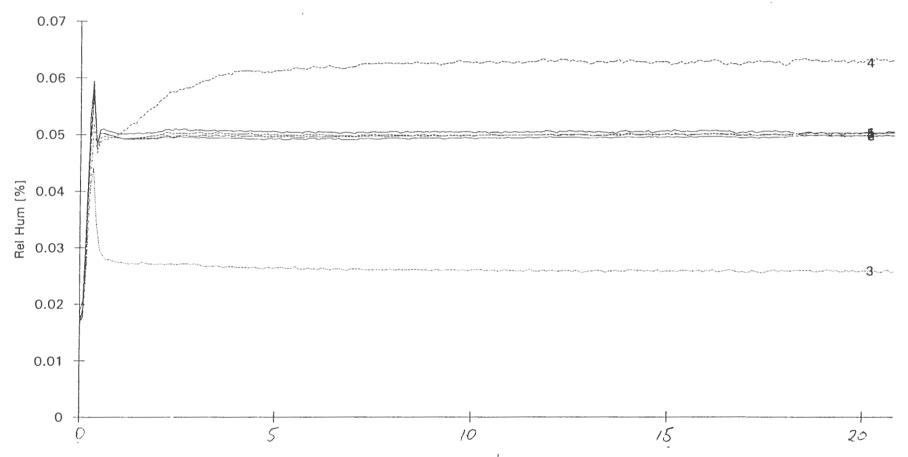
Time [hr]







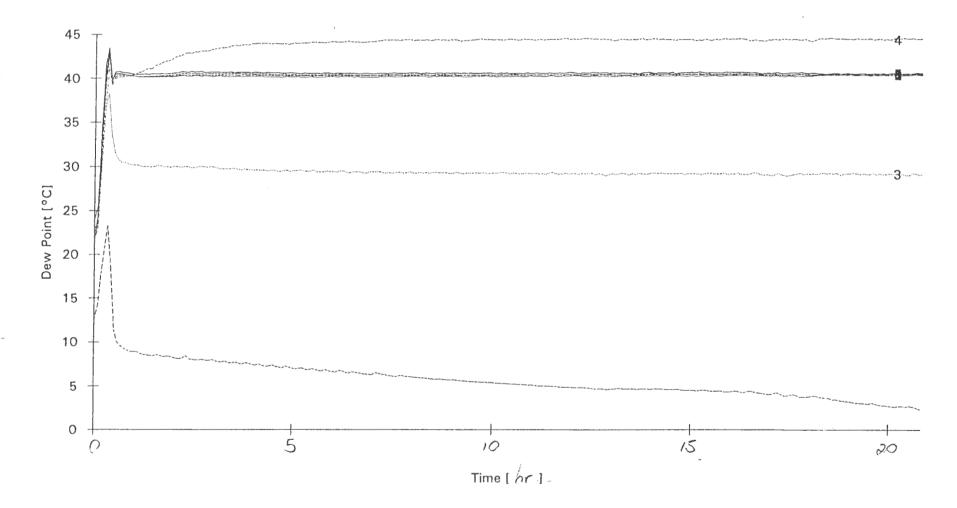
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Relative Humidity

Time [hr]

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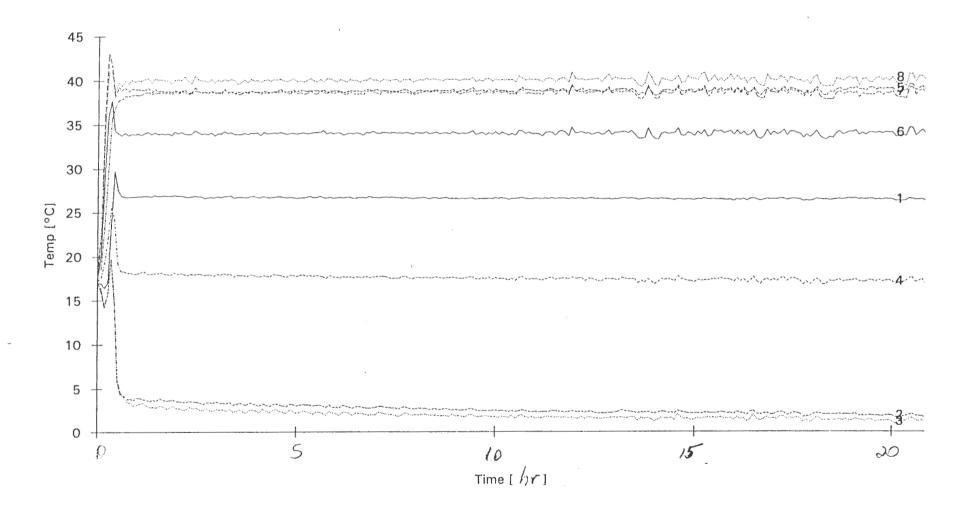
Dewpoint Temperature

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SHRKDRY

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Temperature

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Appendix 3. Routine analyses performed on each batch of shark cartilage powder.

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Date Received:



Product: Laboratory Number:

ANALYTICAL RESULTS

Description Aroma Flavour

Moisture Fat Protein Ash Carbohydrate Total sugars Energy pH

Calcium Phosphorus Zinc Mercury Lead Cadmium Copper Arsenic Mucopolysaccharide (Chondroitin Sulfate) 42.0 g/100 g 49.2 g/100 g 2.1 g/100g <0.1 g/100g 762 KJ 7.417.9 g/100g 8.68 g/100 g 37.1 mg/kg 0.12 mg/kg 0.75 mg/kg <0.05 mg/kg 2.94 mg/kg 0.134 mg/kg 4.7 g/100g

Moisture	AOAC(1990) 952.08
Fat	AOAC(1990) 948.15
Protein	AOAC(1990) 940.25
Ash	AOAC(1990) 938.08
Metals	Atomic Absorption

3 Stell

D. Houlihan Date: 25 January 1995

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Shark Cartilage Powder 94/3219

Free flowing cream powder Dried seafood Slight seafood

6.3 g/100 g 0.4 g/100 g



DEPARTMENT OF PRIMARY INDUSTRIES

Date Received:

IFIQ

ANALYTICAL RESULTS

Product: Sample Code: Laboratory Number: Moisture: Protein (Nitrogen x 5.6): Ash: Calcium: Phosphorus: Magnesium: Zinc: Shark Cartilage Powder No Code 94/2352 5.1 g/100 g 48.4 g/100 g 42.0 g/100 g 14.5 g/100 g 7.5 g/100 g 2097 mg/kg 27.2 mg.kg

CERTIFICATE OF

CHEMICAL ANALYSIS

TEST METHODS

Moisture:	A.O.A.C.(1990) 952.08
Protein:	A.O.A.C.(1990) 940.25
Ash:	A.O.A.C.(1990) 938.08
Metals:	Atomic Absorption

0 Haull

ed. <u>D HOULIHAN</u> Date: 17 October 1994

These results and sample description pertain to the sample as received.

