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Final Report on the Safety Assessment of Butyl Myristate

Butyl Myristate is the ester of butyl alcohol and myristic acid. It is a colorless, oily liquid which is used in cosmetic formulations at concentrations up to 50%. Aliphatic esters such as Butyl Myristate may be readily hydrolyxed *in vivo* to the corresponding alcohol and acid which are then further metabolized. The LD_{50} of Butyl Myristate was greater than 8 g/kg in rats. In animal tests, undiluted Butyl Myristate was moderately irritating but was not a skin sensitizer. No evidence of eye irritation was noted.

Additional information on related compounds, including human test data results on myristyl myristate and isopropyl myristate, is included in the text. On the basis of the available data presented in this report on Butyl Myristate, as well as other related myristate compounds, it is concluded that Butyl Myristate is safe for cosmetic formulation use.

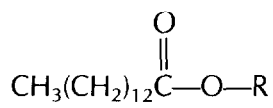
INTRODUCTION

Myristyl Myristate and Isopropyl Myristate have been reviewed previously by CIR and were found to be safe as cosmetic ingredients.[1] Excerpts of appropriate data from these previously published reports will appear in this report.

CHEMISTRY

Definition and Structure

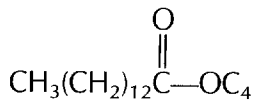
The myristates are esters of myristic acid which have the general formula:



$$CH_3(CH_2)_{12}C(=O)—O—R$$

where R represents the alkyl moiety of the specific alcohol.[1]

Butyl Myristate (CAS No. 110-36-1) is the ester of butyl alcohol and myristic acid. It conforms to the formula:[2]



Other names for Butyl Myristate include butyl *n*-tetradecanoate, butyl ester myristic acid, Bumyr, Wickenol 141, and butyl ester tetradecanoic acid.[2,3]

Butyl Myristate is a light, colorless, oily liquid. It is soluble in acetone, castor oil, chloroform, methanol, mineral oil, and toluene and insoluble in water. Other properties of Butyl Myristate include a freezing point range of 1–7°C, a boiling point range of 167–197°C (at 5 mm Hg), and a specific gravity between 0.850 and 0.858 (at 25°C).[4]

Reactivity

The myristates can be expected to undergo chemical or enzymatic hydrolysis to myristic acid and the corresponding alcohol. Trans-esterification and other typical ester reactions may also occur. Butyl Myristate, if synthesized from a pure, saturated fatty acid, would not significantly autoxidize, discolor, or develop an odor.[5]

Methods of Manufacture and Impurities

Commercially available myristates are mixtures of esters because of the technical grade of the myristic acid and the alcohols which are used as industrial starting materials. Myristic acid is produced commercially by the saponification and fractionation of animal or vegetable fats and oils. The isolated acid fraction is hydrogenated to produce the saturated fatty acid.[6]

Butyl Myristate is derived from the esterification of myristic acid and butyl alcohol in the presence of an acid catalyst. The product is stripped to remove excess alcohol, and alkali refined to neutralize the catalyst. Butyl Myristate is obtained through fractional distillation. Minor impurities which may be present are fatty acids (such as myristic acid) at a maximum of 0.5% and unsaponifiable material, mostly hydrocarbon, at a maximum of 0.2%.[7]

USE

Cosmetic Use

Butyl Myristate is used in the preparation of cosmetics with high fat/wax loads. It reduces viscosity, improves film forming, spreading, and adhesion, and eliminates greasiness. It also acts as an emollient to the skin. Butyl Myristate is an agent for solubilizing lanolin, lanolin alcohols, cholesterol, silicone oils, sunscreens, perfumes, and active medicinal agents.[5]

Butyl Myristate is found in eye makeup, makeup foundations, lipstick, liquifying and vanishing creams, suntan preparations, lotions, hair dressings, and blushers. The FDA cosmetic product formulation computer printout[8] is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[9] 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 opportunity 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 at the highest end of that range, thus introducing the possibility of a two- to tenfold error in the assumed ingredient concentration. Table 1 includes the most up-to-date product formulation data for Butyl Myristate as reported by the FDA.[8] A more detailed listing of the product types and the number of product formulations containing the ingredient can be found in Table 2.[10] Butyl Myristate was included in cosmetic products in concentrations up to 50%.

