

# FINAL REPORT

## September 10, 1999

### Safety Assessment of Wild Yam (*Dioscorea Villosa*) Extract

#### ABSTRACT

*Wild Yam (Dioscorea Villosa) Extract is an extract of the rhizomes of the wild yam, D. villosa prepared by cutting up, grinding, and extracting with water and denatured alcohol. The water and alcohol are removed by distillation and the residue diluted to strength, usually in propylene glycol, but other solvents can be used. The extract contains glycoside and steroidal saponins, diosgenin, alkaloids, tannins, phytosterols, and starch. Levels of heavy metals, 1,4-dioxane, chloroform, methylene chloride, trichloroethylene, and benzene are reported to be below limits of detection. While only one use was reported to the U.S. Food and Drug Administration (in a body and hand preparation), industry reported uses in body and hand creams, lotions, powders, and sprays and in moisturizing creams, lotions, powders, and sprays at concentrations ranging from 0.00001 to 15%. The concentrations of plant solids ranged from 0.000002 to 0.5%. Preparations from D. villosa are used in herbal medicine for treatment of a variety of ailments and by the pharmaceutical industry in the preparation of steroids. No safety test data was available on Wild Yam (Dioscorea Villosa) Extract. Likewise, information was not available on the presence of contaminants other than those listed above, on the quality control processes used in manufacturing this material, or on the specifications established for the various components that may be extracted. Concern was expressed that this material may have estrogen-like or progesterone-like activity, which would not be considered safe in cosmetic formulations. The CIR Expert Panel concluded that the available data are insufficient to support the safety of this ingredient in cosmetic formulations. The data needed (on cosmetic grade material) include: (1) presence of contaminants and quality control issues and specifications; (2) gross pathology and histopathology in skin and other major organ systems associated with repeated dermal exposures; if these data show significant absorption, then dermal developmental and reproductive toxicity data at concentration of use may be needed; (3) skin irritation and sensitization data at concentration of use; and (4) two genotoxicity studies, one using a mammalian system; if positive, a 2-year dermal carcinogenicity assay performed using NTP methods may be needed. If this ingredient is used in cosmetic formulations, it should not deliver any metabolic/endocrine activity.*

#### INTRODUCTION

Wild Yam (*Dioscorea Villosa*) Extract is an extract of the rhizomes of the wild yam, *Dioscorea villosa* (Wenninger and McEwen, 1997). Wild Yam (*Dioscorea Villosa*) Extract functions as a skin conditioning agent and a miscellaneous skin conditioner; other uses are "trade secret" (Cosmetic, Toiletry, and Fragrance Association [CTFA], 1999a).

# CHEMISTRY

## Definition

Wild Yam (*Dioscorea Villosa*) Extract (CAS No. 90147-49-2) is an extract of the rhizomes of the wild yam, *D. villosa* (CTFA, 1999a; Wenninger and McEwen, 1997). Wild Yam (*Dioscorea Villosa*) Extract is also known as Colic Root Extract; Extract of Colic Root; *Dioscorea Villosa* Extract; Extract of *Dioscorea Villosa*; Wild Yam Extract; and Extract of Wild Yam (Wenninger and McEwen, 1997). *D. villosa* is also known as wild yam (Polunin and Robbins, 1992), Mexican wild yam (Ritchason, 1995; Ody, 1993), colic root, rheumatism root (Ritchason, 1995; Polunin and Robbins, 1992), and devil's bones (Ritchason, 1995). Other common names include Mexican yam, Atlantic yam, China root, and yuma (CTFA, 1999a).

## Physical and Chemical Properties

Wild Yam (*Dioscorea Villosa*) Extract has a pH of 4.0-6.8, refractive index of 1.362-1.47 (25°C), and specific gravity of 0.90-1.06 (25°C) (CTFA, 1999a).

## Manufacture And Production

Wild Yam (*Dioscorea Villosa*) Extract is prepared by grounding and cutting the dried rhizomes/root and extracting this material with water/alcohol (denatured) (CTFA, 1999a). The plant material is extracted by maceration or percolation with solvents, and the maceration process generally lasts 3 or more days. The solvents and extractibles are filtered. The water and alcohol can be removed by distillation and the remaining material is diluted to strength with the solvent of choice (usually propylene glycol, but butylene glycol, glycerin, water, vegetable oil, or alcohol can be used).

## Analytical Methods

Published data on the analytical methods used to determine Wild Yam (*Dioscorea Villosa*) Extract were not found.

