

Datensammlung
zur Absicherung kosmetischer Rohstoffe gemäß der EG-Kosmetik-Richtlinien

ADM
Decatur, USA

NovaSoy 400

INCI: Isoflavones

GUSTAV PARMENTIER GmbH
www.parmentier.de

NOVASOY[®] Soya Isoflavon Compound

DESCRIPTION

Novasoy is a soya-based dietary supplement ingredient, rich in the two important isoflavones genistin and daidzin. It is carefully extracted to ensure that the ratios of the various isoflavones are available, as they would be found in soya beans themselves and in natural soya foods such as tofu. The aglycone and glycoside forms are also maintained in their approximate natural proportions. In addition, Novasoy also contains many of the other healthful natural components of soya. Novasoy can be used singly or in combination with other materials to provide a daily dosage suitable for most delivery formats. Based on soya food consumption in Japan, it has been estimated that a typical daily isoflavone intake should be approx. 50 mg* per person. Novasoy is produced in the USA in compliance with the FDA's current Good Manufacturing Practices (cGMP) food regulations. * American Journal of Clinical Nutrition

1995;62:645-9

APPLICATION

Toner, facial moisturizer, treatment (face), body lotion, treatment (body), makeup foundation

GRANULATION

Novasoy is an amber-coloured fine powder, with typically at least 90% passing a US 100 mesh sieve (150 microns).

DIETARY STATUS

Packs bearing the O.U. symbol contain product that is Kosher and Pareve. Novasoy is Halal and does not contain any ingredient that is forbidden according to the Sharia or Islamic dietary laws.

GRAS STATUS

In the USA, Novasoy soya isoflavone compound has GRAS status.

GM STATUS

Non-GM Novasoy is available, produced from soya supplied through ADM's IP programme. A separate Statement can be produced on request.

LOT NUMBER CODING

Example: Lot 0205011 relates to 02 = year of production 05 = month of production (May) 01 = day in the month 1 = daily batch number

PACKAGING

Poly-lined, polyethylene drums: 20 kg net (ADM Code 152400 FD) 5 kg net (ADM Code 152400 PL) 1 kg net (ADM Code 152400 PK)

STORAGE AND SHELF LIFE

Novasoy should be stored in closed packs under cool, dry conditions. A shelf life of three years or more may be expected with storage at below 25° C and less than 60% relative humidity.

IMPORT DUTY TARIFF HEADING

Code 1302.1998

Datenblatt zur Absicherung kosmetischer Rohstoffe gemäß EG-Kosmetik-Richtlinien

Deutsche Lanolin Gesellschaft, Eichendorffstraße 37, 60320 Frankfurt am Main, Tel. 069/56 10 34

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Seite 1/2

BASISINFORMATIONEN für **NovaSoy 400**

1. Angabe zur Identität

a. Handelsname **NovaSoy 400**

b. Chemische Bezeichnung **Isoflavone Extrakt 40%**

As glycosides:	Molecular weight
Genistin C ₂₁ H ₂₀ O ₁₀	432
Daidzin O ₉ 416 5,7,4' – trihydroxyisoflavone	270
(in free form) Daidzein 7,4' – dihydroxyisoflavone	254
Glycitein 7,4' – dihydroxy-6-methoxyisoflavone	284
Glycitin C ₂₂ H ₂₂ O ₁₀	446

c. Typische Analyse

Total isoflavones	min. 40%
Other natural soya components	40-50%
Proteins (N x 6.25)	max. 12%
Fat	max. 1%
Heavy metals (as lead)	max. 5ppm
Moisture	max. 7%
Ash :	max. 4 %
Heavy metals (as lead) :	max. 5 ppm
Extraction solvent :	aqueous ethanol solution
Irradiation :	not irradiated
Nutritional energy :	390 kcal/100 g

