ABSTRACT

The paper examines some historical formulations, with a view to exploring the way in which plant materials were used. It concentrates on some of the active materials present in the medicinal botanicals, and makes an attempt to explain how they affect the physiological processes that occur in the skin.

A traditional Chinese remedy and 12th Century Welsh formulation are considered, where the anecdotal evidence and modern data are reviewed. The paper concludes with a modern formulation based on the principles used in the past, with some recent experimental results.

DEFINITIONS

It is important that a skin care product does not infringe the Medicines Act, and it is therefore prudent to include some definitions:


**Cosmetic** means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration.
A dispensed medicinal product includes a medicinal product prepared or dispensed by a practitioner (doctor, dentist or veterinarian) or prepared or dispensed in a registered pharmacy by or under the supervision of a pharmacist, either in accordance with a specification furnished by the purchaser (for example, a customer's receipt) or in accordance with the pharmacist's own judgement as to the treatment required for a person present in the pharmacy (that is, counter-prescribing).

Medicinal product means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say:

(a) use by being administered to one or more human beings or animals for a medicinal purpose;
(b) use as an ingredient, by a practitioner or in a pharmacy or in a hospital or in a business comprising the sale of herbal remedies, in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

Medicinal purpose means any one or more of the following purposes, that is to say:

(a) treating or preventing disease;
(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
(c) contraception;
(d) inducing anaesthesia
(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

2. The Consumer Products (Safety) Regulations 1989 SI 2233

Cosmetic product means any substance or preparation intended to be applied to any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs), or to the teeth or buccal mucosa wholly or mainly for the purpose of cleaning, perfuming or protecting them, or keeping them in good condition or changing their appearance or combating body odour or perspiration except where such cleaning, perfuming, protecting, keeping, changing or combating is wholly for the purpose of treating or preventing disease;

"Cosmetic products intended to come into contact with the mucous membranes" means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin;

One might summarise all of this by saying that a medicinal product is for treating unhealthy or diseased skin, whereas a cosmetic is for the protection of healthy skin.
CAUTIONS

There are a few words of caution. Natural does not mean safe, indeed, natural can mean poisonous. The pharmaceutical industry calls on a number of plants for their drug use, and they must not be used in cosmetic products:

FORBIDDEN PLANT MATERIALS

According to the 1989 Cosmetic Safety Act

These are summarised in Appendix I.

However, the right plant, using the correct part at the appropriate concentration of the prescribed form for the specific indication is, in all likelihood, safe and beneficial.

COLLECTION OF DATA

The data is collected and stored on an extensive data base, the details of which have been described in a previous article.

POTENTIAL PROBLEMS

There is a distinct lack of understanding with the medical authorities when it comes to herbal preparations, though practitioners of medicine seem to be keeping an open mind and have many beneficial experiences using plant derived products for the treatment of skin problems.

The licensing authorities have difficulty in the following areas:

1. that plant chemical composition may vary season to season
2. that chemicals within a plant might react together synergistically
3. that including more than three plants in a formula constitutes "polypharmacy".
4. that because some historical trials have failed, there is a feeling that all future trials will fail.
5. that a single chemical cannot be held responsible for a single effect, so that in some cases the reason for the effect cannot be assigned.

SKIN TISSUE

There are many processes that occur within the skin, and for each of those mechanisms there is a plant that will encourage or maintain it.

Consider the relatively simple case of wound healing, such as would be experienced in a minor graze or skin chapping (just about allowed as a cosmetic condition). There are three
major stages involved in the return of the skin to normality. These would be:- granulation, re-epithelialisation and cicatrisation.
The healing process

First stage - granulation

The stage of scab formation which is accompanied by swelling, redness and often pain and heat at the site of injury. A simple description of the processes involved is explained by Miller.

The damaged cells trigger the release of chemicals (amongst them histamine) which cause the blood vessels to expand, so allowing more blood into the affected area and causing the redness. There is also a change in the permeability of the vessels, which allows serum to leak into the surrounding tissue (this is a normal process, but usually the leakage is drained away by the lymph glands). In the case of injury, the lymph glands cannot cope with the rate of leakage, so that swelling occurs.

The next stage is the removal of irreparable cell debris, which are removed by the white blood cells. These cells are called up during the inflammation process, and can often build up in such large numbers that they increase the swelling, eventually being discharged as pus.

The process of inflammation and pain is, to a certain extent, a protective process that immobilises the area to localise the infection and damage.

Second stage - re-epithelialisation

The formation of new tissue under the scab.

The second stage of healing follows the inflammatory stage, once the cell debris has been removed. The repair of tissue is a continuous process, however, the body has a mechanism that can put the system into overdrive. This cellular activity needs to have near perfect conditions to function properly.

Problems that can occur include pigmentation and irregular skin profile caused by uneven skin cell activity.

Third stage - resolution of scar tissue.

Having formed the initial, fragile underlying tissue, the cells continue to rebuild the epithelium, refining the tissue and re-establishing the stratum corneum and infrastructure of the underlying tissue.

Providing the environment

Each of the three basic stages would require slightly different environments, in order to be most successful (which can be measured by the rate and quality of healing). It would be agreed that healing could not be achieved very quickly if the skin was excessively dry, since any movement of the tissue would result in further additional damage. Similarly, if the skin was totally occluded in the earliest stages, then the skin cells would rely totally on the blood supply for respiration. It may be that this supply is impaired or inadequate in times of surface damage, especially if the site has become infected.
Thus, in the earliest stages one would want a high level of humectant, but not necessarily a high wax and fat content, which would cut down the excutaneous respiration. One also should aim to reduce some of the inflammation that is part of the initial healing process. There should also be the provision of antioxidants, which have been proven to improve skin healing.

As the skin begins to heal, so the emphasis moves from respiration to maintenance of moisture levels, and so it is reasonable to add oils and fats to the formula in order to build up the occlusive value and reduce TEWL (Trans Epidermal Water Loss).

