

## Japanese Functional Food Update Vol.4 Foods with Function Claims notification as final product: Skin moisturizing effect

People with dry skin issue have expressed that the condition bothers them very much on a daily basis. In recent years, researches related to food ingredients with the skin moisturizing ability have been increasing. In this update, we would like to summarize and review the functional ingredients and functionality evaluation items of products notified as FFC with claims related to “skin moisturizing effect” in this issue.

●Functional ingredients of products with the health claim “Skin moisturizing effect”

Amid products notified as finished products, different functional ingredients are used in a variety of products, and a number of food ingredients have been reported as having potential skin moisturizing effects as shown in Table 1. More specifically, the large variety of notified ingredients include sterols derived from Aloe, collagen peptides, mangosteen peel extract, proantho-cyanidins derived from acacia bark, peptides obtained from placenta, soy isoflavones, eriodictyol-6-C-glucoside, lactic acid

bacteria, sphingomyelin, glucoraphanin, phycocyanin and piceatannol. Amongst all these ingredients, we will focus on collagen peptide, an ingredient that has been most extensively studied in clinical trials.

Functional ingredient	No. of notifications
Collagen Peptide	5
Sterols derived from Aloe	4
Mangosteen peel extract	2
Proanthocyanidins derived from Acacia Bark	2
Peptides obtained from placenta	2
Soy Isoflavones	1
Eriodictyol-6-C-glucoside	1
Lactic acid bacteria	1
Sphingomyelin	1
Glucoraphanin	1
Phycocyanin	1
Piceatannol	1

Table 1. No. of notifications for each functional ingredient

※Multiple ingredients may be used in the same product.

### Collagen peptide

The skin plays an important role in preventing the evaporation of water from the body, and if the structure of the dermis is damaged, moisture cannot be retained, resulting in skin dryness. The main components of the dermis are collagen, elastin, hyaluronic acid and fibroblasts, with collagen making up approximately 70% of the skin<sup>1)</sup>. Therefore, it is thought that many of the numerous factors involved in “ideal skin”, including moisture, firmness and

concentration of blemishes, are closely related to collagen. Researches have shown that prolyl-hydroxyproline (Pro-Hyp), which is produced in the bloodstream when collagen peptides are ingested, increases the number of fibroblasts to produce collagen<sup>2)</sup>. This has led to the widespread attention on the use of health supplements containing collagen peptides for the skin.

● Evaluation items used for functionality assessment

The most common evaluation parameters used to assess skin moisture was found to be the measurement of skin moisture content using specialised measuring instruments(Figure 1).

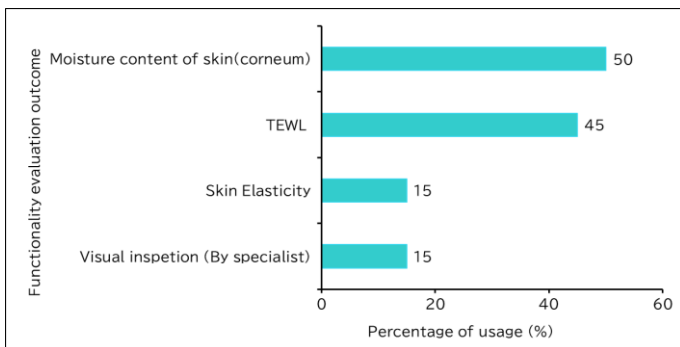


Figure 1. Relative usage percentages of various evaluation items

※1 Multiple evaluation items are used in combination in some clinical trials

※2 Evaluation items with percentage of usage 15% or below are not included in the chart.

Skin moisture content and trans-epidermal water loss (TEWL) measurements are used to assess

functions such as skin moisture retention and skin moisture content.