Enquiries to: Darryl Houlihan 19 Hercules Street, Hamilton Q 4007 Telephone: (07) 26 88561 Facsimile: (07) 86 81853

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water and a second

CERTIFICATE OF CHEMICAL ANALYSIS

Tested for:



Date Received:

IFIQ

ANALYTICAL RESULTS

Product: Laboratory Number:

Description Aroma Flavour

Moisture Fat Protein Ash Carbohydrate Total sugars pH

Calcium Phosphorus Zinc Mercury Lead Cadmium Copper Arsenic

_____;

Shark Cartilage Powder 94/1862

Free flowing cream powder Dried seafood Slight seafood

4.4 g/100 g 1.6 g/100 g 50.4 g/100 g 45.2 g/100 g <0.1g/100g <0.1g/100g 7.4

16.3 g/100g
8.01g/100 g
45.1 mg/kg
0.277 mg/kg
<1.40 mg/kg
0.05 mg/kg
3.5 mg/kg
7.9 mg/kg

Moisture	AOAC(1990) 952.08
Fat	AOAC(1990) 948.15
Protein	AOAC(1990) 940.25
Ash	AOAC(1990) 938.08
Metals	Atomic Absorption

Detrall

D. Houlihan Date: 29 August 1994

CERTIFICATE OF CHEMICAL ANALYSIS

Tested for:

Date Received:

IFIQ

ANALYTICAL RESULTS

Product:	Shark Cartilage	
Sample Code:	1	2
Laboratory Number:	94/1502	94/1503
Moisture	4.8 g/100 g	4.4 g/100 g
Fat	1.5 g/100 g	1.6 g/100 g
Protein	43.6 g/100 g	50.4 g/100 g
Ash	51.3 g/100 g	45.2 g/100 g
Calcium	18.1 g/100g	16.3 g/100 g
Phosphorus	7.55g/100 g	8.01 g/100 g
Zinc	45.2 mg/kg	45.1 mg/kg
Mercury	0.127 mg/kg	0.277 mg/kg
Lead	<1.40 mg/kg	<1.40 mg/kg
Cadmium	<0.40 mg/kg	<0.40 mg/kg

TEST METHODS

Moisture	AOAC(1990) 952.08
Fat	AOAC(1990) 948.15
Protein	AOAC(1990) 940.25
Ash	AOAC(1990) 938.08
Metals	Atomic Absorption

A REED Date: 13 July 1994

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Tested for:



Date Received:

ANALYTICAL RESULTS

IFIQ

Product:	Shark Cartilage Powder
Sample Code:	No Code
Laboratory Number:	94/1583
Moisture:	4.4 g/100 g
Fat:	1.4 g/100 g
Protein (Nitrogen x 5.7):	40.7 g/100 g
Ash:	50.9 g/100 g
Carbohydrates:	2.6 g/100 g
Fructose:	N/D
Glucose:	N/D
Sucrose:	N/D
Maltose:	N/D
pH:	7.2
Calcium:	17.0 g/100 g
Phosphorus:	8.23 g/100 g
Zinc:	51.5 mg/kg
Mercury:	0.26 mg/kg
Lead:	1.52 mg/kg
Cadmium:	0.09 mg/kg

TEST METHODS

Moisture:	A.O.O.C.(1990) 952.08
Fat:	A.O.A.C.(1990) 948.15
Protein:	A.O.A.C.(1990) 940.25
Ash:	A.O.A.C.(1990) 938.08
Carbohydrates:	By Difference
Sugars:	A.O.A.C.(1984) 14.075
Phosphorus:	Pearsons Chemical Analysis of Foods 8th Edition p
Metals:	Atomic Absorption

LT REFERENCE

CERTIFICATE OF

CHEMICAL ANALYSIS

11 p421. 1/6

AL 16.1. 1. 644 8

D HOULIHAN Date: 28 July 1995

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CERTIFICATE OF CHEMICAL ANALYSIS

Shark Cartilage Powder

Free flowing cream powder

94/3219

Dried seafood Slight seafood

6.3 g/100 g

0.4 g/100 g

42.0 g/100 g

49.2 g/100 g

2.1 g/100g <0.1 g/100g

1.15 g/100g

2393 mg/kg 17.9 g/100g

8.68 g/100 g

37.1 mg/kg

0.12 mg/kg

0.75 mg/kg

0.134 mg/kg

4.7 g/100g

<0.05 mg/kg 2.94 mg/kg

762

7.4

Tested for:

Date Received:

IFIQ

ANALYTICAL RESULTS

Product: Laboratory Number:

Description Aroma Flavour

Moisture Fat Protein Ash Carbohydrate **Total sugars** Energy pH

Sodium Potassium Calcium **Phosphorus** Zinc Mercury Lead Cadmium Copper Arsenic

Mucopolysaccharide

Moisture	AOAC(1990) 952.08
Fat	AOAC(1990) 948.15
Protein	AOAC(1990) 940.25
Ash	AOAC(1990) 938.08
Metals	Atomic Absorption
Mucopolysaccharide	Bitter and Muir, expressed as Chondroitin Sulphate

D. Houlihan Date: 15 February 1995

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QUEEKSE DEPARTMENT OF **PRIMARY INDUSTRIES** AGRIBUSINESS

LABORATORY REPORT OF MICROBIOLOGICAL ANALYSIS OF FOOD



Samples were tested as received.

Tested for:		ertificate of alysis no.: 21349 <u>:</u> -	Association The test(s) m in accordance	NATA stamp tory is registered by the National of Testing Authorities, Australia eported herein have been performed e with its terms of registration. This all not be reproduced except in full. Y. VARABIOFF		
Product Descripti	on: Shark Cartilage Po	wder				
Date samples rece	ived:18.12.95	·	Date	testing commenced:18.12.95		
Copies to:	1.T Jordan	l	2. IFIQ, Hamilton			
Sample No.	Code	Standard	plate count per g	Coliforms per g		
95873	А		<100	<1		
95\$74	В	<100		<1		
-	-					
Test Method		AS17	66.2.1 - 1991	AS1766.2.3 - 1992		

ND = Not detected Note: Samples were received in plastic bags.

CERTIFICATE OF CHEMICAL ANALYSIS

Tested for:

GUEENSI / IND DEPARTMENT OF PRIMARY INDUSTRIES AGRIBUSINESS

Date Received:

IFIQ

ANALYTICAL RESULTS

Product: Sample Code: Laboratory Number: Mercury:

Shark A 95/934 1.51 mg/kg

B 95/935 0.28 mg/kg

TEST METHODS

Mercury: Atomic Absorption (Hydride Generation)

D. Hall

These results and sample descriptions pertain to the sample as received.D HOULIHANDate:30 May 1995

The second s

IFIQ

CERTIFICATE OF CHEMICAL ANALYSIS

Tested for:

Date Received:

ANALYTICAL RESULTS

Product: Sample Code: Laboratory Number: Sodium: Potassium: Shark Cartilage No code 94/2744 1.49 g/100 g 1981 mg/kg

TEST METHODS

Sodium: Atomic Absorption Potassium: "

These results and sample description pertain to the sample as received.

D HOULIHANDate:4 November 1994

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OFFICE Environmental Health Unit 2019 Gold Coast Highway Miami Q 4220

POSTAL PO Box 22 Miami O 4220 DX 42588 Miami

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EN	VIR	0	NM	EN	TAL	HE	AL	ТН	UNI	T

PHONE	(075) 769 005
FAX	(075) 763 641
ENQUIRIES	Mal Heymer
PHONE	(075) 769005
OUR REF	FOOD\JORDAN.LTR

YOUR REF

23 November, 1994

Mr T Jordan Pacific Export Services Qld Pty Ltd 5 Jacana Street ASHMORE QLD 4214

Dear Sir,

RE: KARTALIN SHARK CARTILAGE POWDER

1. Thank you for copies of proposed labelling for 500 and 250 gram packs of Kartalin Shark Cartilage Powder.

The labels appear to comply with current Food Act and Australian Food Standards Code requirements for labelling of fish. Fish being described as 'fish or part of a fish ordinarily used for consumption by humankind.

Please ensure that all words or expressions have a letter height not less than the required 1.5mm.

- 2. The sample of shark cartilage powder you provided for metals analysis contained the following levels.
- mercury 0.30mg/kg
- lead <1.0
- cadmium 0.10
- copper 3.10
- zinc 35.0
- inorganic arsenic <0.1
- selenium 0.7

The Code sampling plan for fish for mercury content currently requires a prescribed proportional number of random sample units of fish or packages of fish to form a composite homogenate sample or samples. The plan was originally formulated to address mercury in fish flesh.

