

# Final Report on the Safety Assessment of Cetyl Lactate and Myristyl Lactate

Cetyl Lactate and Myristyl Lactate are the esters of lactic acid and either cetyl or myristyl alcohol. They are used in a wide variety of cosmetic products up to a maximum concentration of 25%.

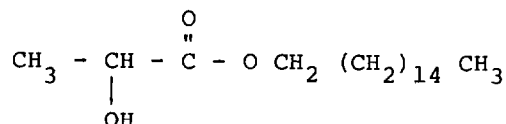
The acute oral LD50 of Cetyl Lactate is estimated from studies with rats to be greater than 20 g/kg. Cetyl Lactate was shown to be minimally irritating to rabbit skin and nonirritating or only slightly irritating to rabbit eyes in Draize irritation tests. At 25%, Cetyl Lactate produced no signs of toxicity or irritation in a 30-day rabbit-skin irritation study. Cetyl Lactate was found to be minimally irritating and nonsensitizing to human skin at concentrations up to 5%.

The acute oral LD50 of Myristyl Lactate is estimated from studies with rats to be greater than 20 g/kg. Myristyl Lactate was shown to be minimally irritating in Draize primary skin irritation tests, but one contradictory study concluded that undiluted Myristyl Lactate produced moderate irritation. It produced no signs of ocular irritation in Draize rabbit eye irritation tests. Mild irritation was elicited by a formulation in a modified Draize rabbit skin irritation test. The same formulation was found to be nonirritating and nonsensitizing in a human repeated insult patch study.

Based on the available information, it is concluded that Cetyl Lactate and Myristyl Lactate are safe in the present practices of use.

## CHEMICAL PROPERTIES

**Cetyl Lactate:** Cetyl Lactate is the ester produced by a catalyzed reaction of either natural or synthetic cetyl alcohol and lactic acid. This ester is then washed to remove any catalyst and unreacted lactic acid. The final product is further washed with alkali and neutralized. Cetyl Lactate conforms to the formula.<sup>(1)</sup>



Other names include:<sup>(2,3)</sup>

1-Hexadecanol Lactate

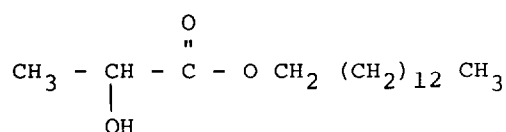
n-Hexadecyl Lactate

2-Hydroxypropanoic acid hexadecyl ester

Lactic acid cetyl ester

Lactic acid hexadecyl ester

**Myristyl Lactate:** Myristyl Lactate is the ester produced by a catalyzed reaction of either natural or synthetic myristyl alcohol and lactic acid. The ester produced by the reaction is washed to remove any catalyst and unreacted lactic acid. The final product is further washed with alkali and neutralized. Myristyl Lactate conforms to the formula:<sup>(4)</sup>



### Physical Properties

**Cetyl Lactate:** Cetyl Lactate is a white to light yellow, soft, waxy solid which has a slight, characteristic, pleasant odor. The presence of a hydroxyl group makes the ingredient particularly soluble in ethyl alcohol and propylene glycol.<sup>(5)</sup>

Measured values for some chemical and physical parameters of Cetyl Lactate are listed below:<sup>(1,5)</sup>

|                          |             |
|--------------------------|-------------|
| Melting point            | 23°–25°C    |
| Specific Gravity at 25°C | 0.893–0.905 |
| Titer                    | 23°–26°C    |
| Saponification Value     | 155–195     |
| Ester Value              | 155–195     |
| Acid Value               | 3.5 maximum |
| Iodine Value             | 1.0 maximum |

**Myristyl Lactate:** Myristyl Lactate is a white to yellow liquid or soft solid. Because a hydroxyl group is present, this ingredient is particularly soluble in ethyl alcohol and isopropyl alcohol. It is dispersible in mineral oil and insoluble in water and glycerine.<sup>(6)</sup>

Measured values for some chemical and physical parameters of Myristyl Lactate are listed below:<sup>(4,6)</sup>

|                          |             |
|--------------------------|-------------|
| Specific Gravity at 25°C | 0.892–0.904 |
| Titer                    | 11°–14°C    |
| Saponification Value     | 166–185     |
| Ester Value              | 166–185     |
| Acid Value               | 3 maximum   |
| Iodine Value             | 1.0 maximum |