● Design of clinical trials used - Selection of participants

Amid notifications that are submitted as final products, about half of them used the results of clinical trials that are contacted only on female subjects (Tables 2-1 and 2-2). However, in one of the dossiers for FFC notification, namely “Supplementary explanatory material on the scientific basis for the functionality to be labelled”, many notifiers claimed that the functionality of the notified product can be applied to both genders, despite using clinical trials where only female subjects were enrolled as their supporting evidence. The reason stated was that there is no difference in terms of skin structure and mechanism of action of the active ingredient(s) on the skin between the two genders. Nevertheless, it was added that when selecting subjects for clinical trials, one should look carefully into whether the result is susceptible to the impact of differences in gender.

In ORTHOMEDICO, detailed review on past findings and related literature are conducted to ensure protocols that can bring about high-quality clinical trials are proposed. Furthermore, we provide “total support” from clinical trials to post-trial related work such as notification submission and dealing with

responses from the CAA. Please feel free to contact us to know more. We will continue to provide you with information about the Japanese functional food regulation and market.

Looking forward to working with you in the future.

Table 2. List of published clinical trials that studied final product and showed scientific evidence for “Skin moisturizing effect” function

FFC Notification No.	Literature	Functional ingredient(s)	Study Participant	Outcomes used in functionality evaluation
D10	Tanaka M, et al (2016) <sup>3)</sup>	Aloe derived lophenol, Aloe derived cycloartanol	30-59 year-old healthy female	TEWL, skin moisture content
D429				
F51				
F60				
D149	Yamamoto T. et al (2018) <sup>4)</sup>	Collagen peptide	30-60 year-old healthy male and female with dry skin	TEWL, moisture content of corneum
E566				
E567				
D422	Najima M, (2017) <sup>5)</sup>	Soybean isoflavone Aglycone	35-59 year-old female who are concerned about wrinkles (Evaluation of wrinkles: Ranking in accordance with related guideline)	TEWL, moisture content of corneum
D583	Iwai T. et al (2018) <sup>6)</sup>	Eriodictyol-6-C-Glucoside (E6CG)	20-64 year-old healthy male and female with subjective dryness of 2 or more parts of the followings: mouth, eye, and skin	Moisture content of corneum, VAS (Subjective evaluation of skin dryness)
E1	Maejima K, (2018) <sup>7)</sup>	Rhodanthenone B	25-59 year-old healthy female	TEWL, moisture content of corneum, anti-glycation evaluation, skin elasticity
E44				
E5	Hoshino T (2018) <sup>8)</sup>	Acacia bark derived proanthocyanin	Healthy Japanese adult male and female who experience uncomfortable skin symptoms	TEWL, moisture content of corneum, skin elasticity
E506				
E29	Meshizuka S. et al (2018) <sup>9)</sup>	Fish scale derived collagen peptide	30-55 year-old healthy male and female	Measurement of moisture and oil content, visual inspection by specialist
E546	Kimura I. et al (2017) <sup>10)</sup>	<i>L. delbrueckii</i> subsp. <i>bulgaricus</i> OLL1247 strain and <i>S. thermophilus</i> 3078 strain (SC-2 lactic acid bacteria), collagen hydrolysates and sphingomyelin	20-49 year-old healthy female with dry skin	TEWL, moisture content of corneum, visual inspection by specialist
E613	Kim K, et al (2018) <sup>11)</sup>	Porcine placenta derived peptide (Glycine-leucine, leucin-glycine)	30-60 year-old healthy male and female	TEWL, moisture content of corneum
F15				
E735	Ono T. et al (2018) <sup>12)</sup>	Glucoraphanin	30-59 year old healthy female who experience dry skin subjectively	Moisture content of corneum, TEWL, visual inspection by specialist
F93	Imai Y et al (2019) <sup>13)</sup>	Phycocyanin (C-phycocyanin, allophycocyanin)	20-65 year-old healthy female who are concerned about their dry skin	TEWL
F297	Yamamoto T. et al (2018) <sup>14)</sup>	Piceatannol	30-60 year old healthy male and female with dry skin	Skin elasticity

## 【Reference】

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- 5) Najima M, et al. Efficacy of supplements on the condition of the human skin containing soybean isoflavonin in healthy Japanese women: a randomized double-blind placebo-controlled study. *New-Remed*. 2017; 54(2): 64-72.
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