The final stage of scar resolution, requires an active balance of skin moisturisation and comfortable occlusion. It is important to encourage skin cell turnover at this stage, whilst also (in deeper scars) to reduce the level of pigmentation.
1. AN HISTORICAL FORMULATION

Chinese formulation

We take as our example a typical Chinese formulation, but it is useful to first view the structure of the formula from the Chinese perspective. In China, a formula is viewed in a different way to Western medicine.

Ode in her lecture to the Society of Cosmetic Scientists, November 1994 at Chepstow on "Natural Ingredients" says that Chinese medicine is based on the principle that every recipe consists of an Emperor herb, which is the main beneficial in the recipe; the Ministers, which support the Emperor herb in its action; the Assistants, which provide a complimentary action; the Harmonisers which help hold the blend together; and finally, a Directional herb, which acts to support the function of the Meridians.

This representation of the formula is not too dissimilar to a modern herbalist's view, who will have one major herb to tackle the key problem, and then perhaps include additional herbs to address related problems and less urgent issues.

The formula was taken from one of many in a recent publication. The names are in Taiwanese pin yin and not the normal Mandarin translation. See Appendix II for equivalent Mandarin names.

HSIAO FENG SAN

Formula for skin diseases with internal heat, copious secretions and pruritis. Effective for eczema with sweat and for scabies. Also urticaria.

| TANG KUEI | ROOT | ANGELICA SINENSIS | TANG KUEI |
| REHMANNIA | RHIZOME | REHMANNIA GLUTINOSA | TI HUANG |
| GYPSUM | MINERAL | | SHIH KAO |
| ANEMARRHENA | RHIZOME | ANEMARRHENA ASPHODELOIDES | CHIH MU |
| SESAME | SEED | SESAMUM INDICUM | HU MA TZU |
| ATRACTYLODES | RHIZOME | ATRACTYLODES OVATA | TSANG CHU |
| ARCTIUM | FRUIT | ARCTIUM LAPP | NIU PANG TZU |
| SILER | ROOT | SILER DIVARICATUM | FANG FENG |
| AKEBIA | STEM | AKEBIA QUINATA | MUTUNG |
| LICORICE | ROOT | GLYCYRRHIZA URALENSIS | KAN TSAO |
| CICADA | EXUVIAE | CRYPTOTYMPSAN ATRATA | CHAN SHUI |
| SOPHORA | ROOT | SOPHORA FLAVESCENS | KU SHENG |
| SCHIZONEPETA | WHOLE HERB | SCHIZONEPETA TENUIFOLIA | CHING CHIEH |

There are numerous books that explain the use of these herbs in Chinese medicine, but we must also look to European and other texts, in order to obtain a clear picture of the ingredients used.
There are too many references to give a full account of the evidence, a flavour of the literature follows:-

Grieve \(^{13}\) in her book says that the antiscorbutic properties make the herb very useful for boils, scurvy and rheumatic conditions. Its demulcent nature makes it very useful as an external wash for ulcers and scaly skin disorders. From the seeds both a medicinal tincture and a fluid extract can be prepared which are of a benefit in chronic skin diseases.

In the Lawrence review of Natural Products \(^{14}\) says that the herb has been used since the Middle Ages. Tinctures have been used to treat skin disorders (acne, boils, eczema). Recent studies suggest that the plant may contain compounds that play a role in suppressing cell mutation and chromosomal aberrations.

Leung \(^{15}\) gives a comprehensive break down of the constituents in his book. It has been reported that burdock has antipyretic, antimicrobial and antitumour activities. It is reportedly useful in cosmetic and toiletry preparations for its alleged skin cleansing properties. Folk medicine has used burdock for treating cancers. Externally it has been used for skin problems (e.g. eczema, scaly skin etc.) Chinese have used the herb for centuries to treat measles, sores, abscesses etc.

Reid \(^{12}\) refers to the plant as Niu Bang Zi in Chinese. It is a member of the Compositae family, and found in Northern China, and Europe. The seeds are used, sometimes the root. Effects: Antipyretic, antiphlogistic; diuretic; expectorant; anti-toxic. A tincture of the seed applied topically is effective in curing psoriasis inveterata, haemorrhoids and chronic sores.

Mindell \(^{16}\) says natural healers revere this herb as nature's best 'blood purifier', that is they believe that it rids the body of dangerous toxins. It is reputed to be helpful for the soreness and swelling caused by arthritis, rheumatism, sciatica and lumbago. Used externally, it is considered a major natural treatment for skin problems such as eczema, psoriasis and even mouth ulcers. Burdock is also soothing for haemorrhoids.

I. Morelli, E. Bonari, A.M. Pagni and P.E. Tomei \(^{17}\), also F. Menichini give an account of the chemical composition.

\[
\text{Arctiol}
\]
Its leaves contain eremophilene, fukinone, dehydrofukinone, fukinanolide, petasitolone, \( \beta \)-eudesmol, arctiol, taraxasterol and its acetate and palmitate.

![Fukinone](image)

Seeds have been reported to contain lignans lappaol A, B, C, D and E; arctiin, arctigenin and metairesinol. Roots contain gamma-guanidobutyric acid and 14-polyacetylene compounds with trideca-1,11-dien-3,5,7,9-tetratetryne (50%) and tridec-1-en-3,5,7,9,11-pentayne together with trideca-1,3,11-trien-5,7,9-triyne (30%) as the main components. Inulin (about 50%), arctic acid, germacrolide, and chlorogenic acid are also present.

![Arctiin](image)

This herb is reported to have diuretic, diaphoretic, cholagogue, and aperient activites, as well as being a stimulant to gustatory nerves. It is indicated in cutaneous eruptions, rheumatism, cystitis, gout, and anorexia nervosa. It is also used for eczema, especially in the dry and desquamatory phase, and psoriasis.

Keys \(^{11}\) reports that the seeds and roots are officinal. The seeds contain arctiin, arctigenin, gobosterin, essential oil, fatty oil; the root contains 40-70% inulin, lappine, the bitter principle lappatin, resin, essential oil, tannin. The root promotes all the secretions and is considered aperient, diuretic, and diaphoretic without irritating qualities; it has been used in rheumatism, gout, pulmonary catarrh, and in chronic cutaneous affections; as an alterative in syphilis and scrofula; as an external application to swellings, haemorrhoids, chronic sores; a tincture of the seed has proved efficient as stomachic tonic, and has cured many cases of psoriasis inveterata.

