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# Safety Assessment of Soy Peptides as Used in Cosmetics

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Status: Draft Report for Panel Review  
Release Date: May 22, 2015  
Panel Meeting Date: June 15-16, 2015

The 2015 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D., Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Christina Burnett, Senior Scientific Analyst/Writer, and Bart Heldreth, Ph.D., Chemist CIR.

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## **Cosmetic Ingredient Review**

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Memorandum

To: CIR Expert Panel Members and Liaisons  
From: Christina L. Burnett, Senior Scientific Writer/Analyst  
Date: May 22, 2015  
Subject: Draft Safety Assessment on Soy Peptides

Enclosed is the Draft Report of the Safety Assessment of Soy Peptides as Used in Cosmetics. (It is identified as *soypepe062015rep* in the pdf document).

In March 2015, CIR issued the Scientific Literature Review (SLR) for soy peptides ingredients. The soy peptides, or soy protein derivatives, form a broad category of materials which are prepared by extraction from soy and partial hydrolysis to yield cosmetic ingredients. Soy peptide ingredients function mainly as skin and hair conditioning agents in personal care products.

Data requested with the issuance of the SLR included clarification on the method of manufacture and types and concentrations of impurities and/or general composition of cosmetic-grade soy peptide ingredients, as well as any additional toxicological data that would help the Panel assess the safety of the use of these ingredients in cosmetics.

Unpublished data were provided by the Personal Care Products Council (Council), and, since the March announcement, the Council has provided comments on the SLR, which have been considered. The data have been incorporated into the report, and both the data and the comments can be found in this report's package (*soypepe062015data1* to *soypepe062015data4* and *soypepe062015pcpc*, respectively).

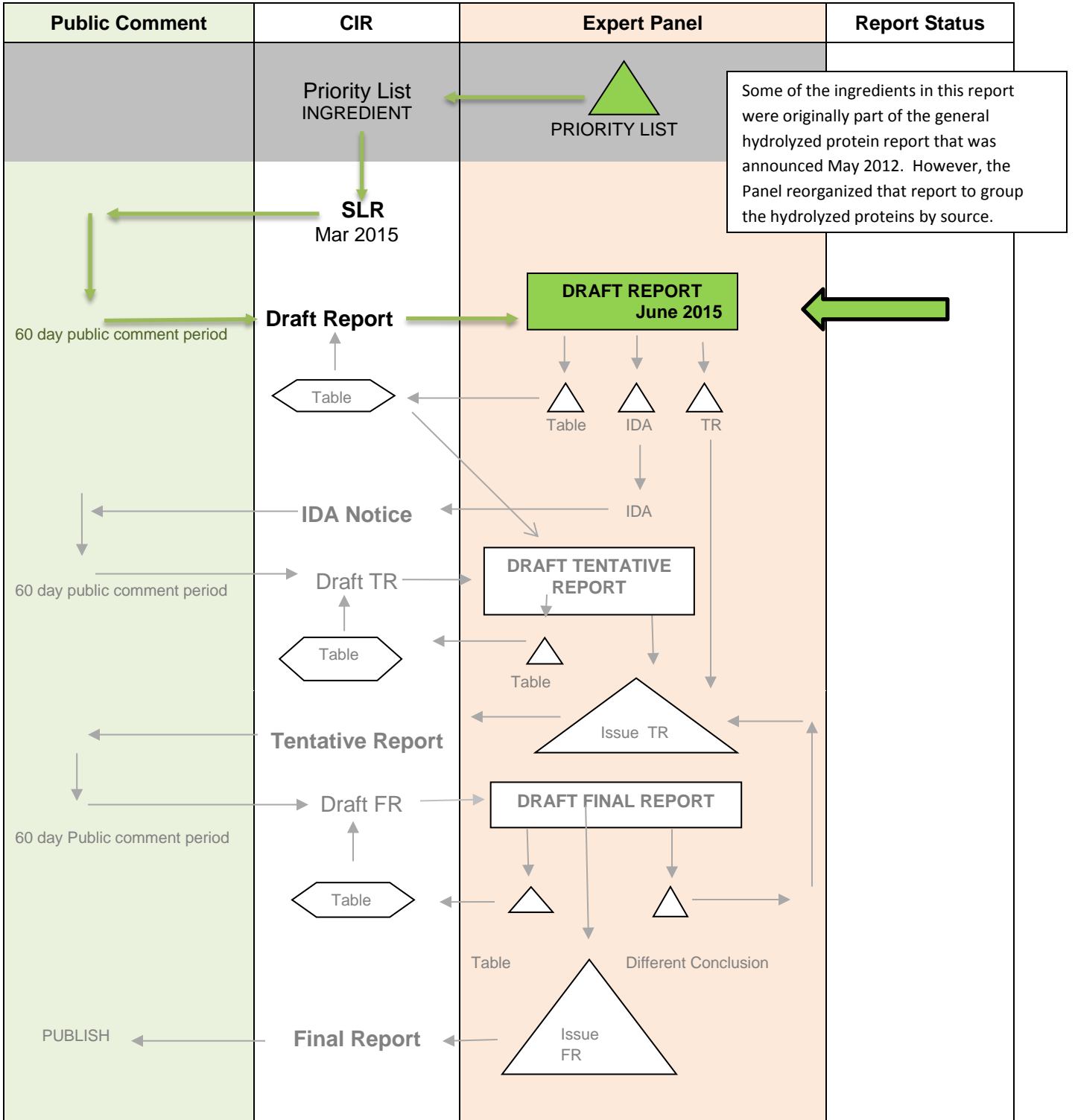
According to the FDA's VCRP database in 2015, hydrolyzed soybean protein has the most reported uses in cosmetic products, with a total of 862; about half of the uses are in non-coloring hair products. Glycine soja (soybean) protein has the second greatest number of overall uses reported, with a total of 313; a third of those are used in leave-on skin care products and another third are used in hair dyes and colors. The results of the Council's concentration of use survey indicate that hydrolyzed soy protein has the highest reported maximum concentration of use; it is used at up to 3.5% in mascara. Glycine soja (soybean) protein is used at up to 0.9% in eye lotion.

If no further data are needed, the Panel should issue a Tentative Report.

# SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Soy Peptides

MEETING June 2015



## **Soy Peptides History**

**May 2012** – Scientific Literature Reviews announced for Hydrolyzed Source Proteins.

**December 2012** - The CIR Expert Panel combined the report with one on source amino acids and called it “plant- and animal-derived amino acids and hydrolyzed proteins”. The Panel requested additional data to support the safety of 75 plant- and animal-derived amino acids and hydrolyzed proteins. The additional data needed are: (1) method of manufacturing data for both plant and animal-derived amino acids and hydrolyzed proteins, especially for hydrolyzed wheat protein; and (2) composition and characterization specifications of plant and animal-derived amino acids and hydrolyzed proteins, including molecular structure and molecular weight ranges from several suppliers to determine if there is a consistency in cosmetic grade plant and animal-derived hydrolyzed proteins, especially hydrolyzed wheat protein.

**March 2013 and Post Meeting** – The Expert Panel tabled further discussion on animal- and plant-derived hydrolyzed proteins to allow CIR staff to reorganize the report. The staff decided to group the hydrolyzed proteins by source for separate evaluations by the Panel. Hydrolyzed wheat protein and hydrolyzed wheat gluten was the first report reviewed. The review of the other animal- and plant-derived hydrolyzed proteins will be performed sometime in the future.

**March 2015** – Scientific Literature Review announced on soy peptides, including hydrolyzed soy protein and hydrolyzed soymilk protein.

<b>Soy Peptides Data Profile - June 2015 - Writer, Christina Burnett</b>										
	<b>In-Use</b>	<b>Physical/Chemical Properties</b>	<b>Method of Manufacturing</b>	<b>Composition</b>	<b>Genotoxicity</b>	<b>Irritation/Sensitization - Nonhuman</b>	<b>Irritation/Sensitization - Clinical</b>	<b>Ocular/Mucosal</b>	<b>Phototoxicity</b>	<b>Case Studies</b>
Glycine Max (Soybean) Polypeptide	X									
Glycine Soja (Soybean) Peptide				X						
Glycine Soja (Soybean) Protein	X		X							
Hydrolyzed Soy Protein	X	X	X	X	X	X	X	X		
Hydrolyzed Soy Protein Extract										
Hydrolyzed Soymilk Protein	X	X		X		X		X		
<b>Soy - Generic</b>										X

“X” indicates that data were available in the category for that ingredient.

**SEARCH STRATEGY FOR SOY PEPTIDES**

(Performed by Christina Burnett)

**February 2015:** SCIFINDER search for “soy, soy peptides, or soy protein” yielded 0 hits.  
-search for “soy proteins peptides polypeptides oligopeptides” yielded 7815 hits.  
- Limit to “adverse effect, including toxicity” yielded 291 hits.  
- Further limit to “proteins and allergens” yielded 76 hits.

*Many of the references were dietary focused reports.*

**February 2015:** PubMed search for “soy protein” yielded 200 hits, 6 ordered and 2 downloaded.  
-search for “soy protein dermal” yielded 1 hit.  
-search for “soy protein skin” yielded 5 hits, 1 downloaded.  
-search for “hydrolyzed soy” yielded 1 hit.

**6 references were ordered.**

**Search updated April 2015. No new relevant references identified.**

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## INTRODUCTION

Soy peptide ingredients function mainly as skin and hair conditioning agents in personal care products.<sup>1</sup> This report assesses the safety of the following 6 soy peptides:

Glycine Max (Soybean) Polypeptide	Hydrolyzed Soy Protein
Glycine Soja (Soybean) Peptide	Hydrolyzed Soy Protein Extract
Glycine Soja (Soybean) Protein	Hydrolyzed Soymilk Protein

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) previously has reviewed the safety of  $\alpha$ -amino acids, plant and animal derived amino acids, hydrolyzed collagen, and hydrolyzed corn protein, and concluded that these ingredients are safe for use in cosmetic ingredients.<sup>2-6</sup> Additionally, the Panel concluded that hydrolyzed wheat gluten and hydrolyzed wheat protein are safe for use in cosmetics when formulated to restrict peptides to a weight-average MW of 3500 Da or less.<sup>7</sup>

Soy peptides are used as food, and daily exposure from food use would result in much larger systemic exposures than from use in cosmetic products. Additionally, the U.S. Food and Drug Administration (FDA) determined that the use of peptones as direct food substances is generally recognized as safe (GRAS) and that soybean protein is GRAS for substances migrating to food from paper and paperboard products. Thus, the systemic toxicity potential of soy peptide ingredients via oral exposure is not addressed further in this report. The primary focus of the safety assessment of these soy peptides ingredients as used in cosmetics is on the potential for irritation and sensitization from dermal exposure.

Note: Ingredients with the name glycine soja (soybean) are undergoing a name change to glycine max (soybean). This change represents more commonly accepted nomenclature.

## CHEMISTRY

### Definition and Manufacture

The definitions and functions of the soy peptide ingredients included in this report are provided in Table 1. The soy peptides, or soy protein derivatives, form a broad category of materials which are prepared by extraction from soy and partial hydrolysis to yield cosmetic ingredients. Protein hydrolysates, including those of soy, are used as conditioning agents in hair and skin products. Soy peptides can also be separated on the basis of molecular size. By removing oil at lower temperatures, soy protein isolate is obtained, and is widely used in the food industry.<sup>8-10</sup> Whole aqueous extractable soybean proteins can be separated into storage globulin and whey fractions by acidification.

The acid-precipitable fraction of whole aqueous extractable soybean proteins includes the major soybean storage proteins. The remaining part consists of the minor globulin,  $\gamma$ -conglycinin, and contaminating proteins, including whey proteins. Whey proteins are composed of lipoyxygenase (102 kDa), bamylase (61.7 kDa), lectin (33 kDa), and Kunitz trypsin inhibitors (20 kDa). The proportion represented by these whey proteins in the acid-precipitated globulins is unknown. Soy protein isolate is a mixture of various proteins, and the main ingredients are classified into four protein categories according to their sedimentation coefficients 2S, 7S, 11S, and 15S which sediment at different gravitational forces when the solution is subjected to a centrifugal field. Among these proteins, 7S ( $\beta$ -conglycinin) and 11S (glycinin) represent 80%-90% of all soybean protein, and the ratio 7S/11S has been reported to be about 0.5-1.3 depending on varieties. The 7S globulin consists of three subunits  $\alpha$  (ca 67 kDa),  $\alpha'$  (ca 71 kDa) and  $\beta$  (ca 50 kDa). The 11S globulin is a hexamer, and is made up of five different subunits, each of which consists of an acidic subunit A (ca 35 kDa) and a basic subunit B (ca 20 kDa), linked by a disulfide bond. 11S was found to dissociate into 2S, 3S or 7S forms in various pH and ionic strengths. Amino acid compositions of  $\beta$ -conglycinin and glycinin have been analyzed, but the three dimensional structure is not well established in spite of many efforts.

The FDA defines the term "protein" to mean any  $\alpha$ -amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size.<sup>11</sup> The FDA considers a "peptide" to be any polymer composed of 40 or fewer amino acids. However, these definitions of protein and peptide are not necessarily adhered to in the naming of cosmetic ingredients.

### Chemical and Physical Properties

The available chemical and physical properties for some of these soy peptide ingredients are presented in Table 2.



***Soy Peptide***

Dipeptide- or tripeptide-rich forms of soy peptide were described to have a molecular weight of around 500 Da.<sup>12</sup>

***Hydrolyzed Soy Protein***

A histogram showing the approximate distribution of molecular weights for hydrolyzed soy protein from one supplier is shown in Figure 1. The figure shows that approximately 35% of the molecular weight distribution falls between 490 and 1030 Da. One source has indicated the average molecular weight is 300 Da<sup>13</sup>; however, other sources have reported the molecular weight of their hydrolyzed soy protein product to be approximately 1000-2000 Da.<sup>14-16</sup>

***Hydrolyzed Soymilk Protein***

A supplier has reported the molecular weight of their hydrolyzed soymilk protein product to be approximately 1000-2000 Da.<sup>16</sup>

**Method of Manufacturing*****Glycine Soja (Soybean) Protein***

Glycine soja (soybean) protein can be prepared from defatted low-heat soybean meal.<sup>9</sup> A dispersion of soy flour is prepared by adding distilled water (1: 15, w/v) with final protein concentration of 3.1% (w/w). Then, 2 mol/L NaOH is used to adjust the dispersion to pH 8.5. The dispersion is stirred for 1 h at room temperature and then centrifuged (10000 × g, 20 min). The supernatant is adjusted to pH 4.5 with 2 mol/L HCl and centrifuged (10000 × g, 20 min). The obtained sediment is resuspended with distilled water (1: 5, v/v) and adjusted to pH 7.0 with 2 mol/L NaOH. Then it is dialyzed against deionized water and freeze-dried.

***Hydrolyzed Soy Protein***

A manufacturing flow chart from a hydrolyzed soy protein supplier is shown in Figure 2.

The preparation of hydrolysates can be afforded via acid and enzyme.<sup>9</sup> The above glycine soja (soybean) protein dispersion (4% w/v) is adjusted to pH 2.0 with 1 mol/L HCl, and incubated at 37 °C for 30 min. Then, an enzyme (such as pepsin) is added to each part at an enzyme to substrate ratio of 0.3% (w/w) to start the enzymatic hydrolysis reaction. Each fraction is incubated at 37 °C (10-900 min) and the enzyme is deactivated by adjusting the pH to 7.0 with 2 mol/L NaOH.

A supplier has reported that hydrolyzed soy protein is produced from isolated soy proteins that are hydrolyzed with a protease enzyme for 2 hours.<sup>18</sup> The enzyme is inactivated by heat once the target molecular weight is achieved. The resultant solution may then be concentrated.

Another supplier reported that hydrolyzed soy protein (MW = 300 Da) may be prepared by both alkaline and enzyme hydrolysis.<sup>13</sup> These processes occur for several hours until the desired molecular weight is reached. The final product is a 25% water solution of hydrolyzed soy protein.