Products containing the myristates are applied to all areas of the skin, hair, nails, and mucous membranes. They may be applied several times a day and remain in contact with the skin for variable periods of time following each application. Daily or occasional use may extend over many years.

Noncosmetic Use

Butyl Myristate, along with other fatty acid esters, has been studied as a possible vehicle to control the percutaneous absorption of drugs used in topical preparations[11] and the release rate of drugs in polylactic acid (PLA)[12] and poly-β-hydroxybutyric acid (PHB)[13] microspheres. Butyl Myristate was incorporated as an additive during microsphere preparation. The release rate of a drug was controlled by adjusting the type and amount of the fatty acid esters added. Results of these and other similar studies were varied and many were not fully understood.

TABLE 1. Product Formulation Data for Butyl Myristate[8]

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (%)		
			>25–50	>10–25	>1–5
Eye, lip and face makeup products	2570	31	11	1	19
Other makeup and fragrance products	464	5	3		2
1988 Totals		36	14	1	21

TABLE 2. Product Formulation Data for Butyl Myristate[10]

Product category	Total no. containing ingredient	No. unknown concentration	No. of product formulations within each concentration range (%)			
			>25–50	>10–25	>5–10	>1–5
Eye shadow	2	1			1	
Other eye makeup preparations	4	1	3			
Foundations	7	3	4			
Lipstick	50	31				19
Makeup bases	8	4	3	1		
Blusher	1					1
Other makeup preparations	12	9	3			
1984 Totals	84	49	13	1	1	20

Butyl Myristate is also used as a plasticizer, as a lubricant for textiles, and in paper stencils.[4]

International Use

Butyl Myristate has been approved for formulations marketed in Japan and is included in the *Informal MHW List of Traditional Cosmetic Ingredients*.[14]

BIOLOGICAL PROPERTIES

General Effects

Although no general biological effects of Butyl Myristate are available, data for Isopropyl Myristate are reviewed here.

Isopropyl Myristate was more toxic to gram-negative than to gram-positive bacteria; *Pseudomonas aeruginosa* was the most sensitive of the gram-negative bacteria tested. Trace amount of acidic catalysts that remain after production of Isopropyl Myristate may cause this toxicity. Isopropyl Myristate also was used as a source of carbon by some of the many different microorganisms that can be isolated from cosmetic products. Microorganisms capable of utilizing the ingredient for growth included 12 of 23 strains of bacteria, 25 strains of yeast, and 17 strains of molds.[1]

Isopropyl Myristate was found to affect the percutaneous absorption of some drugs. As a vehicle on the intact and damaged skin of male guinea pigs, Isopropyl Myristate was considered intermediate as compared with mineral oil, oleic acid, and hexadecyl alcohol. Dexamethasone penetrated human skin seven times better in gelled Isopropyl Myristate than in petrolatum USP. Decreased antifungal activity of paraben esters solubilized by surfactants have occurred in the presence of Isopropyl Myristate. The solvent properties of Isopropyl myristate also may alter the particle size of the active ingredients in pharmaceutical formulations and in this way influence their therapeutic activity.[1]

Absorption, Metabolism, Storage, and Excretion

Butyl Myristate, like other higher molecular weight aliphatic esters, may be readily hydrolyzed *in vivo* to its corresponding acid and alcohol, which are then further metabolized.[15] Myristic acid is a digestible constituent of most vegetable and animal fats and is nontoxic when ingested.[16] Less than 2% of the myristic acid fed to dogs (as the ethyl ester) was recovered as unabsorbed material in the feces, with no increase in ether-soluble acids in the urine.[1] Gosselin et al.[16] reported that butanol had a toxicity rating of three on a scale of one to six, which is considered moderately toxic to humans (probable oral lethal dose = 0.5–5 g/kg). Sax[17] reported that butanol caused reversible to irreversible changes to exposed tissue in dermal and oral routes; in clinical studies, inhalation of butanol caused moderate irritation and discomfort.

No specific data under this heading were available on Butyl Myristate. A study with Isopropyl Myristate, however, is included.

Four monkeys were exposed for 5 s to the spray of an aerosol antiperspirant containing ^{14}C-Isopropyl Myristate. The distribution of ^{14}C in the exhaled air and in several tissues indicated that only 0.25% of the dose was absorbed with about 10% of

this reaching the lower respiratory tract. About 85% of the absorbed Isopropyl Myristate was eliminated in 24 h, mainly as exhaled carbon dioxide. Very little radioactive material reached any tissues other than the lungs.[1]

ANIMAL TOXICOLOGY

Studies of the myristates other than Butyl Myristate are included here under each heading and follow the Butyl Myristate data without additional introduction.