### Reactivity

Esters undergo nucleophilic substitution. Typical ester reactions include acidic hydrolysis, alkaline hydrolysis, ammonolysis, transesterification, and reduction to alcohols.<sup>(7)</sup>

### Analytical Methods

Cetyl Lactate and Myristyl Lactate can be positively identified through close matching to standard IR spectra.<sup>(5,6)</sup> A method for thin-layer chromatography identification has also been described.<sup>(8)</sup>

### Impurities

**Cetyl Lactate:** Unspecified amounts of myristyl and/or stearyl lactate may be present in commercial Cetyl Lactate. It may also contain a maximum concentration of 0.1% ash.<sup>(1)</sup>

**Myristyl Lactate:** Depending on the purity of the starting materials, unspecified amounts of decyl, lauryl, and/or cetyl lactate may be present in commercial Myristyl Lactate.<sup>(4)</sup>

## PURPOSE AND FREQUENCY OF USE IN COSMETICS

Cetyl Lactate and Myristyl Lactate are used in cosmetic formulations because of their physical properties. A solid at room temperature, Cetyl Lactate liquifies upon application to the skin. While Myristyl Lactate is a liquid at room temperature, just below this temperature it becomes a soft solid. These lactate esters are nongreasy, nonoily, and nondrying. As they fulfill the functions of lubricant, emollient, and texturizer, they also impart silkiness, sheen, and a degree of water repellancy to the skin and hair. They are extensively used in the production of creamy lipsticks, and at levels of 0.5–2%, they reduce the tackiness of aluminum salt antiperspirants.<sup>(8,9)</sup>

Neither Cetyl nor Myristyl Lactate reacted in a 52-day period with polystyrene, a material widely used in the packaging of cosmetic products.<sup>(10)</sup> No evidence was available that suggested any interaction between the Lactates and other ingredients.

Cetyl Lactate and Myristyl Lactate are used in a wide variety of product formulations. Product types and the number of formulations reported for each preset concentration range are listed in Table 1.<sup>(11)</sup> The cosmetic product formulation computer printout which is made available by the Food and Drug Administration (FDA) is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations (1979). Ingredients are listed in prescribed 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 true, effective concentration found in the finished product; the effective concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework

TABLE 1. Product Formulation Data.<sup>a</sup>

| <i>Ingredient/<br/>Cosmetic product type</i>                | <i>Concentration<br/>(%)</i> | <i>No. of product<br/>formulations</i> |
|---|------------------------------|--|
| <i>Cetyl Lactate</i>  |                              |  |
| Eyebrow pencil  | > 10-25                      | 1                                      |
|   | > 1- 5                       | 6                                      |
| Eyeshadow   | > 10-25                      | 1                                      |
|   | > 5-10                       | 5                                      |
|   | > 1- 5                       | 2                                      |
| Other eye makeup<br>preparations                            | > 5-10                       | 1                                      |
|   | > 1- 5                       |  |
| Sachets   | >0.1- 1                      | 4                                      |
| Other fragrance preparations                                | > 1- 5                       | 7                                      |
| Hair conditioners   | > 1- 5                       | 12                                     |
|   | >0.1- 1                      | 3                                      |
| Rinses (noncoloring)  | > 1- 5                       | 5                                      |
|   | >0.1- 1                      | 2                                      |
| Other hair preparations                                     | >0.1- 1                      | 1                                      |
| Blushers (all types)  | > 5-10                       | 2                                      |
|   | > 1- 5                       | 4                                      |
|   | >0.1- 1                      | 16                                     |
| Foundations   | >0.1- 1                      | 2                                      |
| Lipstick  | > 10-25                      | 2                                      |
|   | > 5-10                       | 29                                     |
|   | > 1- 5                       | 44                                     |
| Makeup bases  | >0.1- 1                      | 24                                     |
| Other makeup preparations                                   | >0.1- 1                      | 1                                      |
| Face, body, and hand<br>(excluding shaving<br>preparations) | > 10-25                      | 1                                      |
|   | >0.1- 1                      | 1                                      |
| Moisturizing  | >0.1- 1                      | 1                                      |
| Night   | > 10-25                      | 1                                      |
|   | > 1- 5                       | 1                                      |
| Wrinkle smoothing (removers)                                | > 5-10                       | 2                                      |
| Suntan gels, creams, and<br>liquids                         | >0.1- 1                      | 1                                      |
| <i>Myristyl Lactate</i>                                     |                              |  |
| Bath oils, tablets, and salts                               | >0.1- 1                      | 4                                      |
| Other bath preparations                                     | >0.1- 1                      | 1                                      |
| Eyeshadow   | > 10-25                      | 1                                      |
|   | > 5-10                       | 7                                      |
|   | > 1- 5                       | 17                                     |
|   | >0.1- 1                      | 1                                      |
| Aftershave lotions  | > 1- 5                       | 1                                      |
|   | >0.1- 1                      | 1                                      |
| Face, body, and hand<br>(excluding shaving<br>preparations) | > 1- 5                       | 1                                      |
| Moisturizing  | > 5-10                       | 1                                      |
|   | > 1- 5                       | 5                                      |
|   | >0.1- 1                      | 2                                      |
| Night   | > 1- 5                       | 2                                      |
| Other skin care<br>preparations                             | > 1- 5                       | 2                                      |
|   | >0.1- 1                      | 1                                      |
| Suntan gels, creams, and<br>liquids                         | > 1- 5                       | 1                                      |
| Other suntan preparations                                   | > 5-10                       | 1                                      |
| Perfumes  | >0.1- 1                      | 4                                      |