**Composition and Impurities**

A supplier-provided list of allergens certified NOT to be in their products containing 25% and 35% hydrolyzed soy protein and 21.5% hydrolyzed soymilk protein is presented in Table 3.<sup>19-21</sup>

***Soy Peptide***

The amino acid composition of a soy peptide sample is presented in Table 4. The analysis found that soy peptide is rich in aspartic acid (12.6%) and glutamic acid (22.1%).<sup>12</sup>

***Hydrolyzed Soy Protein***

A supplier states that hydrolyzed soy protein (MW = 300 Da) has heavy metals, arsenic, and iron at levels ≤ 10 ppm, 1 ppm, and 10 ppm, respectively.<sup>13</sup>

The compositional breakdown of products containing 25% and 35% hydrolyzed soy protein included 74.6% or 64.6% water, respectively, and 0.2% methylparaben, and 0.2% quaternium-15, each.<sup>19,20</sup>

### ***Hydrolyzed Soymilk Protein***

The compositional breakdown of a product containing 21.5% hydrolyzed soymilk protein included 76.6% water, 1.2% phenoxyethanol, and 0.7% DMDM hydantoin.<sup>21</sup>

#### **USE**

##### **Cosmetic**

The safety of the cosmetic ingredients included in this safety assessment is evaluated on the basis of the expected use in cosmetics. The Panel utilizes data received from the FDA and the cosmetics industry in determining the expected cosmetic use. The data received from the FDA are those it collects from manufacturers on the use of individual ingredients in cosmetics by cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP), and those from the cosmetic industry are submitted in response to a survey of the maximum reported use concentrations by category conducted by the Personal Care Products Council (Council).

According to the 2015 VCRP survey data, hydrolyzed soybean protein has the most reported uses of the ingredients listed in this safety assessment in cosmetic products, with a total of 862; about half of the uses are in non-coloring hair products (Table 5). Glycine soja (soybean) protein has the second greatest number of overall uses reported, with a total of 313; a third of those are used in leave-on skin care products and another third are used in hair dyes and colors. The results of the concentration of use survey conducted in 2014 by the Council indicate hydrolyzed soy protein has the highest reported maximum concentration of use; it is used at up to 3.5% in mascara. Glycine soja (soybean) protein is used at up to 0.9% in eye lotion. No use concentrations were reported for the remaining 4 ingredients.

Based on the VCRP data and the results of the Council's concentration of use survey, glycine soja (soybean) peptide and hydrolyzed soy protein extract are not in use.

Some of these ingredients may be used in products that can be incidentally ingested or come into contact with mucous membranes. For example, hydrolyzed soy protein is used in bath soaps and detergents at up to 1.5%. Additionally, some of these ingredients were reported to be used in hair sprays and body and hand sprays and could possibly be inhaled. For example, glycine soja (soybean) protein was reported to be used in body and hand sprays at a maximum concentration of 0.07%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles below 10 µm compared with pump sprays.<sup>22-25</sup> Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.<sup>23,24</sup>

The soy peptide ingredients in this report are not restricted from use in any way under the rules governing cosmetic products in the European Union.<sup>26</sup>

##### **Non-Cosmetic**

The FDA determined that the use of peptones as direct food substances is GRAS. These GRAS peptones are defined as "the variable mixture of polypeptides, oligopeptides, and amino acids that are produced by partial hydrolysis of ...soy protein isolate..." (21 CFR §184.1553). Additionally, soybean protein (described as glycine soja (soybean) protein) is GRAS for substances migrating to food from paper and paperboard products (21CFR §182.90).

The FDA has also reviewed soybean protein for use as an active ingredient in over-the-counter drugs. Based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of this ingredient in weight control drug products (21CFR §310.545).

The FDA requires allergen labeling when major allergens are included in food.<sup>27</sup> The major allergens include wheat, milk, egg, fish, Crustacean shellfish, tree nuts, peanuts, and soybeans.

Soy proteins are used in adhesives and plastics industries.<sup>28</sup>

#### **TOXICOKINETICS**

##### ***Hydrolyzed Soy Protein***

While no experimental data were available for the dermal absorption of hydrolyzed soy protein, gastrointestinal absorption would allow for significantly higher bioavailability than dermal absorption.<sup>29</sup> In worst-case scenarios of oral exposures greater than 2000 mg/kg, no signs of systemic toxicity were observed and therefore it was concluded that no systemic toxicity would occur for cutaneous exposure.

## **TOXICOLOGICAL STUDIES**

The soy peptides that serve as the sources for the ingredients that are addressed in this safety assessment are found in the foods we consume daily. The potential for systemic effects, other than sensitization, from the possible absorption of soy peptide ingredients through the skin is much less than the potential for systemic effects from absorption through oral exposures. This is because the rates of absorption and metabolism of these ingredients in the skin are expected to be negligible compared to the corresponding rates in the digestive tract. Thus, the potential for systemic effects, other than sensitization, are not discussed in detail in this report. This assessment focuses on evaluating the potential for these ingredients to cause sensitization reactions and irritation.

## **GENOTOXICITY**

### ***Hydrolyzed Soy Protein***

Hydrolyzed soy protein was analyzed for mutagenic potential in an assay using *Salmonella typhimurium* TA 1535/pSK1002 with and without S9 metabolic activation.<sup>29</sup> Concentrations tested were 625, 1250, 2500, or 5000 µg/ml. No sign of mutagenicity was observed with or without S9. It was concluded that hydrolyzed soy protein was not mutagenic.

## **IRRITATION AND SENSITIZATION**

### **Irritation**

#### ***Dermal***

Non-human and human dermal irritation studies are presented in Table 6. Hydrolyzed soy protein was not a dermal irritant in non-human studies when tested neat and up to 35% and in human studies when tested neat and up to 25%.<sup>15,29-36</sup>

#### ***Ocular***

Ocular irritation studies are presented in Table 7. Hydrolyzed soy protein was not irritating to slightly irritating in non-human studies when tested neat and at 35%.<sup>15,29,30,33-37</sup>

#### ***Sensitization***

Non-human and human dermal sensitization studies are presented in Table 8. Hydrolyzed soy protein was not a dermal sensitizer in non-human and human studies when tested up to 25%.<sup>29,33,38</sup>

#### ***Type 1 Hypersensitivity***

No occurrences of Type 1 (i.e., immediate) hypersensitivity reactions to personal care products that contain soy peptide ingredients were reported in the public literature. An allergen must have at least 2 IgE-binding epitopes, and each epitope must be at least 15 amino-acid residues long, to trigger a Type 1 hypersensitivity reaction.<sup>39</sup> Type 1 responses can be elicited in sensitized patients when pairs of IgE molecules against a specific allergen are bound to receptors on the surface of mast cells and other cells that mediate immune reactions. The binding of an allergen molecule to two receptor-bound IgE molecules results in the crosslinking of the pair of IgE molecules. The cross-linking of sufficient numbers of IgE pairs bound to the receptors on the surface of a mast cell results in degranulation of the mast cell and the release of vasoactive amines, which are responsible for the Type 1 reaction.

## **CASE STUDIES**

A 43-year-old female presented with a 4-year history of dramatic erythematous eruption of the cheeks and nasal tip.<sup>40</sup> The patient had rosacea but did not respond to topical and systemic treatments. On examination, erythema was observed on the nasal tip and erythematous plaques with fine scale and pustules were observed on the cheeks. Also noted was partially eczematized seborrheic dermatitis of the scalp. The patient's history included seborrheic dermatitis, lifelong atopic eczema and reactions to jewelry, perfumes, and certain cosmetics. The patient did not wear makeup but used topical products on her face, some of which contained soy ingredients. Previous patch testing yielded a +++ reaction to soy. The patient discontinued use of the facial products containing soy and was treated with hydrocortisone ointment, oral erythromycin, and clobetasol foam. At 48 h, the cheek erythema and edema had resolved, and by 96 h all pustules had cleared and the seborrheic dermatitis was nearly cleared.

## **SUMMARY**

Soy peptide ingredients function mainly as skin and hair conditioning agents in personal care products.

Soy peptides are used as food, and daily exposure from food use would result in much larger systemic exposures than from use in cosmetic products. Additionally, the FDA determined that the use of peptones as direct food substances is GRAS and that soybean protein is GRAS for substances migrating to food from paper and paperboard products.

According to the 2015 VCRP survey data, hydrolyzed soybean protein has the most reported uses of the ingredients listed in this safety assessment in cosmetic products with a total of 862; about half of the uses are in non-coloring hair products. Glycine soja (soybean) protein has the second greatest number of overall uses reported, with a total of 313; a third of those are used in leave-on skin care products and another third are used in hair dyes and colors. The results of the concentration of use survey conducted in 2014 by the Council indicate hydrolyzed soy protein has the highest reported maximum concentration of use; it is used at up to 3.5% in mascara. Glycine soja (soybean) protein is used at up to 0.9% in eye lotion.

Soy proteins may also be used in adhesives and plastics industries.

While no experimental data were available for the dermal absorption of hydrolyzed soy protein, it was noted that gastrointestinal absorption allows for significantly higher bioavailability than dermal absorption.

Hydrolyzed soy protein was not mutagenic in an assay using *S. typhimurium* TA 1535/pSK1002 with and without S9 metabolic activation at concentrations up to 5000 µg/ml.

Hydrolyzed soy protein was not a dermal irritant in non-human studies when tested neat and up to 35% and in human studies when tested neat and up to 25%. This ingredient was also not an ocular irritant in non-human studies when tested neat and up to 35%. Hydrolyzed soy protein was not a dermal sensitizer in non-human and human studies when tested up to 25%.

A case study described aggravation of rosacea in a patient following use of facial products containing soy.

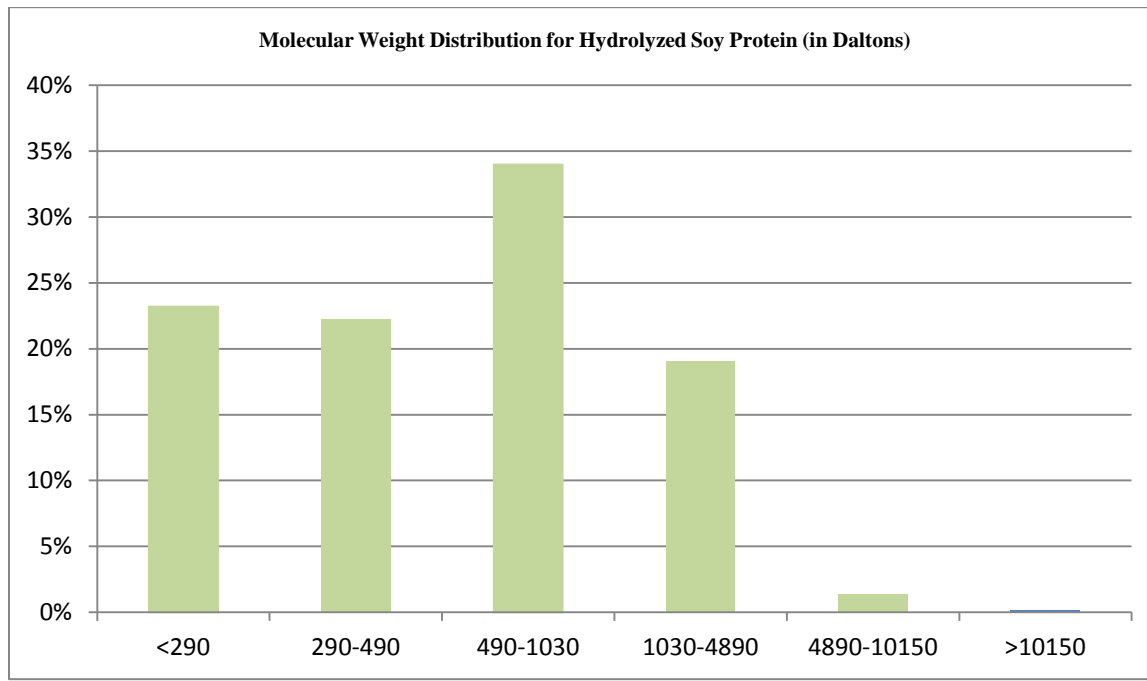
#### **DISCUSSION**

To be determined.

#### **CONCLUSION**

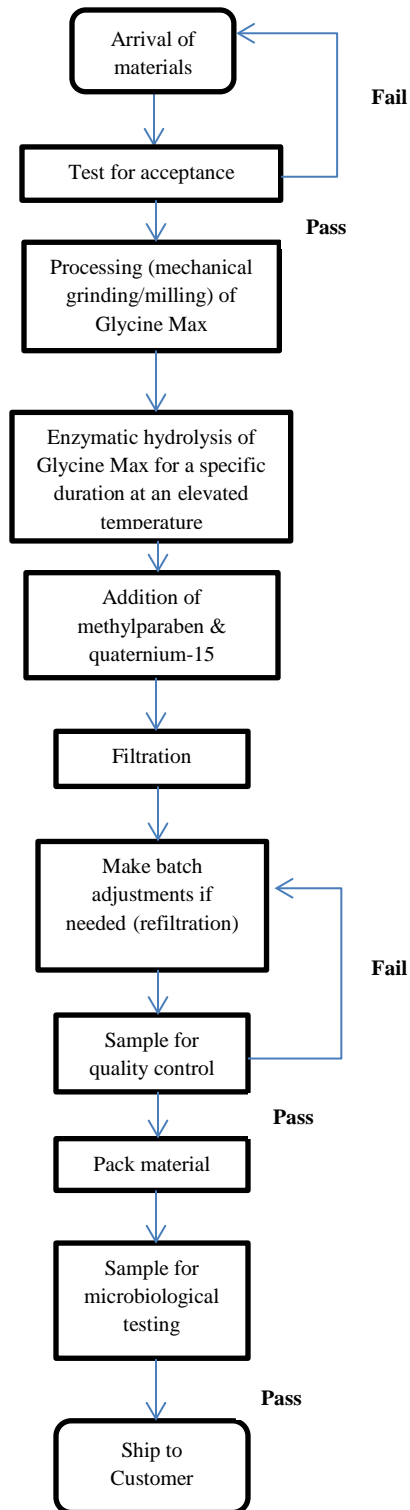
To be determined.