Acute Studies

Oral Toxicity

An acute oral toxicity study of Butyl Myristate was conducted in 10 rats. Daily observations were made over a period of 14 days. The LD_{50} was greater than 8 g/kg.[5] No information on strain or weight of animals tested, range of chemical concentration, or individual subject data was available.

Five acute oral toxicity studies were reported, using Myristyl Myristate as the test ingredient. The acute oral LD_{50} of undiluted Myristyl Myristate in rats was greater than 14.4 g/kg.[1]

Undiluted Isopropyl Myristate was evaluated in rats in four separate studies and in mice in two studies. Product formulations were also evaluated. The acute oral LD_{50} of undiluted Isopropyl Myristate was greater than 16 ml/kg in rats and 49.7 ml/kg in mice.[1]

Dermal Toxicity

Ten New Zealand white rabbits were used to evaluate the acute dermal toxicity of Butyl Myristate. A single 2.0 g/kg dose of Butyl Myristate was applied to the clipped and abraded skin of the rabbit, and the sites were then covered with gauze and wrapped in impervious material. At 24 h, the area was cleansed and evaluated by the Draize method.[18] Daily observations were recorded for 14 days. Slight erythema was found in all rabbits tested. Five of the rabbits had slight to moderate edema. One death was recorded on day 10. A gain in weight over the course of the study was observed in all but one of the nine surviving rabbits. The researchers concluded that Butyl Myristate was nontoxic when applied to the skin of rabbits.[19]

Undiluted Myristyl Myristate was tested for acute dermal toxicity on 10 albino rabbits. Draize scores up to 2 for erythema and 1 for edema were recorded. No deaths resulted from treatment with Myristyl Myristate.[1]

Undiluted Isopropyl Myristate and three product formulations containing it were tested. The acute dermal LD_{50} of undiluted Isopropyl Myristate was 5 g/kg in rabbits.[1]

Three guinea pigs were immersed up to their axillae in a 0.5% dispersion of Isopropyl Myristate in water. The reactions of the abdominal skin were graded on a scale of 10 to 1 (10 = normal; 1 = most severe skin reaction). Each animal received a score of 8 or 7; there was moderate scaling and slight scurfing of the skin.[1]

Dermal Irritation

A dermal irritation study was conducted on Butyl Myristate using 9 female albino rabbits. A 0.5 ml volume of undiluted Butyl Myristate was applied to a one-inch filter

disc, which was placed in contact with the clipped rabbit skin. The area was then wrapped in an occlusive dressing. After 24 h of chemical contact, the dressing was removed and the skin evaluated for irritation and edema after 24 and 72 h. According to the Draize scale, Butyl Myristate had a primary irritation index of 2.88. The investigators reported the ingredient to be a moderate skin irritant in rabbits.[5] No other information on test protocol was available.

The primary skin irritancy potential of Myristyl Myristate was tested in seven studies by a Draize single insult patch test (SIPT) technique or slight modification of the test on the clipped intact and abraded skin of albino rabbits. Undiluted Myristyl Myristate produced minimal to mild irritation, with a primary irritation index of 0.11–1.50.[1]

Undiluted Isopropyl Myristate was evaluated in five studies and four product formulation studies for primary skin irritation using the Draize procedure. The undiluted ingredient produced minimal irritation.[1]

A 0.5 ml sample of undiluted Isopropyl Myristate was applied for three consecutive days to the clipped skin of 42 rabbits. Edema, severe erythema, drying, cracking, and scaling of the skin resulted. Isopropyl Myristate was moderately to severely irritating under the conditions of the tests.[1]