## Composition/Impurities

Wild yam (*D. villosa*) contains glycoside saponins (Mowrey, 1986), steroidal saponins, diosgenin, alkaloids, tannins, phytosterols, and starch (Ody, 1993).

At a concentration of 1-2% plant material, Wild Yam (*Dioscorea Villosa*) Extract contained 0.4% steroidal saponins (CTFA, 1999a). The concentration of other components of raw material in Wild Yam (*Dioscorea Villosa*) Extract as sold to the trade is 97-99.5% solvents. The other components included the solvents water:alcohol, propylene glycol, propylene glycol:water, butylene glycol, butylene glycol:water, glycerin, glycerin:water, safflower oil, and vegetable oil and 1% of preservatives phenonip or phenoxyethanol. Other contaminants are not known, but the following are below the limit of detection: 1,4-dioxane (<50 ppm), benzene (<50 ppm), chloroform (<25 ppm), methylene chloride (<50 ppm), trichloroethylene (<50 ppm), heavy metals, i.e. lead (<20 ppm), arsenic (<3 ppm), and iron (<100 ppm).

## Ultraviolet Absorption

Wild Yam (*Dioscorea Villosa*) Extract had very low absorption at short wavelengths (CTFA, 1999a). Complete absorption data for the UVA wavelengths were absent.

# USE

## Cosmetic

Wild Yam (*Dioscorea Villosa*) Extract is reported to function as skin conditioning agent; other uses are "trade secret" in cosmetic formulations (CTFA, 1999a). The product formulation data submitted to the Food and Drug Administration (FDA) in 1998 reported that Wild Yam (*Dioscorea Villosa*) Extract was used in one cosmetic formulations, a body and hand preparation (FDA, 1998).

Data submitted to CTFA reported the concentration of plant material in raw material as sold to the trade as 0.5-2% (CTFA, 1999a). Concentration of use information stated that the maximum concentration of Wild Yam (*Dioscorea Villosa*) Extract used in body and hand creams, lotions, powders, and sprays (excluding shaving preparations) was 0.00001% (0.000002% maximum solids from Wild Yam) and of the Extract used in moisturizing creams, lotions, powders, and sprays was 15% (0.5% maximum solids from Wild Yam) (CTFA, 1999b).

## International

Wild Yam (*Dioscorea Villosa*) Extract is not listed in the Japanese *Comprehensive Licensing Standards of Cosmetics by Category* (Rempe and Santucci, 1997). It does not appear in Annex II (list of substances which must not form part of the composition of cosmetic products) or Annex III (list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down) of the Cosmetics Directive of the European Union (European Economic Community, 1995).

## Non-cosmetic

*D. villosa* is used in herbal medicine for treatment of rheumatic diseases, colic, inflammation of the colon, cramps, intermittent claudication, menstrual cramps, and ovarian and uterine pain (Polunin and Robbins, 1992). *D. villosa* root is used in the preparation of steroids by the pharmaceutical industry.

# GENERAL BIOLOGY

Published data on Wild Yam (*Dioscorea Villosa*) Extract normally summarized in the "General Biology" section, including absorption, distribution, and metabolism were not found.

## ANIMAL TOXICOLOGY

No published data on the toxicity of Wild Yam (*Dioscorea Villosa*) Extract, including dermal irritation and sensitization, phototoxicity, and ocular irritation, were found.

# REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Published data on the reproductive and developmental toxicity of Wild Yam (*Dioscorea Villosa*) Extract were not found.

# GENOTOXICITY AND CARCINOGENICITY

No published data on either the mutagenic or the carcinogenic potential of Wild Yam (*Dioscorea Villosa*)

Extract were found.

## CLINICAL ASSESSMENT OF SAFETY

Published data on the irritation nor the sensitization potential of Wild Yam (*Dioscorea Villosa*) Extract were not found. Anecdotal information on the use in herbal medicine was not considered.

## SUMMARY

Wild Yam (*Dioscorea Villosa*) Extract, an extract of the rhizomes of the wild yam, *D. villosa*, was reported in 1998 to be used in one body and hand preparation. Concentration of use data submitted by industry reported that the maximum concentration of use of Wild Yam (*Dioscorea Villosa*) Extract in body and hand creams, lotion, powders, and sprays and in moisturizing creams, lotions, powders, and sprays was 0.00001 and 15%, respectively (0.000002 and 0.5% maximum solids, respectively, from wild yam.) Wild yam (*D. villosa*), which is used in herbal medicine, contains diosgenin, steroidal saponins, glycosides saponins, alkaloids, tannin, phytosterols, and starch. No other data on Wild Yam (*Dioscorea Villosa*) Extract were available.

