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# Final Report on the Safety Assessment of Arachidyl Propionate

Arachidyl Propionate is an amber-colored semisolid wax, which is used in cosmetics at concentrations up to 10%. Arachidyl Propionate is practically nontoxic when ingested. No systemic toxicity was associated with subchronic oral exposure to Arachidyl Propionate. In test animals, Arachidyl Propionate was neither a primary dermal irritant, nor a skin sensitizer, and it did not have comedogenic potential. It was nonirritating to rabbit eyes.

In clinical studies, Arachidyl Propionate was neither an irritant nor a sensitizer. In additional clinical studies, Arachidyl Propionate was neither phototoxic nor a photoallergen.

On the basis of the data included in this report, it is concluded that Arachidyl Propionate is safe as a cosmetic ingredient in the present practices of use and concentration.

## INTRODUCTION

Arachidyl Propionate is structurally, and chemically, similar to the stearates, specifically butyl stearate. The stearates have been previously reviewed,<sup>(1)</sup> and the data contained in the stearates report are applicable to the evaluation of the safety of Arachidyl Propionate as a cosmetic ingredient.

## CHEMISTRY

### Definition and Structure

Arachidyl Propionate is the propionic acid ester of the corresponding C<sub>20</sub> fatty alcohol. It is manufactured as a mixture of the esters of the C<sub>18</sub>–C<sub>28</sub> fatty alcohols, of which the C<sub>20</sub> fatty alcohol ester is the major constituent. Arachidyl Propionate conforms to the following structure:<sup>(2)</sup>



Arachidyl Propionate (CAS No. 65591-14-2) is commercially known as Waxenol® 801.<sup>(2)</sup>

### Properties

Arachidyl Propionate is a soft waxy solid, amber in color, with a slight characteristic odor.<sup>(2,3)</sup> It is insoluble in water<sup>(3)</sup> and soluble in mineral oil.<sup>(4)</sup> It has a boiling point of 435°F<sup>(3)</sup> and a melting range of 36–38°C.<sup>(4)</sup> The specific gravity of Arachidyl Propionate is 0.83, the acid value is 1.0 maximum, the ester value is 100–116, and the iodine value is 15 maximum.<sup>(2)</sup>

### Analytical Methods

Ultraviolet spectral analyses have been performed on Arachidyl Propionate.<sup>(5,6)</sup> When diluted in cyclohexane, Arachidyl Propionate absorbed strongly in the 200–260 nm region, but, above 290 nm, absorption is poor.

## CHEMICAL REACTIONS

Arachidyl Propionate is chemically stable, but will decompose upon high-temperature heating and will react with strong bases to form the parent alcohol and propionic acid.<sup>(3)</sup>

## USE

### Cosmetic

Arachidyl Propionate is a “specialty wax” used in cosmetic and toiletry products to provide emolliency, lubricity, gloss, and film-forming capabilities to the finished products. Arachidyl Propionate melts upon contact with the human body, leaving a nonoily feeling to the skin.

Data submitted to the Food and Drug Administration in 1987 by cosmetic firms participating in their voluntary registration program indicated that Arachidyl Propionate was used in a total of 31 cosmetic products (Table 1). The cosmetic formulations containing the greatest amount of Arachidyl Propionate were lipsticks (24 formulations) with a reported concentration range of >5–10%. Other products containing Arachidyl Propionate (at concentrations of ≤5%) include “other” fragrance preparations (one product), moisturizing skin care preparations, and face, body, and hand care preparations, excluding shaving preparations.<sup>(7)</sup>

The FDA cosmetic product formulation computer printout<sup>(7)</sup> is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.<sup>(8)</sup> Ingredients are listed in preset concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the actual concentration would be a fraction of that reported to the FDA. Data submitted within the framework of preset concentration ranges provides the opportu-

**TABLE 1.** Product Formulation Data for Arachidyl Propionate<sup>(7)</sup>

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (percent)	
			>5-10	≤5
Other fragrance preparations	180	1		1
Lipstick	1494	24	20	4
Face, body, and hand skin care preparations (excluding shaving preparations)	1005	3		3
Moisturizing skin care preparations	775	3		3
1987 Totals		31	20	11

nity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered as one entered at the highest end of that range, thus introducing the possibility of a two- to tenfold error in the assumed ingredient concentration.