**FIGURES AND TABLES**



**Figure 1. Molecular weight distribution of hydrolyzed soy protein.<sup>30</sup>**

Figure 2. Manufacturing process of hydrolyzed soy protein.<sup>41</sup>



**Table 1.** Definitions and functions of the ingredients in this safety assessment.<sup>1</sup>

<b>Ingredient and CAS No.</b>	<b>Definition</b>	<b>Function</b>
Glycine Max (Soybean) Polypeptide	Glycine Max (Soybean) Polypeptide is a polypeptide fraction isolated from Glycine max soybean protein.	skin-conditioning agents - miscellaneous
Glycine Soja (Soybean) Peptide	Glycine Soja (Soybean) Peptide is the di-/tri- peptide fraction isolated from Glycine Soja (Soybean) Protein by ultra-membrane filtration.	film formers; hair conditioning agents; skin-conditioning agents - miscellaneous
Glycine Soja (Soybean) Protein 68153-28-6 9010-10-0	Glycine Soja (Soybean) Protein is a protein obtained from the soybean, <i>Glycine soja</i> .	hair conditioning agents; skin-conditioning agents – miscellaneous; surfactants – emulsifying agents
Hydrolyzed Soy Protein 68607-88-5 [generic to degree of hydrolyzation]	Hydrolyzed Soy Protein is the hydrolysate of soy protein derived by acid, enzyme or other method of hydrolysis.	hair conditioning agents; skin-conditioning agents - miscellaneous
Hydrolyzed Soy Protein Extract	Hydrolyzed Soy Protein Extract is the extract of the Hydrolyzed Soy Protein.	skin-conditioning agents - miscellaneous
Hydrolyzed Soymilk Protein	Hydrolyzed Soymilk Protein is the hydrolysate of the proteins obtained from Soymilk derived by acid, enzyme or other method of hydrolysis.	skin-conditioning agents - miscellaneous

**Table 2.** Chemical and physical properties

Property	Value	Reference
Hydrolyzed Soy Protein		
Physical Form	Clear to slightly hazy, yellow or light tan to amber liquid	42,43
Odor	Characteristic	42,43
Molecular Weight (Da)	1000-2000	42,43
Specific Gravity	1.05	44,45
Boiling Point (°C)	100	44
Freezing Point (°C)	0	44
Non-Volatile Matter (1g-2h-105°C)	20.0-34.0%	42,43
pH	4.0-7.0	42,43
Ash (800°C)	1.5% max	42
Solubility	Soluble in water	44
Hydrolyzed Soymilk Protein		
Physical Form	Slightly hazy colorless to amber liquid, may darken over time	46
Odor	Characteristic	46
Molecular Weight (Da)	1000-2000	46
Specific Gravity	1.20	47
Boiling Point (°C)	100	47
Freezing Point (°C)	0	47
Non-Volatile Matter (1g-2h-105°C)	18.0-25.0%	46
pH (25°C)	5.5-7.0	46
Solubility	Soluble in water	47



**Table 3.** A supplier-provided list of allergens certified NOT to be in products containing 25% and 35% hydrolyzed soy protein and 21.5% hydrolyzed soymilk protein.<sup>19-21</sup>

alpha-isomethyl inone	amyl cinnamal	anise alcohol
benzyl alcohol	benzyl benzoate	benzyl cinnamate
benzyl salicylate	butylphenyl methylpropional	cinnamal
cinnamyl alcohol	citral	citronellol
coumarin	eugenol	farnesol
geraniol	hexyl cinnamal	hydroxycitronellal
hydroxymethylpentyl 3-cyclohexane carboxaldehyde	isoeugenol	limonene
linalool	methyl-2-octynoate	<i>Evernia prunastri</i>
<i>Evernia furfuracea</i>	amylcinnamyl alcohol	

**Table 4.** Amino acid composition for soy peptides.<sup>12</sup>

Amino Acid	% Composition
glutamic acid	22.1
aspartic acid	12.6
arginine	8.1
leucine	6.7
lysine	6.6
proline	5.6
serine	5.5
phenylalanine	4.6
glycine	4.2
valine	4.0
alanine	3.9
isoleucine	3.8
threonine	3.8
tyrosine	3.4
histidine	2.7
cysteine	1.3
methionine	1.1

Not detected: hydroxylysine and hydroxyproline

**Table 5.** Frequency (2015) and concentration of use (2014) according to duration and type of exposure for soy peptide ingredients.<sup>48,49</sup>

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
	<b>Glycine Max (Soybean) Polypeptide</b>		<b>Glycine Soja (Soybean) Protein*</b>		<b>Hydrolyzed Soy Protein</b>		<b>Hydrolyzed Soymilk Protein</b>	
<b>Totals<sup>†</sup></b>	<b>2</b>	<b>NR</b>	<b>313</b>	<b>0.00004-0.9</b>	<b>862</b>	<b>0.00003-3.5</b>	<b>6</b>	<b>NR</b>
<b><i>Duration of Use</i></b>								
Leave-On	2	NR	166	0.00004-0.9	487	0.00003-3.5	3	NR
Rinse Off	NR	NR	147	0.0005-0.42	375	0.0001-0.63	3	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	0.0001-1.5	NR	NR
<b><i>Exposure Type</i></b>								
Eye Area	1	NR	36	0.00004-0.9	55	0.0038-3.5	NR	NR
Incidental Ingestion	NR	NR	5	0.25	1	0.0001-0.48	NR	NR
Incidental Inhalation-Spray	NR	NR	2; 56 <sup>a</sup> ; 51 <sup>b</sup>	0.07; 0.00004 <sup>a</sup>	12; 196 <sup>a</sup> ; 76 <sup>b</sup>	0.00003-0.021; 0.0001-1.3 <sup>a</sup>	1 <sup>a</sup>	NR
Incidental Inhalation-Powder	NR	NR	51 <sup>b</sup>	0.006-0.6 <sup>c</sup>	3; 76 <sup>b</sup>	0.01-0.23; 0.0018- 2.9 <sup>c</sup>	NR	NR
Dermal Contact	2	NR	175	0.00004-0.9	320	0.0001-2.9	1	NR
Deodorant (underarm)	NR	NR	NR	NR	1 <sup>a</sup>	0.013 <sup>d</sup>	NR	NR
Hair - Non-Coloring	NR	NR	36	0.0005-0.0055	405	0.00003-1.3	5	NR
Hair-Coloring	NR	NR	96	NR	78	0.0015-0.3	NR	NR
Nail	NR	NR	NR	0.23	37	0.0001-0.018	NR	NR
Mucous Membrane	NR	NR	8	0.0015-0.025	9	0.0001-1.5	NR	NR
Baby Products	NR	NR	3	NR	NR	0.003	NR	NR

NR = Not reported.

<sup>†</sup> Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

\*The VCRP database lists entries for glycine max (soybean) protein, but not for glycine soja (soybean) protein. This ingredient is undergoing a name change and was surveyed by the Council as glycine soja (soybean) protein.

<sup>a</sup> It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

<sup>b</sup> Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

<sup>c</sup> It is possible these products may be powders, but it is not specified whether the reported uses are powders.

<sup>d</sup> Not a deodorant spray.

**Table 6.** Dermal irritation studies.

<b>Ingredient</b>	<b>Concentration</b>	<b>Method</b>	<b>Results</b>	<b>Reference</b>
<b>Non-Human</b>				
Hydrolyzed Soymilk Protein	21.5% (MW=1000-2000 Da)	EpiDerm dermal irritation test	Non-irritating	36
Hydrolyzed Soy Protein	25% (MW=1000-2000 Da)	EpiDerm dermal irritation test	Non-irritating	34
Hydrolyzed Soy Protein	35% (MW=1000-2000 Da)	EpiDerm dermal irritation test	Non-irritating	35
Hydrolyzed Soy Protein	Not reported	Dermal irritation study performed under OECD Guideline 404	Non-irritating	30
Hydrolyzed Soy Protein	20% in distilled water	Draize test in 6 male White New Zealand rabbits; occluded	Non-irritating	29
Hydrolyzed Soy Protein	Neat (MW = 2000 Da)	Draize primary dermal irritation in 6 New Zealand white rabbits; occluded for 24 h	PII = 0.33. Not a primary irritant.	15
Hydrolyzed Soy Protein	25% in water (MW = 300 Da)	Primary dermal irritation in 6 New Zealand white rabbits; occluded for 24 h	PII = 0.46. Not a primary irritant	31,33
<b>Human</b>				
Hydrolyzed Soy Protein	20% in distilled water	50 subjects received 9 topical applications over 3 weeks; 24 h in duration; occluded	Non-irritating	29
Hydrolyzed Soy Protein	25% in water (MW = 300 Da)	20 female subjects received a single dermal dose under occlusive conditions for 24 h	Not a dermal irritant	32,33

**Table 7.** Ocular irritation studies.

<b>Ingredient</b>	<b>Concentration</b>	<b>Method</b>	<b>Results</b>	<b>Reference</b>
<b>Non-Human</b>				
Hydrolyzed Soymilk Protein	21.5% (MW=1000-2000 Da)	EpiOcular eye irritation test	Not irritating	36
Hydrolyzed Soy Protein	20% dilution, w/v	HET-CAM method	Slightly irritating	29
Hydrolyzed Soy Protein	25% (MW= 1000-2000 Da)	EpiOcular eye irritation test	Not irritating	34
Hydrolyzed Soy Protein	35% (MW=1000-2000 Da)	EpiOcular eye irritation test	Not irritating	35
Hydrolyzed Soy Protein	20% active matter in distilled water	Ocular irritation study performed under OECD guideline 405 in 3 albino White New Zealand rabbits	Very slight irritant reactions to the conjunctiva that appeared reversible in less than 72 h	29
Hydrolyzed Soy Protein	Neat	Ocular irritation study performed under OECD guideline 405	Very slight irritant	30
Hydrolyzed Soy Protein	Neat (MW = 2000 Da)	Ocular irritation study in 6 New Zealand white rabbits; unrinsed eyes	Not irritating	15
Hydrolyzed Soy Protein	25% in water (MW = 300 Da)	Ocular irritation study in 6 albino rabbits; unrinsed	Not a primary eye irritant	33,37

**Table 8.** Dermal sensitization studies.

<b>Ingredient</b>	<b>Concentration</b>	<b>Method</b>	<b>Results</b>	<b>Reference</b>
<b>Non-Human</b>				
Hydrolyzed Soy Protein	20% for the intracutaneous and epicutaneous induction, 10% and 20% solutions for challenge	Maximization test in male and female albino Dunkin Hartley guinea pigs	No skin reactions	29
<b>Human</b>				
Hydrolyzed Soy Protein	25% in water (MW = 300 Da)	HRIPT in 50 subjects; occlusive	No dermal irritation or sensitization	33,38
Hydrolyzed Soy Protein	20% dilution	HRIPT in 41 subjects; occlusive	No dermal irritation or sensitization	29

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**2015 FDA Raw Data on Soy Peptides**

03D - Eye Lotion	999002536	GLYCINE MAX (SOYBEAN) POLYPEPTIDE	1
12J - Other Skin Care Preps	999002536	GLYCINE MAX (SOYBEAN) POLYPEPTIDE	1
01A - Baby Shampoos	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
01C - Other Baby Products	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	2
03D - Eye Lotion	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	19
03F - Mascara	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
03G - Other Eye Makeup Preparations	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	16
05A - Hair Conditioner	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	16
05B - Hair Spray (aerosol fixatives)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	2
05F - Shampoos (non-coloring)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	11
05G - Tonics, Dressings, and Other Hair Grooming Aids	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	5
05I - Other Hair Preparations	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	96
07C - Foundations	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
07E - Lipstick	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	5
10A - Bath Soaps and Detergents	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	2
10E - Other Personal Cleanliness Products	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
11A - Aftershave Lotion	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	1
12A - Cleansing	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	15
12C - Face and Neck (exc shave)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	42
12D - Body and Hand (exc shave)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	9
12F - Moisturizing	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	36
12G - Night	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	11
12H - Paste Masks (mud packs)	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	5
12I - Skin Fresheners	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	2
12J - Other Skin Care Preps	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	11
13A - Suntan Gels, Creams, and Liquids	9010100	GLYCINE MAX (SOYBEAN) PROTEIN	2
03A - Eyebrow Pencil	68607885	HYDROLYZED SOY PROTEIN	1
03D - Eye Lotion	68607885	HYDROLYZED SOY PROTEIN	13
03E - Eye Makeup Remover	68607885	HYDROLYZED SOY PROTEIN	1
03F - Mascara	68607885	HYDROLYZED SOY PROTEIN	21

03G - Other Eye Makeup Preparations	68607885	HYDROLYZED SOY PROTEIN	19
05A - Hair Conditioner	68607885	HYDROLYZED SOY PROTEIN	128
05B - Hair Spray (aerosol fixatives)	68607885	HYDROLYZED SOY PROTEIN	12
05C - Hair Straighteners	68607885	HYDROLYZED SOY PROTEIN	4
05D - Permanent Waves	68607885	HYDROLYZED SOY PROTEIN	3
05E - Rinses (non-coloring)	68607885	HYDROLYZED SOY PROTEIN	1
05F - Shampoos (non-coloring)	68607885	HYDROLYZED SOY PROTEIN	114
05G - Tonics, Dressings, and Other Hair Grooming Aids	68607885	HYDROLYZED SOY PROTEIN	76
05H - Wave Sets	68607885	HYDROLYZED SOY PROTEIN	7
05I - Other Hair Preparations	68607885	HYDROLYZED SOY PROTEIN	60
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	68607885	HYDROLYZED SOY PROTEIN	73
06D - Hair Shampoos (coloring)	68607885	HYDROLYZED SOY PROTEIN	1
06H - Other Hair Coloring Preparation	68607885	HYDROLYZED SOY PROTEIN	4
07B - Face Powders	68607885	HYDROLYZED SOY PROTEIN	3
07C - Foundations	68607885	HYDROLYZED SOY PROTEIN	14
07E - Lipstick	68607885	HYDROLYZED SOY PROTEIN	1
07F - Makeup Bases	68607885	HYDROLYZED SOY PROTEIN	2
07I - Other Makeup Preparations	68607885	HYDROLYZED SOY PROTEIN	6
08A - Basecoats and Undercoats	68607885	HYDROLYZED SOY PROTEIN	6
08B - Cuticle Softeners	68607885	HYDROLYZED SOY PROTEIN	1
08C - Nail Creams and Lotions	68607885	HYDROLYZED SOY PROTEIN	1
08E - Nail Polish and Enamel	68607885	HYDROLYZED SOY PROTEIN	22
08G - Other Manicuring Preparations	68607885	HYDROLYZED SOY PROTEIN	7
10A - Bath Soaps and Detergents	68607885	HYDROLYZED SOY PROTEIN	2
10B - Deodorants (underarm)	68607885	HYDROLYZED SOY PROTEIN	1
10E - Other Personal Cleanliness Products	68607885	HYDROLYZED SOY PROTEIN	6
11E - Shaving Cream	68607885	HYDROLYZED SOY PROTEIN	3
11F - Shaving Soap	68607885	HYDROLYZED SOY PROTEIN	3
11G - Other Shaving Preparation Products	68607885	HYDROLYZED SOY PROTEIN	1
12A - Cleansing	68607885	HYDROLYZED SOY PROTEIN	12
12B - Depilatories	68607885	HYDROLYZED SOY PROTEIN	9
12C - Face and Neck (exc shave)	68607885	HYDROLYZED SOY PROTEIN	76
12D - Body and Hand (exc	68607885	HYDROLYZED SOY PROTEIN	25



shave)			
12F - Moisturizing	68607885	HYDROLYZED SOY PROTEIN	68
12G - Night	68607885	HYDROLYZED SOY PROTEIN	16
12H - Paste Masks (mud packs)	68607885	HYDROLYZED SOY PROTEIN	3
12I - Skin Fresheners	68607885	HYDROLYZED SOY PROTEIN	5
12J - Other Skin Care Preps	68607885	HYDROLYZED SOY PROTEIN	25
13A - Suntan Gels, Creams, and Liquids	68607885	HYDROLYZED SOY PROTEIN	1
13B - Indoor Tanning Preparations	68607885	HYDROLYZED SOY PROTEIN	2
13C - Other Suntan Preparations	68607885	HYDROLYZED SOY PROTEIN	3
05A - Hair Conditioner	999002352	HYDROLYZED SOYMILK PROTEIN	2
05F - Shampoos (non-coloring)	999002352	HYDROLYZED SOYMILK PROTEIN	1
05G - Tonics, Dressings, and Other Hair Grooming Aids	999002352	HYDROLYZED SOYMILK PROTEIN	1
05I - Other Hair Preparations	999002352	HYDROLYZED SOYMILK PROTEIN	1
12J - Other Skin Care Preps	999002352	HYDROLYZED SOYMILK PROTEIN	1



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** January 6, 2015

**SUBJECT:** Concentration of Use by FDA Product Category: Soy Protein Ingredients

**Concentration of use by FDA Product Category\***

Hydrolyzed Soy Protein  
 Glycine Soja (Soybean) Protein  
 Glycine Max (Soybean) Polypeptide

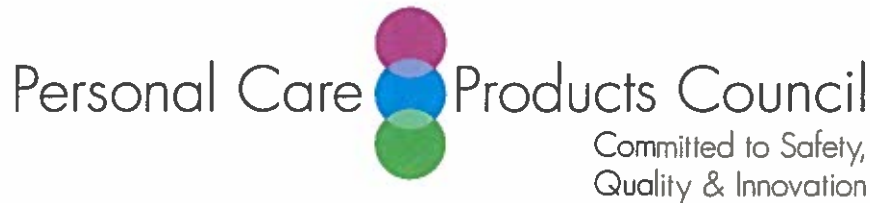
Glycine Soja (Soybean) Peptide  
 Hydrolyzed Soy Protein Extract  
 Hydrolyzed Soymilk Protein