Hong-Yen Hsu \(^4\) refers to the plant as Niu Pang Tzu. Arctii Fructus is a general drug recorded in *Ming I Pieh Lu* (A.D. 500). Its chemical components are arctiin and fatty oil. It has antitoxic, antipyretic, diuretic, and diaphoretic actions. Chinese medicines uses it for the common cold, cough, swelling and pain in the throat, swelling carbuncles and measles.
LIQUORICE
\textit{Glycyrrhiza uralensis}

Bone\textsuperscript{18} says that liquorice is one of the most widely used herbs by practitioners of western herbal medicine, and is also a major herb of Chinese, Kanpo and Ayurvedic traditions. It also has a long history and was used by the ancient Chinese, Egyptians and Greeks.

A wide variety of activities have been found for the plant, including the development of a major anti-ulcer drug. Studies have also revealed new information about the biochemistry of steroid hormones.

It contains 2-9\% of an intensely sweet saponin known as glycyrrhizin, glycyrrhetinic acid, the aglycone of glycyrrhizin is also present in the root at levels of 0.5-0.9\%. Liquorice also contains a large quantity of flavanoids which impart the characteristic yellow colour to the root. Liquiritin is the main flavanoid glycoside naturally present in the root, but on heating is converted to isoliquoritigenin.

Glycyrrhetinic acid and the aglycone of glycyrrhizin were investigated as anti-inflammatory agents because of their ulcer healing properties, and these effects were demonstrated on a number of animal models. The anti-inflammatory mechanism is not understood. Glycyrrhetinic acid was found to have similar anti-inflammatory activity to hydrocortisone in experimental arthritis in normal rats and it is used in France for rheumatoid arthritis.

A recent Russian study has shown an anti-inflammatory action on skin for a liquorice extract which was similar to a 0.5\% prednisolone liniment. An ointment containing crude liquorice powder gave good results in the treatment of chronic eczema and this has been confirmed by a Russian study.

Schauenberg and Paris\textsuperscript{19} report it contains a saponoside, glycyrrhizine (50-60 times sweeter than sugar); glycyrrhizic acid in the form of its calcium and magnesium salts, flavonoids, liquiritoside and isoliquiritoside, and steroid hormones (oestrogens) which activate the ovaries. The glycyrrhizic acid acts as an anti-inflammatory.
Merck describes the content as 6-14% glycyrrhiza, asparagin, sugars and resin and cites its therapeutic use only as a flavour for pharmaceuticals. It is the anti-inflammatory action of the glycyrrhitinic acid component of liquorice that has led to the preparation of special forms of the extract. It is especially the 18-ß-configuration of the different glycyrrhitinic acids that exhibit a measurable anti-phlogistic activity.

In clinical tests performed by the Faculty of Pharmacy at the University of Aix-Marseilles on a wide range of skin syndromes including solar erythema, seborrheic inflammation of the facial skin, irritation of the armpits after depilation, shaving or the application of alcoholic deodorants, irritation or inflammation of the inner sides of the thighs, after-shave irritation of the throat, chapped lips, insect stings and anal itching, it was unmistakably evident, as measure against a blind control, that a product containing glycyrrhitinic acid had a distinct soothing and anti-inflammatory effect.

Trease and Evans say that Manchurian liquorice is derived from *G. uralensis*. It bears a chocolate brown exfoliating cork and differs from *G. glabra* in internal structure. It appears to contain as much glycyrrhizin as the other varieites, and a number of triterpene acids have been characterised after methylation and hydrolysis of the extract.

Only traces of sugar are present and it gives an unpleasantly pungent extract. As with *G. glabra* the yellow colouring matter contains the flavonoid glycoside liquiritin and a new glycoside involving liquiritigenin, apiose and glucose. *G. hirsuta* is also used in the USSR and a number of other species (*G. echinata*, *G. macedonia*, *G. pallidiflora*) have recently been investigated by Russian workers.

Liquorice owes most of its sweet taste to glycyrrhizin, the potassium and calcium salts of glycyrrhizinic acid. Glycyrrhizinic acid is the diglucopyranosiduronic acid of glycyrrhetic (glycyrrhetinic) acid, which has triterpenoid structure. Work in Italy and Russia has resulted in the isolation of other hydroxy- and deoxytriterpenoid acids, which are related to glycyrrhetic acid; the C-20 epimer of glycyrrhetic acid has been isolated and named liquiritic acid.

The yellow colour of liquorice is due to flavonoids. The paper goes on to discuss further complex materials present in the root.

Liquorice has long been employed in pharmacy as a flavouring agent, demulcent and mild expectorant. Gibson in a summary of the uses of liquorice from 2100 B.C. points out that many of the early claims for a broad spectrum of uses for this drug appear to be borne out by modern pharmacological research; a view which has been furthe substantiated during the last decade. The recognition of the deoxycorticosterone effects of liquorice extracts and glycyrrhetinic acid has led to its use for rheumatoid arthritis, Addison's disease and various inflammatory conditions. Interestingly, the flavonoid component of the root, which possesses antimicrobial properties also exerts spasmolytic and anti-ulcerogenic activity. Unlike cortisone, liquorice may give symptomatic relief from peptic ulcer pain. It has recently been reported that glycyrrhizin gel can act as a useful vehicle for various drugs used topically; not only are the anti-inflammatory and antiviral effects relevant but also glycyrrhizin enhances skin penetration by the drug.
Leung 22 refers to the plant as Gancao and is of various *Glycyrrhiza* spp where the roots are used. It is anti-inflammatory, antiallergic, antihistaminic, detoxicant, promotes flesh growth, good for burns, itching, chapped skin and skin rashes.

The Pharmaceutical Journal 23, The Medicinal and Aromatic plants section of the International Pharmaceutical Federation held a symposium on recent developments in plant research on 17.09.93 during the FIP congress in Lyons, France. The topical route, as opposed to the systemic route, was of increasing relevance to anti-inflammatory therapy. Prof. Roberto Della Loggia (Institute of Pharmacology and Pharmacognosy, University of Trieste) told the symposium.