Products containing Arachidyl Propionate may be applied to the skin of all parts of the body, especially the lips, several times daily, and may be used repeatedly over a number of years.

### Noncosmetic

Arachidyl Propionate is used in such nonprescription over-the-counter products as ointments and emulsions.<sup>(9)</sup>

## ANIMAL TOXICOLOGY

### Acute Toxicity

#### Oral

Male Wistar rats were given Arachidyl Propionate by oral intubation at 10.4, 12.8, 16.0, and 20.0 g/kg.<sup>(10)</sup> Those rats receiving the three largest doses experienced mild diarrhea. No rats died. It was concluded that Arachidyl Propionate was not a hazardous substance under the conditions of the test.

#### Dermal

Arachidyl Propionate was tested for acute dermal toxicity in ten New Zealand White rabbits.<sup>(10)</sup> The abdominal area of the rabbits was shaved and the skin of one side was abraded while the skin of the other side remained intact. The test substance, 2.0 g/kg, was applied to the skin and the area was wrapped with gauze. The Arachidyl Propionate was allowed to remain in contact with the skin for 24 h, after which the material was removed. The rabbits were weighed on days 1 and 14, and were observed for signs of toxicity during the treatment period. There were no signs of toxicity, no deaths, and the rabbits each gained an average of 0.4 kg during the study.

## Subchronic Toxicity

### Oral

Groups of 20 Sprague-Dawley rats, equally divided by sex, were given Arachidyl Propionate by gavage for 5 days a week for 13 weeks.<sup>(11)</sup> The rats were divided into four dosage groups: controls received the corn oil vehicle, and three groups received 250, 750, and 2500 mg/kg, respectively, of the test substance at concentrations of 25% in corn oil. The test doses were determined in a 15-day range-finding study, with the highest dose administered being limited by the amount of corn oil vehicle which could be administered without altering the serum chemistries of the rats. All rats were weighed prior to the study and weekly during the study, and doses were adjusted for any changes in body weight. The rats were observed daily for any toxicologic or pharmacologic signs, and for general appearance. Blood and urine samples were obtained for analysis during weeks 7 and 13. At the end of the study, the rats were sacrificed, and various tissues were obtained for microscopic examination.

During the study, no statistically significant differences were found in the mean body weights or mean body weight gains of the rats in the experimental or control groups, and no deaths were attributed to treatment with the test material. A few rats had soft feces and some male rats had dried blood around their noses, a sign attributed to treatment.

The hematologic parameters measured were percent hemoglobin values and packed cell volume, MCV, red blood cells (RBC), white blood cells (WBC), neutrophil/lymphocyte ratio, and percent MCHC. Also measured were glucose, blood urea nitrogen (BUN), serum glutamic pyruvate transaminase (SGPT), serum alkaline phosphatase (SAP), and serum glutamic oxaloacetic transaminase (SGOT). The low- and mid-dose male rats had statistically significant differences in the week 7 neutrophil/lymphocyte ratio values when compared with the control values. There were some statistically significant differences in the hematologic parameters between female rats and their controls; however, none of the differences indicated a dose-response relationship. Some clinical chemistry values differed significantly among groups. In male rats, the SGPT and SAP values varied from those of the controls, but again no dose-response relationship was established. In female rats, differences were found in the SGOT and SAP values between control and treated rats, but there were no dose-response trends. The SAP values for the corn oil controls were higher than previously observed in that laboratory. No significant differences were found between control and experimental groups in the results of urinalyses.