TABLE 1. (Continued.)

| <i>Ingredient/<br/>Cosmetic product type</i> | <i>Concentration<br/>(%)</i> | <i>No. of product<br/>formulations</i> |
|--|------------------------------|--|
| Sachets                                      | >0.1- 1                      | 2                                      |
| Hair conditioners                            | >0.1- 1                      | 1                                      |
| Hair sprays (aerosol<br>fixatives)           | >0.1- 1                      | 1                                      |
| Blushers (all types)                         | > 10-25                      | 2                                      |
|  | > 5-10                       | 2                                      |
|  | > 1- 5                       | 15                                     |
|  | >0.1- 1                      | 3                                      |
| Foundations                                  | > 5-10                       | 1                                      |
|  | >0.1- 1                      | 2                                      |
| Lipstick                                     | > 10-25                      | 14                                     |
|  | > 5-10                       | 39                                     |
|  | > 1- 5                       | 48                                     |
|  | >0.1- 1                      | 2                                      |
| Makeup bases                                 | >0.1- 1                      | 4                                      |
| Rouges                                       | > 1- 5                       | 5                                      |
| Other makeup preparations                    | > 1- 5                       | 2                                      |
| Other personal cleanliness<br>products       | > 1- 5                       | 1                                      |
|  | >0.1- 1                      | 1                                      |

<sup>a</sup>Data from Ref. 11.

of preset concentration ranges also 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 ten-fold error in the assumed ingredient concentration.

It can be inferred from Table 1 that products containing these ingredients are applied to all areas of the skin, hair, and nails and have a potential for introduction through all body orifices. The most prevalent uses involve application around the eyes and mouth. Formulations containing the Lactates may be applied as often as several times a day and successively day after day. Furthermore, they may remain in contact with the skin for hours after each application.

## BIOLOGICAL PROPERTIES

### General Effects

In doses that are considered normal for cosmetic use, the Lactates would not be expected to have any cumulative toxic effects; for they are hydrolyzed to materials that are either ordinarily found in the diet or to substances that are readily converted to such materials.<sup>(12)</sup> The hydrolysis of these ingredients would result in lactic acid and the corresponding alcohol.