Skin Sensitization

Male Hartley albino guinea pigs were used in a skin sensitization study of Butyl Myristate. The study involved two control groups and eight treatment groups of 10 animals each. The available condensed report presented results of both control groups but only of one treatment group. The guinea pigs weighed from 300 to 375 g and were provided with food and water *ad libitum*. Following the Draize procedure,[20] the test material was injected intradermally three times/week with skin reaction observations being made 24 h after each treatment. Undiluted Butyl Myristate was administered as a dose of 0.05 ml for the first treatment and in 0.1 ml volumes for the remaining nine treatments. Treatment ceased for two weeks following the tenth treatment, after which a challenge dose of 0.05 ml was given. The reactions to the challenge dose in control and treated groups were compared using the average reading for the ten treatments. Slight erythema was observed in three animals of the two control groups during the treatment period, and one had edema. No control animals reacted to the challenge dose. All the guinea pigs treated with Butyl Myristate had moderate erythema and edema after each treatment. The challenge dose also produced moderate reactions, with scores averaging 2.0 for erythema and 2.1 for edema. Butyl Myristate was a moderate skin irritant when intradermally administered to guinea pigs. The investigators reported that Butyl Myristate was not a sensitizer for guinea pigs.[21]

Ocular Irritation

Six New Zealand white rabbits were used to study ocular irritation. A 0.1 ml dose of Butyl Myristate was placed into the conjuctival sac of one eye of each rabbit. The contralateral eye of each rabbit was considered the control. Observations were recorded 1, 2, and 3 days after the introduction of the test ingredient. The reactions were graded as determined by the Consumer Product Safety Act regulations.[22] None of the six rabbits tested had any irritation of the cornea or iris. Four rabbits had slight conjunctivitis. Three of these continued to have the condition beyond the observation period, while one rabbit had conjunctival redness only on the first day of testing. The Draize maximum average score for the ingredient was calculated as 2.3. Butyl Myristate was considered nonirritating to the rabbit eye.[5,23]

Six studies used the Draize rabbit eye irritation procedure to evaluate Myristyl Myristate. An additional study tested the ingredient in product formulation. Treated eyes were examined and graded on the Draize eye irritation scale. The undiluted ingredient produced only minimal ocular irritation.[1]

Isopropyl Myristate was used to evaluate eye irritation in ten separate studies and four studies using product formulations. Only minimal eye irritation resulted from treatments with undiluted Isopropyl Myristate in the rabbit.[1]

Inhalation Toxicity

No data on the inhalation toxicity of Butyl Myristate are currently available.

Two product formulations containing Isopropyl Myristate were tested for acute inhalation toxicity in rats. Twenty animals were exposed to an antiperspirant containing a myristate concentration of 33–41 mg/L (dispensed for 6.5 s/min) for 1 h. During the 14-day postexposure observation period, no deaths occurred, and no evidence of systemic toxicity was found at necropsy. The other antiperspirant had an Isopropyl Myristate concentration of 9.7 mg/L and exposure included separations by 5-min fresh air periods. No significant adverse effects during exposure, no deaths, and no abnormal findings at necropsy were found.[1]

Parenteral Irritation/Toxicity

No data are available for parenteral irritation and toxicity studies for Butyl Myristate.

Isopropyl Myristate (0.3 ml) was injected intracutaneously into the abdominal skin of rabbits. Using injected trypan blue as a diagnostic aid the investigators found no indication of parenteral irritation.[1]

No deaths occurred within 72 h after approximately 100 ml/kg of Isopropyl Myristate was injected intraperitoneally into two mice over a 4-h period. Another study reported that the intraperitoneal and subcutaneous LD_{50}s for Isopropyl Myristate exceeded 79.5 ml/kg in rats and 50.2 ml/kg in mice.[1]

Subchronic Studies

No subchronic studies on Butyl Myristate are available. Studies on other myristates are included.

Inhalation Toxicity

A 13-week inhalation toxicity study was done on an aerosol antiperspirant containing 16–20% Isopropyl Myristate. Twenty guinea pigs were exposed daily to a mean concentration of 63.3 or 224 mg/m^3 in air for three 1-h exposures per day. Both absolute and relative lung weights increased. At gross necropsy and microscopic examination of tissues, no other evidence of treatment-related effects was found.[1]

The same aerosol antiperspirant as above was tested in another 13-week inhalation toxicity study using cynomolgus monkeys. Test groups of nine animals were exposed daily to a gravimetric concentration of 5.3, 8.4, 33.6, or 37.0 mg/m^3 in air. Animals coughed and wheezed during exposure, with bloody discharge from the noses of two. Pulmonary function tests after 6 and 13 weeks were normal, as were the results of hematology, blood chemistry, and urinalysis. No gross lesions were seen at necropsy, and organ/body weight ratios were comparable to those of controls. Macrophage accumulations within the alveolar and brochiolar walls were noted in the lungs of the

treated animals. The severity of this response was directly proportional to the dosage of the aerosol.[1]

Parenteral Toxicity

A mixture of 25% Isopropyl Myristate and 75% peanut oil was injected intramuscularly once a week for up to 12 weeks at doses of 0.3 ml/kg in 48 rats, 0.14 ml/kg in four beagle dogs, and 0.15–0.33 ml/kg in two rhesus monkeys. Minor local damage without definitive systemic effects was observed.[1]

Chronic Studies

No information was available on any of the myristates with respect to chronic studies in animal toxicology.