In the case of glycyrrhetic acid (from *Glycyrrhiza glabra*), the free molecule and its phytosome appeared to have the same potency, similar to hydrocortisone. However, if the whole time course of the inflammatory reaction was followed, indomethacin or glycyrrhetic acid lost their activity after six hours, whereas the latter's phytosome was still able to inhibit the inflammatory response after 24 hours.

**THE ASSISTANTS**

**CHINESE ANGELICA**

*Angelica sinensis*

Leung 14 says that it is vasodilatory, anti-inflammatory, invigourates/nourishes the blood, removes dark spots on the skin, is good for chapped skin, hand and facial wrinkles.

**REHMANNIA**

*Rehmannia glutinosa*

Tang and Paris 10 say that the root is used (fresh or oven dried). The meridians are the heart, liver, kidneys. The taste is sweet. It is used to counter the cold in blood. For a macula or dark spot on the skin

Reid 12 refers to *Rehmannia glutinosa* as Gan Di Huang in Chinese. It is a member of the Scrophulariaceae family, and found in Northern China. The roots are used. It is demulcent; haemostatic; diuretic.

In data sheet from Ikeda through S. Black Ltd. we learn that the components sitosterol and β-mannitol are identified. Catalpol, an iridoid glycoside is also present.
It also contains eight types of sugars, amino acids like mannitol, arginine etc., and phosphoric acid.

ANEMARRHENA
_Aнемаррена асподелойдес_ Бунге

The root-like stem of the perennial herb _Anemarrhena asphodeloides_ Bunge of the Liliaceae family is used. Its chemical components are saponin, asphonin, sarsapogenin, maykogenin, neogitogenin, and timosaponin. It has tonic, anti-inflammatory and sedative effects.

ATRACTYLIS
_Atractylis macrocephala_ or _Atractylodes macrocephala_

It is used for "damp-heat" injuries; aching joints and muscles, swelling and pain in feet and legs, weakness and sluggishness. (Other species include _Atractylis lancea, A. chinensis, A. lyrata, Acraria chinensis, Atractylodes ovata, A. lancea, A. lyrata_ etc.).

AKEBIA
_Akebia quinata_

_Akebia quinata_ is a creeping woody vine, with monoecious flowers; odoriferous, perianth petaloid, purplish brown. Eastern China, Japan. (Syn. _Rajania quinata_ Thunb.). The taste is pungent. The plant contains the crystalline alkaloid akebin, which hydrolyses to yield hederagenin, rhamnose and oleanolic acid; and 30% potassium salts. Prescribed as an antiphlogistic.

Reid 12 says that the stems are used, which he confirms are antiphlogistic. Used for abscesses on tongue and mouth, pain and swelling in feet and legs.

It is a general drug recorded in _The Herbal by Shen Nung_ (A.D. 25-220). Chinese medicine often uses Akebiae Caulis as a diuretic for oedema, urethritis, nephritis, and cystitis. Its principal chemical constituents are akebin, hederagenin and oleanolic acid.

**DIRECTIONAL HERBS**

SILER
_Siler divaricatum_ Benth. et Hook

The roots are used medicinally. They occur as yellowish brown, 15 cm long by 1 cm in diameter, crowned at the tip with fragments of the stem. The taste is sweet and aromatic. Used as antipyretic and analgaesic.

CICADA
_Cryptotympana pustulata_ (Cicadidae)

It is an insect called Chan Tui in Chinese. It is a member of the Cicadidae family, and found in China, Taiwan and Japan. The exuviae are used (molting). Antipyretic; antispasmodic, used for "wind-heat" injuries.
Windridge 5 refers to Cicada as Cryptotympana pustulata. Medicine. Distribution: China, Taiwan, Japan. Parts: exuviae (moultings). It is an antipyretic and used for wind-heat injuries.

Hong-Yen Hsu 4 refers to the plant as Chan Shui. Cicadae Pellicula, a commonly used drug first recorded in Ming I Pieh Lu (A.D. 500), but refers to the dried exuviae of Cryptotympana atrata Fabr. of the Cicadidae family. Chinese medicine also recognises this species for its antipyretic and antispasmodic effects.

SOPHORA
Sophora flavescens

The root is used to produce an extract that is antibacterial, beautifying and fairing, promotes hair growth, and has sun protection factors 24. It is classified as one of the middle class drugs in the first Chinese herbal Shen nung Pen ts'ao King. Sophora has been used as an antipyretic, diuretic and warming remedy since olden times. The name Kurara derived from kuramu meaning getting dizzy, was due to the dizziness felt when licking the root juice.

As a household medicine, decoction of sophora is used for exterminating hair lice and noxious insects and externally for eczema or parasitic dermal lesions. So sophora is also called uji-koroshi or maggot killer and haetori-gusa or fly-catching grass.

In Chinese medicine, sophora is used as an insect repellant, as well as for bitter stomach strengthener, antipyretics, and diuretics, while in Japan at the present time, the demand for it is high for materials as household medicine and especially applied as medicament as bathing agent as well as for hair tonics for hair growth promotion and nourishing hair. Sophora is also listed in the Japanese Pharmacopoeia as Kujin.

Hair growth promotion, depression of growth of dermal eumycetes, prevention of dandruff and urtication, and beautifying and fairing effect. The bitter principles of sophora effectively promote hair growth by directly stimulating the hair root and promoting the blood stream around the hair root.

At the lower concentration, sophora extract exerts antibacterial activity against P.ovale, a bacterium continually present in dandruff, to depress dandruff and urtication. There is also an ingredient that has a potent restriction against tyrosinase activity, thus exerting beautifying effect by preventing spots and freckles.

Sophora is reportedly found to increase the skin temperature and shorten the recovery time when conducted in skin patch test using rabbits to check the recovery time of the surface temperature of the skin changed with chilly cold.

The minimum concentration to inhibit P.ovale and P.orbiculare was found to be 0.4% and 0.6% respectively. It was also found to be effective to restrict 90% of the tyrosinase activity at the concentration of 5%.