### Absorption, Metabolism, Storage, and Excretion

Information regarding absorption, metabolism, storage, and excretion of the Lactates is lacking. However, details of the metabolism of lactic acid and alcohols are readily available.<sup>(13)</sup>

## Animal Toxicology

### Acute Studies

#### *Oral toxicity*

*Cetyl Lactate:* Female Holtzman strain rats were used in an acute oral toxicity study on undiluted Cetyl Lactate. Doses of 5, 10, or 20 ml/kg were administered by gavage to 10 rats at each dosage level. Over a seven-day period, the animals were observed for such signs of toxicity as loss of body weight, convulsions, emesis, and/or death. Neither deaths nor other visible toxic effects occurred at any of the three dosage levels.<sup>(14)</sup>

*Myristyl Lactate:* An acute oral toxicity study on undiluted Myristyl Lactate was conducted in a manner identical to that just described for Cetyl Lactate. No deaths or other visible toxic effects were observed at the three dosage levels.<sup>(15)</sup>

Ten rats (5M, 5F) were used to evaluate the acute oral toxicity of a sample of synthetic Myristyl Lactate. After a single dose of 5.0 g/kg was administered to each via gavage, the rats were allowed food and water ad libitum. They were observed for signs of pharmacologic activity and drug toxicity at 1, 3, 6, and 24 hours post-dosage and daily thereafter for 14 days. All animals were then sacrificed and subjected to complete gross necropsy. Although in nine cases no gross changes or toxic signs were observed, one rat developed fibrous tissue around the heart and lungs and died on Day 10. No explanation nor correlation with the ingredient under study was reported.<sup>(16)</sup>

An acute oral toxicity study on a lipstick formulation containing 13.8 percent Myristyl Lactate was conducted with 10 Sprague-Dawley rats of mixed sex. Single doses of 25 g/kg administered by gavage resulted in neither deaths nor other signs of toxicity.<sup>(17)</sup>

#### *Primary skin irritation*

*Cetyl Lactate:* A solution of 5% Cetyl Lactate in light mineral oil was tested using the Draize technique; the purpose of this study was to determine the degree of irritation the material might produce when it was applied to the clipped, intact, and abraded skin of three normal albino rabbits.<sup>(18)</sup> A single 0.5 ml dose of the test material was applied at each site and occluded for 24 hours. Patch sites were scored separately for erythema and edema at 24 and 72 hours. All scores were zero, and it was concluded that the test material "cannot be considered a primary irritant."<sup>(19)</sup>

The Draize technique was used with three albino rabbits to test the primary irritancy of a 25 percent solution of Cetyl Lactate in mineral oil. All scores were zero.<sup>(20)</sup>

The Draize technique was used with six albino rabbits to test a 25% gravimetric suspension of Cetyl Lactate in corn oil. The Primary Irritation Index (PII) was 0.25 for the average means of 24- and 72-hour gradings; all scores were zero at 72 hours. It was concluded that the tested material was not a primary irritant to rabbits.<sup>(21)</sup>

*Myristyl Lactate:* To determine the degree of irritation the material might produce when it was applied to the clipped, intact, and abraded skin of three normal albino rabbits, undiluted Myristyl Lactate was tested according to the Draize technique. A single 0.5 ml dose of the test material was applied at each site and occluded for 24 hours, and patch sites were scored separately for erythema and edema at 24 and 72 hours. The reported PII was 3.0. Recalculation

from the original data according to the method of Draize yields a PII of 0.38, a score which indicates little potential for skin irritation.<sup>(22)</sup>

A 25% gravimetric suspension of synthetic Myristyl Lactate was tested on six rabbits according to the Draize technique; the resultant PII was 0.15 for the averaged means of 24- and 72-hour data; all scores were zero at 72 hours.<sup>(23)</sup>

When Myristyl Lactate at 10% in mineral oil was evaluated in a Draize test with three rabbits, all scores were zero.<sup>(24)</sup>

Three rabbits were used in a Draize test that was conducted on a 3% solution of Myristyl Lactate in light mineral oil. A PII score of 2.0 was reported. When the original data are recalculated according to the method of Draize, the PII is 0.25.<sup>(25)</sup>

Undiluted synthetic Myristyl Lactate was tested according to the Draize technique on six rabbits of mixed sex. The averaged means of 24- and 72-hour data produced a PII of 2.2; all scores were 0.0 at 72 hours. This result indicates a potential for moderate skin irritation.<sup>(16)</sup>