A maximum permitted concentration mean levels of 0.5ppm is set when such plan is followed.

The National Food Authority is currently reviewing the permitted mercury level for fish and individual samples of fish. It is anticipated that the maximum permitted concentration will be raised in the near future.

The sample should then conform to Code requirements in respect of the level of mercury and sampling method.

3. There is a prohibition under Section 38 of the Food Act 1981 on the use of results of analysis.

Such results when relating to a sample obtained by an Authorised Officer cannot be used for trade or advertisement purposes.

Yours faithfully,

- 4

Harry.

Philip Flay ^Y REGIONAL ENVIRONMENTAL HEALTH OFFICER Appendix 4. The marketing profile for shark cartilage products used by the commercial partner.

PACIFIC EXPORT SERVICES5 JACANA STREET,QUEENSLAND Pty. Ltd.ASHMORE 4214

ACN 050 872 743

5 JACANA STREET, ASHMORE 4214 GOLD COAST, Qld. Ph./Fax. 617 5597 2727 Mobile 0412 764850

DETAILS OF COMPANY

PACIFIC EXPORT SERVICES QLD. Pty. Ltd. Australian Incorporation 1990, Private Company. ACN 050 872 743				
Directors:-	Trevor Ian Jordan (M.D.) Vicki Evelyn Jordan			
Office:-	5 Jacana Street, Ashmore, Gold Coast, Queensland 4214 Ph/Fax. 617 5597 2727			
Factory:-	19 Olympic Crt., Southport, Gold Coast, Queensland 4215 Ph. 617 5591 8788			
Registered:- Office	Paul Eggars and Associates 5/115 Currumburra Road, Ashmore, Gold Coast Queensland 4214 Ph. 617 5597 2550 Fax. 617 5597 2551			
Bank:-	Commonwealth Bank Southport-Nerang Road, Ashmore, Gold Coast Queensland 4214 Ph. 617 5597 2566 Fax. 617 5597 2584 Acct. No. 064 450 00115 1306			
Primary:- Business	Dehydrated Seafood			

SAMPLES

SHARK CARTILAGE POWDER

SQUALENE 1000mg CAPSULE

SHARK CARTILAGE POWDER 500mg CAPSULE

SHARK CARTILAGE POWDER 500mg TABLET

SEAFOOD POWDER 500mg CAPSULE

ABALONE POWDER 500mg CAPSULE

With kind regards, for Pacific Export Services Queensland Pty Ltd.

Trevor Jordan Managing Director

KARTALIN

KARTALIN is a 100% pure shark cartilage powder product.

It is manufactured on Queensland's Gold Coast by Pacific Export Services Queensland Pty Ltd.

The raw material used is sourced only from Government (DPI) approved premises which catch and process shark in Australian waters for commercial products.

The investigations into the processing and development of this product were funded by the National Seafood Centre, to enable better utilisation of what is regarded in Australia as waste. The work was done by Dr. Craig Davis, Research Biochemist, of the Seafood Group attached to the International Food Institute of Queensland, Hamilton, Brisbane.

Great care is taken in the selection of raw materials and during the various processing stages to avoid bacterial and heat spoilage, assuring a high quality finished product, tested by the NATA registered laboratory at the Queensland Department of Primary Industry.

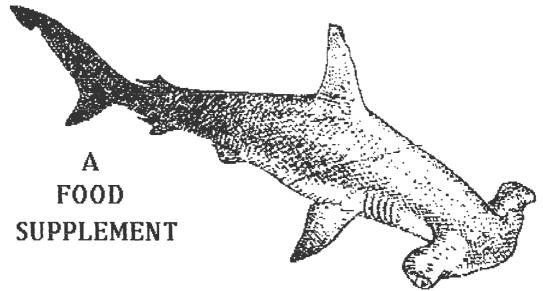
KARTALIN is marketed as a Food Supplement.

There has been, and continues to be, many researchers here in Australia in various scientific fields, investigating the properties of shark products.

Until there is published data on these Australian investigations, any information pertaining to shark cartilage powder is restricted by the Therapeutic Goods Administration of Australia.

KARTALIN is an all Australian product.

KARTALIN 100% PURE SHARK CARTILAGE POWDER



NATURALLY DERIVED FROM PROCESSED SHARK **PREMIUM QUALITY - NO ADDITIVES**

AN EXCELLENT SOURCE OF PROTEIN & AMINO ACIDS RICH IN VITAL NUTRIENTS ESSENTIAL FOR GOOD HEALTH & NUTRITION

CARTILAGE SOURCED FOR THE PRODUCTION OF KARTALIN IS FROM ONLY COMMERCIALLY FISHED SHARK SPECIES ABUNDANT IN THE PRISTINE COASTAL WATERS OF AUSTRALIA

VERY LOW LEVELS OF TOXIC METALS, PRODUCT APPEARANCE AND ODOUR ARE YOUR ASSURANCE OF THE MANUFACTURERS ATTENTION TO CAREFULL SELECTION OF RAW MATERIAL AND METHODS OF PROCESSING.

PROXIMATE ANALYSIS:	PROTEIN FAT MOISTURE ASH LEAD MERCURY COPPER MUCOPOLYSACCHARIDE	43.6 % 1.5 % 4.8 % 45.4 % 1.4 mg/Kg 0.3 mg/Kg 3.5 mg/Kg 4.7%
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PRODUCT OF AUSTRALIA

PACIFIC EXPORT SERVICES	5 JACANA STREET,
QUEENSLAND Pty. Ltd.	ASHMORE 4214
ACN 050 872 743	GOLD COAST, Qld.
	Ph./Fax. 617 5597 2727
	Mobile 0412 764850

SHARK CARTILAGE POWDER is prepared from the backbone of shark which has been meticulously cleaned of any adhering flesh. Being a cartilaginous fish, the shark skeleton is entirely composed of cartilage. Once cleaned, the cartilage is further processed under carefully controlled conditions (drying, milling, etc.) before the final product is tested for composition.

MANUFACTURING FLOW DIAGRAM

RAW MATERIAL

Shark cartilage is sourced entirely from Government Department of Primary Industries (DPI) registered commercial shark processors. These carefully selected suppliers process their shark post rigour for meat. The cartilage is removed during meat processing, thus avoiding any bacterial or enzymatic breakdown. The cartilage is frozen immediately and processed in areas approved by Government standards.

RECEIVAL OF GREEN CARTILAGE MATERIAL

Material is received frozen from suppliers who have passed our processing and pre-shipment standards. Material, free of blood, flesh and other debris, is packed in clean, poly bags or boxes.

CLEANING

Material is inspected and any remaining traces of blood and flesh are removed prior to further processing.

MILLING (PRELIMINARY)

Crude milling of green cartilage is performed to improve drying.

DRYING

Low temperature and humidity controlled.

Heat pump drying is a most cost efficient and effective method of drying heat sensitive proteins. Its most significant advantage is that low temperature heat pump drying does not generate the high surface temperatures (45 deg C - 60 deg C) freeze drying does.

MILLING

There are several low temperature milling stages done to specification in low temperature, humidity controlled conditions.

SIEVING AND SEGREGATION

PACKAGING (BULK, POWDER & ENCAPSULATING)

ALL STAGES are process quality controlled. All milling, sieving and packaging is done in an aseptic, dehumidified atmospherically controlled environment.

have abundant natural Pollution free Australian coastal waters abound in many different breeds of Several shark. resources and species of shark are targeted by shark fisherman in the tropical waters of Queensland and the tepid waters of southern Australia. The cartilage sourced for the production of this cartilage powder product is from these commercial species of shark which are caught primarily for their meat.

