Saw Palmetto Fruit Supercritical Extract
(Serenoa repens)
Euromed has been a longstanding leader in the manufacturing of saw palmetto berry extract. The popularity of saw palmetto started in Germany decades ago for use in men’s health issues associated with aging.1 Since that time, aging male populations globally have increased the demand for saw palmetto supplements supporting maintenance of normal prostate health. Prosterol® proprietary saw palmetto supercritical extracts are the culmination of three decades of research into identifying, characterizing, and concentrating the naturally occurring lipidic phytochemicals present in saw palmetto fruit.2,3,4,5,6,7,8

**Traceability and Authenticity:**

The composition and biological activity of each saw palmetto extract is uniquely dependent on the maturity of the starting fruit and applied method of extraction.9 Saw palmetto extract is phytochemically complex, containing three known active groups: fatty acids, sterols and fatty alcohols.10 The absence of one of these constituents is indicative of adulteration with undeclared vegetable oils. The fraudulent addition of animal derived oils to “saw palmetto oil” has been reported in the scientific literature.11

Euromed provides complete traceability and product custody documentation for legal harvesting of saw palmetto. Florida law mandates a native plant harvest permit from the Florida Department of Agricultural and Consumer Services (FDACS), for all fruit that is harvested in the state. Euromed’s Florida facility is licensed by the state of Florida as an agricultural dealer and certified as an organic fruit processor.

Euromed’s Florida staff selects later harvest wildcrafted fruit in Florida and South Georgia for Prosterol®, as the fatty acid composition i.e. lauric acid content of the fruit changes with maturity.9 The fruit is dried within 48 hours after harvest, at its central Florida facility to avoid degradation of active constituents. Every batch of fruit is put through an extensive battery of laboratory tests including identity, potency and potential impurities.

The fruit is concentrated ten-fold yielding an oil extract providing 85-95% total fatty acids by GC analysis. The content of nine fatty acids are tested in relation to lauric acid, a fatty acid present in unusually high levels in saw palmetto, verifying the authenticity of the product. The sterol content must comply with a range of 0.2-0.4% and fatty alcohols must be 0.15-0.3%. The acid value 150-220 range adopted from the European Pharmacopeia saw palmetto monograph is another test for potential adulteration and batch-to-batch consistency.

Euromed’s extract possesses the characteristic odor and presence of natural fruit pigments like carotenoids i.e. beta-carotene, unlike adulterated extracts.

The fruit is extracted following the Phyto-Proof® process of quality control, specifying proprietary supercritical production parameters for time, temperature and pressure. A minimum of twenty laboratory tests are performed for every batch.

**Biological Efficacy:**

One of the biological mechanisms of activity of saw palmetto is inhibition of the 5α-reductase enzyme present in high content in the prostate converting testosterone to dihydrotestosterone. Euromed’s supercritical extract has been tested and shown to have a high level of inhibitory activity at a low concentration, as compared to a commonly consumed pharmaceutical substance, used as a standard for the assay.12

In addition to this inhibitory activity, saw palmetto extract has been known to have a cellular antiproliferative influence and to positively modulate prostate changes.13

**Suggested Dosage:**

Scientific studies propose a daily intake of 320 mg of extract to support healthy men’s aging and maintenance of normal prostate function12,2,13

**Formulations:**

- For liquid formulations, soft gelatin and 2-piece liquid fill capsules; an 8:12:1 supercritical oil extract providing 85-95% total fatty acids by GC analyses, minimum 0.2% sterols by GC and fatty alcohols minimum 0.15% by GC.
- For tablets and 2-piece hard shell capsules, a 45% total fatty acid dry extract.
- For tablets and 2-piece hard shell capsules, a 25% total fatty acid dry extract.
- Organic certified extracts are also available

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Determination of the potency of a novel saw palmetto supercritical CO$_2$ extract (SPSE) for 5\(\alpha\)-reductase isoform II inhibition using a cell-free in vitro test system

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Background: The nicotinamide adenine dinucleotide phosphate-dependent membrane protein 5\(\alpha\)-reductase catalyses the conversion of testosterone to the most potent androgen – 5\(\alpha\)-dihydrotestosterone. Two 5\(\alpha\)-reductase isoenzymes are expressed in humans: type I and type II. The latter is found primarily in prostate tissue. Saw palmetto extract (SPE) has been used extensively in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH). The pharmacological effects of SPE include the inhibition of 5\(\alpha\)-reductase, as well as anti-inflammatory and antiproliferative effects. Clinical studies of SPE have been inconclusive – some have shown significant results, and others have not – possibly the result of varying bioactivities of the SPEs used in the studies.

Purpose: To determine the in vitro potency in a cell-free test system of a novel SP supercritical CO$_2$ extract (SPSE), an inhibitor of the 5\(\alpha\)-reductase isoenzyme type II.

Materials and methods: The inhibitory potency of SPSE was compared to that of finasteride, an approved 5\(\alpha\)-reductase inhibitor, on the basis of the enzymatic conversion of the substrate androstenedione to the 5\(\alpha\)-reduced product 5\(\alpha\)-androstenedione.