MUTAGENICITY AND CARCINOGENICITY

Mutagenicity

No information was available for Butyl Myristate with respect to mutagenicity and carcinogenicity. No mutagenicity studies were reported for any myristates previously reviewed.

Carcinogenicity

The carcinogenicity of Isopropyl Myristate was studied using mice. A preliminary study of a 50% Isopropyl Myristate solution in isopropyl alcohol accelerated the carcinogenic activity of 0.15% benzo[a]pyrene for the skin of mice. No neoplasms were produced when 0.1 ml of a 1% solution of Isopropyl Myristate was applied once a week for 18 weeks.[1]

Isopropyl Myristate was applied twice a week to the backs of mice from seven weeks of age until their deaths between 10 and 110 weeks. Groups of animals were treated with 0.02 ml of Isopropyl Myristate diluted with acetone in concentrations of 10%, 50%, and 100%. Of the treated animals, one from the 50% group developed a keratoacanthoma on an eyelid, and one from the 10% group developed a squamous cell papilloma on the abdomen. Frequency of skin neoplasms in the treated animals did not differ from that of the acetone or untreated control animals. No lesions were produced in other organs.[1]

CLINICAL ASSESSMENT OF SAFETY

No clinical studies on Butyl Myristate were available. Studies of the other myristates are included.

Dermal Irritation Studies

A cologne stick product containing 8% Myristyl Myristate was tested for primary skin irritation using a 24-h occlusive patch test technique. A single reaction scored 1.0 on the Draize scale. No other irritation resulted. The primary irritation index was calculated as 0.05.[1]

Undiluted Isopropyl Myristate was tested in a 24-h occlusive patch test for primary skin irritation. Fifteen subjects had no adverse reactions.[1]

In a 48-h occlusive patch test with 20% Isopropyl Myristate in petrolatum, no irritation was reported.[1]

Seven studies tested product formulations containing Isopropyl Myristate for primary skin irritation. An aerosol antiperspirant containing 52–58% Isopropyl Myristate was applied under occlusive patches for 24 h every other day for three applications; no irritation was observed. Bath oil with a concentration of 42.9% Isopropyl Myristate was applied repeatedly under occlusion in 0.3 ml doses for 10 days; no irritation resulted. Three separate studies used an aerosol antiperspirant containing 43–47% Isopropyl Myristate. A single 24-h application resulted in one case of mild and six cases of doubtful erythema from the 50 subjects for a combined primary irritation index of 0.05 by the Draize scale. Two studies tested a facial mask containing 15.0% Isopropyl Myristate for 24 h on 38 subjects. One case of mild and two cases of doubtful erythema resulted in a combined Draize primary irritation index of 0.1.[1]

Cumulative skin irritation of undiluted Isopropyl Myristate was evaluated in two studies. Daily application for 21 days resulted in very slight irritation with scores totaling less than the baby oil control.[1]

Two aerosol antiperspirant samples containing 52–58% Isopropyl Myristate were tested in a modified Lanman-Maibach 21-day irritancy test. A 0.3 ml volume was applied to two test sites on the back. There was no evidence of pigmentation changes, and skin irritation was slight.[1]

In another Lanman-Maibach-type 21-day cumulative irritancy assay, a facial mask formulation containing 15% Isopropyl Myristate was tested. The cumulative irritation score was 50 of a maximum 520, indicating minimal irritation.[1]

Skin Sensitization Studies

A cologne stick containing 8% Myristyl Myristate was tested in a repeated insult patch test (RIPT). The product was applied under occlusive patches three times a week for a total of 10 exposures. After the challenge exposure, no evidence of skin sensitization resulted.[1]

A facial mask formulation containing 15% Isopropyl Myristate was used in a repeated insult patch test. Slight irritation resulted without evidence of sensitization.[1]