In the treated female rats, a trend toward a smaller heart/body weight ratio was found, and uterine weights and uterus weight/body weight ratios were decreased. A high incidence of lobular patterns in the livers of all four groups of rats was attributed to vascular congestion and was not considered a result of treatment. No microscopic lesions were found, with the exception of multifocal pneumonitis in the high-dose rats. Foamy macrophages were found in the lungs of both the control and high dose rats. The aspiration of oily substances has been considered a cause of pneumonitis, and, thus, the differences observed between the control and high dose groups were due to the combination of the corn oil and Arachidyl Propionate rather than to corn oil alone. No deaths were attributed to treatment, and no systemic toxic effects other than pneumonitis were observed. The researchers concluded that no systemic toxicity would be expected from the normal use of Arachidyl Propionate.

### Dermal Irritation

A primary dermal irritation study was performed using six New Zealand White rabbits.<sup>(10)</sup> The backs of the rabbits were shaved and the skin on one side of the spinal column was abraded. Arachidyl Propionate, 0.5 g, was applied to gauze squares which were then placed on the skin on both sides of the spinal column and left in place for 24 h. The skin was observed for signs of dermal irritation upon removal of the pads and again 48 h later. The Primary Irritation Index (PII) was 1.38; Arachidyl Propionate was not a primary irritant.

A primary dermal irritation study (in rabbits, occlusive patch test, abraded and intact skin) with Arachidyl Propionate had a PII of 0.13 for the undiluted material.<sup>(12)</sup> The Arachidyl Propionate tested as a 10% aqueous emulsion had a PII of 0.0. Arachidyl Propionate was classified as a nonirritant.

In another dermal irritation study, a lipstick product containing 7.0% Arachidyl Propionate was tested using six rabbits (strain not specified) with a single insult, occlusive patch test.<sup>(13)</sup> The animals were examined for signs of irritation 2 and 24 h after removal of the patches. None of the rabbits had any signs of irritation; the group PII was 0.00, and the lipstick containing Arachidyl Propionate was classified as nonirritating.

In another study performed by Guillot et al.,<sup>(12)</sup> the cumulative dermal irritation potential of Arachidyl Propionate was determined. Three New Zealand White rabbits had their backs and flanks clipped; the clipping was repeated once weekly as necessary. The test substances, undiluted Arachidyl Propionate and a 10–15% emulsion of Arachidyl Propionate, were applied to the right and left flanks, respectively, of each rabbit. The test substance was massaged into the skin and any excess was wiped off. This procedure was repeated 5 days per week for 8 weeks. The animals were weighed weekly, and the skin was evaluated daily, with the daily scores expressed as a weekly average. At the end of the 8-week period, the skin was not treated for 7 days, and was then re-evaluated; a challenge assay was then performed. Also at the end of the treatment period, two skin samples (from areas differing macroscopically) were obtained for histopathological evaluation. For the pure test material, the Mean Maximum Irritation Index (MMII) was 1.00. This score classifies Arachidyl Propionate as a slight irritant. Additional observations were "slight epidermal exfoliation" and upon histopathological evaluation, the findings were "slight congestion of the dermis" with "no pathological reaction." The MMII for the 10% emulsion of Arachidyl Propionate was 0.50, a score reflective of a nonirritant. The emulsion was well tolerated, though vesicles were observed in two rabbits. Results of histopathological evaluation were no lesions due to treatment. Arachidyl Propionate was well tolerated by the rabbit and did not appear to have allergic potential.

### Dermal Sensitization

Twenty male albino guinea pigs were used in a dermal sensitization study.<sup>(10)</sup> The skin in the area of sample application was shaved. Ten of the animals served as controls, receiving injections of saline instead of warm, undiluted Arachidyl Propionate. A total of ten injections were administered, the first was a volume of 0.05 ml, and the remaining nine were volumes of 0.1 ml. The animals were treated three times per week, and the sites were scored 24 h after each injection. There was a 2-week nontreatment period after the tenth injection. At the end of this period, a 0.05 ml dose of the test

substance or saline was administered below the site of the original injections. This challenge site was scored 24 h later. No reaction was observed in any of the guinea pigs during the treatment or challenge phases of the test. The researchers concluded that Arachidyl Propionate was not a skin sensitizer.