Results: By concentration-dependent inhibition of 5\(\alpha\)-reductase type II in vitro (half-maximal inhibitory concentration 3.58±0.05 µg/mL), SPSE demonstrated competitive binding toward the active site of the enzyme. Finasteride, the approved 5\(\alpha\)-reductase inhibitor tested as positive control, led to 63%–75% inhibition of 5\(\alpha\)-reductase type II.

Conclusion: SPSE effectively inhibits the enzyme that has been linked to BPH, and the amount of extract required for activity is comparatively low. It can be confirmed from the results of this study that SPSE has bioactivity that promotes prostate health at a level that is superior to that of many other phytotherapeutic extracts. The bioactivity of SPSE corresponds favorably to that reported for the hexane extract used in a large number of positive BPH clinical trials, as well as to finasteride, the established standard of therapy among prescription drugs. Future in vitro and clinical trials involving SPEs would be useful for elucidating their comparative differences, as well as appropriate patient selection for their use.

Keywords: benign prostatic hyperplasia, prostate, saw palmetto supercritical CO$_2$ extract, SPSE, 5\(\alpha\)-reductase

Introduction

5\(\alpha\)-reductase and androgen biosynthesis

A nicotinamide adenine dinucleotide phosphate (NADPH)-dependent membrane protein, 5\(\alpha\)-reductase catalyzes the reduction of 4-en-3-oxosteroids irreversibly,
ISL EA-09 Authentic and non-adulterated botanical ingredients in an unethical market situation. Full traceability, high quality production and exhaustive analytical control

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Adulteration and fraud are a menace to the botanical ingredients sector and generate growing demand for transparency for all the processes associated with production [1,2]. Manufacturers cannot ultimately avoid market scrutiny. Full traceability of the entire process is key, starting with the plant material from cultivated or wild sources, and including quality and sustainability criteria. The multilayer set of control methods of plant material starts with the taxonomic and phytochemical identity, continues with purity controls, including contaminants, and ends with the determination of active or marker compounds. Besides classical methods, modern techniques such as metabolomic evaluations and DNA barcoding should be employed. These methods allow a more robust ingredient identification and lower instances of adulteration. The subsequent physical and chemical production processes, and the set of specifications and control methods, will finally determine the quality and authenticity of the botanical ingredient.

Abstracts of 67th International Congress and Annual Meeting of the Society for Medicinal Plant and Natural Product Research (CA) in cooperation with the French Society of Pharmacognosy AFRP

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Congress president: Univ.-Prof. Dr. Hermann Stuppner

Saw Palmetto Lipidic Sterolic Extract (SPE), made from Serenoa repens berries, is the most expensive oil of the pharmaceutical and health food market, hence, its adulteration is frequent. Substitution of the saw palmetto berry with fruit from closely-related palm species, dilution of products with exhaustively extracted berry powder, the use of unripe berries, the addition of vegetable oils to extracts, and/or full substitution of SPE with other lower-cost vegetable or animal oils, have all been detected and documented by Euromed3. Wide variation of fatty acid content in authentic and adulterated saw palmetto extracts can explain differences in clinical trial outcomes and threaten the market reputation of the extract.

Euromed Upcycles Saw Palmetto Residue
January 3, 2020

A Conversation with Andrea Zangara of Euromed

by Ann Armbrecht

If food waste were a country, its emissions would rank third in the world, after China and the US, producing 8% of manmade emissions. While there hasn’t been as much attention to the role of waste in the botanical industry, companies are increasingly talking about Zero Waste and finding alternative packaging. Less attention is paid to waste of raw materials in growing, harvesting and post-harvest handling.

Andrea Zangara, Scientific Marketing Manager at Euromed
As part of the Sustainable Herbs Program efforts to highlight innovative approaches to tackling sustainability challenges in the industry, Ann spoke with Andrea Zangara, Scientific Marketing Manager at Euromed, an ingredient supplier in Barcelona, Spain, about upcycling residue from extracting saw palmetto fruit. Our conversation was over email.

**Sustainability and Euromed’s Company Culture**

**Ann:** Can you talk a bit about Euromed’s approach to sustainability overall?

**Andrea:** A commitment to the environment is one of Euromed’s key values and is integral to our company culture. We pursue this through supporting sustainable farming, reducing the collection of wild plants, establishing sustainable plantations whenever possible, respecting GACP, and fully complying with local legislations and regulations such as those established by the European Commission and by the CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora). In recent years, we have developed goals and projects focusing on specific environmental efforts. These include for example:

- Reducing CO2 emissions and energy consumption;
- Increasing greener energy use;
- Increasing our focus on researching extracts with plants and fruits grown near our production plants that are representative of the Mediterranean diet (figs, olives, pomegranates, artichokes etc.);
- Cooperating with local farmers for the renewal of crops and research for more respectful cultivation techniques including organic;
- Recycling biomass, the company’s manufacturing waste product.