<b>Ingredient</b>	<b>Product Category</b>	<b>Maximum Concentration of Use</b>
Hydrolyzed Soy Protein	Baby lotions, oils and creams Not powder	0.003%
Hydrolyzed Soy Protein	Bath oils, tablets and salts	0.0001%
Hydrolyzed Soy Protein	Other bath preparations	0.0001-1.5%
Hydrolyzed Soy Protein	Eye lotion	0.0038-2%
Hydrolyzed Soy Protein	Mascara	3.5%
Hydrolyzed Soy Protein	Hair conditioners	0.0005-0.63%
Hydrolyzed Soy Protein	Hair sprays Aerosol Pump spray	0.00003-0.021% 0.008%
Hydrolyzed Soy Protein	Hair straighteners	0.01%
Hydrolyzed Soy Protein	Shampoos (noncoloring)	0.0082-0.5%
Hydrolyzed Soy Protein	Tonics, dressings and other hair grooming aids	0.0023-1.3%
Hydrolyzed Soy Protein	Other hair preparations (noncoloring)	0.0025-0.2%
Hydrolyzed Soy Protein	Hair dyes and colors	0.0015-0.3%
Hydrolyzed Soy Protein	Face powders	0.01-0.23%
Hydrolyzed Soy Protein	Foundations	0.01-0.5%
Hydrolyzed Soy Protein	Lipstick	0.48%
Hydrolyzed Soy Protein	Makeup fixatives	0.48%
Hydrolyzed Soy Protein	Basecoats and undercoats (manicuring preparations)	0.01%
Hydrolyzed Soy Protein	Cuticle softeners	0.018%
Hydrolyzed Soy Protein	Nail creams and lotions	0.0001%
Hydrolyzed Soy Protein	Nail polish and enamel	0.01%
Hydrolyzed Soy Protein	Other manicuring preparations	0.0003-0.011%
Hydrolyzed Soy Protein	Mouthwashes and breath fresheners (liquids and sprays)	0.0001%
Hydrolyzed Soy Protein	Bath soaps and detergents	0.003-0.025%
Hydrolyzed Soy Protein	Deodorants Not spray	0.013%
Hydrolyzed Soy Protein	Aftershave lotions	0.026%
Hydrolyzed Soy Protein	Other shaving preparations	0.013%
Hydrolyzed Soy Protein	Skin cleansing (cold creams, cleansing lotions, liquid and pads)	0.00018-0.12%
Hydrolyzed Soy Protein	Face and neck products Not spray	0.0018-2.9%
Hydrolyzed Soy Protein	Body and hand products	

	Not spray	0.007-0.5%
Hydrolyzed Soy Protein	Moisturizing products Not spray	0.013-2%
Hydrolyzed Soy Protein	Night products Not spray	0.0014-0.48%
Hydrolyzed Soy Protein	Paste masks and mud packs	0.02-0.034%
Hydrolyzed Soy Protein	Other skin care preparations	0.013%
Hydrolyzed Soy Protein	Indoor tanning preparations	0.013%
Glycine Soja (Soybean) Protein	Eye lotion	0.00004-0.9%
Glycine Soja (Soybean) Protein	Hair conditioner	0.0005-0.0055%
Glycine Soja (Soybean) Protein	Shampoos (noncoloring)	0.0005-0.0055%
Glycine Soja (Soybean) Protein	Foundations	0.0005-0.18%
Glycine Soja (Soybean) Protein	Lipstick	0.025%
Glycine Soja (Soybean) Protein	Nail creams and lotions	0.23%
Glycine Soja (Soybean) Protein	Bath soaps and detergents	0.0015%
Glycine Soja (Soybean) Protein	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.02%
Glycine Soja (Soybean) Protein	Face and neck products Not spray	0.006-0.6%
Glycine Soja (Soybean) Protein	Body and hand products Not spray Spray	0.01% 0.07%
Glycine Soja (Soybean) Protein	Moisturizing products Not spray	0.34%
Glycine Soja (Soybean) Protein	Night products Not spray	0.3%
Glycine Soja (Soybean) Protein	Paste masks and mud packs	0.42%
Glycine Soja (Soybean) Protein	Other skin care preparations	0.035%
Glycine Soja (Soybean) Protein	Suntan products Not spray	0.00004%
Glycine Soja (Soybean) Protein	Indoor tanning preparations	0.00004%

\*Ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

Information collected in 2014  
Table prepared January 5, 2015



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

A handwritten signature in black ink, appearing to read "Beth A. Lange", is written over the printed name.

**DATE:** April 2, 2015

**SUBJECT:** Information on Hydrolyzed Soy Protein

The studies listed below were submitted to CIR on July 11, 2012 as part of the original report on hydrolyzed proteins (memo 8 in the hydrolyzed protein file). The references listed below are reference numbers 13, 27, 28, 29 and 30 in the current Scientific Literature Review (SLR) on soy peptide ingredients.

The company providing the studies listed below read the SLR and has indicated that the concentration of test material used in reference numbers 27, 28, 29 and 30 of the SLR was 25% of Hydrolyzed Soy Protein (MW=300) in water (the concentration and molecular weight listed in information sheet provided with the studies).

Anonymous. 2012. Information of Hydrolyzed Soy Protein-1 (method of manufacture; molecular weight, impurities, summary of safety data [studies are attached]).

Leberco Testing Inc. 1994. Eye irritation assay Hydrolyzed Soy Protein. Assay Number: 947859.

Leberco Testing Inc. 1994. Primary dermal irritation in rabbits Hydrolyzed Soy Protein. Assay Number: 947860.

Dermis Research Center Co., Ltd. 2006. Human patch test under occlusive patch for 48 hours Hydrolyzed Soy Protein.

AMA Laboratories. 50 Human subject repeat insult patch test skin irritation/sensitization evaluation (occlusive patch) Hydrolyzed Soy Protein. AMA Ref. No.: MS06.K90190.50.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** April 2, 2015

**SUBJECT:** Information on Hydrolyzed Soy Protein and Hydrolyzed Soymilk Protein

AC Soy Hydrolysate (20603), AC Soy Hydrolysate 30 (20627) and AC Soy Milk Hydrolysate (20574) all have a molecular weight of 1000 - 2000 Da.

Note: NVM on the specification sheets stands for Non-Volatile Matter.

Active Concepts. 2010. Manufacturing flow chart: AC Soy Hydrolysate - 20603.

Active Concepts. 2011. Compositional breakdown: AC Soy Hydrolysate - 20603.

Active Concepts. 2012. Product specification: AC Soy Hydrolysate - 20603.

Active Concepts. 2012. Dermal and ocular irritation tests: AC Soy Hydrolysate - 20603.

Active Concepts. 2014. Safety data sheet: AC Soy Hydrolysate 20603.

Active Concepts. 2011. Compositional breakdown: AC Soy Hydrolysate 30 - 20627.

Active Concepts. 2013. Product specification: AC Soy Hydrolysate 30 - 20627.

Active Concepts. 2012. Dermal and ocular irritation tests: AC Soy Hydrolysate 30 - 20627.

Active Concepts. 2013. Material safety data sheet: AC Soy Hydrolysate 30.

Active Concepts. 2014. Compositional breakdown: AC Soy Milk Hydrolysate - 20574.

Active Concepts. 2014. Product specification: AC Soy Milk Hydrolysate - 20574.

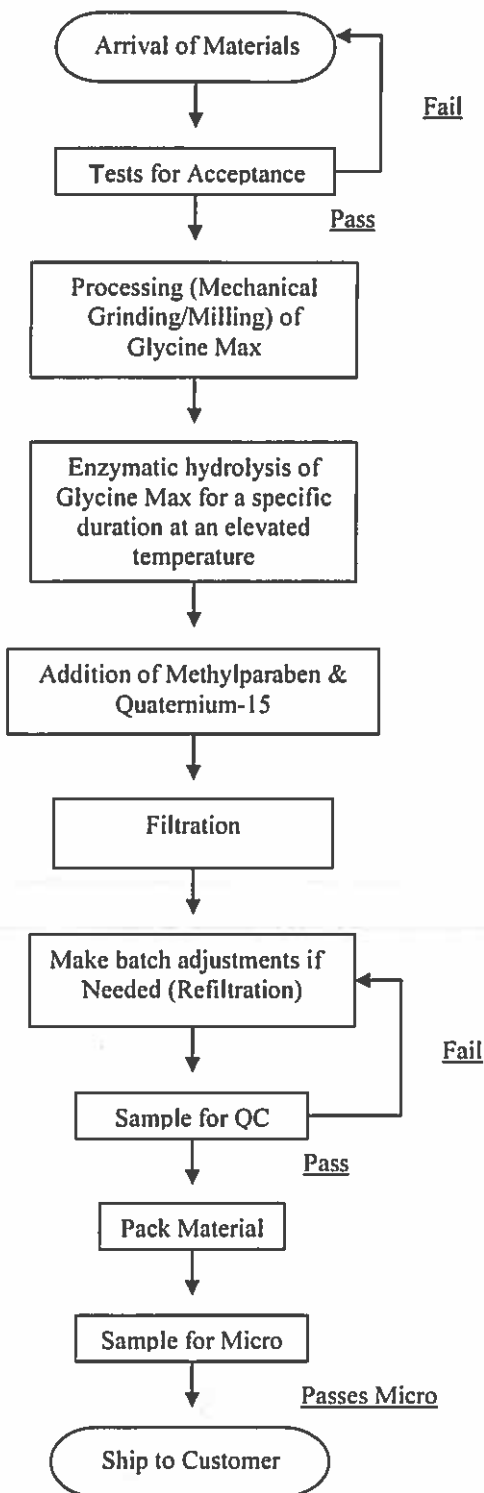
Active Concepts. 2012. Dermal and ocular irritation tests: AC Soy Milk Hydrolysate - 20574.

Active Concepts. 2014. Safety data sheet: AC Soy Milk Hydrolysate 20574.



# 20603-AC Soy Hydrolysate- Manufacturing Flow Chart

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## Compositional Breakdown

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### AC Soy Hydrolysate Code: 20603

Compositional Breakdown:

Ingredient	%
Water	74.60
Hydrolyzed Soy Protein	25.00
Methylparaben	0.20
Quaternium-15	0.20

**\* To our knowledge the above material is free of materials classified as CMR in accordance with the Directive 2004/93 of 21 September 2004.**

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## Compositional Breakdown

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This is to certify that the following allergens were not detected in AC Soy Hydrolysate:

ALLERGENS Dir 2003 15 CEE	
INCI NAME	CAS NUMBER
Alpha-IsoMethyl Ionone	127-51-5
Amyl Cinnamal	122-40-7
Anise Alcohol	105-13-5
Benzyl Alcohol	100-51-69
Benzyl Benzoate	120-51-4
Benzyl Cinnamate	103-41-3
Benzyl Salicylate	118-58-1
Butylphenyl Methylpropional	80-54-6
Cinnamal	104-55-2
Cinnamyl Alcohol	104-54-1
Citral	5392-40-5
Citronellol	106-22-9
Coumarin	91-64-5
Eugenol	97-53-0
Farnesol	4602-84-0
Geraniol	106-24-1
Hexyl Cinnamal	101-86-0
Hydroxycitronellal	107-75-5
Hydroxymethylpentyl 3-Cyclohexene carboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Limonene	5989-27-5
Linalool	78-70-6
Methyl 2 Octynoate	111-12-6
Evernia prunastri	90028-68-5
Evernia furfuracea	90028-67-4
Amylcinnamyl Alcohol	101-85-9

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## Product Specification

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**Product Name:** AC Soy Hydrolysate  
**Code Number:** 20603  
**CAS #'s:** 68607-88-5  
**EINECS #'s:** 271-770-5  
**INCI Name:** Hydrolyzed Soy Protein  
**Status:** Approved

Specification	Parameter
Appearance	Clear to Slightly Hazy Liquid
Color	Yellow to Amber
Color (Gardner)	12 Maximum
Odor	Characteristic
NVM (1g-2hrs-105°C)	20.0 – 26.0%
pH (direct)	4.0 – 6.0
Ash (800°C)	1.5% Maximum
Nitrogen (Kjeldahl)	2.6 – 4.0%
Microbial Content	< 100 opg No pathogens

**May Sediment upon Standing; Mix Well Prior to Use**

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## Dermal and Ocular Irritation Tests

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**Trade Name:** AC Soy Hydrolysate

**Code:** 20603

**CAS #:** 68607-88-5

**Test Request Form #:** 269

**Lot #:** 24259D

**Sponsor:** Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092

**Study Director:** Erica Segura

**Principle Investigator:** Meghan Darley

**Test Performed:**

In Vitro EpiDerm™ Dermal Irritation Test (EPI-200-SIT)

EpiOcular™ Eye Irritation Test (OCL-200-EIT)

### SUMMARY

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether AC Soy Hydrolysate would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays.

The product was tested according to the manufacturer's protocol. The test article solution was found to be a non-irritant. Reconstructed human epidermis and cornea epithelial model were incubated in growth media overnight to allow for tissue equilibration after shipping from MatTek Corporation, Ashland, MA. Test substances were applied to the tissue inserts and incubated for 60 minutes for liquid and solid substances in the EpiDerm™ assay and 30 minutes for liquid substances and 90 minutes for solid substances in the EpiOcular™ assay at 37°C, 5% CO<sub>2</sub>, and 95% relative humidity (RH). Tissue inserts were thoroughly washed and transferred to fresh plates with growth media. After post substance dosing incubation is complete, the cell viability test begins. Cell viability is measured by dehydrogenase conversion of MTT [(3-4,5-dimethyl thiazole 2-yl)], present in the cell mitochondria, into blue formazan salt that is measured after extraction from the tissue. The irritation potential of the test chemical is dictated by the reduction in tissue viability of exposed tissues compared to the negative control.

Under the conditions of this assay, the test article was considered to be non-irritating. The negative and positive controls performed as anticipated.

### I. Introduction

#### A. Purpose

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether a test article would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays. MatTek Corporation's reconstructed human epidermal and human ocular models are becoming a standard in determining the irritancy potential of test substances. They are able to discriminate between irritants and non-irritants. The EpiDerm™ assay has accuracy for the prediction of UN GHS R38 skin irritating and no-label (non-skin irritating) test substances. The EpiOcular™ assay can

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## Dermal and Ocular Irritation Tests

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differentiate chemicals that have been classified as R36 or R41 from the EU classifications based on Dangerous Substances Directive (DSD) or between the UN GHS Cat 1 and Cat 2 classifications.

### II. Materials

- A. Incubation Conditions:** 37°C at 5% CO<sub>2</sub> and 95% relative humidity
- B. Equipment:** Forma humidified incubator, ESCO biosafety laminar flow hood, Synergy HT Microplate reader; Pipettes
- C. Media/Buffers:** DMEM based medium; DPBS; sterile deionized H<sub>2</sub>O
- D. Preparation:** Pre-incubate (37°C) tissue inserts in assay medium; Place assay medium and MTT diluent at 4°C, MTT concentrate at -20°C, and record lot numbers of kit components
- E. Tissue Culture Plates:** Falcon flat bottom 96-well, 24-well, 12-well, and 6-well tissue culture plates
- F. Reagents:** MTT (1.0mg/mL); Extraction Solution (Isopropanol); SDS (5%); Methyl Acetate
- G. Other:** Nylon Mesh Circles (EPI-MESH); Cotton tip swabs; 1mL tuberculin syringes; Ted Pella micro-spatula; 220mL specimen containers; sterile disposable pipette tips; Parafilm

### III. Test Assay

#### **A. Test System**

The reconstructed human epidermal model, EpiDerm™, and cornea epithelial model, EpiOcular™, consist of normal human-derived epidermal keratinocytes which have been cultured to form a multilayer, highly differentiated model of the human epidermis and cornea epithelium. These models consist of organized basal, spinous, and granular layers, and the EpiDerm™ systems also contains a multilayer stratum corneum containing intercellular lamellar lipid layers that the EpiOcular™ system is lacking. Both the EpiDerm™ and EpiOcular™ tissues are cultured on specially prepared cell culture inserts.