Four studies tested an aerosol antiperspirant concentrate containing 52–58% Isopropyl Myristate by nine daily exposures and one challenge patch exposure. The product was mildly irritating but was not considered to be a sensitizer to human skin.[1]

A maximization test used 20% Isopropyl Myristate in petrolatum on skin pretreated with sodium lauryl sulfate. The 48-h exposures and challenge patch tests resulted in no skin sensitization reactions in human subjects.[1]

Another maximization assay evaluated the sensitization properties of a bath oil formulation containing 42.9% Isopropyl Myristate. No reactions were observed after induction or challenge patches.[1]

Phototoxicity Studies

A bath oil formulation containing 42.9% Isopropyl Myristate was applied undiluted at 5 μl/cm^2 under an occlusive patch and the sites were irradiated after 6 and 24 h with a UVA irradiance of 25–30 mW/cm^2. No evidence of phototoxicity was observed.[1]

Photocontact Allergenicity Studies

A bath oil containing 42.9% Isopropyl Myristate was tested for photocontact allergenicity. Applications of 5 μl/cm^2 under an occlusive patch for 24 h, followed by three minimal erythema doses of irradiation, were repeated twice a week for three weeks. A challenge patch followed by 25–30 mW/cm^2 UVA for five minutes was performed with no evidence of photocontact allergenicity.[1]

SUMMARY

Butyl Myristate is the ester of butyl alcohol and myristic acid. It is a colorless, oily liquid which is not expected to autoxidize, discolor, or develop an odor. No impurities exist in any significant concentration.

Butyl Myristate is used in eye makeup, foundations, lipstick, vanishing creams, lotions, suntan preparations, and blushers in concentrations up to 50%. Products containing the ingredient may be applied several times a day and remain in contact with all areas of the skin, hair, nails, and mucous membranes for variable periods of time following each application. Daily or occasional use may extend over many years. Butyl Myristate also has been approved for use in formulations marketed in Japan. Noncosmetic use of Butyl Myristate includes its use as a vehicle in microsphere preparations for controlled drug release rate and absorption in pharmaceuticals, a plasticizer, a lubricant for textiles, and a component in paper stencils.

Aliphatic esters such as Butyl Myristate may be readily hydrolyzed *in vivo* to the corresponding alcohol and acid which are then further metabolized. These constituents pose no human hazard as products of metabolism.

The LD_{50} in an acute oral toxicity study of Butyl Myristate was greater than 8 g/kg in rats.

In an acute dermal toxicity study, a 2.0 g/kg dose of Butyl Myristate was nontoxic when applied to the skin of rabbits. In a dermal irritation study in rabbits, undiluted Butyl Myristate was moderately irritating to the skin. Undiluted Butyl Myristate was not a skin sensitizer in guinea pigs.

An occular irritation study of Butyl Myristate was nonirritating to the rabbit eye.

Additional information and studies of Myristyl Myristate and Isopropyl Myristate supplemented the text. Both ingredients were nontoxic to the skin of rabbits and minimally irritating to the rabbit eye. In dermal irritation studies using rabbits, Myristyl Myristate was minimally to mildly irritating, while Isopropyl Myristate was moderately to severely irritating under the conditions of the tests. No toxic effects were observed in animal or human inhalation toxicity, parenteral irritation, or carcinogenicity studies using Isopropyl Myristate. Neither Myristyl Myristate nor Isopropyl Myristate was irritating, sensitizing, or phototoxic to human skin.

DISCUSSION

Butyl Myristate has structural and chemical similarities to myristic acid, myristyl myristate, and isopropyl myristate which have been previously reviewed by the Cosmetic Ingredient Review Expert Panel. These compounds were all determined safe at current practices of use. In data reported to the FDA, Butyl Myristate, myristic acid, myristyl myristate, and isopropyl myristate are used in cosmetics at concentrations up to 50%. Although the available toxicological data on Butyl Myristate are limited, the data available in the myristic acid and myristyl and isopropyl myristate reports are appropriate and relevant to this evaluation of the safety of Butyl Myristate. Because of the availability of toxicological data in the aforementioned reports, as well as in this report, the Panel does not require additional data to determine the safety of Butyl Myristate.

CONCLUSION

On the basis of the available data presented in this report on Butyl Myristate as well as data on other myristates previously reviewed, the Expert Panel concludes that Butyl Myristate is safe as a cosmetic ingredient in the present practices of use and concentration.

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