Contains matrine, oxymatrine, sophoranol, anagyrine, lupin alkaloids (e.g. matrin, oxymatrine etc.) are marked as the main pharmacologically active constituents.
Reid refers to the plant as Ku Shen in Chinese. It is a member of the Leguminosae family, and found in China. It is antipyretic, drying, anthelmintic. It is indicated for "damp-heat" ailments; vaginal infections, sores and itchy skin, allergic reactions, leprosy. Used internally and externally, the drug is an excellent remedy for sores, pruritis and other skin ailments.

**HARMONISING HERB**

**SCHIZONEPETA**
*Schizonopeta tenuifolia* (Benth)

The details of this species comes from the William Gardener Collection on Chinese Plants, which will (hopefully) be published in 1996 in memory of his extensive work on Chinese Medicinal plants.

*Schizonopeta tenuifolia* (Benth). Briq. (*Nepta tenuifolia* Benth.; *Elsholtza tenuifolia* Benth.; *Nepeta vaniotiana* Levl.), Labiatae. A low stylish annual herb, coarsely textured, slightly hairy, 0.3-1m. in height disclosing a lively perfume. The leaves are trilobed, or on occasion more, 1-3.5cm. long and 1.5-2.5cm, broad, the lobes themselves being 1.5-4mm. broad. The inflorescence is a spike carrying a succession of many-flowered whorls, or verticillasters, bearing purple corollas.

Distribution is in all provinces of north-eastern China, and westward as far as Kokonor, and then down the western side of the country. It is much cultivated, and cultivation extends to the province of Yunnan in the south-west and of Zhejiang on the coast, below the Yangtze estuary. In the wild it is to be found besides forests and roads, and in wasteland and dry watercourses, at altitudes of 540-2,700m. Roadside appearances could well be escapes from cultivation.

The species is happiest in a damp, warm, rich environment, where it can take up much water and is food for draining the soil, and development is then very rapid. Cultivation on a rich fertile soil of a sandy nature leads to excellent results. The whole plant contains a fragrant volatile oil. The principle constituents are menthol and limonene. Elsewhere menthone and d-limonene are given as constituents.
Medicinal use is at least as old as the culinary 28, and the plants is still employed in a variety of conditions. Among skin complaints, it is said to be useful in nettle-rash (urticaria), scrofulous swellings and painful swellings generally, and weeping pustules of infected scores. Feverish influenza, and the cold spell that precedes fever (malaria for example), and measles in early stages to bring out the rash, wherein the spike alone, that carries the flowers, is said to possess greater power 29.

Still another concerns the blood-nose-bleed, haematemesis, blood in the stool, menorrhagia, and dizziness resulting from post-partum loss of blood, and regulating the blood generally 26, 27, 30.

**SESAME**
*Sesamum indicum*

Harry 31 says that sesame seed oil may be used as a substitue for olive and other oils in cosmetic creams, anti-wrinkle oils, massage and lubricating creams. Sesame seed oil is emollient and possesses the lubricating properties common to other vegetable oils. Dermatologically it is innocuous and is neither a primary irritant nor a sensitiser.

Potter 32 says that it is known as sesame, sesam, gingelly or benne. It is indigenous to India, but cultivated in other warm climates. The leaves and the seeds are used. It is demulcent and laxative. The Indian natives steep a leaf or two in water and drink the resulting mucilage freely. Externally they also apply this in ophthalmic and cutaneous complaints.

Keys 11 says that sesame is an annual herb 1 m tall. The flowers are axillary, solitary, white with yellow or red spots. Fruit is an oblong capsule, prismatic, with 4 ribs, 2.5 cm long by 6 mm wide. Tropical Asia; cultivated in warm regions of the Old and New World. (Syn. *Sesame orientale*)

The seeds are officinal, and two varieties exist, one black and the other white. They occur as compressed, oval, nearly smooth, 3 mm long. The seeds contain 45-58% fatty oil (comprising 47% olein, 35% linolein, 9% palmitin, 6% stearin, myristin), a resinous principle sesamin, sesamol, pentosan, phytin, lecithin, choline, 1% calcium oxalate, chlorogenic acid, vitamins A and B.

Sesame oil is employed externally to soften the skin, as well as a dressing for burns, and a vehicle for liniments.
REASONS FOR SUCCESS

The reasons for the success of this ancient remedy are many. It can be seen that the various plants have a proliferation of activities that would address many aspects of the healing process, all of which are stimulated by a broad range of different actives contained within the plants.

Thus, looking through the key words mentioned for each plant one finds demulcent, antipyretic, antitoxic, antiphlogistic, anti-inflammatory, antipruritic, antulcer, haemostatic, antispasmodic, antibacterial and other skin regulating activities.

Such a formula need not be used purely for the remedial action, but could be used at a lower concentration for a protective effect in the care and maintenance of healthy skin.

Looking at further existing research, Whittle had already taken a single product through an impressive level of clinical trials with a traditional Chinese remedy for atopic eczema (not the one detailed in this paper). The author has taken a similar formulation through the same bibliographical examination as already demonstrated and shown the composition to be technically sound from a theoretical viewpoint.

Hardman 34 summarising the proceedings of a recent conference said in summary of Whittle's presentation that unlike ‘magic bullets’ for specific bacteria, many diseases, particularly those which involve disorders of the immune system, required treatment with a number of therapeutic agents, because few diseases were based on a single pathological effect. Traditional Chinese prescriptions, by a process of trial and error over a period of hundreds, sometimes thousands of years had demonstrated their efficacy and safety.

To treat long-standing steroid-resistant eczema, it was necessary to hit several inflammatory mediators simultaneously and to assist the immune system. The complex formulation contained elements which were chemically related to corticosteroids; adrenocortical stimulants; inhibitors of 11-ß hydroxy steroid dehydrogenase; others showed NSAID activity; others antioxidant activity.

Those who criticise Chinese traditional medicine, because it uses a quaint and picturesque language to describe its effect, had better look very carefully at the science of the constituents, before they voice a judgement.
2. ANOTHER HISTORICAL FORMULATION

Formula from Physicians of Myddvai

Pughe 33 mentions a formula to be used as a healing ointment. The Physicians of Myddvai were 12th Century healers from Wales, U.K.