#### **B. Negative Control**

Sterile DPBS and sterile deionized water are used as negative controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **C. Positive Control**

Known dermal and eye irritants, 5% SDS solution and Methyl Acetate, were used as positive controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **D. Data Interpretation Procedure**

##### **a. EpiDerm™**

An irritant is predicted if the mean relative tissue viability of the 3 tissues exposed to the test substance is reduced by 50% of the mean viability of the negative controls and a non-irritant's viability is > 50%.

##### **b. EpiOcular™**

An irritant is predicted if the mean relative tissue viability of the 2 tissues exposed to the test substance is reduced by 60% of the mean viability of the negative controls and a non-irritant's viability is > 40%.

### IV. Method

#### **A. Tissue Conditioning**

Upon MatTek kit arrival at Active Concepts, LLC the tissue inserts are removed from their shipping medium and transferred into fresh media and tissue culture plates and incubated at 37°C at 5% CO<sub>2</sub> and 95% relative humidity for 60 minutes. After those 60 minutes the inserts are transferred into fresh media and tissue culture plates and incubated at 37°C at 5% CO<sub>2</sub> and 95% relative humidity for an additional 18 to 21 hours.

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## Dermal and Ocular Irritation Tests

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### B. Test Substance Exposure

#### a. EpiDerm™

30 $\mu$ L (liquid) or 25mg (solid) of the undiluted test substance is applied to 3 tissue inserts and allowed to incubate for 60 minutes in a humidified incubator (37°C, 5% CO<sub>2</sub>, 95% RH).

#### b. EpiOcular™

Each tissue is dosed with 20 $\mu$ L DPBS prior to test substance dosing. 50 $\mu$ L (liquid) or 50mg (solid) of the undiluted test substance is applied to 2 tissue inserts and allowed to incubate for 90 minutes in a humidified incubator (37°C, 5% CO<sub>2</sub>, 95% RH).

### C. Tissue Washing and Post Incubation

#### a. EpiDerm™

All tissue inserts are washed with DPBS, dried with cotton tipped swab, and transferred to fresh media and culture plates. After 24 hours the inserts are again transferred into fresh media and culture plates for an additional 18 to 20 hours.

#### b. EpiOcular™

Tissue inserts are washed with DPBS and immediately transferred into 5mL of assay medium for 12 to 14 minutes. After this soak the inserts are transferred into fresh media and tissue culture plates for 120 minutes for liquid substances and 18 hours for solid substances.

### D. MTT Assay

Tissue inserts are transferred into 300 $\mu$ L MTT media in pre-filled plates and incubated for 3 hours at 37°C, 5% CO<sub>2</sub>, and 95% RH. Inserts are then removed from the MTT medium and placed in 2mL of the extraction solution. The plate is sealed and incubated at room temperature in the dark for 24 hours. After extraction is complete the tissue inserts are pierced with forceps and 2 x 200 $\mu$ L aliquots of the blue formazan solution is transferred into a 96 well plate for Optical Density reading. The spectrophotometer reads the 96-well plate using a wavelength of 570 nm.

### V. Acceptance Criterion

#### A. Negative Control

The results of this assay are acceptable if the mean negative control Optical Density (OD<sub>570</sub>) is  $\geq 1.0$  and  $\leq 2.5$  (EpiDerm™) or  $\geq 1.0$  and  $\leq 2.3$  (EpiOcular™).

#### B. Positive Control

##### a. EpiDerm™

The assay meets the acceptance criterion if the mean viability of positive control tissues expressed as a % of the negative control is  $\leq 20\%$ .

##### b. EpiOcular™

The assay meets the acceptance criterion if the mean viability of positive control tissues is  $< 60\%$  of control viability.

#### C. Standard Deviation

Since each irritancy potential is predicted from the mean viability of 3 tissues for EpiDerm™ and 2 tissues for EpiOcular™, the variability of the replicates should be  $< 18\%$  for EpiDerm™ and  $< 20\%$  EpiOcular™.

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## Dermal and Ocular Irritation Tests

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### VI. Results

#### A. Tissue Characteristics

The tissue inserts included in the MatTek EpiDerm™ and EpiOcular™ assay kits were in good condition, intact, and viable.

#### B. Tissue Viability Assay

The results are summarized in Figures 1 and 2. In no case was the tissue viability  $\leq 50\%$  for EpiDerm™ or  $\leq 60\%$  for EpiOcular™ in the presence of the test substance. The negative control mean exhibited acceptable relative tissue viability while the positive control exhibited substantial loss of tissue viability and cell death.

#### C. Test Validity

The data obtained from this study met criteria for a valid assay.

### VII. Conclusion

Under the conditions of this assay, the test article substance was considered to be non-irritating. The negative and positive controls performed as anticipated.

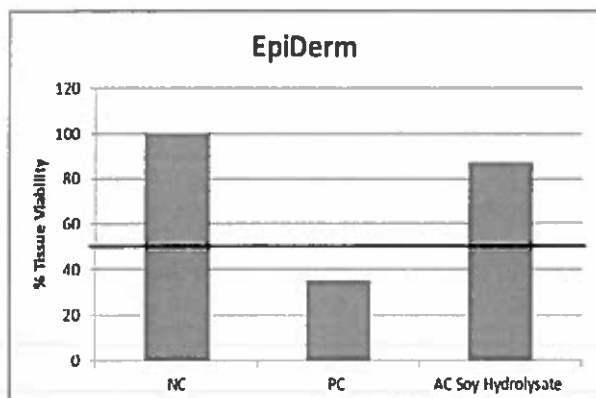


Figure 1: EpiDerm tissue viability

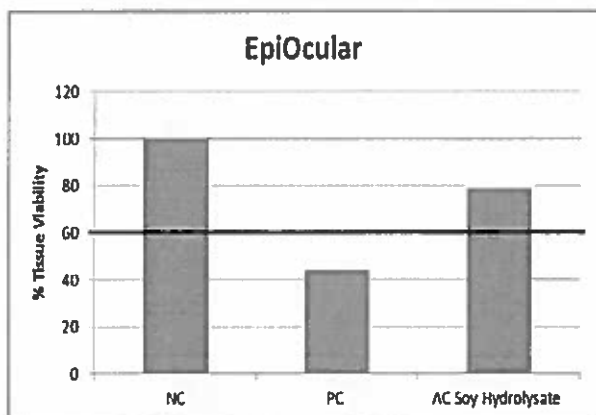


Figure 2: EpiOcular tissue viability

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# Safety Data Sheet

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AC Soy Hydrolysate

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Date: 03 / 20 / 2014

Version: 2

Cancels and replaces version: 1

## SECTION 1. IDENTIFICATION

<b>Product Name/Identifier</b>	AC Soy Hydrolysate
<b>Product Code</b>	20603
<b>Recommended Use</b>	Topical Cosmetic Use
<b>Restrictions on Use</b>	Refer to the detailed list of labeling/restrictions (Section 15 Regulatory Information)
<b>Supplier/Manufacturing Site</b>	Active Concepts, LLC
<b>Address</b>	107 Technology Drive Lincolnton, NC 28092, USA
<b>Telephone No. (24hrs)</b>	1-704-276-7100
<b>Fax No.</b>	1-704-276-7101
<b>Emergency Telephone #</b>	1-704-276-7100 (Mon-Fri: 8:00AM – 5:00PM EST)

## SECTION 2. HAZARD(S) IDENTIFICATION

### Classification:

#### GHS / CLP

**Basis for Classification:** Based on present data no classification and labeling is required according to GHS taking into account the national implementation (United Nations version 2011)

#### USA

**OSHA Regulatory Status:** This material is non-hazardous as defined by the American OSHA Hazard Communication Standard (29 CFR 1910.1200).

#### Europe

**Basis for Classification:**  
 -According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.  
 -This product is not classified as hazardous to health or environment according to the CLP regulation.

### Labeling Elements:

**Pictograph:** No hazard symbol expected

**Hazard statements/Signal Word:** Not applicable

**Precautionary statements:**  
 P233: Keep container tightly closed  
 P281: Use personal protective equipment as required  
 P402: Store in a dry place  
 P404: Store in a closed container  
 P410: Protect from sunlight  
 P411: Store at temperatures not exceeding 25°C

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**Other hazards which do not result in classification:**

No particular fire or explosion hazard.

By mechanical effect: No particular hazards.

By hydroscopic effect: No particular hazards.

**US NFPA 704 (National Fire Protection Association) Hazard Rating System:**

Health hazard: Rating 0; Normal Material

Flammability: Rating 0, Will Not Burn

Reactivity: Rating 0, Stable

Other Hazard Information: None

**Results of PBT and vPvB assessment:**

-PBT: Not applicable

-vPvB: Not applicable

**SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS**

**Common Chemical Name:** Hydrolyzed Soy Protein

**Generic name:**

**Chemical Family:** Hydrolyzed Protein

**Description:** Mixture: consisting of the following components. This section describes all components of the mixture

<u>Substance</u>	<u>CAS Numbers</u>	<u>EC Numbers</u>	<u>Percentage</u>
Water	7732-18-5	231-791-2	74.60%
Hydrolyzed Soy Protein	68607-88-5	271-770-5	25.00%
Methylparaben	99-76-3	204-785-7	0.20%
Quaternium-15	4080-31-3	223-805-0	0.20%

**Formula:** Not applicable

**SECTION 4. FIRST-AID MEASURES**

**General:** In all cases of doubt, or when symptoms persist, seek medical attention.

**Inhalation:** Move to fresh air from exposure area. Get medical attention for any breathing difficulty.

**Skin contact:** Rinse with soap and water. Get medical advice if irritation develops.

**Eye contact:** Immediately rinse with plenty of water for at least 15 minutes, while keeping the eyes wide open. Consult with a physician.

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**Ingestion:** Consult with a physician.  
**Protection of first-aiders:** No special protection required.

#### SECTION 5. FIRE-FIGHTING MEASURES

**Fire and explosion hazards:** Not considered to be a fire and explosion hazard

**Extinguishing media:**

**Suitable:** Water, dry chemicals, foam and carbon dioxide

**Not suitable:** None known

**Fire fighting:** Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low area

**Protection for fire-fighters:** Boots, gloves, goggles.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Avoid contact with eyes.

**Personal Protective Equipment:**  
 -Protective goggles

**Environmental precautions:** Prevent entry into sewers and waterways. Do not allow material to contaminate ground water system

**Methods for cleaning up:**

**Recovery:** Pick up free liquid for recycling or disposal. Residual liquid can be absorbed on an inert material.

**Cleaning/Decontamination:** Wash non-recoverable remainder with water.

**Disposal:** For disposal of residues refer to sections 8 & 13.

#### SECTION 7. HANDLING AND STORAGE

**Handling**

**Technical measures:** Labeling: Keep out of the reach of children.

**Measures:** For industrial use, only as directed.

**Safe handling advice:** Wash hands after use. Avoid storage near feed or food stuff.

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### Storage

Technical measures: Keep container closed.  
 Recommended Storage Conditions: Store in a cool, dry place. This material must be stored at room temperature (23 - 25°C). It should not be exposed to excessive heat or cold. Do not freeze.

Incompatible products: Avoid contact with strong oxidizers.  
 Refer to the detailed list of incompatible materials (Section 10 Stability/Reactivity)

Packaging: Product may be packaged in normal commercial packaging.  
 Packaging materials: Recommended - Polypropylene & High Density Polyethylene

## SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Precautionary statements: Ensure adequate ventilation

### Control parameters

#### Occupational exposure Limits:

France: Not Determined  
 ACGIH: Not Determined  
 Korea: Not Determined  
 UK: Not Determined

Surveillance procedures: Not Determined  
 Engineering measures: Not Determined

### Personal Protective Equipment:

Respiratory protection: Local exhaust  
 Hand protection: Protective gloves made of rubber or neoprene.  
 Eye protection: Safety glasses.  
 Collective emergency equipment: Eye fountain.  
 Skin and Body Protection: Suitable protective clothing

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Measures related to the Environment: No particular measures.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear to slightly hazy liquid  
 Color: Yellow to amber  
 Color (Gardner): 10 Maximum

Odor: Characteristic

NVM (1g-2hrs-105°C): 20.0 – 26.0%

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<b>pH (Direct):</b>	4.0 – 6.0
<b>Ash (800°C):</b>	1.5% Maximum
<b>Nitrogen (Kjeldahl):</b>	2.6 – 4.0%
<b>Microbial Content:</b>	< 100 CFU/g No pathogens
<b>Specific Gravity:</b>	1.05
<b>Vapor density:</b>	Not applicable
<b>Boiling Point:</b>	100°C
<b>Freezing Point:</b>	0°C
<b>Melting point:</b>	Not applicable
<b>Flash point:</b>	> 200°F
<b>Oxidizing properties:</b>	Non oxidizing material according to EC criteria.
<b>Solubility:</b>	
In water:	Soluble
In organic solvents:	Not determined
Log P:	Not determined

#### SECTION 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under ordinary conditions of use and storage up to one year then re-test to full product specifications to extend shelf life
<b>Hazardous reactions:</b>	None known
<b>Conditions to avoid:</b>	No dangerous reactions known under use of normal conditions. Avoid extreme heat.
<b>Materials to avoid:</b>	No dangerous reaction known with common products.
<b>Hazardous decomposition products:</b>	None known

#### SECTION 11. TOXICOLOGICAL INFORMATION

<b>Ingestion:</b>	Not Determined
<b>Dermal:</b>	Non-Irritant (Dermal Irritation Model)
<b>Ocular:</b>	Non-Irritant (Ocular Irritation Model)
<b>Inhalation:</b>	Not Determined
<b>Acute toxicity data:</b>	Not Determined
<b>Sensitization:</b>	Non-Primary Sensitizers

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**AC Soy Hydrolysate**

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**Repeated dose toxicity:** No known effects  
**Subacute to chronic toxicity:** Not Determined

**Additional Toxicological Information:** This product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

**Specific effects:**

**Carcinogenicity:** No known effects  
**Mutagenicity:** No known effects  
**Reproductive toxicity:** No known effects  
**Neuro-toxicity:** No known effects

**For more information:** Does not present any particular risk on handling under normal conditions of good occupational hygiene practice.

This product has not been tested for the following:

- Primary cutaneous and corrosive irritation
- Acute oral toxicity
- Mutagenicity/genotoxicity

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Effects on the aquatic environment:** Not Determined

**Biodegradability:**

**Persistence:** Not Determined

**Bioaccumulation:**

**Octanol / water partition coefficient:** Not Determined

**Mobility:**

**Precipitation:**

**Expected behavior of the product:** Ultimate destination of the product: Soil & sediment.

**Other Adverse Effects:** None known

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Residues from product**

**Prohibition:** Do not allow the product to be released into the Environment.  
**Destruction/Disposal:** Dispose of in accordance with relevant local regulations

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**AC Soy Hydrolysate**

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### Contaminated packaging

Decontamination/cleaning: Cleaning is not required prior to disposal.  
Destruction/Disposal:

Note: Take all necessary precautions when disposing of this product according to local regulations.

### SECTION 14. TRANSPORT INFORMATION

UN Number: None  
UN Shipping Name: None

Transport Hazard Class: Not classified as dangerous for transport

Land (rail/road): Not restricted  
Sea: Not restricted  
Air: Not restricted

Marine Pollutant: No

Transport/Additional Information: Not regulated for US DOT Transport in non-bulk containers

Special Precautions for User: None known

The above regulatory prescriptions are those valid on the date of publication of this sheet. However, given the possible evolution of transport regulations for hazardous materials and in the event of the MSDS in your possession dating back more than 12 months, it is advisable to check their validity with your sales office.