*Lactic Acid:* Although this possibility is not documented, small amounts of lactic acid may be formed by hydrolysis of the cosmetic Lactates that are applied to the skin. Concentrated solutions of lactic acid can cause severe burns of the skin or eye,<sup>(12,26,27)</sup> but dilute solutions of 1% are reported to be harmless.<sup>(26)</sup> Lactic acid is applied topically in the treatment of ichthyosiform dermatoses. To circumvent irritation when large areas of the body are treated, manufacturers reduce the concentration from the normal 5–10% to 2–5%. Still, even a 10% concentration has been seen to produce degrees of irritancy that were mild, quickly detected, and readily reversed by temporary discontinuance or reduction in the frequency of application.<sup>(27)</sup> It is highly unlikely that lactic acid would be liberated from the cosmetic ingredients under consideration in concentrations sufficient to cause skin irritation.

#### *Eye irritation*

*Cetyl Lactate:* A 5% solution of Cetyl Lactate in mineral oil was tested according to the Draize technique to determine whether it produced irritation when instilled into rabbits' eyes. Each of three albino rabbits received a 0.1 ml sample in the right eye. They were examined every 24 hours for four days and again on the seventh day and scored according to the Draize scale for ocular lesions. All scores were zero.<sup>(28)</sup>

Cetyl Lactate, at a concentration of 15% in corn oil, was evaluated in a similar test on six albino rabbits. The result was a mean Draize score of 1.3 of a total possible 110. It was concluded that the test material had a potential for only very slight ocular irritation.<sup>(29)</sup>

Undiluted Cetyl Lactate was tested on six albino rabbits according to the Draize technique. A mean score of 0.3 out of a total possible 110 necessitated the conclusion that the material was not an ocular irritant under the conditions of the test.<sup>(30)</sup>

*Myristyl Lactate:* Instillation of 0.1 ml of 3% Myristyl Lactate in mineral oil into the right eye in each of three rabbits produced a Draize score of zero.<sup>(31)</sup>

Undiluted synthetic Myristyl Lactate was tested in two separate studies, each using a modified Draize procedure for ocular irritation on six rabbits. Treated eyes remained unwashed, and contralateral eyes served as controls. All scores were zero, and it was concluded that under the conditions of the tests, the material was not an ocular irritant to rabbits.<sup>(16,32)</sup>

A lipstick formulation containing 13.8% Myristyl Lactate was tested on six

rabbits according to the Federal Hazardous Substance Act (FHSA) method for ocular irritation. The animals were observed three days, and showed no sign of eye irritation.<sup>(17)</sup>

### **Subchronic Studies**

#### *Skin irritation and sensitization*

**Cetyl Lactate:** A skin irritation study on a 25% solution of Cetyl Lactate in mineral oil was conducted using three rabbits with clipped intact and abraded skin. For 30 days, 5 ml of the solution were applied each morning to the back of each animal, after which the animals were restrained in stocks for four hours. Blood counts were made at the beginning of the experiment, at the end of the second week, when the last application was made, and one week after the last application. Sections of skin were removed from test application sites and fixed in formalin for histological examination. Weight gains and blood counts were normal throughout the test period. No irritation as evidenced by erythema and edema was found following any of the applications. Scarified areas showed normal healing, and histological examination of the skin showed a normal picture. It was concluded that no irritation occurred upon daily application of a 25% solution of Cetyl Lactate for 30 days.<sup>(33)</sup>

A guinea pig sensitization study was conducted to determine the sensitization potential of Cetyl Lactate. Eight male guinea pigs were injected intracutaneously with a 0.1% solution of Cetyl Lactate in physiological saline. The injections were made every other day until there was a total of 10 injections. While the first injection was of 0.5 ml, all subsequent injections were of 0.1 ml. Two weeks after the final injection, a challenge of 0.5 ml freshly prepared solution was administered. Reaction readings were made 24 hours after each injection. Small raised areas with a slight increase in color were observed at each reading. The challenge reaction score was less than the average of induction readings, so the solution as tested was considered to be a nonsensitizer.<sup>(34)</sup>

**Myristyl Lactate:** A modified Draize skin irritation technique was employed to test a lipstick formulation containing 13.8 percent Myristyl Lactate. Six rabbits had their backs and flanks clipped free of hair and received epidermal abrasions on one side. A 0.5 g sample of the product was applied to each test site daily for three consecutive days under open patch conditions. Four of six animals reacted with Draize irritation scores of one or two. It was concluded that the product elicited mild irritation on the skin of rabbits under conditions of the test.<sup>(17)</sup>