Some of these species are:

Sphyrna Zygaena Carcharodon Carcharias Carcharhinus Limbatus Isurus Oxyrinchus Galeorhinus Australis Mustelus Antacticus

In the preliminary investigations done by Dr. Craig Davis of the Industry (Seafood Department of Primary Group, Queensland International Food Institute of Queensland) and this company, indicate that material sourced from the tropical waters of Queensland have metal levels far below the standards set by the Australian Government. certificate of analysis is typical of the proximate The enclosed composition of the material sourced under our strict requirements. The very low levels of toxic metals is your assurance of the manufacturers attention to careful selection of raw material. The product appearance and odour is you assurance of correct methods of processing.

This SHARK CARTILAGE POWDER is of premium quality, having absolutely no additives or diluents. Some of its redeeming features are: 100% pure shark cartilage Particle size of 40 microns. Meets the production criteria for food, health and hygiene.

Sourced from the pristine waters of Australia.

Quality assured by a National Association of Testing

Authorities Laboratory.

Product of Australia.

SHARK CARTILAGE POWDER

- ITS COMPONENTS AND MODE OF ACTION.

The **PROTEIN** component of shark cartilage is predominantly composed of collagen. Collagen is a long triple coiled protein structure which is a major component of all extracellular matrices and is commonly found in the connective tissues.

MUCOPOLYSACCHARIDES are also found in these matrices and are generally composed of a protein backbone with a number of sugar side chains. In shark cartilage, the extracellular matrices are made more resilient by the integration of calcium and phosphorous into the matrix.

The main mucopolysaccharide in shark cartilage is CHONDROITIN SULPHATE, along with heparin, dermatin, keratin, and hyaluronan. Mucopolysaccharide analyses often quantitate the number of Glucuronic Acid residues and determine the percentage contribution of Chondroitin sulphate from this value.

Consequently, in the proximate analyses, "protein" predominantly refers to "collagen", and "mucopolysaccharide" predominantly refers to "Chondroitin Sulphate".

Cancer cells secrete factors which stimulate the body to increase the blood supply to the cancer tissue. This increased blood supply (called angiogenesis) provides the energy for the cancer to grow. Cartilage is a very rich source of material which may inhibit this blood vessel formation around cancers. Consequently, many cancers can potentially be treated using cartilage.

While all cartilage contains factors capable of inhibiting the angiogenic process, shark cartilage has been reported to be some 1000 times more potent. Additionally, unlike any other animal, the shark has a skeleton which is entirely composed of cartilage. Hence, shark cartilage is an ideal source of material which can inhibit the angiogenic process.

Shark cartilage powder should be taken under the supervision of qualified medical personnel if on a treatment course. The summarised protocol below is a compilation of information from limited literature and from discussions with various people on the topic. It should be taken only as a suggested protocol.

The recommended dosage is 1 gram per kg of body weight per day. This equates to about 60 grams a day for a person of "average" weight. This dose of shark cartilage should be administered <u>throughout the day</u>, possibly in <u>4 equal doses</u> spaced over the waking hours.

The cartilage powder can be administered either orally or rectally. The rectal mode of administration can be less appealing to the patient, but would be expected to be more effective because the protein factor would not be exposed to digestive enzymes and the acid environment of the stomach. The cartilage powder is resuspended in 50-100 ml of water with stirring or gentle inversion before it is administered with an appropriate syringe.

The syringe should be inverted during the administration to ensure that the tube does not become blocked. The enema should be retained for at least 30 minutes, although longer (up to 4 hours) would permit maximal absorption of the factor. If administered orally, it is suggested that the cartilage be mixed with nectar or fruit juice.

Shark cartilage powder should not be administered to patients where active vascularisation (new blood vessel formation) is occurring. The most important situations to be aware of are patients with a history of heart problems, people who are recovering from an accident or surgery, pregnant and breast-feeding women. Administration to children should also be carefully considered.

For good health and well being generally, a daily intake of between 1 and 4 grams, either in capsule form or free flowing powder, served in fruit nectar, drinking yoghurt or a stirred yoghurt, is desirable. This serving is also recommended for arthritis sufferers and people with sports related joint pain.

For arthritis in particular, the treatment course can be manipulated to suit the person until a desired level of good health is achieved. As an indication, the daily serving should equate to a tenth of that taken for cancer.

Under no circumstances should the shark cartilage powder be "dissolved" in hot drinks or hot food. Shark cartilage powder is a heat sensitive protein and can be denatured under strong acid- high temperature conditions.

PACIFIC EXPORT SERVICES5 JACANA STREET,QUEENSLAND Pty. Ltd.ASHMORE 4214

ACN 050 872 743

5 JACANA STREET, ASHMORE 4214 GOLD COAST, Qld. Ph./Fax. 617 5597 2727 Mobile 0412 764850

SPECIFICATION & PRODUCT FORMULA

PRODUCT: DESCRIPTION:	Shark Cartilage Powder 500 mg tablets. A 7/16" standard convex white to off-white tablet.
TABLET Wt:	510 mg +/- (585 - 535 mg)
Product type:	Tablet.
Identification:	Characteristic dried seafood odour.
Size:	10.8 - 11.4mm dia. x 4.8 - 5.3mm thick
Colour:	Off-white
Weight:	average 510mg
Hardness:	8-12 Kg.
Disintegration:	Not more than 15 mins.
Friability:	Not more than 1.0%
Bacto:	less than 500 col/gm
E.Coli	negative.
Product type:	
Description:	
Aroma:	Dried seafood
Flavour:	
Moisture:	less than 7%
Fat:	less than 2%
Protein:	
Ash:	less than 50%
Total sugars:	less than 0.5%
Bacto:	less than 500 col/gm.
E.Coli:	less than 1 / gm.
Shelf Life:	2 years.

Signed: Trevor Jordan

PACIFIC EXPORT SERVICES QUEENSLAND Pty. Ltd.

ACN 050 872 743

5 JACANA STREET,

ASHMORE 4214

GOLD COAST, Qld.

Ph./Fax. 617 5597 2727

Mobile 0412 764850

SPECIFICATION & PRODUCT FORMULA

PRODUCT: DOSAGE: DESCRIPTION: CAPSULE Wt:	Seafood Powder 500 mg capsules. Capsule, hard. A clear hard gelatin capsule, containing powder. 500 mg +/- 1% (495 - 505 mg)
Product type: Size: Colour: Length: Weight: S.O.2 (ppm): Heavy Metals: Loss on Drying: Arsenic: Bacto: E.Coli	less than 50 ppm
Product type: Description: Aroma: Flavour: Moisture: Fat: Protein: Ash: Total sugars: Bacto: E.Coli: Shelf Life:	Seafood powder, containing Beche De Mer, Shark Fin Cartilage powder, Sea plants and Herbs. Free flowing green powder. Dried seafood Seafood less than 7% less than 2% not less than 60% less than30% less than 0.5% less than 500 col/gm. less than 1 / gm. 2 years.

Signed: Trevor Jordan

SEAFOOD POWDER

A 100% Natural Food Supplement SEAFOOD POWDER is derived from extracts of specially selected varieties of BECHE-DER-MERE, SHARK FIN CARTILAGE, SEA PLANTS and HERBS, which are then processed into fine powders and blended together in controlled environments, to protect the sensitive nature of the product.

Clinical studies done by the University of Queensland confirmed the beneficial effect of these types of blends have on the symptoms of arthritis.

There are no known side effects, and by taking the recommended two capsules per day, many have found a wide range of relief from the symptoms of conditions ranging from lack of muscle integrity to inflammation, joint immobility and fatigue.

In sport, athletes have reported improved circulation, increased strength, eliminates joint and muscle pain, a more stable mental outlook, increased libido, improved recovery rate, plus a feeling of well being.

The raw materials are sourced and collected from only Government (DPI) establishments in the northern tropical waters of Queensland. The careful selection of all the raw material and the manufacturing process guarantees a premium quality product.