### SECTION 15. REGULATORY INFORMATION

#### Labeling/Restrictions:

**EC regulations:**  
Restrictions: Prohibited in aerosol dispensers (sprays)  
Labeling Requirements: Protect cuticles with grease or oil; Contains formaldehyde

**USA regulations:**  
Restrictions: Prohibited in aerosol dispensers (sprays)  
This material contains Quaternium-15, which is considered a formaldehyde donor. Formaldehyde is listed on the California Proposition 65 list.

**Japanese regulations:**  
Restrictions: Quaternium-15 is not on Japan's allowed formaldehyde-donor type preservatives list

This information is presented in good faith but is not warranted as to accuracy of results. Also, freedom from patent infringement is not implied.  
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AC Soy Hydrolysate

Page: 8/9

Date: 03 / 20 / 2014

Version: 2

Cancels and replaces version: 1

**Canada regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays)

**China regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays)

**Brazil regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays)  
Labeling Requirements: Protect cuticles with wax or oil; Contains formaldehyde

**ASEAN regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays)

**Mexico regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays); Not for children or infants

**Further regulations**

**United Kingdom:**

Handle in accordance with relevant British regulation: control of substance Hazardous to Health Regulations Environmental Hygiene Guidance: EH40  
Workplace Exposure Limits (revised annually)

**Korea regulations:**

Industrial safety and hygiene regulation: No  
Hazardous material control regulation: No  
Fire prevention regulation: No

**Other regulations:**

EINECS inventory status:	Aqua: 231-791-2 Hydrolyzed Soy Protein: 271-770-5 Methylparaben: 202-785-7 Quaternium-15: 223-805-0
TSCA inventory status:	Exempt
AICS inventory status:	7732-18-5 & 68607-88-5 & 99-76-3 & 4080-31-3
Canadian (CEPA DSL) inventory status:	Listed as Water (DSL) & Protein hydrolyzates, soya (DSL) & Benzoic acid, 4-hydroxy-, methyl ester (DSL) & 3,5,7-Triaza-1-azoniatricyclo [3.3.1.1 <sup>2</sup> #,n]decane, 1-(3-chloro-2-propenyl)-chloride (DSL)
Japan (MITI list):	Not Allowed: Quaternium-15 Listed: Water & Hydrolyzed Soy Protein & Methylparaben
Korea:	Water & Hydrolyzed Soy Protein & Methylparaben & Quaternium-15
China inventory status:	Water & Hydrolyzed Soy Protein* & Methylparaben* & Quaternium-15*
Philippines inventory status:	Listed as Water & Protein hydrolyzates, soya & Benzoic acid, 4-hydroxy-, methyl ester & 3,5,7-Triaza-1-azoniatricyclo[3.3.1.13,7]decane, 1-(3-chloro-2-propenyl)-, chloride

\*Listed on 2010 INCI Standard Chinese Name Directory

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**AC Soy Hydrolysate**

**Page: 9/9**

Date: 03 / 20 / 2014

Version: 2

Cancels and replaces version: 1

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the products described in this sheet. The user's attention is drawn to the possible existence of additional provision which complete these regulations. Please refer to all applicable international, national and local regulations and provisions

## SECTION 16. OTHER INFORMATION

Prohibited uses:	For specific uses, food industry, ask the manufacturer for more information.
Last Revision Date:	01/30/2014
Preparation Date:	03/20/2014
MSDS summary of changes	- Added Precautionary Statements - Section 2 (Hazards Identification)

The information given is based on our knowledge of this product, at the time of publication in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than which it was intended. This is not in any way excuse the user from knowing and applying all the regulations governing their activity. It is sole responsibility of the user to take all precautions required in handling the product. The purpose of mandatory regulation mentioned is to help the user to fulfill his obligations regarding the use of products. This information is not exhaustive, this is not exonerate the user from ensuring that legal obligations other than those mentioned, relating to the use and storage.

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## Compositional Breakdown

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### AC Soy Hydrolysate 30 Code: 20627

Compositional Breakdown:

Ingredient	%
Water	64.60
Hydrolyzed Soy Protein	35.00
Methylparaben	0.20
Quaternium-15	0.20

**\* To our knowledge the above material is free of materials classified as CMR in accordance with the Directive 2004/93 of 21 September 2004.**

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## Compositional Breakdown

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This is to certify that the following allergens were not detected in AC Soy Hydrolysate 30:

ALLERGENS Dir 2003 15 CEE	
INCI NAME	CAS NUMBER
Alpha-IsoMethyl Ionone	127-51-5
Amyl Cinnamal	122-40-7
Anise Alcohol	105-13-5
Benzyl Alcohol	100-51-69
Benzyl Benzoate	120-51-4
Benzyl Cinnamate	103-41-3
Benzyl Salicylate	118-58-1
Butylphenyl Methylpropional	80-54-6
Cinnamal	104-55-2
Cinnamyl Alcohol	104-54-1
Citral	5392-40-5
Citronellol	106-22-9
Coumarin	91-64-5
Eugenol	97-53-0
Farnesol	4602-84-0
Geraniol	106-24-1
Hexyl Cinnamal	101-86-0
Hydroxycitronellal	107-75-5
Hydroxymethylpentyl 3-Cyclohexene carboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Limonene	5989-27-5
Linalool	78-70-6
Methyl 2 Octynoate	111-12-6
Evernia prunastri	90028-68-5
Evernia furfuracea	90028-67-4
Amylcinnamyl Alcohol	101-85-9

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## Product Specification

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**Product Name:** AC Soy Hydrolysate 30  
**Code Number:** 20627  
**CAS #'s:** 68607-88-5  
**EINECS #'s:** 271-770-5  
**INCI Name:** Hydrolyzed Soy Protein  
**Status:** Approved

Specification	Parameter
Appearance	Clear Light Tan to Amber Liquid
Odor	Characteristic
NVM (1g-1hr-105°C)	28.0 – 34.0%
pH (direct)	5.0 – 7.0
Microbial Content	< 100 opg No pathogens

**May Sediment upon Standing; Mix Well Prior to Use**

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## Dermal and Ocular Irritation Tests

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**Trade Name:** AC Soy Hydrolysate 30

**Code:** 20627

**CAS #:** 68607-88-5

**Test Request Form #:** 270

**Lot #:** NC110425-G

**Sponsor:** Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092

**Study Director:** Erica Segura

**Principle Investigator:** Meghan Darley

**Test Performed:**

In Vitro EpiDerm™ Dermal Irritation Test (EPI-200-SIT)

EpiOcular™ Eye Irritation Test (OCL-200-EIT)

### SUMMARY

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether AC Soy Hydrolysate 30 would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays.

The product was tested according to the manufacture's protocol. The test article solution was found to be a **non-irritant**. Reconstructed human epidermis and cornea epithelial model were incubated in growth media overnight to allow for tissue equilibration after shipping from MatTek Corporation, Ashland, MA. Test substances were applied to the tissue inserts and incubated for 60 minutes for liquid and solid substances in the EpiDerm™ assay and 30 minutes for liquid substances and 90 minutes for solid substances in the EpiOcular™ assay at 37 °C, 5% CO<sub>2</sub>, and 95% relative humidity (RH). Tissue inserts were thoroughly washed and transferred to fresh plates with growth media. After post substance dosing incubation is complete, the cell viability test begins. Cell viability is measured by dehydrogenase conversion of MTT [(3-4,5-dimethyl thiazole 2-yl)], present in the cell mitochondria, into blue formazan salt that is measured after extraction from the tissue. The irritation potential of the test chemical is dictated by the reduction in tissue viability of exposed tissues compared to the negative control.

Under the conditions of this assay, the test article was considered to be **non-irritating**. The negative and positive controls performed as anticipated.

### I. Introduction

#### A. Purpose

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether a test article would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays. MatTek Corporation's reconstructed human epidermal and human ocular models are becoming a standard in determining the irritancy potential of test substances. They are able to discriminate between irritants and non-irritants. The EpiDerm™ assay has accuracy for the prediction of UN GHS R38 skin irritating and no-label (non-skin irritating) test substances. The EpiOcular™ assay can

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## Dermal and Ocular Irritation Tests

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differentiate chemicals that have been classified as R36 or R41 from the EU classifications based on Dangerous Substances Directive (DSD) or between the UN GHS Cat 1 and Cat 2 classifications.

### II. Materials

- A. Incubation Conditions:** 37 °C at 5% CO<sub>2</sub> and 95% relative humidity
- B. Equipment:** Forma humidified incubator, ESCO biosafety laminar flow hood, Synergy HT Microplate reader; Pipettes
- C. Media/Buffers:** DMEM based medium; DPBS; sterile deionized H<sub>2</sub>O
- D. Preparation:** Pre-incubate (37 °C) tissue inserts in assay medium; Place assay medium and MTT diluent at 4 °C, MTT concentrate at -20 °C, and record lot numbers of kit components
- E. Tissue Culture Plates:** Falcon flat bottom 96-well, 24-well, 12-well, and 6-well tissue culture plates
- F. Reagents:** MTT (1.0mg/mL); Extraction Solution (isopropanol); SDS (5%); Methyl Acetate
- G. Other:** Nylon Mesh Circles (EPI-MESH); Cotton tip swabs; 1mL tuberculin syringes; Ted Pella micro-spatula; 220mL specimen containers; sterile disposable pipette tips; Parafilm

### III. Test Assay

#### **A. Test System**

The reconstructed human epidermal model, EpiDerm™, and cornea epithelial model, EpiOcular™, consist of normal human-derived epidermal keratinocytes which have been cultured to form a multilayer, highly differentiated model of the human epidermis and cornea epithelium. These models consist of organized basal, spinous, and granular layers, and the EpiDerm™ systems also contains a multilayer stratum corneum containing intercellular lamellar lipid layers that the EpiOcular™ system is lacking. Both the EpiDerm™ and EpiOcular™ tissues are cultured on specially prepared cell culture inserts.

#### **B. Negative Control**

Sterile DPBS and sterile deionized water are used as negative controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **C. Positive Control**

Known dermal and eye irritants, 5% SDS solution and Methyl Acetate, were used as positive controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **D. Data Interpretation Procedure**

##### **a. EpiDerm™**

An irritant is predicted if the mean relative tissue viability of the 3 tissues exposed to the test substance is reduced by 50% of the mean viability of the negative controls and a non-irritant's viability is > 50%.

##### **b. EpiOcular™**

An irritant is predicted if the mean relative tissue viability of the 2 tissues exposed to the test substance is reduced by 60% of the mean viability of the negative controls and a non-irritant's viability is > 40%.

### IV. Method

#### **A. Tissue Conditioning**

Upon MatTek kit arrival at Active Concepts, LLC the tissue inserts are removed from their shipping medium and transferred into fresh media and tissue culture plates and incubated at 37 °C at 5% CO<sub>2</sub> and 95% relative humidity for 60 minutes. After those 60 minutes the inserts are transferred into fresh media and tissue culture plates and incubated at 37 °C at 5% CO<sub>2</sub> and 95% relative humidity for an additional 18 to 21 hours.

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## Dermal and Ocular Irritation Tests

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### B. Test Substance Exposure

#### a. EpiDerm™

30µL (liquid) or 25mg (solid) of the undiluted test substance is applied to 3 tissue inserts and allowed to incubate for 60 minutes in a humidified incubator (37 °C, 5% CO<sub>2</sub>, 95% RH).

#### b. EpiOcular™

Each tissue is dosed with 20µL DPBS prior to test substance dosing. 50µL (liquid) or 50mg (solid) of the undiluted test substance is applied to 2 tissue inserts and allowed to incubate for 90 minutes in a humidified incubator (37 °C, 5% CO<sub>2</sub>, 95% RH).

### C. Tissue Washing and Post Incubation

#### a. EpiDerm™

All tissue inserts are washed with DPBS, dried with cotton tipped swab, and transferred to fresh media and culture plates. After 24 hours the inserts are again transferred into fresh media and culture plates for an additional 18 to 20 hours.

#### b. EpiOcular™

Tissue inserts are washed with DPBS and immediately transferred into 5mL of assay medium for 12 to 14 minutes. After this soak the inserts are transferred into fresh media and tissue culture plates for 120 minutes for liquid substances and 18 hours for solid substances.

### D. MTT Assay

Tissue inserts are transferred into 300µL MTT media in pre-filled plates and incubated for 3 hours at 37 °C, 5% CO<sub>2</sub>, and 95% RH. Inserts are then removed from the MTT medium and placed in 2mL of the extraction solution. The plate is sealed and incubated at room temperature in the dark for 24 hours. After extraction is complete the tissue inserts are pierced with forceps and 2 x 200µL aliquots of the blue formazan solution is transferred into a 96 well plate for Optical Density reading. The spectrophotometer reads the 96-well plate using a wavelength of 570 nm.

### V. Acceptance Criterion

#### A. Negative Control

The results of this assay are acceptable if the mean negative control Optical Density (OD<sub>570</sub>) is  $\geq 1.0$  and  $\leq 2.5$  (EpiDerm™) or  $\geq 1.0$  and  $\leq 2.3$  (EpiOcular™).

#### B. Positive Control

##### a. EpiDerm™

The assay meets the acceptance criterion if the mean viability of positive control tissues expressed as a % of the negative control is  $\leq 20\%$ .

##### b. EpiOcular™

The assay meets the acceptance criterion if the mean viability of positive control tissues is  $< 60\%$  of control viability.

#### C. Standard Deviation

Since each irritancy potential is predicted from the mean viability of 3 tissues for EpiDerm™ and 2 tissues for EpiOcular™, the variability of the replicates should be  $< 18\%$  for EpiDerm™ and  $< 20\%$  EpiOcular™.

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## Dermal and Ocular Irritation Tests

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### VI. Results

#### A. Tissue Characteristics

The tissue inserts included in the MatTek EpiDerm™ and EpiOcular™ assay kits were in good condition, intact, and viable.

#### B. Tissue Viability Assay

The results are summarized in Figures 1 and 2. In no case was the tissue viability  $\leq 50\%$  for EpiDerm™ or  $\leq 60\%$  for EpiOcular™ in the presence of the test substance. The negative control mean exhibited acceptable relative tissue viability while the positive control exhibited substantial loss of tissue viability and cell death.

#### C. Test Validity

The data obtained from this study met criteria for a valid assay.

### VII. Conclusion

Under the conditions of this assay, the test article substance was considered to be non-irritating. The negative and positive controls performed as anticipated.