"Take avens, violet, daisy, bugle, ribwort plantain and feverfew; pound and boil them well with fresh butter, and strain. keep it for it is useful."

Notice again, how the use of numerous components is commonplace. The full and exhaustive study of each component will not be undertaken in this particular formula, because we have already demonstrated that such a study is possible in the Chinese remedy. However, the data does exist for each plant component of this formula and, in total, would account for many dozens of pages.

Those plants which have the suffix "wort" are normally medicinal herbs, which have been used for centuries e.g lungwort, liverwort, eyewort etc., and it is not uncommon to find more than one plant that has the same name. Bruisewort not only applies to Daisy (Bellis perennis), but also to Soapwort (Saponaria officinalis) and Comfrey (Symphitum officinale).

Avens (Geum urbanum) or Colewort is anti-inflammatory, astringent and traditionally used for skin problems. Violet (Viola tricolor) used traditionally for eczema and other cutaneous disorders, relieves inflammation, antipruritic and anodyne (soothes pain). Daisy (Bellis perennis) or Bruisewort reduces bruising and swelling, used for suppurating wounds, furuncles and boils etc. Bugle (Ajuga reptans) or Sicklewort is a haemostatic and was used to stop bleeding caused by cuts. Ribwort Plantain (Plantago lanceolata) is antipruritic, haemostatic, anti-inflammatory and anodyne. Feverfew (Tanacetum parthenium) soothes swellings, anti-inflammatory and soothing on insect bites.

Perhaps their use of butter might cause a few problems with some purists, however, in the 12th Century, the knowledge of emulsions was not understood, and so the use of animal fats, milk and butter was very often the only way to make a topical emollient or ointment.

The use of these materials in modern herbalism either alone or in combination, would not present a problem to those practitioners.

Thus it can be seen that the principle of using numerous plants in combination to produce an efficacious remedy can be found throughout history, and similar explorations can be made on ancient Egyptian recipes, recipes employed by the American Indians, traditional tribal African blends and so forth.

Indeed, many exciting possibilites for new emollients, new waxes, new active materials for the cosmetic industry are coming from these researches, whilst the pharmaceutical industry is finding new and intriguing sources of complex chemical molecules from the study of plant taxonomy.
3. A MODERN FORMULATION REGIME

Returning our thoughts to the various stages of healing, it did not seem unreasonable to propose that the use of a regime of products that would cater for each of those stages could be developed. It also occurred to us that it did it seem unreasonable to propose that a single product could be developed which contained all the medicinal plant elements necessary to address each of the functions required for a particular stage to be successful.

It is also useful to remember, that those preparations that can aid in a healing process, can also act in a protective capacity, when used at lower concentrations. There is also the thought, that continual use of a single product can result in the skin becoming accustomed to that product and that skin benefit might decrease with time. The use of a suite of products should overcome these problems, especially in recurring conditions such as psoriasis.

The three products in one particular suite are not intended as skin care products, but are intended as post surgical cosmetics. The principle and function of the first product is described.

The experimental product

This product is a cooling and soothing gel to improve the comfort of the skin, to relieve inflammation and to help in the healing process. It helps maintain the normal moisture balance in the skin, whilst providing an ideal environment for skin healing during granulation.

A special form of *Aloe barbadensis* Miller (100%) and a humectant are the principle ingredients, to which are added plants that specifically target:-

- an increase in the microcirculation of the skin, particularly the blood capillaries
- an improvement to the drainage of lymphocytes
- a reduction in inflammation
- an antipruritic action
- protection of the site from external organisms.

The additional fresh plant materials account for 20% of the formula, making the total plant loading 120% (achieved by the removal of water from the plant components).

The other products in the suite are based on the same ideal, that targets specific skin functions.

MOISTURISATION

CORNEOMETER ASSESSMENT

Product #1, #2 and #3 were tested using a leading pharmaceutical moisturising cream as a control.

METHOD USED
The template was placed on the forearm of the test subject and secured. The base of the hand was used as a guide to initial positioning and the application areas marked onto the skin. Into each zone were placed the test materials.

Nearest the wrist was placed Product #1, the second contained Product #2, the third from the wrist was Product #3, the fourth was the control cream. The fifth zone was left untouched as an untreated control. Twenty five panellists were used.

The corneometer was used to take five readings from each of the zones and the readings averaged. Hair in the path of the measurement probe generally had an effect on the result and so was avoided.

The measurements were taken immediately after application, at 3 hours following application and finally at 24 hours following application. The procedure was repeated for a four day period, with products being applied immediately after the 24 hour period.

**RESULTS**

See figure 1 for moisturisation measurements.

In order to simplify the handling of the data the results were averaged for each set of results.

**Time of application**

The immediate results showed that at the time of application (time = 0). The effectiveness immediately after application showed Product #1 was better than Product #2 was better than Product #3 was better than the control was better than the skin untreated.

**3 hours after application**

The results after 3 hours showed that the order of moisturisation was Product #3 better than Product #1 and Product #2, which were both better than the control which was better than untreated skin.

**24 hours after application**

Products #1, #2 and #3 were all better than the control, which was better than untreated skin. There is an indication that the moisturising capability of Product #3 is increasing with time, and this is the subject of further experimentation and investigation.

**Repeat testing**

The results show four sets of 3 hour experiments, which refer to day 1, 2, 3 and 4, when the product was reapplied, similarly there are three 24 hour, which refer to the results after each day of application. The reproducibility of the results was encouraging.

Extended tests over a longer trial period is anticipated, these results were "hot off the press" for the conference!
From this study, it is seen that all of the products in the range increase the moisture content of the skin, and that they are all more efficient at this task than the most frequently provided pharmaceutical cream.

We also believe that these products will prove to have a beneficial effect in the overall physiological condition of the skin, and this will be the subject of a clinical trial in the near future.

**Volunteer study**

The next study, though not a scientific admission of evidence, was conducted with a panel of volunteers who were asked to use each product in the regime for 3-4 months. They were post surgical patients who had suffered traumatic scarring (ranging from 1-20 years post operative).