SEAFOOD POWDER is 100% naturally derived with absolutely no preservatives, additives, artificial colourings or diluents. The products appearance and odour is your assurance of quality and correct methods of production.

Some redeeming features of SEAFOOD POWDER are: 100% pure and natural. Particle size of less than 100 microns. Sourced from the pristine tropical waters of Australia. Quality meets with all the criteria for good food and health standards set by the Australia Government. Quality assured by an independent NATA registered laboratory at the Qld. Department of Primary Industries, Hamilton, Brisbane.

A PRODUCT OF AUSTRALIA.

PACIFIC EXPORT SERVICES 5 JACANA STREET, QUEENSLAND Pty. Ltd.

ACN 050 872 743

ASHMORE 4214 GOLD COAST, Qld.

Ph./Fax. 617 5597 2727

Mobile 0412 764850

SPECIFICATION & PRODUCT FORMULA

PRODUCT: DOSAGE: DESCRIPTION: CAPSULE Wt:	 Shark Cartilage Powder 500 mg capsules. Capsule, hard. A clear hard gelatin capsule, containing white to off-white powder. 500 mg +/- 1% (495 - 505 mg)
Product type: Size: Colour: Length: Weight: S.O.2 (ppm): Heavy Metals: Loss on Drying: Arsenic: Bacto:	less than 700 ppm less than 50 ppm
E.Coli	negative.
Product type: Description: Aroma: Flavour: Moisture: Fat: Protein: Ash: Total sugars: Bacto: E.Coli: Shelf Life:	Free flowing white to off-white powder. Dried seafood Seafood

Signed: Trevor Jordan

PACIFIC EXPORT SERVICES	5	5 JACANA STREET,
QUEENSLAND Pty. Ltd.		ASHMORE 4214
ACN 050 872 743		GOLD COAST, Qld.
	Ph./Fax.	617 5597 2727
	Mobile	0412 764850

PROXIMATE ANALYSIS

PRODUCT:	Squalene 100%
CHEMICAL NAME:	2,6,10,15,19,23-Hexamethyl-2,6,10,14, 18,22-tetracosahexaene.
PURITY:	99.5% min. by GC analysis.
ACID No:	< 0.04
PEROXIDE VALUE:	$0.5 \mathrm{meq/Kg}$
IODINE No:	365
REFRACTIVE INDEX:	1.495 at 25 deg. C
SPECIFIC GRAVITY:	0.857 at 20 deg. C
COLOFORMS:	NEGATIVE
ARSENIC:	< 0.2 mg/Kg (as AS203)
HEAVY METAL:	< 4.6 mg/Kg (as Pb)
PACKAGING:	In 170Kg stell epon lined closed head drums, gas flushed.
SHELF LIFE:	Gas flushed, no light, at <5 deg. C, - 12 months
VISCOSITY:	12 cps at 25 deg. C.
BOILING POINT:	285 deg. C
CALORIFIC VALUE:	19,400 BTU/pound

PACIFIC EXPORT SERVICES 5 JACANA STREET,					STREET,	
QUEENSLAND	Pty.	Ltd.		ASH	MORE	4214
ACN 050 872 743				GOL	D COAS	T, Qld.
			Ph./Fax.	617	5597	2727
			Mobile	04	12 76	4850

The oil expressed from the livers of certain breeds of sharks has been used in the manufacture of commercial products since the 18th century. Some of these products were marketed for the therapeutic value, and others for their application in certain cosmetic.

Typically Shark Liver Oil is composed of three major components:

1.	SQUALENE	60%
2.	D.A.G.E. (Diacyl glyceryl ethe	r) 30%
3.	Triglycerides.	10%

1. SQUALENE

Occurs ubiquitously in human tissues in small amounts, but it is the major component in certain shark liver oils, comprising sometimes up to 85% in some species.

It is said to be useful in fighting cancer both prophylactically as an antioxidant, and as a potentiator of chemotherapeutic agents.

It is a product of the highest purity, being 99.5% pure and extremely low in toxic heavy metals. The clear liquid is filtered and deodorised. 2. D.A.G.E.

Diacyl glyceryl ethers are unusual glyceride fats. They are heterogeneous containing over 15 major fatty acids and 6 major fatty alcohols. They occur at levels up to 60% in some shark liver oils.

There is still confusion in the scientific arena regarding the active principle of DAGE. The fatty alcohol-glycerol ether portion of DAGE, known as "ALKOXYGLYCEROLS", previously commercially available, has been studied for its beneficial effects in stimulating the lymphatic immune system. DAGE has not been studied, but from a medical view point, DAGE in the human body converts into "alkoxyglycerols" rapidly, and is therefore, equivalent to "alkoxyglycerols".

3. TRIGLYCERIDES.

Remaining fraction of fat present, but is a mixture of fatty acid triglycerides which are no commercial value.

PACIFIC EXPORT SERVICES 5 JACANA STREET, QUEENSLAND Pty. Ltd.

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ASHMORE 4214

GOLD COAST, Qld.

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Mobile 0412 764850____

SPECIFICATION & PRODUCT FORMULA

PRODUCT:	SQUALENE.
DOSAGE:	1000 mg capsules.
DESCRIPTION:	A clear soft capsule, containing clear liquid.
CAPSULE Wt:	1550 mg +/- 1%
Product type: Size: Colour: Length: Weight: S.O.2 (ppm): Heavy Metals: Loss on Drying: Arsenic: Bacto: E.Coli	less than 50 ppm
EXCIPIENTS:	GELATIN 380mg GLYCEROL 170mg
Product type:	SQUALENE (Shark Liver Oil derivative).
Description:	Free flowing clear viscous liquid.
Aroma:	Seafood oil.
Flavour:	Seafood oil.
Puriy:	99.5% min. by G.C analysis
R.I.	1.495 at 25 deg. C.
S.G.	0.857 at 20 deg. C.
Viscosity:	12 cps at 25 deg. C
Iodine No.	365.
Coliforms:	less than 1 / gm.
Shelf Life:	2 years.

Signed: Trevor Jordan

PACIFIC EXPORT SERVICES 5 JACANA STREET,					
QUEENSLAND Pty. Ltd.		AS	HMORE	4214	
ACN 050 872 743		GO	LD COAS	ST, Qld.	
	Ph./Fax.	617	5597	2727	
	Mobile	041	2 76485	50	

DRIED ABALONE GUT POWDER

PROXIMATE	ANALYSIS	NUTRITIONAL PANEL	Per 100gm
Protein	55%	Energy	1100Kj
Carbohydrate	e 16%	Protein	55gm
Moisture	5%	Carbohydrate	16gm
Fat	10%	Fat	10gm
Ash	14%	Calcium	0.6gm
		Phosphorous	0.9gm
		Potassium	0.9gm
		Sodium	3.1gm
		Zinc	0.1gm
		Magnesium	0.5gm

100% PURE ABALONE POWDER

Naturally derived from fresh abalone harvested in the pristine coastal waters of southern Australia.

High in protein, abalone powder is a rich source of vital amino acids, electrolytes and nutrients for good health and well being.

Product is sold as a FOOD SUPPLEMENT.

Serving suggestions: Two to four 500mg capsules per day

Redeeming features:

- 100% Natural
- superfine powder (particle size below 75 microns)
- sourced from only Australian abalone.
- no additives or preservatives.

PACIFIC EXPORT SERVICES QUEENSLAND Pty. Ltd.

ACN 050 872 743

5 JACANA STREET,

ASHMORE 4214

GOLD COAST, Qld.