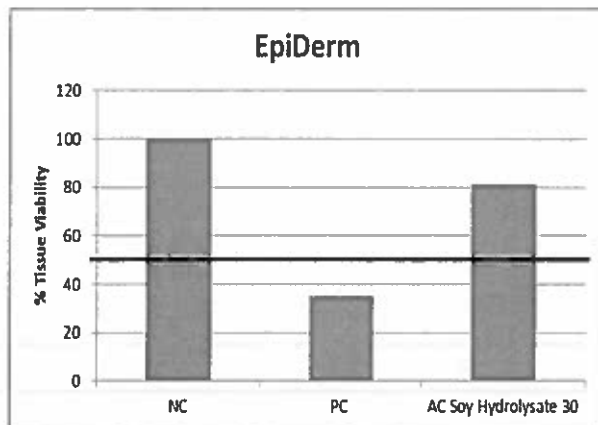


Figure 1: EpiDerm tissue viability

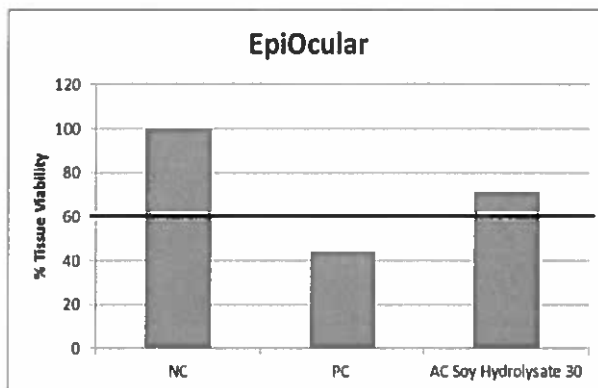


Figure 2: EpiOcular tissue viability

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# Material Safety Data Sheet

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## SECTION I – MATERIAL AND MANUFACTURING IDENTIFICATION

Manufacturers Name:  
**Active Concepts LLC**

Emergency Phone Number  
**1-704-276-7100**

Product Name: **AC Soy Hydrolysate 30**  
 Chemical Family: Hydrolyzed Protein  
 Chemical Names: Hydrolyzed Soy Protein

CAS #'s: 68607-88-5  
 EINECS #'s: 271-770-5

## SECTION II – HAZARDS IDENTIFICATION

Main Hazards: None

## SECTION III – COMPOSITION / PRODUCT DESCRIPTION

Hazardous components: None

TWA: N/A

Hazard: None

HMIS Codes:           H     0  
                               F     0  
                               R     0

## SECTION IV –FIRST AID MEASURES

Effects of Single Overexposure: None

### EMERGENCY AND FIRST AID PROCEDURES

Skin Absorption: Rinse with soap and water.  
 Eye Contact: Rinse with water. Consult with a physician.  
 Inhalation: Remove from exposure area. Consult with a physician.  
 Skin Contact: Rinse with soap and water. Consult with a physician.  
 Swallowing: Consult with a physician.

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# Material Safety Data Sheet

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## SECTION V – MEASURES IN CASE OF FIRE

Flash Point: >200°F  
 Extinguishing Media: Water, dry chemicals, foam, carbon dioxide  
 Special Fire Fighting Procedures: None known  
 Unusual Fire and Explosion Hazards: None known

## SECTION VI – MEASURES IN CASE OF ACCIDENTAL SPREADING

After Spillage or Leakage:

On Soil Pick up free liquid for recycling or disposal. Residual liquid can be absorbed on an inert material.  
 On Water Prevent entry into sewers and waterways.

Effect of Single Overexposure: None

## EMERGENCY AND FIRST AID PROCEDURES

Skin Absorption: Rinse with soap and water.  
 Eye Contact: Rinse with water. Consult with a physician.  
 Inhalation: Remove from exposure area. Consult with a physician.  
 Skin Contact: Rinse with soap and water. Consult with a physician.  
 Swallowing: Consult with a physician.

## SECTION VII – HANDLING AND STORAGE

Precautions to be taken in handling and storage:

Labeling: Keep out of the reach of children. For industrial use, only as directed.  
 Handling Conditions: Wash hands after use. Avoid storage near feed or food stuffs.  
 Storage Conditions: Keep container closed. Store in a cool, dry place. This product should be stored at room temperature (23 - 25°C). It should not be exposed to excessive heat or cold. Do not freeze.

## SECTION VIII – CONTROL EXPOSURE – PERSONAL PROTECTION

Respiratory Protection: N/A  
 Ventilation: Local exhaust  
 Protective Gloves: Rubber or neoprene  
 Other Protective Equipment: Protective clothing to avoid skin contact and eye protection

## SECTION IX – PHYSICAL AND CHEMICAL DATA

Vapor Pressure: 20C N/A  
 Specific Gravity: 1.05  
 Solubility in Water: Soluble  
 Appearance and Odor: Clear light tan to amber liquid; Characteristic odor

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# Material Safety Data Sheet

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## SECTION X – STABILITY AND REACTIVITY

Stability: Stable  
 Conditions to Avoid: Avoid extreme heat  
 Incompatibility: Avoid contact with strong oxidizers  
 Hazardous Decomposition: None known  
 Hazardous Polymerization: Will not occur

## SECTION XI – INFORMATION ON TOXICITY

Ingestion: Not determined  
 Dermal: Non-Irritant (Dermal Irritation Model)  
 Ocular: Non-Irritant (Ocular Irritation Model)  
 Inhalation: Not determined

## SECTION XII – INFORMATION ON ECOLOGICAL EFFECT

Biodegradation: Not determined

## SECTION XIII – DISPOSAL CONSIDERATION

Recover if possible. In so doing, comply with local and national regulations currently in force.

## SECTION XIV- INFORMATION ON TRANSPORT

Road (ADR) - Not dangerous for conveyance. Sea transport (IMO/IMDG) - Not dangerous for conveyance. Air transport (ICA/IATA) – Not dangerous for conveyance. Rail (RID) - Not dangerous for conveyance.

## SECTION XV - REGULATORY INFORMATION

This product and its components are not classified as dangerous or hazardous according to 67/548/EEC or 99/45/EC as amended and CLP Regulation EC1272/2008.

TSCA Status: All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances

This product contains the following non-hazardous components:

	CAS Number
Water	7732-18-5

### OSHA:

Contents of this MSDS comply with OSHA Hazard Communication Standard 29 CFR 1910.1200.

### Clean Air Act Section 112:

This product contains the following components present at or above the OSHA de minus level and listed as Hazardous Air Pollutants:

None

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# Material Safety Data Sheet

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## SECTION XV - REGULATORY INFORMATION (Continued)

### SARA Section 302 Extremely Hazardous Materials:

This product contains the following components listed as Extremely Hazardous Substances:

None

### SARA Section 304 CERCLA Hazardous Substances:

None

### SARA Section 312 Hazard Class:

Acute:	NO
Chronic:	NO
Fire:	NO
Pressure:	NO
Reactive:	NO

### SARA Section 313 Toxic Chemicals:

None present or none present in regulated quantities.

### STATE REGULATIONS:

This product contains the following non-hazardous components subject to disclosure under New Jersey Right-To-Know legislation:

	CAS Number
Water	7732-18-5

## SECTION XVI - OTHER INFORMATION

Prepared by: Active Concepts LLC

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## Compositional Breakdown

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### AC Soy Milk Hydrolysate Code: 20574

Compositional Breakdown:

Ingredient	%
Water	76.60
Hydrolyzed Soymilk Protein	21.50
Phenoxyethanol	1.20
DMDM Hydantoin	0.70

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## Compositional Breakdown

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This is to certify that the following allergens were not detected in AC Soy Milk Hydrolysate:

ALLERGENS Dir 2003 15 CEE	
INCI NAME	CAS NUMBER
Alpha-IsoMethyl Ionone	127-51-5
Amyl Cinnamal	122-40-7
Anise Alcohol	105-13-5
Benzyl Alcohol	100-51-69
Benzyl Benzoate	120-51-4
Benzyl Cinnamale	103-41-3
Benzyl Salicylate	118-58-1
Butylphenyl Methylpropional	80-54-6
Cinnamal	104-55-2
Cinnamyl Alcohol	104-54-1
Citral	5392-40-5
Citronellol	106-22-9
Coumarin	91-64-5
Eugenol	97-53-0
Farnesol	4602-84-0
Geraniol	106-24-1
Hexyl Cinnamal	101-86-0
Hydroxycitronellal	107-75-5
Hydroxymethylpentyl 3-Cyclohexene carboxaldehyde	31906-04-4
Isoeugenol	97-54-1
Limonene	5989-27-5
Linalool	78-70-6
Methyl 2 Octynoate	111-12-6
Evernia prunastri	90028-68-5
Evernia furfuracea	90028-67-4
Amylcinnamyl Alcohol	101-85-9

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## Product Specification

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**Product Name:** AC Soy Milk Hydrolysate  
**Code Number:** 20574  
**CAS #'s:** N/A  
**EINECS #'s:** N/A  
**INCI Name:** Hydrolyzed Soymilk Protein  
**Status:** Approved

Specification	Parameter
Appearance	Slightly Hazy Colorless to Amber Liquid*
Odor	Characteristic
pH (25°C)	5.5 – 7.0
NVM (1g-1hr-105°C)	18.0 – 25.0%
Microbial Content	< 100 opg No pathogens

**May Sediment upon Standing; Mix Well Prior to Use**

\*Product may darken over time

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## Dermal and Ocular Irritation Tests

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**Trade Name:** AC Soy Milk Hydrolysate

**Code:** 20574

**CAS #:** N/A

**Test Request Form #:** 271

**Lot #:** 24278P

**Sponsor:** Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092

**Study Director:** Erica Segura

**Principle Investigator:** Meghan Darley

**Test Performed:**

In Vitro EpiDerm™ Dermal Irritation Test (EPI-200-SIT)

EpiOcular™ Eye Irritation Test (OCL-200-EIT)

### SUMMARY

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether AC Soy Milk Hydrolysate would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays.

The product was tested according to the manufacture's protocol. The test article solution was found to be a non-irritant. Reconstructed human epidermis and cornea epithelial model were incubated in growth media overnight to allow for tissue equilibration after shipping from MatTek Corporation, Ashland, MA. Test substances were applied to the tissue inserts and incubated for 60 minutes for liquid and solid substances in the EpiDerm™ assay and 30 minutes for liquid substances and 90 minutes for solid substances in the EpiOcular™ assay at 37 °C, 5% CO<sub>2</sub>, and 95% relative humidity (RH). Tissue inserts were thoroughly washed and transferred to fresh plates with growth media. After post substance dosing incubation is complete, the cell viability test begins. Cell viability is measured by dehydrogenase conversion of MTT [(3-4,5-dimethyl thiazole 2-yl)], present in the cell mitochondria, into blue formazan salt that is measured after extraction from the tissue. The irritation potential of the test chemical is dictated by the reduction in tissue viability of exposed tissues compared to the negative control.

Under the conditions of this assay, the test article was considered to be non-irritating. The negative and positive controls performed as anticipated.

### 1. Introduction

#### A. Purpose

*In vitro* dermal and ocular irritation studies were conducted to evaluate whether a test article would induce dermal or ocular irritation in the EpiDerm™ and EpiOcular™ model assays. MatTek Corporation's reconstructed human epidermal and human ocular models are becoming a standard in determining the irritancy potential of test substances. They are able to discriminate between irritants and non-irritants. The EpiDerm™ assay has accuracy for the prediction of UN GHS R38 skin irritating and no-label (non-skin irritating) test substances. The EpiOcular™ assay can

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## Dermal and Ocular Irritation Tests

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differentiate chemicals that have been classified as R36 or R41 from the EU classifications based on Dangerous Substances Directive (DSD) or between the UN GHS Cat 1 and Cat 2 classifications.

### II. Materials

- A. Incubation Conditions:** 37 °C at 5% CO<sub>2</sub> and 95% relative humidity
- B. Equipment:** Forma humidified incubator, ESCO biosafety laminar flow hood, Synergy HT Microplate reader; Pipettes
- C. Media/Buffers:** DMEM based medium; DPBS; sterile deionized H<sub>2</sub>O
- D. Preparation:** Pre-incubate (37 °C) tissue inserts in assay medium; Place assay medium and MTT diluent at 4 °C, MTT concentrate at -20 °C, and record lot numbers of kit components
- E. Tissue Culture Plates:** Falcon flat bottom 96-well, 24-well, 12-well, and 6-well tissue culture plates
- F. Reagents:** MTT (1.0mg/mL); Extraction Solution (Isopropanol); SDS (5%); Methyl Acetate
- G. Other:** Nylon Mesh Circles (EPI-MESH); Cotton tip swabs; 1mL tuberculin syringes; Ted Pella micro-spatula; 220mL specimen containers; sterile disposable pipette tips; Parafilm

### III. Test Assay

#### **A. Test System**

The reconstructed human epidermal model, EpiDerm™, and cornea epithelial model, EpiOcular™, consist of normal human-derived epidermal keratinocytes which have been cultured to form a multilayer, highly differentiated model of the human epidermis and cornea epithelium. These models consist of organized basal, spinous, and granular layers, and the EpiDerm™ systems also contains a multilayer stratum corneum containing intercellular lamellar lipid layers that the EpiOcular™ system is lacking. Both the EpiDerm™ and EpiOcular™ tissues are cultured on specially prepared cell culture inserts.

#### **B. Negative Control**

Sterile DPBS and sterile deionized water are used as negative controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **C. Positive Control**

Known dermal and eye irritants, 5% SDS solution and Methyl Acetate, were used as positive controls for the EpiDerm™ and EpiOcular™ assays, respectfully.

#### **D. Data Interpretation Procedure**

##### **a. EpiDerm™**

An irritant is predicted if the mean relative tissue viability of the 3 tissues exposed to the test substance is reduced by 50% of the mean viability of the negative controls and a non-irritant's viability is > 50%.

##### **b. EpiOcular™**

An irritant is predicted if the mean relative tissue viability of the 2 tissues exposed to the test substance is reduced by 60% of the mean viability of the negative controls and a non-irritant's viability is > 40%.

### IV. Method

#### **A. Tissue Conditioning**

Upon MatTek kit arrival at Active Concepts, LLC the tissue inserts are removed from their shipping medium and transferred into fresh media and tissue culture plates and incubated at 37 °C at 5% CO<sub>2</sub> and 95% relative humidity for 60 minutes. After those 60 minutes the inserts are transferred into fresh media and tissue culture plates and incubated at 37 °C at 5% CO<sub>2</sub> and 95% relative humidity for an additional 18 to 21 hours.

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## Dermal and Ocular Irritation Tests

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### B. Test Substance Exposure

#### a. EpiDerm™

30µL (liquid) or 25mg (solid) of the undiluted test substance is applied to 3 tissue inserts and allowed to incubate for 60 minutes in a humidified incubator (37°C, 5% CO<sub>2</sub>, 95% RH).

#### b. EpiOcular™

Each tissue is dosed with 20µL DPBS prior to test substance dosing. 50µL (liquid) or 50mg (solid) of the undiluted test substance is applied to 2 tissue inserts and allowed to incubate for 90 minutes in a humidified incubator (37°C, 5% CO<sub>2</sub>, 95% RH).

### C. Tissue Washing and Post Incubation

#### a. EpiDerm™

All tissue inserts are washed with DPBS, dried with cotton tipped swab, and transferred to fresh media and culture plates. After 24 hours the inserts are again transferred into fresh media and culture plates for an additional 18 to 20 hours.

#### b. EpiOcular™

Tissue inserts are washed with DPBS and immediately transferred into 5mL of assay medium for 12 to 14 minutes. After this soak the inserts are transferred into fresh media and tissue culture plates for 120 minutes for liquid substances and 18 hours for solid substances.

### D. MTT Assay

Tissue inserts are transferred into 300µL MTT media in pre-filled plates and incubated for 3 hours at 37°C, 5% CO<sub>2</sub>, and 95% RH. Inserts are then removed from the MTT medium and placed in 2mL of the extraction solution. The plate is sealed and incubated at room temperature in the dark for 24 hours. After extraction is complete the tissue inserts are pierced with forceps and 2 x 200µL aliquots of the blue formazan solution is transferred into a 96 well plate for Optical Density reading. The spectrophotometer reads the 96-well plate using a wavelength of 570 nm.

## V. Acceptance Criterion

### A. Negative Control

The results of this assay are acceptable if the mean negative control Optical Density (OD<sub>570</sub>) is  $\geq 1.0$  and  $\leq 2.5$  (EpiDerm™) or  $\geq 1.0$  and  $\leq 2.3$  (EpiOcular™).

### B. Positive Control

#### a. EpiDerm™

The assay meets the acceptance criterion if the mean viability of positive control tissues expressed as a % of the negative control is  $\leq 20\%$ .

#### b. EpiOcular™

The assay meets the acceptance criterion if the mean viability of positive control tissues is  $< 60\%$  of control viability.

### C. Standard Deviation

Since each irritancy potential is predicted from the mean viability of 3 tissues for EpiDerm™ and 2 tissues for EpiOcular™, the variability of the replicates should be  $< 18\%$  for EpiDerm™ and  $< 20\%$  EpiOcular™.