Each volunteer was given a diary, the first page to describe the condition of there skin and any conditions that bothered them (such as itching, soreness, tautness, etc.). They were then instructed in the information on how to use the regime. No personal contact was made with the volunteer.

The volunteers then used the products in place of their normal moisturisers or recommended pharmaceutical cream (having obtained permission from their doctor or physician) in the manner recommended. Each week they reported on the condition of their skin and wrote their
The following responses were received:-

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>scar fading</td>
<td>20%</td>
</tr>
<tr>
<td>moisturising</td>
<td>20%</td>
</tr>
<tr>
<td>softening</td>
<td>60%</td>
</tr>
<tr>
<td>skin comfort</td>
<td>20%</td>
</tr>
<tr>
<td>relief of itching</td>
<td>25%</td>
</tr>
<tr>
<td>soothing</td>
<td>25%</td>
</tr>
<tr>
<td>pleasing, pleasant</td>
<td>65%</td>
</tr>
<tr>
<td>supleness</td>
<td>25%</td>
</tr>
<tr>
<td>smoothness</td>
<td>40%</td>
</tr>
</tbody>
</table>

As might have been expected, those patients who were more than ten years post operative, benefitted less than the more recent cases.

CONCLUSIONS

The use of multi-component formulae is justified from a scientific argument, but will continue to meet opposition from the regulatory authorities. Where plant data has been given in reference, this only accounts for a small fraction of the data available, and should serve only to give a "flavour" of the information available.

This paper has put forward a view, that will undoubtedly be challenged and hopefully open up a debate in the future.
REFERENCES


14. The Lawrence review of Natural Products. Copyright 1994 by Facts and Comparisons (ISSN 0734-4961). 111 West Port Plaza Suite 400, St. Louis, Missouri 63146-3098.


24. A data sheet from Maruzen Pharmaceuticals (through K&K Greeff)


34. F.I.P. (Federation of International Pharmacy) Medicinal and Aromatic Plants Section. Dr. Roland Hardman (United Kingdom), President of the Section

   A joint symposium with the Section for Community Pharmacists

   Licensed phytomedicines, Lisbon September 1994.
## APPENDIX I

<table>
<thead>
<tr>
<th>Schedule No.</th>
<th>Name of Substance</th>
<th>Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Aconitine and its salts</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Aconitum napellus</td>
<td>Monkshood (leaves, roots and galenical preps)</td>
</tr>
<tr>
<td>13.</td>
<td>Adonis vernalis and its preparations</td>
<td>Adonis</td>
</tr>
<tr>
<td>43.</td>
<td>Ammi majus and its galenical preparations</td>
<td>Bishopsweed</td>
</tr>
<tr>
<td>51.</td>
<td>Anamirta cocculus (fruit)</td>
<td>*******</td>
</tr>
<tr>
<td>57.</td>
<td>Apocynum cannabinum and its preparations</td>
<td>Cannabis</td>
</tr>
<tr>
<td>63.</td>
<td>Atropa belladonna and its compounds</td>
<td>Belladonna</td>
</tr>
<tr>
<td>129.</td>
<td>Calabar bean (see 547)</td>
<td></td>
</tr>
<tr>
<td>130.</td>
<td>Cantharis vesicatoria and cantharides</td>
<td>*******</td>
</tr>
<tr>
<td>144.</td>
<td>Chenopodium ambrosioides (essential oil)</td>
<td>American wormseed oil or Mexican goosefoot</td>
</tr>
<tr>
<td>145.</td>
<td>Cherry laurel water (see 577)</td>
<td></td>
</tr>
<tr>
<td>180.</td>
<td>Claviceps purpurea</td>
<td>Ergot</td>
</tr>
<tr>
<td>187.</td>
<td>Colchicum autumnale and its galenical preparations</td>
<td>Autumn Crocus or Meadow Saffron</td>
</tr>
<tr>
<td>193.</td>
<td>Conium maculatum (fruit, powder, galenical preparations)</td>
<td>Hemlock</td>
</tr>
<tr>
<td>197.</td>
<td>Croton tiglium (oil)</td>
<td>Croton</td>
</tr>
<tr>
<td>212.</td>
<td>Datura stramonium and its galenical preparations</td>
<td>Thornapple or Jimsonweed</td>
</tr>
<tr>
<td>243.</td>
<td>Digitalis purpurea (digitaline and all of its heterosides)</td>
<td>Foxglove</td>
</tr>
<tr>
<td>379.</td>
<td>Hyoscyamus niger</td>
<td>Henbane (leaves, seeds powder and galenical preparations)</td>
</tr>
<tr>
<td>386.</td>
<td>Cephaelis ipecacuanha and related species (roots, powder and galenical preps.)</td>
<td></td>
</tr>
<tr>
<td>396.</td>
<td>Juniperus sabina</td>
<td>Savine (leaves, essential oil and galenical preparations)</td>
</tr>
<tr>
<td>397.</td>
<td>Laurel oil</td>
<td></td>
</tr>
<tr>
<td>398.</td>
<td>Laurus nobilis (oil from seeds)</td>
<td>Laurel</td>
</tr>
<tr>
<td>402.</td>
<td>Lobelia inflata and its galenical preparations</td>
<td>Lobelia</td>
</tr>
<tr>
<td>486.</td>
<td>Nux vomica and its preparations</td>
<td>Quaker Buttons Poisons nuts</td>
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<tr>
<td>547.</td>
<td>Physostigma venenosum</td>
<td>Calabar bean</td>
</tr>
<tr>
<td>549.</td>
<td>Phytolacca spp and their preparations</td>
<td>Poke Root</td>
</tr>
<tr>
<td>553.</td>
<td>Pilocarpus jaborandi Holmes and its galenical preparations</td>
<td>Jaborandi</td>
</tr>
<tr>
<td>577.</td>
<td>Prunus laurocerasus</td>
<td>Cherry Laurel</td>
</tr>
<tr>
<td>579.</td>
<td>Pyrethrum album and its galenical preparations</td>
<td>Pyrethrum</td>
</tr>
</tbody>
</table>
585. **Rauwolfia serpentina**
   alkaloids and their salts
   Indian Snakerooot