### **Clinical Assessment of Safety**

#### **Cetyl Lactate**

##### *Skin irritation*

A single insult, 24-hour, occlusive patch test on Cetyl Lactate was performed using 2.5% and 5% aqueous preparations of the ingredient. One group of 20 subjects was employed per concentration level. Two subjects in each group exhibited signs of mild irritation, scoring 0.5 and 1.0, respectively, out of a maximum possible score 4. It was concluded that both the 2.5% and 5% dilutions elicited minimal transient reactions.<sup>(35)</sup>



### *Skin sensitization*

The Draize–Shelanski repeated insult patch technique for human contact allergenicity was used to test a 5% aqueous preparation of Cetyl Lactate on a group of 200 individuals. Lintine discs moistened with the test solution were placed on the upper arm and occluded for 24 hours. Applications were made three days a week to a total of 15, each of 24 hours duration. Patch sites were examined and graded on a scale of zero to four after the patches were removed and before re-application. Following the 15th application, participants rested for two weeks. The sites of contact were then challenged with the test material for 24 hours under occlusion. During the test, no visible skin changes signifying reaction to injury were observed in any of the 200 subjects; the solution was, therefore, considered nonirritating and nonsensitizing.<sup>(36)</sup>

**Myristyl Lactate:** A lipstick formulation containing 13.8% Myristyl Lactate was tested on 200 subjects using a modified Draize repeated insult patch technique. There was no evidence of skin irritation or sensitization.<sup>(17)</sup>

## SUMMARY

Cetyl Lactate and Myristyl Lactate are the esters of lactic acid and either cetyl or myristyl alcohol. They are used in a wide variety of cosmetic products and may be applied to all areas of the skin.

One would expect Cetyl Lactate to be nontoxic with normal cosmetic use, for it is hydrolyzed to lactic acid and cetyl alcohol. From studies with rats, the acute oral LD50 is estimated to be greater than 20 g/kg. Cetyl Lactate was shown to be minimally irritating to rabbits' skin and nonirritating or only slightly irritating to rabbits' eyes in Draize irritation tests. At 25%, Cetyl Lactate produced no signs of toxicity or irritation in a 30-day rabbit skin irritation study; the concentration thus tested coincided nicely with the maximum concentration found in cosmetics. A guinea pig sensitization study on the ingredient produced no signs of sensitization. Cetyl Lactate was found to be minimally irritating and nonsensitizing to human skin at concentrations up to 5%. It is found at concentrations greater than 5% in some cosmetic formulations.

Myristyl Lactate would also be expected to be nontoxic with normal cosmetic use; for it hydrolyzed to lactic acid and myristyl alcohol. From studies with rats, the acute oral LD50 is estimated to be greater than 20 g/kg. Myristyl Lactate was shown to be minimally irritating in Draize primary skin irritation tests, but one contradictory study concluded that undiluted Myristyl Lactate produced moderate irritation. It produced no signs of ocular irritation in Draize rabbit eye irritation tests. In a 3-day modified Draize rabbit skin irritation test, a lipstick formulation containing 13.8% Myristyl Lactate elicited mild irritation. The same lipstick formulation was found to be nonirritating and nonsensitizing in a human repeated insult patch study.

There are no data on absorption, metabolism, storage, excretion, carcinogenicity, mutagenicity, and teratogenicity, nor are photosensitization data available on either Cetyl or Myristyl Lactate. The clinical information on Cetyl Lactate is limited to testing at 5% concentration.

## CONCLUSION

On the basis of the available information, the Panel concludes that Cetyl Lactate and Myristyl Lactate are safe in the present practices of use.

## ACKNOWLEDGMENT

Mr. Jeffrey Moore, Scientific Analyst and writer, prepared the literature review and technical analysis used by the Expert Panel in developing this chapter.

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\*Available upon request: Administrator, Cosmetic Ingredient Review, Suite 810, 1110 Vermont Ave., N.W., Washington, DC, 20005.

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