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## Dermal and Ocular Irritation Tests

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### VI. Results

#### A. Tissue Characteristics

The tissue inserts included in the MatTek EpiDerm™ and EpiOcular™ assay kits were in good condition, intact, and viable.

#### B. Tissue Viability Assay

The results are summarized in Figures 1 and 2. In no case was the tissue viability  $\leq 50\%$  for EpiDerm™ or  $\leq 60\%$  for EpiOcular™ in the presence of the test substance. The negative control mean exhibited acceptable relative tissue viability while the positive control exhibited substantial loss of tissue viability and cell death.

#### C. Test Validity

The data obtained from this study met criteria for a valid assay.

### VII. Conclusion

Under the conditions of this assay, the test article substance was considered to be non-irritating. The negative and positive controls performed as anticipated.

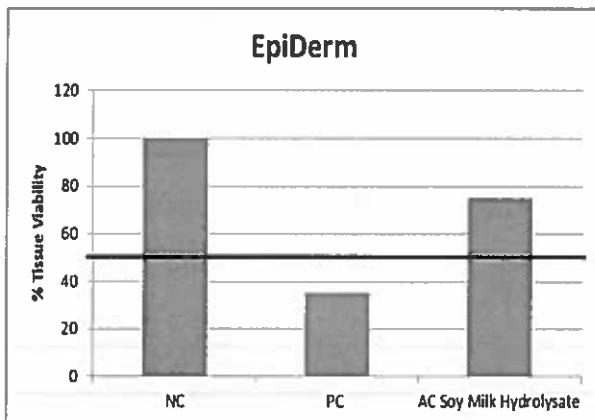


Figure 1: EpiDerm tissue viability

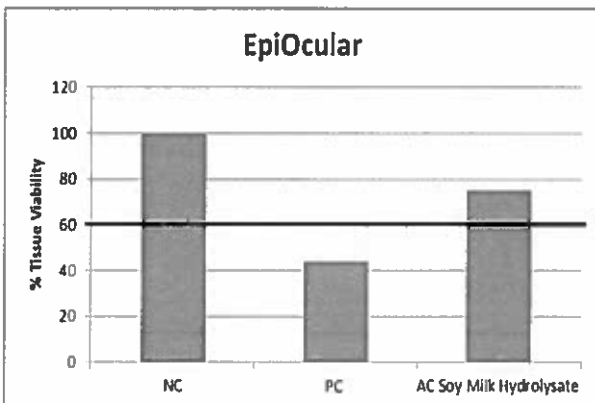


Figure 2: EpiOcular tissue viability

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# Safety Data Sheet

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Version: 1

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## SECTION 1. IDENTIFICATION

<b>Product Name/Identifier</b>	AC Soy Milk Hydrolysate
<b>Product Code</b>	20574
<b>Recommended Use</b>	Topical Cosmetic Use
<b>Restrictions on Use</b>	None
<b>Supplier/Manufacturing Site Address</b>	Active Concepts, LLC 107 Technology Drive Lincolnton, NC 28092, USA
<b>Telephone No. (24hrs)</b>	1-704-276-7100
<b>Fax No.</b>	1-704-276-7101
<b>Emergency Telephone #</b>	1-704-276-7100 (Mon-Fri: 8:00AM – 5:00PM EST)

## SECTION 2. HAZARD(S) IDENTIFICATION

### Classification:

#### GHS / CLP

**Basis for Classification:** Based on present data no classification and labeling is required according to GHS taking into account the national implementation (United Nations version 2011)

#### USA

**OSHA Regulatory Status:** This material is non-hazardous as defined by the American OSHA Hazard Communication Standard (29 CFR 1910.1200).

#### Europe

**Basis for Classification:**

- According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.
- This product is not classified as hazardous to health or environment according to the CLP regulation.

### Labeling Elements:

**Pictograph:** No hazard symbol expected

**Hazard statements/Signal Word:** Not applicable

**Precautionary statements:**

- P233: Keep container tightly closed
- P281: Use personal protective equipment as required
- P402: Store in a dry place
- P404: Store in a closed container
- P410: Protect from sunlight
- P411: Store at temperatures not exceeding 25°C

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**Other hazards which do not result in classification:**

No particular fire or explosion hazard.

By mechanical effect: No particular hazards.

By hydroscopic effect: No particular hazards.

**US NFPA 704 (National Fire Protection Association) Hazard Rating System:**

Health hazard: Rating 0; Normal Material

Flammability: Rating 0, Will Not Burn

Reactivity: Rating 0, Stable

Other Hazard Information: None

**Results of PBT and vPvB assessment:**

-PBT: Not applicable

-vPvB: Not applicable

**SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS**

**Common Chemical Name:** Hydrolyzed Soymilk Protein

**Generic name:**

**Chemical Family:** Proteins

**Description:** Mixture: consisting of the following components. This section describes all components of the mixture

<u>Substance</u>	<u>CAS Numbers</u>	<u>EC Numbers</u>	<u>Percentage</u>
Water	7732-18-5	231-791-2	76.60%
Hydrolyzed Soymilk Protein	N/A	N/A	21.50%
Phenoxyethanol	122-99-6	204-589-7	1.20%
DMDM Hydantoin	6440-58-0	229-222-8	0.70%

**Formula:** Not applicable

**SECTION 4. FIRST-AID MEASURES**

**General:** In all cases of doubt, or when symptoms persist, seek medical attention.

**Inhalation:** Move to fresh air from exposure area. Get medical attention for any breathing difficulty.

**Skin contact:** Rinse with soap and water. Get medical advice if irritation develops.

**Eye contact:** Immediately rinse with plenty of water for at least 15 minutes, while keeping the eyes wide open. Consult with a physician.

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**Ingestion:** Consult with a physician.  
**Protection of first-aiders:** No special protection required.

#### SECTION 5. FIRE-FIGHTING MEASURES

**Fire and explosion hazards:** Not considered to be a fire and explosion hazard

**Extinguishing media:**

**Suitable:** Water, dry chemicals, foam and carbon dioxide

**Not suitable:** None known

**Fire fighting:** Move container from fire area if it can be done without risk.  
 Avoid inhalation of material or combustion by-products.  
 Stay upwind and keep out of low area

**Protection for fire-fighters:** Boots, gloves, goggles.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Avoid contact with eyes.

**Personal Protective Equipment:**  
 -Protective goggles

**Environmental precautions:** Prevent entry into sewers and waterways. Do not allow material to contaminate ground water system

**Methods for cleaning up:**

**Recovery:** Pick up free liquid for recycling or disposal. Residual liquid can be absorbed on an inert material.

**Cleaning/Decontamination:** Wash non-recoverable remainder with water.

**Disposal:** For disposal of residues refer to sections 8 & 13.

#### SECTION 7. HANDLING AND STORAGE

**Handling**

**Technical measures:** Labeling: Keep out of the reach of children.

**Measures:** For industrial use, only as directed.

**Safe handling advice:** Wash hands after use. Avoid storage near feed or food stuff.

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#### Storage

Technical measures: Keep container closed.  
 Recommended Storage Conditions: Store in a cool, dry place. This material must be stored at room temperature (23 - 25°C). It should not be exposed to excessive heat or cold. Do not freeze.

Incompatible products: Avoid contact with strong oxidizers.  
 Refer to the detailed list of incompatible materials (Section 10 Stability/Reactivity)

Packaging: Product may be packaged in normal commercial packaging.  
 Packaging materials: Recommended - Polypropylene & High Density Polyethylene

### SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Precautionary statements: Ensure adequate ventilation

#### Control parameters

#### Occupational exposure Limits:

France: Not Determined  
 ACGIH: Not Determined  
 Korea: Not Determined  
 UK: Not Determined

Surveillance procedures: Not Determined  
 Engineering measures: Not Determined

#### Personal Protective Equipment:

Respiratory protection: Local exhaust  
 Hand protection: Protective gloves made of rubber or neoprene.  
 Eye protection: Safety glasses.  
 Collective emergency equipment: Eye fountain.  
 Skin and Body Protection: Suitable protective clothing  
 Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Measures related to the Environment: No particular measures.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Slightly hazy colorless to amber liquid – Product may darken over time  
 Odor: Characteristic  
 pH (25°C): 5.5 – 7.0  
 NVM (1g-1hr-105°C): 18.0 – 25.0%

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<b>Microbial Content:</b>	< 100 CFU/g No pathogens
<b>Specific Gravity:</b>	1.20
<b>Vapor density:</b>	Not applicable
<b>Boiling Point:</b>	100°C
<b>Freezing Point:</b>	0°C
<b>Melting point:</b>	Not applicable
<b>Flash point:</b>	> 200°F
<b>Oxidizing properties:</b>	Non oxidizing material according to EC criteria.
<b>Solubility:</b>	
In water:	Soluble
In organic solvents:	Not determined
Log P:	Not determined

#### SECTION 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under ordinary conditions of use and storage up to one year then re-test to full product specifications to extend shelf life
<b>Hazardous reactions:</b>	None known
<b>Conditions to avoid:</b>	No dangerous reactions known under use of normal conditions. Avoid extreme heat.
<b>Materials to avoid:</b>	No dangerous reaction known with common products.
<b>Hazardous decomposition products:</b>	None known

#### SECTION 11. TOXICOLOGICAL INFORMATION

<b>Ingestion:</b>	Not Determined
<b>Dermal:</b>	Non-Irritant (Dermal Irritation Model)
<b>Ocular:</b>	Non-Irritant (Ocular Irritation Model)
<b>Inhalation:</b>	Not Determined
<b>Acute toxicity data:</b>	Not Determined
<b>Sensitization:</b>	Non-Primary Sensitizers
<b>Repeated dose toxicity:</b>	No known effects
<b>Subacute to chronic toxicity:</b>	Not Determined

**Additional Toxicological Information:** This product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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**Specific effects:**

Carcinogenicity:	No known effects
Mutagenicity:	No known effects
Reproductive toxicity:	No known effects
Neuro-toxicity:	No known effects

**For more information:** Does not present any particular risk on handling under normal conditions of good occupational hygiene practice.

This product has not been tested for the following:

- Primary cutaneous and corrosive irritation
- Acute oral toxicity
- Mutagenicity/genotoxicity

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Effects on the aquatic environment: Not Determined

**Biodegradability:**

Persistence: Not Determined

**Bioaccumulation:**

Octanol / water partition coefficient: Not Determined

**Mobility:**

Precipitation:

Expected behavior of the product: Ultimate destination of the product: Soil & sediment.

**Other Adverse Effects:** None known

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Residues from product**

Prohibition:	Do not allow the product to be released into the Environment.
Destruction/Disposal:	Dispose of in accordance with relevant local regulations

**Contaminated packaging**

Decontamination/cleaning:	Cleaning is not required prior to disposal.
Destruction/Disposal:	

**Note:** Take all necessary precautions when disposing of this product according to local regulations.

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#### SECTION 14. TRANSPORT INFORMATION

UN Number:	None
UN Shipping Name:	None
Transport Hazard Class:	Not classified as dangerous for transport
Land (rail/road):	Not restricted
Sea:	Not restricted
Air:	Not restricted
Marine Pollutant:	No
Transport/Additional Information:	Not regulated for US DOT Transport in non-bulk containers
Special Precautions for User:	None known

The above regulatory prescriptions are those valid on the date of publication of this sheet. However, given the possible evolution of transport regulations for hazardous materials and in the event of the MSDS in your possession dating back more than 12 months, it is advisable to check their validity with your sales office.

#### SECTION 15. REGULATORY INFORMATION

##### Labeling/Restrictions:

##### EC regulations:

Restrictions:	Prohibited in aerosol dispensers (sprays)
Labeling Requirements:	Protect cuticles with grease or oil; Contains formaldehyde

##### USA regulations:

Restrictions:	Prohibited in aerosol dispensers (sprays) This material contains DMDM Hydantoin, which is considered a formaldehyde donor. Formaldehyde is listed on the California Proposition 65 list.
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##### Japanese regulations:

Restrictions:	Not to be used on leave-on or mucous membrane applications
Labeling Requirements:	Should not be used by infants or by people who are hypersensitive to formaldehyde.

##### Canada regulations:

Restrictions:	Prohibited in aerosol dispensers (sprays)
---------------	---

##### China regulations:

Restrictions:	Prohibited in aerosol dispensers (sprays)
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##### Brazil regulations:

Restrictions:	Prohibited in aerosol dispensers (sprays)
Labeling Requirements:	Protect cuticles with wax or oil; Contains formaldehyde

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**ASEAN regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays)

**Mexico regulations:**

Restrictions: Prohibited in aerosol dispensers (sprays); Not for children or infants

**Further regulations**

**United Kingdom:**

Handle in accordance with relevant British regulation: control of substance Hazardous to Health Regulations Environmental Hygiene Guidance: EH40 Workplace Exposure Limits (revised annually)

**Korea regulations:**

Industrial safety and hygiene regulation: No  
Hazardous material control regulation: No  
Fire prevention regulation: No

**Other regulations:**

**EINECS inventory status:**

Aqua: 231-791-2  
Hydrolyzed Soymilk Protein: N/A  
Phenoxyethanol: 204-589-7  
DMDM Hydantoin: 229-222-8

**TSCA inventory status:**

Exempt

**AICS inventory status:**

Exempt: Hydrolyzed Soymilk Protein  
Listed: 7732-18-5 & 122-99-6 & 6440-58-0

**Canadian (CEPA DSL) inventory status:**

Exempt: Hydrolyzed Soy Milk Protein  
Listed as Water (DSL) & Ethanol, 2-phenoxy- (DSL) & Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)- (DSL)

**Japan (MITI list):**

Water & Hydrolyzed Soymilk Protein & Phenoxyethanol & DMDM Hydantoin

**Korea:**

Water & Hydrolyzed Soymilk Protein\*\* & Phenoxyethanol & DMDM Hydantoin

**China inventory status:**

Water & Hydrolyzed Soymilk Protein\* & Phenoxyethanol\* & DMDM Hydantoin\*

**Philippines inventory status:**

Exempt: Hydrolyzed Soymilk Protein  
Listed as Water & Ethanol, 2-phenoxy- & Urea, N-[1,3-bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]-N,N'-bis(hydroxymethyl)-

\*Listed on 2010 INCI Standard Chinese Name Directory

\*\*Not listed in 2004 CTFA Dictionary – Registered with Personal Care Products Council

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the products described in this sheet. The user's attention is drawn to the possible existence of additional provision which complete these regulations. Please refer to all applicable international, national and local regulations and provisions

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## SECTION 16. OTHER INFORMATION

Prohibited uses: For specific uses, food industry, ask the manufacturer for more information.

Last Revision Date: N/A

Preparation Date: 06/20/2014

MSDS summary of changes No deletion, addition or revision to date

The information given is based on our knowledge of this product, at the time of publication in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than which it was intended. This is not in any way excuse the user from knowing and applying all the regulations governing their activity. It is sole responsibility of the user to take all precautions required in handling the product. The purpose of mandatory regulation mentioned is to help the user to fulfill his obligations regarding the use of products. This information is not exhaustive, this is not exonerate the user from ensuring that legal obligations other than those mentioned, relating to the use and storage.

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## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** April 17, 2015

**SUBJECT:** Comments on the Scientific Literature Review: Safety Assessment of Soy Peptides as Used in Cosmetics

### Key Issues

As soy proteins are considered to be food allergens, it would be helpful to include some information about the characteristics of the protein(s) in soy that are allergenic. In addition, some general information from the paper Huby RD, Dearman RJ, and Kimber I. Why are some proteins allergens? Toxicol Sci. 2000;55:235-246 - that was cited in the Hydrolyzed Wheat Protein report, discussing the properties of proteins that result in allergenicity would be helpful.

### Additional Comments

Definition and Manufacture - Please provide a reference for the third paragraph of this section (method of how soybean protein is prepared).

Summary -Where is the information on the “biological activity” of peptides derived from soy discussed previously in the report? What type of “biological activity” has been associated with soy peptides?