

Meeting Report of the Special Committee for the Safety of Protein Hydrolysates in Cosmetics

5th Meeting

Date and Time: 11:45-12:45, May 13, 2012

Venue: Osaka International Convention Center (Room No. 10-2)

Attendee: 16 committee members including President, 8 observers

Kayoko Matsunaga (Chair), Michiko Aihara, Yoshiro Ikezawa, Atsuo Urisu, Zenichiro Kato, Reiko Kishikawa, Mitsuru Sawa, Shinichi Sugiura, Hiroyuki Tanaka, Reiko Teshima, Michihiro Hide, Yuma Fukutomi, Eishin Morita, Akiko Yagami, Yuko Chinuki, Kazuo Akiyama (President of the Japanese Society of Allergology)

Absentee: Atsuki Fukushima, Yasuharu Itagaki

Witness: Manabu Takeda, Keito Kurihara from Croda Japan (material maker)

Norio Takeda from Yuuka Co., Ltd. (sales company)

Observer: Masashi Nakamura (Fujita Health University); Kazumi Sasaki from National Institute of Technology and Evaluation; Katsuhiro Takano, Hitoshi Sasa, Mariko Sugiyama (Japan Cosmetic Industry Association)

Minutes:

1. As to the presentation on “Cha no Shizuku” induced allergy at the 24th Spring Meeting of Japanese Society of Allergology, reporters have been asked to refrain from interviewing presenters and symposium chair, as the “Cha no Shizuku” health hazard is under the legal proceedings. Instead, press conference will be held to report on current situation and stance of the Committee.
2. How to answer questions from media
Glupearl 19S has been identified as a causative antigen of wheat allergy induced by Cha no Shizuku soap bar.
As to this incident, the number of victims increased while causes were not identified. Typical symptom observed is periorbital edema that can develop even in individuals without past allergy history. Out of 463 cases registered as positive, females account for 95% and victims range from 9-year-old boy to 93-year-old woman.
Some have recovered from disorder. But there are some cases where sensitization to Glupearl 19S remains although allergic reaction to wheat-containing food disappears.
3. Research progress report by each member
4. Dr. Teshima made an interim report on “New Type of Sensitization to Hydrolyzed Wheat” based on animal experiment data, which indicated possibility of sensitization caused by hydrolyzed wheat protein other than Glupearl 19S. However, validity of this animal model needs to be determined. It

will be necessary to re-examine or perform another test under slightly changed conditions to reach the final conclusion.

5. What was heard from Mr. Takeda (Croda Japan)

Croda's lanolin has gained profound confidence in Europe. Its wheat protein products have been used as cosmetics ingredients for more than 20 years and considered to have little risk. Allergy development cases reported so far are 10 at most (powder inhalation at plant, rash in a person with allergic constitution and others) against 100 million products sold internationally. There have been no anaphylaxis cases reported. UK headquarters also keeps an eye on the progress in Japan and is ready to give as much assistance as possible.

Members will confirm the safety of products again. Details will be discussed this evening at the session to exchange information with researchers from UK headquarters. Sales amount data will be presented.

In response to the report indicating high cross-reactivity to Glupearl 19S, sales in Japan has been stopped, but it is uncertain how long it will take till all the products in question are totally removed from the market.

6. Report by Yuuka

Number of cases at present (collected from May 20, 2011 through April 6, 2012)

- 1) Medical certificates submitted: 1,971
- 2) Cases notified to Pharmaceutical and Medical Devices Agency by healthcare professionals based on the Side Effect and Infectious Disease Report System of the Agency: 219

7. Cases examined by each member

Materials will be mutually sent among members via e-mail to share information.

8. Information exchange meeting

Information will be exchanged with researchers from Croda headquarters in England.

17:00~18:30 (after the Spring Meeting), May 13

At the conference room (Nishiki) on the 6th floor at RIHGA ROYAL HOTEL