### Comedogenicity

Three male albino rabbits, free from evidence of ear mites, were used in a comedogenicity assay of Arachidyl Propionate.<sup>(14)</sup> Undiluted Arachidyl Propionate, 0.1 ml, was applied daily to the internal base of the right ear of each animal on the weekdays of three weeks (15 applications); the left external ear served as the control. Twenty-four hours after each application, the rabbits' external ears were examined for signs of comedogenicity. The animals were examined, weighed, and sacrificed 24 hours after the last application. Necropsy was performed and histopathological observations were made of the collected tissues.

Two of the rabbits had lost weight during the study, while the third had normal weight gain. Diarrhea, reduced passage of feces, and emaciation were noted (rabbits not specified) during the observation period. Observation during treatment indicated hyperkeratosis with possible comedone formation in all three rabbits. Follicular hyperkeratosis was observed in the treated ears, but not comedone formation. Hyperkeratosis was also observed in the skin of the untreated ears. The researchers concluded that Arachidyl Propionate did not have comedogenic potential.

### Ocular Irritation

An ocular irritation test of Arachidyl Propionate was performed using six New Zealand White rabbits.<sup>(10)</sup> Warm Arachidyl Propionate, 0.1 ml, was instilled into the conjunctival sac of one eye of each rabbit; the contralateral eye served as the control. The ocular reaction was scored 24, 48, and 72 h after instillation of the test material. Two of the rabbits had conjunctival redness and discharge on day 1, but these signs had cleared by day 2. One rabbit had redness, chemosis, and discharge on day 1, persisting through days 2 and 3 (with the exception of the chemosis which was not noted on day 3). A fourth rabbit had redness, chemosis, and discharge on day 1, with the chemosis subsiding on day 2 and the discharge no longer evident on day 3. The remaining two rabbits had no reactions. Arachidyl Propionate was not an ocular irritant under the conditions of the study.

A study in rabbits using official French testing procedures was performed to determine the ocular irritation index for a number of cosmetic raw ingredients, including Arachidyl Propionate.<sup>(4)</sup> Several modifications of the official test procedures included: the inclusion of a reading of the eye at 1 h in addition to the readings at 1, 2, 3, 4, and 7 days. A photomotor reflex study was done, fluorescein dye was used, a qualitative evaluation of ulceration and granulation was performed, an ophthalmoscope and a retinograph were used, and the results were scored on a scale of 1 to 100. The Ocular Irritation Index (OII) for Arachidyl Propionate was 3.83 at 1 h, 1.50 at 24 h, and 0.00 at 48 h.

In another study, a lipstick containing 7.0% Arachidyl Propionate was tested for ocular irritation using six rabbits.<sup>(13)</sup> The product was not rinsed from the conjunctival sac of the eyes, and the eyes were graded 1 and 2 days after the instillation. None of the

rabbits had reactions to the product. The lipstick containing 7.0% Arachidyl Propionate was classified a nonirritant according to the Draize classification of ocular irritation.

## CLINICAL ASSESSMENT OF SAFETY

### Dermal Irritation and Sensitization

A repeated insult patch test of a lipstick containing 7.0% Arachidyl Propionate was performed using a panel of 85 human subjects.<sup>(15)</sup> The study group consisted of 82 females and 3 males between the ages of 18 and 70. Approximately 0.1 ml of the test material was applied to an occlusive patch, which was then placed on the upper back of the test subject. The patches were applied every Monday, Wednesday, and Friday for 3 weeks, and remained in place for 24 h. The test sites were scored before the application of each new patch and 24 h after the removal of the last patch. After a 2-week nontreatment period, a challenge patch, which remained in place for 24 h, was applied to a previously untreated site on the back of the test subjects. The sites were scored 24 and 48 h after removal of the patch. None of the panelists had reactions during either the induction or the challenge phases of the test. The lipstick containing 7.0% Arachidyl Propionate did not have a sensitization potential under the conditions of the study.