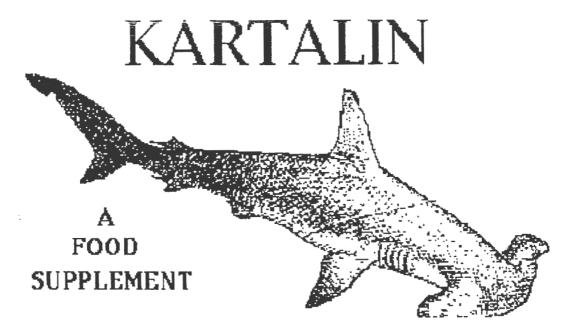
Ph./Fax. 617 5597 2727

Mobile 0412 764850

SPECIFICATION & PRODUCT FORMULA

PRODUCT: DOSAGE: DESCRIPTION: powo CAPSULE Wt:	
Product type: Size: Colour: Length: Weight: S.O.2 (ppm): Heavy Metals: Loss on Drying: Arsenic: Bacto: E.Coli	less than 50 ppm
Product type: Description: Aroma: Flavour: Moisture: Fat: Protein: Ash: Carbohydrates: Bacto: E.Coli: Shelf Life:	Dried Abalone Gut Powder. Free flowing green powder. Dried seafood Seafood less than 7% not less than 10% not less than 50% less than 12% not less than 7% less than 500 col/gm. less than 1 / gm. 2 years.

Signed: Trevor Jordan



100% PURE SHARK CARTILAGE POWDER

KARTALIN is prepared from the backbone of shark which has been meticulously cleaned of any adhering flesh. Being a cartilaginous fish, the shark skeleton is entirely composed of cartilage. Once cleaned, the cartilage is further processed under carefully controlled conditions (drying, milling, etc.) before the final product is tested for composition.

MANUFACTURING FLOW DIAGRAM

RAW MATERIAL

Shark cartilage is sourced entirely from Government Department of Primary Industries (DPI) registered commercial shark processors. These carefully selected suppliers process their shark post rigour for meat. The cartilage is removed during meat processing, thus avoiding any bacterial or enzymatic breakdown. The cartilage is frozen immediately and processed in areas approved by Government standards.

RECEIVAL OF GREEN CARTILAGE MATERIAL

Material is received frozen from suppliers who have passed our processing and pre-shipment standards. Material, free of blood, flesh and other debris, is packed in clean, poly bags or boxes.

CLEANING

Material is inspected and any remaining traces of blood and flesh are removed prior to further processing .

DISINFECTION

To minimise bacterial infection.

MILLING (PRELIMINARY)

Crude milling of green cartilage is performed to improve drying.

DRYING

Low temperature and humidity controlled.

Heat pump drying is a most cost efficient and effective method of drying heat sensitive proteins. Its most significant advantage is that low temperature heat pump drying does not generate the high surface temperatures (45 deg C - 60 deg C) freeze drying does.

MILLING (INTERMEDIATE)

Low temperature milling in a dehumidified environment produces a course cartilage powder.

MILLING (FINAL)

The final milling is performed to specification in low temperature, humidity controlled conditions.

SIEVING AND SEGREGATION

PACKAGING (BULK, POWDER & ENCAPSULATING)

FUTURE DEVELOPMENTS include a deodorising stage and a blending stage for flavouring of the final product.

ALL STAGES are process quality controlled. All milling, sieving and packaging is done in an aseptic, dehumidified atmospherically controlled environment.

Pollution free Australian coastal waters have abundant natural resources and abound in many different breeds of shark. Several species of shark are targeted by shark fisherman in the tropical waters of Queensland and the tepid waters of southern Australia. The cartilage sourced for the production of this cartilage powder product is from these commercial species of shark which are caught primarily for their meat.

Some of these species are: Sphyrna Zygaena

Carcharodon Carcharias Carcharhinus Limbatus Isurus Oxyrinchus Galeorhinus Australis Mustelus Antacticus In the preliminary investigations done by Dr. Craig Davis of the Queensland Department of Primary Industry (Seafood Group, International Food Institute of Queensland) and this company, indicate that material sourced from the tropical waters of Queensland have metal levels far below the standards set by the Australian Government. The enclosed certificate of analysis is typical of the proximate composition of the material sourced under our strict requirements. The very low levels of toxic metals is your assurance of the manufacturers attention to careful selection of raw material. The product appearance and odour is you assurance of correct methods of processing.

This shark cartilage powder is of premium quality, having absolutely no additives or diluents. Some of its redeeming features are:

100% pure shark cartilage Product of Australia. Particle size of 40 microns. Meets the production criteria for food, health and hygiene. Sourced from the pristine waters of Australia. Quality assured by a National Association of Testing Authorities Laboratory.

The COMPONENTS of SHARK CARTILAGE.

The "protein" component of shark cartilage is predominantly composed of collagen. Collagen is a long triple coiled protein structure which is a major component of all extracellular matrices and is commonly found in the connective tissues.

Mucopolysaccharides are also found in these matrices and are generally composed of a protein backbone with a number of sugar side chains. In shark cartilage, the extracellular matrices are made more resilient by the integration of calcium and phosphorous into the matrix.

The main mucopolysaccharide in shark cartilage is CHONDROITIN SULPHATE, along with heparin, dermatin, keratin, and hyaluronan. Mucopolysaccharide analyses often quantitate the number of Glucuronic Acid residues and determine the percentage contribution of Chondroitin sulphate from this value.

Consequently, in the proximate analyses, "protein" predominantly refers to "collagen", and "mucopolysaccharide" predominantly refers to "Chondroitin Sulphate".

PACIFIC EXPORT SERVICES QUEENSLAND Pty. Ltd.

ACN 050 872 743

5 JACANA STREET,

ASHMORE 4214

GOLD COAST, Qld. Ph./Fax. 617 5597 2727

Mobile 0412 764850

SPECIFICATION & PRODUCT FORMULA

PRODUCT: DOSAGE: DESCRIPTION:	Shark Cartilage Powder 500 mg capsules. Capsule, hard. A clear hard gelatin capsule, containing white to off-white powder.
CAPSULE Wt:	500 mg +/- 1% (495 - 505 mg)
Product type:	Hard Gelatin Capsules (Lock type)
Size:	#O
Colour:	Clear
Length:	Cap 10.10 - 12.10mm, Body 17.50 - 19.50mm.
Weight:	89.1 - 108.9 mg
S.O.2 (ppm):	less than 700 ppm
Heavy Metals:	less than 50 ppm
Loss on Drying:	12.5 - 16.0%
Arsenic:	less than 1 ppm
Bacto:	less than 500 col/gm
E.Coli	negative.
Product type:	shark cartilage powder
Description:	Free flowing white to off-white powder.
Aroma:	Dried seafood
Flavour:	Seafood
Moisture:	less than 7%
Fat:	less than 2%
Protein:	not less than 40%
Ash:	less than 50%
Total sugars:	less than 0.5%
Bacto:	less than 500 col/gm.
E.Coli:	less than 1 / gm.
Shelf Life:	2 years.

Signed: Trevor Jordan

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To whom may care.....

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I would like the opportunity to present my credentials and those of my company. I am a Food Technologist with a background in collagen chemistry. I began my professional career at Davis Gelatine in Sydney in the Research and Development Laboratory. I progressed to become the Development Technologist at Davis Germantown, a sister company to Davis Gelatine. When I left Davis Germantown, as the Operations Manager, after 15 years service, I joined A.C. Hatricks as the National Marketing Manager for their Food Division. For the past three years, I have worked as an Export Marketing Consultant, working in Japan, representing various manufacturers from S. E. Qld.

In late 1993, I took over the plant and machinery of an established company here on the Gold Coast and adapted my company name. Pacific Export Services Queensland is a small food manufacturing company producing dehydrated food products such as yeast, dried fruit and vegetables, dried seafood and meat products. I have been working with Dr. Craig Davis of the International Food Institute of Queensland (IFIQ) to develop and commercialise shark cartilage а powder product called KARTALIN. We have been given financial assistance from Seafood Centre for the National these investigations.