## DISCUSSION

The Panel concluded that there were no safety test data available on Wild Yam (*Dioscorea Villosa*) Extract. Likewise, information was not available on the presence of contaminants other than those listed above, on the quality control processes used in manufacturing this material, or on the specifications established for the various components that may be extracted. Concern was expressed that this material may have estrogen-like or progesterone-like activity, which would not be considered safe in cosmetic formulations.

Section 1, paragraph (p), of the CIR Procedures states that "A lack of information about an ingredient shall not be enough to justify a determination of safety." In accordance with Section 30(j)(2)(A) of the Procedures, the Expert Panel informed the public of its decision that the data on Wild Yam (*Dioscorea Villosa*) Extract were insufficient to determine whether Wild Yam (*Dioscorea Villosa*) Extract was either safe or unsafe. The Expert Panel released a 'Notice of Insufficient Data Announcement' on September 11, 1998 outlining the data needed to assess the safety of Wild Yam (*Dioscorea Villosa*) Extract. The remaining data needs include<sup>1</sup>:

1. presence of contaminants and quality control issues and specifications<sup>2</sup>
2. gross pathology and histopathology in skin and other major organ systems associated with repeated dermal exposures; if these data show significant absorption, then dermal developmental and reproductive toxicity data at concentration of use may be needed
3. skin irritation and sensitization data at concentration of use
4. two genotoxicity studies, one using a mammalian system; if positive, a 2-year dermal carcinogenicity assay performed using NTP methods may be needed

<sup>1</sup> all testing is to be on cosmetic-grade material

<sup>2</sup> this ingredient as used in cosmetic formulations should not deliver any metabolic/endocrine activity, e.g., estrogen-like or progesterone-like activity

No offer to supply the remaining data was received. In accordance with Section 45 of the CIR Procedures, the Expert Panel will issue a Final Report - Insufficient Data. When the requested data are available, the Expert Panel will reconsider the Final Report in accordance with Section 46 of the CIR Procedures, Amendment of a Final Report.

# CONCLUSION

The CIR Expert Panel concludes that the available data are insufficient to support the safety of Wild Yam (*Dioscorea Villosa*) Extract for use in cosmetic products.

# ACKNOWLEDGMENT

Monice Zondlo Fiume, Scientific Analyst/Report Management Coordinator, prepared this report.

# REFERENCES

- Cosmetic, Toiletry, and Fragrance Association (CTFA). 1999a. Botanical Cosmetic Ingredient Description for Wild Yam (*Dioscorea Villosa*) Extract. Dated June 28. Unpublished data submitted by CTFA. 2 pp.<sup>1</sup>
- CTFA. 1999b. Product type and concentration of use for Wild Yam (*Dioscorea Villosa*) Extract. Dated July 19. Unpublished data submitted by CTFA. 1 p.<sup>1</sup>
- European Economic Community. 1995. Cosmetics Directive of the European Union. Updated version - Incorporating all amendments until August 1, 1995. Dir. 76/768/EEC.
- Food and Drug Administration (FDA). 1998. Frequency of use of cosmetic ingredient. *FDA database*. Washington, DC:FDA.
- Mowrey DB. 1986. *The Scientific Validation of Herbal Medicine*. New Canaan, Conn:Keats Publishing, Inc, 111-2.
- Ody P. 1993. *The Complete Medicinal Herbal*. New York, NY:DK Publishing, Inc, 52.
- Polunin M, Robbins C. 1992. *The Natural Pharmacy. An Illustrated Guide to Natural Medicine*. New York:Macmillan Publishing Co, 48, 99.
- Rempe JM, Santucci LG. 1997. *CTFA List of Japanese Cosmetic Ingredients*, 3<sup>rd</sup> edn. Washington, DC:CTFA, 9.
- Ritchason J. 1995. *The Little Herb Encyclopedia*, 3<sup>rd</sup> edn. Utah:Woodland Health Books, 248-9.
- Wenninger JA, McEwen GN Jr, eds. 1997. *International Cosmetic Ingredient Dictionary and Handbook*, 7<sup>th</sup> ed., vol. 2. Washington, D.C.:CTFA, 1493.

---

<sup>1</sup> Available for review: Director, Cosmetic Ingredient Review, 1101 17<sup>th</sup> Street, N.W., Suite 310, Washington, D.C. 20036.