A lipstick containing 7.0% Arachidyl Propionate was tested in a 4-day mini-cum assay (a repeat insult test).<sup>(16)</sup> The test material had an irritation score of 0 in 20 test subjects (test subjects not identified), resulting in a PII of 0 and the conclusion that the lipstick containing 7.0% Arachidyl Propionate was essentially nonirritating.

A lipstick containing 7.0% Arachidyl Propionate was tested in use by a group of 62 women.<sup>(17)</sup> The women were divided into two groups balanced by product use, skin type, and skin sensitivity. The women were required to apply the lipstick at least twice daily. During the first three weeks of the study, one group used the test lipstick while the second group used a control lipstick—a product that was already “in-line.” After 3 weeks, the products were crossed over; in other words, the panelists originally using the test lipstick were then using the “in-line” lipstick. The panelists’ lips were evaluated dermatologically at the beginning of the study, at the crossover date, and at the end of the study. A summary of the clinical test results was not given. No dermatologic changes were noted in any of the panelists lips during the study. One panelist noted “discomfort” with the test lipstick, but no further details were given. One panelist complained of “dry feeling,” but it was not clear if this was the same panelist who noted discomfort. The table of panelist comments and problems was not included in the report. The results of the study of the lipstick containing 7.0% Arachidyl Propionate were acceptable when compared with the in-line (control) product; the reactivity of the test product was very low.

The irritation potential of a lip makeup containing 10% Arachidyl Propionate was evaluated in a supervised usage test using 30 subjects aged 29–66 years.<sup>(18)</sup> The test subjects were evaluated for signs of dermatitis or allergic reactions after they had used the lip makeup under normal conditions for 4 weeks. The test subjects had no complaints about the lip makeup, and no evidence of dermatitis or other allergic reactions were noted.

A 21-day cumulative irritation test on a lip makeup containing 10% Arachidyl Propionate was performed using 25 human subjects between the ages of 18 and 65.<sup>(19)</sup>

The lip makeup was tested along with other makeup products, and with sodium lauryl sulfate (SLS) in petrolatum at concentrations of 0.5 and 4.0% as standards (4.0% SLS is a known irritant). Approximately 0.02 ml of the test product was applied under an occlusive patch on the back of each subject. Patches remained in place for 24 h, and the sites were evaluated several minutes after patch removal. After evaluation, a new patch was applied to the same site. This procedure was continued for 21 consecutive days, excluding Sundays. The sites were scored on a scale of 0 (no reaction) to 4 (intense erythema with edema and vesicles). Of the 25 test subjects, two received scores of 1 (mild erythema), one on day 12 and one on day 15. The total cumulative score for the lip makeup containing 10% Arachidyl Propionate was 2, compared with 67 for 0.5% SLS and 519 for 4% SLS, and the lip makeup containing 10% Arachidyl Propionate was considered nonirritating to minimally irritating under the conditions of the study.

The irritation and sensitization potential of a lip makeup containing 10% Arachidyl Propionate was evaluated using a modified Draize-Shelanski-Jordan repeat insult patch test.<sup>(20)</sup> A total of 207 test subjects completed the study. The test sample (amount not specified) was applied under an occlusive patch to the back of each subject, patches remained in place for 24 h, and the sites were evaluated upon patch removal. Patches were applied every other day, Monday through Friday, for a total of ten induction applications. A 2 week nontreatment period followed the last induction application. After the nontreatment period a challenge patch was applied to a new site. This patch remained in place for 48 h, and the test areas were evaluated after patch removal. A second challenge patch was applied a week later, remaining in place for 48 h. The test sites were evaluated after patch removal and again 24 h later. Test sites were scored on a scale of 0–4, with a score of 0 indicating no reaction, and a score of 4 indicating intense erythema with edema and vesicles. No reactions were observed in any of the test subjects during either the induction or challenge phases of the study, and the lip makeup containing 10% Arachidyl Propionate was considered neither an irritant nor a sensitizer under the conditions of the study.