589. **Schoenocaulon officinale** Lind.
   (seeds and galenical preparations).
   Sabadilla

596. **Solanum nigrum**
   Black Nightshade
   and its galenical preparations

600. Squill and its preparations (see 649)

603. **Strophanthus** species
   Strophanthus
   and their galenical preparations

605. **Strychnos** species and their galenical preparations

649. **Thevetia neriifolia** Juss.
   Thevetia tree nut
   glycoside extract

696. **Urginea scilla** Stern. (see 600)
   Squill
   and its galenical preparations

700. **Veratrum spp** and their preparations
   Hellebores

703. Vitamin D2 and Vitamin D3
## APPENDIX II

## TRANSLATION OF CHINESE FORMULA

<table>
<thead>
<tr>
<th>Linnean name</th>
<th>Taiwan name</th>
<th>Mandarin name</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Angelica sinensis</em></td>
<td>Tang Kuei</td>
<td>Dong Quoi</td>
</tr>
<tr>
<td><em>Rehmannia glutinosa</em></td>
<td>Ti Huang</td>
<td>Di Hang</td>
</tr>
<tr>
<td>Gypsum</td>
<td>Shih Kao</td>
<td>Shi Gao</td>
</tr>
<tr>
<td><em>Anemarrhena asphodeloides</em></td>
<td>Chih Mu</td>
<td>Zhi Mu</td>
</tr>
<tr>
<td><em>Sesamum indicum</em></td>
<td>Hu Ma Tzu</td>
<td>Hei Zi Ma</td>
</tr>
<tr>
<td><em>Atractylodes ovata</em></td>
<td>Tsang Chu</td>
<td>Cang Zhu</td>
</tr>
<tr>
<td><em>Arctium lappa</em></td>
<td>Niu Pang Tzu</td>
<td>Niu Bang Zi</td>
</tr>
<tr>
<td><em>Siler divaricatum</em></td>
<td>Fang Feng</td>
<td>Fang Feng</td>
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<tr>
<td><em>Akebia quinata</em></td>
<td>Mu Tung</td>
<td>Mu Tong</td>
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<tr>
<td><em>Glycyrrhiza uralensis</em></td>
<td>Kan Tsao</td>
<td>Gan Cao</td>
</tr>
<tr>
<td><em>Cryptotympana atrata</em></td>
<td>Chan Shui</td>
<td>Chan Tui</td>
</tr>
<tr>
<td><em>Sophora flavescens</em></td>
<td>Ku Sheng</td>
<td>Ku Shen</td>
</tr>
<tr>
<td><em>Schizonepeta tenuifolia</em></td>
<td>Ching Chieh</td>
<td>Jing Jie</td>
</tr>
</tbody>
</table>
The Royal Pharmaceutical Society of Great Britain.

Cosmetic means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration.

The Royal Pharmaceutical Society of Great Britain.

Medicinal product means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say:

(a) use by being administered to one or more human beings or animals for a medicinal purpose;

(b) use as an ingredient, by a practitioner or in a pharmacy or in a hospital or in a business comprising the sale of herbal remedies, in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.
**The Consumer Products (Safety) Regulations 1989 SI 2233**

*Cosmetic product* means any substance or preparation intended to be applied to any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs), or to the teeth or buccal mucosa wholly or mainly for the purpose of cleaning, perfuming or protecting them, or keeping them in good condition or changing their appearance or combating body odour or perspiration except where such cleaning, perfuming, protecting, keeping, changing or combating is wholly for the purpose of treating or preventing disease;

**SLIDE 5**

**POTENTIAL PROBLEMS**

1. Variation in plant chemical composition
2. Chemicals within a plant might react together synergistically
3. More than three plants in a formula constitutes "polypharmacy".
4. Historical failures influence future trials
5. A single chemical cannot be held responsible for a single effect

**SLIDE 6**

**THE HEALING PROCESS**

**STAGE ONE**

GRANULATION

**SLIDE 7**

**THE HEALING PROCESS**

**STAGE TWO**

RE-EPITHELIALISATION

**SLIDE 8**

**THE HEALING PROCESS**

**STAGE THREE**

CICATRISATION
AN HISTORICAL FORMULATION

CHINESE TRADITIONAL REMEDY

THE CHINESE PRINCIPLE

THE EMPEROR
THE MINISTERS
THE ASSISTANTS
THE HARMONISERS
THE DIRECTIONAL HERBS

A TRADITIONAL REMEDY

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<tr>
<td>Schizonepeta tenuifolia</td>
<td>Ching Chieh</td>
<td>Jing Jie</td>
</tr>
</tbody>
</table>
THE EMPEROR HERB

BURDOCK SEEDS  *Arctium lappa*

SLIDE 13

THE MINISTERS

LIQUORICE  *Glycyrrhiza uralensis*

SLIDE 14

THE ASSISTANTS

CHINESE ANGELICA  *Angelica sinensis*
REHMANNIA  *Rehmannia glutinosa*
ANEMARRHENA  *Anemarrhena asphodeloides*
ATRACTYLIS  *Atractylis macrocephela*
AKEBIA  *Akebia quinata*

SLIDE 15

THE DIRECTIONAL HERBS

SILER  *Siler divaricatum*
CICADA  *Cryptotympana atrata*
SOPHORA  *Sophora flavescens*

SLIDE 16

THE HARMONISING HERB

SCHIZONEPETA  *Schizonepeta tenuifolia*
SESAME  *Sesamum indicum*

SLIDE 17

ANOTHER HISTORICAL FORMULATION

PHYSICIANS OF MYDDVAI

"Take avens, violet, daisy, bugle, ribwort plantain and feverfew; pound and boil them well with fresh butter, and strain. Keep it, for it is useful."

SLIDE 18
A MODERN FORMULATION

A SKIN REGIME

SLIDE 19

MOISTURISATION
CORNEOMETER ASSESSMENT

SLIDE 20

VOLUNTEER STUDY
SPONTANEOUS RESPONSES

scar fading 20%
moisturising 20%
softening 60%
skin comfort 20%
relief of itching 25%
soothing 25%
pleasing, pleasant 65%
suppleness 25%
smoothness 40%