KARTALIN is a functional food supplement which is rich in Calcium, Phosphorous and Zinc. It is manufactured from the frames of processed shark, and following a careful defleshing procedure, the powder is dried at low temperature and humidity to protect the sensitive nature of the protein from undesirable heat denaturation. Once dried, the powder is milled to a particle size less than 75 microns by a series of highly specialised milling steps, designed to produce a very fine material without heating. Kartalin is of premium quality, 100% pure, having absolutely no additives.

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We have sourced samples of shark cartilage from only DPI registered establishments all over Australia and the work we have done confirm which sharks are more suitable, and more economical to process for our requirements. We have an effective and efficient method of manufacture guaranteeing high quality finished products. I have worked to develop a narrow network of suppliers who are committed to similar ideals of quality. I have been working under the close scrutiny of the Qld. DPI, and I believe the time and money spent in development of the various products will be well worth it. We are working on developing a range of shark derived products for the health food market. There are numerous ethical reasons for producing high grade products from Shark waste, and at the end of Dr. Davis' work, we hope to have a range of products marketable both domestically and internationally.

Our initial market and technical research, the bulk of which emanated from the USA, indicated that there was a substantial market for such products as Shark Cartilage Powder, and the demand here in Australia was being met by highly priced imported material of dubious origin. Our research also indicated the abundant supply of raw material. By utilising all the parts of the shark it is possible to alleviate the senseless waste of a resource. This has been our charter from the National Seafood Centre.

Shark Cartilage Powder, as of May 1995, is a prescribed good, it is now illegal to irradiate the product for export. All manufacture of the product must now conform to AQIS regulations.



 OFFICE
 OUEENSLAND DEPARTMENT OF HEALTH 147-163 CHARLOTTE ST BRISBANE O 4000

 POSTAL
 GPO BOX 48 BRISBANE Q 4001

 PHONE
 (07) 3234 0111 FAX
 (07) 3221 0951

CENTRAL OFFICE

Environmental Health Branch Fax 07 3234 1480 ENQUIRIES

PHONE

R V Holmes (07) 3234 0957 PHD 1-7-198

YOUR REF

OUR REF

19 June 1996

Mr T Jordan Managing Director Pacific Export Services Queensland Pty Ltd 5 Jacana Street ASHMORE QLD 4214

Dear Sir,

I refer to your letter dated 12 April 1996, concerning the marketing of powdered Shark Cartilage, and apologise for the delay in our response. This was due to the need to properly consider your view that this product should be considered to be a food and not a therapeutic substance.

I am now advised that a meeting of representatives of food authorities across Australia has agreed that encapsulated, or tableted, powdered shark cartilage would be considered to be a food. This agreement was subject to the following conditions :-

- 1) The product package is labelled as a food in accordance with the requirements of the Food Standards Code;
- 2) No therapeutic claims are made either on the product package, or any promotional literature or advertisement; and
- 3) No dosage regime is specified.

In interpreting this advice it should be understood that this decision is not binding on the Therapeutic Goods Administration.

ours faithfully

RV Holmes Assistant Director Food Services

Appendix 5. Heavy metal analyses on shark cartilage.

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STANDARD A12

METALS AND CONTAMINANTS IN FOOD

For the purposes of this Standard and save where the contrary intention

appears -

(1)

- (a) 'metal' includes compounds of a metal;
- (b) where food contains a metal and any compound or compounds of that metal, that metal and compound or compounds shall be expressed as the metal;
- (c) antimony, arsenic and selenium are deemed to be metals;
- (d) maximum permitted concentration shall be determined on the edible content of the food that is ordinarily consumed and, in the case of food in a dried, dehydrated or concentrated form, shall be calculated with respect to the mass of the food after dilution or reconstitution;
- (da) maximum permitted concentration for seaweed (edible kelp) whether dried, dehydrated, concentrated or not shall be calculated with respect to the mass of the seaweed at 85% hydration; and
- (e) 'beverages and other liquid foods' include fruit juices and beverages with a fruit juice content, milk, alcoholic beverages and frozen liquid foods, but do not include thick gels or other semi-solid foods.

(2) Subject to clause (2A), food specified in column 2 of the Table below shall not contain a metal specified in column 1 thereof in a concentration greater than the maximum permitted concentration specified opposite and in relation to that food in column 3 thereof.

Column 1	Column 2	Column 3
Metal	Food	Maximum permitted concentration in food (mg/kg calculated as the metal)
Antimony	Beverages and other liquid foods All other foods	0.15 1.5
Arsenic	Beverages and other liquid foods Galline (chicken) livers Fish, crustaceans and molluscs (inorganic arsenic only) Seaweed (edible kelp) (inorganic arsenic only) Water All other foods	0.1 2.0 1.0 1.0 0.05 1.0
Cadmium	Beverages and other liquid foods Bran Cocoa Cocoa paste Chocolate Drinking chocolate, powder	0.05 0.2 0.5 0.35 0.25 0.25

TABLE

May 1994

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	Crustaceans and the crustacean content of products containing crustaceans Fish and fish content of	0.2	
	products containing fish Edible offal other than liver Liver	0.2 2.5	
	Meat muscle Molluscs and the mollusc content of	1.25 0.2	
	products containing molluscs Seaweed (edible kelp) Water	2.0 0.2 0.005	
	Wheat germ All other foods	0.2 0.05	
Copper	Beverages and other liquid foods Cocoa and chocolate Edible offal other than ovine livers	5.0 50.0 100.0	
	Molluscs and the mollusc content of products containing molluscs Nuts Ovine livers	70.0 50.0 200.0	
•	Water All other foods	1.0 10.0	
Lead	Beverages and other liquid foods Bran Fish in tinplate containers Fruit juices	0.2 2.5 2.5 0.5	I
	Infants' foods in containers other than tinplate Infants' foods in tinplate containers	0.3 A mean level of 0.3 in 10 sample units.	
-	Meat in tinplate containers	No sample unit shall exceed 0.8. 2.5	
-	Milk, condensed milks and liquid milk products in tinplate containers Molluscs	0.3 2.5	
	Tomato products, as specified in Standard F2, in tinplate containers Vegetables Water	2.5 2.0 0.05	
	Wheat germ All other foods	2.5 1.5	
Mercury	Fish which can be sampled in accordance with clause (7), crustaceans, molluscs and the fish content of products containing fish	A mean level of 0.5*	
	Fish which cannot be sampled in accordance with clause (7) Water	1.0 0.001	
	All other foods	0.03	
Selenium	Beverages and other liquid foods Brazil nuts Edible offal	0.2 10.0 2.0	

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	Water All other foods	0.01 1.0
Tin	Foods not packed in direct contact with tin Any of the following canned foods in direct contact with tin:	50.0
	Asparagus Fruits Fruit juices Green beans Tomato products as specified in Standard F2 Foods packed in tomato containing medium All other foods	250.0 250.0 250.0 250.0 250.0 250.0 200.0 150.0
Zinc	Beverages and other liquid foods Oysters Water All other foods	5.0 1000.0 5.0 150.0

* The mean level of mercury in fish, crustaceans, molluscs and the fish content of products containing fish in the prescribed number of sample units, as determined by the methods prescribed by clause (7) of this Standard.

(2A) A maximum permitted concentration of a metal specified in the Table in clause (2) does not apply to carbonated water, soda water or mineralised water, or to mineral water, if a maximum concentration of that metal is specified in Standard O3 or Standard O8 in relation to that food.

(3) (a) The proportion of vinyl chloride monomer in any food shall not be greater than 0.05 mg/kg.

(b) The proportion of acrylonitrile monomer in any food shall not be greater than 0.02 mg/kg.

(c) The proportion of vinylidene chloride monomer in any food shall not be greater than 0.01 mg/kg.