### Phototoxicity

The phototoxicity of a lip makeup containing 10% Arachidyl Propionate was evaluated in 10 human subjects.<sup>(21)</sup> The lip makeup, 0.02 ml, was applied to duplicate sites on the back of each test subject. One site was covered, and the other site received 2–4 min [approximately 6 unfiltered minimal erythematous doses (MED)] of window glass-filtered UVA radiation from a Blue Point hot quartz spot lamp, followed by a 0.5 MED of UVB radiation. No details on the wavelength or irradiance of the light were given. Evaluations were then made of both the irradiated and nonirradiated sites, including a site which was irradiated but to which no lip makeup was applied. The sites were then covered and were reevaluated 1, 3, and 24 h after irradiation. Reactions were scored on a scale of 0–4, with 0 indicating no reaction, and 4 indicating intense erythema with edema and vesicles. No adverse reactions were noted in any of the test subjects, and the lip makeup containing 10% Arachidyl Propionate was considered nonphototoxic.

### Photoallergenicity

A photoallergenicity test of a lip makeup containing 10% Arachidyl Propionate was performed using 25 test subjects between the ages of 18 and 65.<sup>(22)</sup> The test substance,



0.02 ml, was applied under an occlusive patch on either side of the spinal column. Patches remained in place for 24 h. Upon patch removal, the test site on one side of the spinal column was irradiated for 2–4 min with window-glass filtered light from a Blue Point solar simulating lamp. In addition, a nonpatched site was also irradiated. Evaluations of skin reactions were made a few minutes after exposure to the UV light. This procedure was repeated twice a week for 2 ½ weeks, for a total of five applications. This was followed by a 12-day nontreatment period. At the end of the nontreatment period, patches were applied to new sites on the back, remaining in place for 24 h. After patch removal, one patch site, as well as one nonpatched site, were irradiated and the test sites were then evaluated for signs of irritation, and again evaluated 24 h later. Skin reactions were scored on a scale of 0–4, with 0 indicating no reaction, and 4 indicating intense erythema with edema and vesicles. No reactions were noted in any of the test subjects at any time during the study. The lip makeup containing 10% Arachidyl Propionate was not considered a photoallergen under the conditions of the study.

## SUMMARY

Arachidyl Propionate is an amber-colored semisolid wax. In ultraviolet spectral studies, it absorbed strongly in the 200–260 nm region, and absorbed little above 290 nm.

Arachidyl Propionate is used in cosmetic formulations at concentrations of up to 10% to provide emolliency, gloss, and film-forming capabilities to the finished product. It has also been used as a substitute for lanolin and lanolin derivatives.

According to the toxicity classification of Hodge and Sterner,<sup>(23)</sup> Arachidyl Propionate is practically nontoxic when ingested. No systemic toxicity was associated with subchronic oral exposure to Arachidyl Propionate. The substance was also nontoxic by dermal absorption.

In test animals, Arachidyl Propionate was neither a primary dermal irritant, nor a skin sensitizer, nor did it have comedogenic potential. It was nonirritating to rabbit eyes.

In clinical studies, Arachidyl Propionate was neither an irritant nor a sensitizer. In additional clinical studies, Arachidyl Propionate was neither phototoxic nor a photoallergen.

## DISCUSSION

Arachidyl Propionate has some structural and chemical similarities to the stearates, for which a safety assessment has already been published. Although there is limited toxicological data available for Arachidyl Propionate, the data available in the stearates report are relevant to the safety evaluation of Arachidyl Propionate. Structure–activity relationships would indicate that Arachidyl Propionate would not absorb in the UVA and UVB ranges and spectral analyses as well as clinical studies support this conclusion.

## CONCLUSION

On the basis of the data included in this report and in the stearates report, the CIR Expert Panel concludes that Arachidyl Propionate is safe as a cosmetic ingredient in the present practices of use and concentration.

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