**Why Saw Palmetto?**

**Ann:** How was this project utilizing waste from saw palmetto berries initiated?

**Andrea:** The Lipidic Sterolic Saw Palmetto Extract (SPE) produced by Euromed is obtained from *Serenoa repens*, a unique botanical. Florida and a small area of Georgia are the only areas in the world where the ripe berries of Saw palmetto palm trees, a wild harvested plant considered endangered, are collected, by hand. The wild harvest takes place in late summer (when the berries are ripened and contain the right profile of active compounds), during the hurricane season, and it is vulnerable to these unpredictable weather conditions.
Euromed Florida installations (stocking silo and dryers), photo by Euromed.

In 2005 we built a dedicated facility near Lake Okeechobee, in the heart of the Everglades, to process and dry saw palmetto berries close to where they are collected. This ensures the optimal fatty acid content of the berries and allows us to have complete traceability of the raw material. By ensuring proper handling, drying (within 48 hours) and extraction, we take steps to help us produce a superior Saw palmetto extract. We have tested this extract in multiple clinical trials.

**Upcycling Raw Material Waste**

Saw palmetto is vulnerable to commercial exploitation. To make full use of the plant and to close the usage circle of the intense labor involved, we focused on ideas for upcycled products such as dyes from nature, using the remaining residues of the fruit extraction.

We developed the project in collaboration with Archroma®. In 2017, Archroma® launched a patented dyes line, up-cycling natural waste material from other industries to create natural colors for the textile industry. In this project called EarthColors®, waste products from our Saw palmetto production are used to develop ecological dyes that are fully traceable from nature to fashion. Archroma® shares traceability information on smart tags attached to each clothing item. This video, produced by Archroma®, introduces the manufacturing process natural dyes and their traceability program: Diresul® Earth-Forest and Earth-Stone dyes uses Euromed’s Saw palmetto extracted biomass. Between 70% to 90% of the raw material comes from the remaining residues after the extraction of Saw palmetto. This closes the cycle of usage of this botanical and makes the most possible use of the whole plant. More information can be found at: [https://www.archroma.com/innovations/earth-colors-by-archroma](https://www.archroma.com/innovations/earth-colors-by-archroma)
Research and Scaling Up

Ann: How did you go about making sure this project would work?
Andrea: We had to identify an approach that was compatible with our sustainability and traceability model and was feasible. We began this ambitious and demanding project in 2013 and successfully completed it in 2017. Our scientists performed the laboratory feasibility tests with success. Following, we ran a larger industrial scale trial with good yield and good results. So, we prepared the documentation and completed the first full-scale industrial batch trial with Saw Palmetto biomass.

Ann: What have the impacts been in terms of waste redirected? Are there any measurable savings?
Andrea: The savings from waste management costs not incurred and lower transportation costs are modest but increasing. These savings show that the model works!

Saw Palmetto production, photo by Steven Foster.

Other Innovative Technologies
Ann: What can you take from this project for thinking about waste with other raw materials you source?
Andrea: We have researched using other waste material from biomass extraction for natural dyes with promising results, so we may add other items to the project. However, the waste from only a few plants may be suitable.

We keep brainstorming other innovative technologies. Recently we launched a line of fruit extracts from plants grown locally, obtained with a proprietary eco-friendly water-only extraction. In addition to other benefits, this avoids the release of any potentially contaminant solvents in the environment.
We also maintain our commitment to reduce waste production and eco-friendly waste management. Waste from the biomass extracted at the manufacturing facility goes to companies that create greener energy. We also compost this waste or send it for use as animal feed. Milk thistle residual, for example, has a high nutritional value. We send this residue for free to a company to dry and clean and then add to feed for farm animals.

Saw palmetto berries, photo by Euromed.

**Small Initiatives Matter**

**Ann:** Do you have advice to other companies thinking about finding ways to use waste in their supply chains? Any other lessons learned?

**Andrea:** Supply chain and quality control management are essential to Euromed, from farm to finished products and their waste. This project shows an innovative upcycle approach to waste. It indicates that creativity should not only confined to the extraction research lab. And it shows that with a good plan and determination, even small initiatives contribute to promoting a stronger culture of environmental respect and sustainability. This project also points to the importance of addressing waste management at any level. We spent a lot of money to purchase new equipment to accomplish our environmental goals. This includes on-site wastewater treatment, water purification plants, and botanical extraction technologies with osmotized water-only solvent (Pure-Hydro Process®). We also invested in equipment to reduce atmospheric emissions. But it was money well spent.

As Joe Veilleux, former president of Euromed USA and involved with sustainable upgrades to our facilities, remarked in 2012, “We rely on plants, the Earth's natural renewable resources, not only for our business but for our health. We have a special interest in making everyone aware of how vital it is that we all take steps to prevent environmental damage.”
Botanical Adulteration

About Euromed

Founded in 1971 by the 100-year-old German pharmaceutical company MADAUS, EUROMED S.A. is now part of the German pharmaceutical group DERMAPHARM. Euromed is a vertically integrated producer of standardized botanical extracts and natural active substances for the pharmaceutical, nutraceutical, health food and cosmetic industries.

Euromed develops products complying with worldwide GACP, GMPs, International Pharmacopoeias and the strictest environmental regulations.

We are very grateful for Euromed's support of the Sustainable Herbs Program as an inaugural underwriter.