(4)

Ver The

The proportion of aflatoxins in food shall not be greater than -

- (a) in peanut butter or peanut paste, nuts and the nut portion of products containing nuts, $15 \mu g/kg$;
- (b) in all other foods, $5 \mu g/kg$.

(4A) The proportion of phomopsin in any food shall not be greater than $5 \mu g/kg$.

(5) Ergot shall not be detectable in a 2.25 litre sample of cereal grain.

(6) The proportion of polychlorinated biphenyls shall not be greater than -

(a) in fat of meat, fat of meat of poultry, milk, milk products and eggs, 0.2 mg/kg;

(b) in fish, 0.5 mg/kg.

(7) Methods of sampling and analysis. The methods specified in this clause are the prescribed methods for the sampling for analysis of mercury in fish and fish products.

May 1994

Appendix 6. Chondroitin Sulfate analysis.



DEPARTMENT OF BIOCHEMISTRY AND MOLECULAR BIOLOGY



1.181.1.8

18 March 1996

Dr. Craig Davis International Food Inst. of Queensland 17 Hercules Street HAMILTON. QLD. 4007

REFERENCE NO	:	SC 2/96
DATE	:	1/3/96
CLIENT NAME	:	IFIQ Seafood Group
SAMPLE RECEIVED	:	20/1/96
SAMPLE ANALYSED	:	25/2/96
SAMPLE DESCRIPTION	:	Shark cartilage powder, batch 3540
Sample preparation	:	Duplicate samples (200 mg) were papain digested overnight at 60°C, insolubles centrifuged and washed (3 x) combined supernatant and workings analysed for glucuronic acid content
ANALYSIS	:	Glucuronic acid (mg/100 mg 2.32 Chondroitin sulphate (%) 7.42

Dr. W.H. Murphy Senior Lecturer

CONSULT2.doc-6



DEPARTMENT OF BIOCHEMISTRY

9 December 1994

ANALYSIS:

Dr. Craig Davis International Food Inst. of Queensland 17 Hercules Street HAMILTON. QLD. 4007

REFERENCE NO: SC5/94

DATE: 7/12/94

CLIENT NAME: Seafood Group IFIQ

SAMPLE RECEIVED: 21/10/94

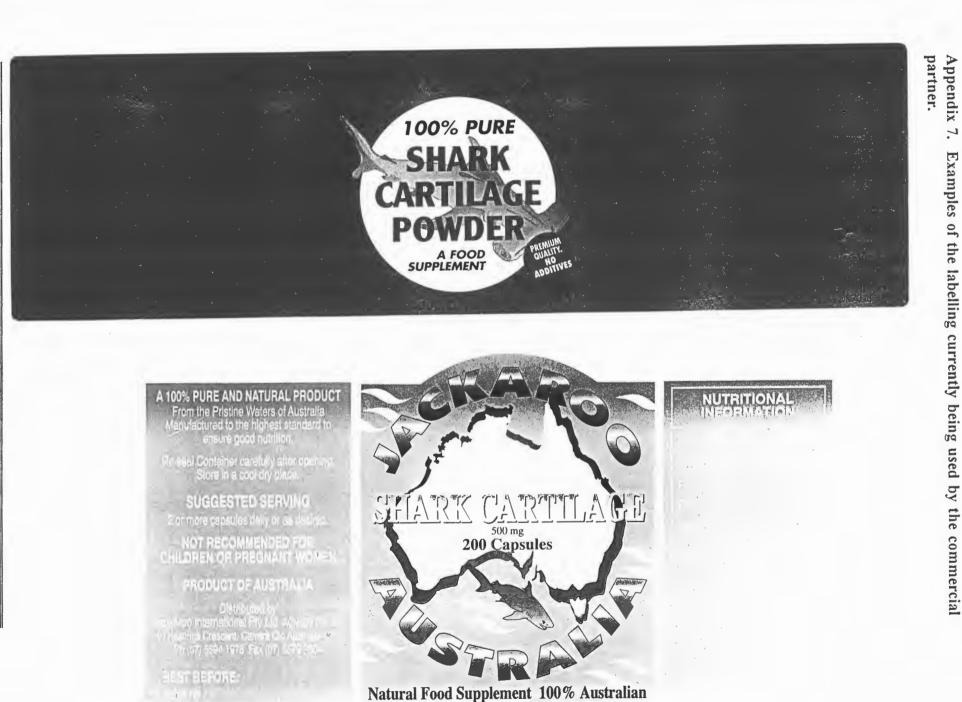
SAMPLE ANALYSED: 4/11/94

SAMPLE DESCRIPTION: Shark cartilage product (white)

SAMPLE PREPARATION: Duplicate samples (200mg) digested overnight with papain at 60°. Insoluble material removed by centrifugation and washed (3x). Combined supernatant and washings assay for glucuronic acid (Bitter & Muir).

Glucuronic acid (mg/200mg/powder) 2.922 ± 0.097 % w/w 1.46 Expressed as % chondroitin sulphate 4.67

Evang, It was great to see you at the Warburton meeting. It was a mixed bog of science! Multiple That you enjoyed it, & trust That we talk again in 95. Itave Senior Lecturer a Happy Festive Season. Bast regards Toree



CENTRE FOR FOOD TECHNOLOGY

Page 24

A 100% PURE AND NATURAL PRODUCT

Store in a cool dry place.

SERVING SUGGESTIONS Service up to 5 gms im 200 mill of fruit nector. Service difficit minimum of 100 millions deliv

PREGNANT WOMEN

PRODUCT OF AUSTRALIA

Alexandreal Process and Process ACN 075 (524-36)
 Alexandreal Process Active Activ

2 2 28 2 2 2 F



Natural Food Supplement 100% Australian





Appendix 8. Shark Cartilage Powder - Cost of Full-Scale Production

The information summarised below outlines the important steps in the process for the manufacture of shark cartilage powder and the associated costs of manufacture.

1. Purchase of raw materials	 a. Large, clean bone - \$3.50 - 5.50/Kg b. Small, clean bone - \$5.50 - 6.50/Kg c. Small, dirty bone - \$1.50 - 3.50/Kg. 		
2. Cost of flesh removal	 a. Large, clean bone - \$3-4/Kg b. Small, clean bone - \$6-7/Kg c. Small, dirty bone - \$15/Kg. 		
3. Drying - \$4.50/hour for between 22 and 30 hours (depending on product density).			

4.	Milling of dried cartilage	a.	Coarse milling	\$4.50/Kg
		b.	Fine milling	\$4.50/Kg
		c.	Superfine milling	\$6.00/Kg.

5. Chemical Analysis and Product Certification - \$350 for each batch.

6. Packagi	ng a.	Bulk \$30 per 25 Kg drum
	b.	Retail \$1.50 per 500gm pack
		\$2.00 per 300gm pack
		\$2.50 per 150gm pack
	с.	Encapsulated/tableted \$1.50 per 200 capsules (500 mg).

The final yield of cartilage powder from various bone sources varies. For large, clean bone, about a 35% yield is expected. The yield from small clean bone and from small dirty bone is of the order of 25 and 10%, respectively.

In 1994, the wet cartilage was being sold for up to \$15/Kg, while it is now worth \$3-4/Kg. Similarly, the price for the bulk product has decreased from \$130/kg to \$90/Kg since 1994. Consequently, the profit margin has been considerably reduced in the past 3 years.

The final value of the various end-products would be:

- a. \$90/Kg for bulk powder
- b. \$150/Kg for the retail packs, and
- c. \$220/kg for the encapsulated/tableted product.

Capital Outlay

Factory	4500 sq ft. \$	64200/month lease	
Equipment	Cleaning machinery, heat pump drier, mills, packaging.		
\$250 000 outlay.			
Waste disposal		\$1500/year	
Council registration,	AQIS, etc.	\$7000/year	
Power		\$1200/month	