Ratio of genistin:daidzin:glycitin similar to unfermented soya products
such as tofu (1 : 1,3 : 0,3)

a. Rohstoffbasis

Extrakt aus der Sojabohne

b. Mikrobiologie

Standard plate count max. 3000 per g

Yeasts and moulds max. 100 per g

E. coli Negative to test

Salmonella Negative in 100g

2. Akute Toxizität und allergene Wirkung:

- a. Angaben zur akuten Toxizität: LD_{50} bei Ratten größer 3g/kg
- b. Hautreizungen: keine Untersuchung
- c. Schleimhautreizungen: keine Untersuchung
- d. allergene Wirkung: Soja-Produkte können Allergien erzeugen

3. Informationen zur perkutanen Permeation:

nicht bekannt

4. Erfahrungen am Menschen:

Soja-Isoflavone stammen von der Sojabohne, Bestandteil der menschlichen Nahrung.

5. Ökologie:

- a. Isoflavone sind in Kläranlagen biologische abbaubar. Werte liegen nicht vor.
- b. Ergebnisse über akute aquatische Toxizität liegen nicht vor.

6. Wirksamkeitsnachweis: siehe Literatur auf beiliegendem Blatt

8. Lagerung: kühl (unter 20°C) und trocken (unter 60% rel. Luftfeuchte) gelagert mindestens 2 Jahre haltbar.

Informationen zur Wirksamkeit

Soya has long been the subject of widespread scientific research, and whilst initial studies investigated the potential health benefits of diets rich in soya based foods,^(1,2) interest has now moved towards the use of soya isoflavones in topically applied skincare products. In particular, research is focusing on two key areas: the role of isoflavones in sunscreen products designed for protection against ultraviolet radiation and their use in ‘anti-aging’ skin creams.

Skin Health: Effects of Ultraviolet Radiation

Modern trends for sunbathing and taking holidays in hotter, sunnier climates, together with alterations in atmospheric composition, means there is greater exposure of the skin to the sun – particularly to ultraviolet radiation - than ever before. This lifestyle change is thought to be a major contributor towards the marked increases in the incidence of skin problems, including various cancers and photo-aging.⁽³⁾

The two most abundant isoflavones in soya, genistein and daidzein, in both conjugated (glycone) and unconjugated (aglycone) form, have been found to be effective antioxidants and antiproliferative agents in animal models designed to simulate chemically-induced skin tumour initiation. Of the two isoflavones, however, genistein was found to be the most promising on the basis of this model.^(4,5)

In experiments designed to investigate the protective effects of isoflavones used as topical agents against ultraviolet B (UVB)-induced skin damage, genistein is found to be a powerful inhibitor of carcinogenesis. Two possible mechanisms for the action of genistein have been proposed on the basis of these scientific models:

- Protection against oxidative DNA damage, which is related to tumour initiation.^(4,6)
- Down-regulation of signal transduction pathways involved in cell proliferation and tumour promotion.⁽⁷⁾

In these experiments, optimal protection resulted from topical application of the isoflavone 30-60 minutes before UVB irradiation, although there was also some, albeit reduced, benefit from post-exposure genistein application.⁽⁷⁾

In trials with human skin,⁽⁸⁾ the topical application of genistein 30 minutes before UVB exposure resulted in substantial blocking of UVB-induced erythema at different radiation doses. At one minimal erythema dose (1 MED), genistein effectively inhibited UVB-induced erythema in human skin. These trials demonstrated that genistein could be used as an effective agent in protecting human skin against sunlight-induced photo-damage.

In addition to its cancer-promoting effects, exposure to UVB rays is also implicated in skin wrinkling, referred to as “premature photo-aging”. UVB radiation is believed to stimulate production of certain protein fragments and metalloproteinase genes, which are implicated in the physical changes in the skin that result in visual signs of premature photo-aging. In human skin exposed to 2 MED of UVB, genistein was found to inhibit expression of these factors by 70% and 72%, respectively, but not because it acted as a UVB sunscreen.⁽⁹⁾

Results to date of research into skin protection from UVB radiation by isoflavones, particularly genistein, open up the way for their use in a wide variety of skincare systems developed to provide dermatologic protection.

Recently, there have been a number of new cosmetic product launches containing soya isoflavones as “active” ingredients. The isoflavone-containing skin care products that are available from pharmacies, mail order firms and/or internet companies are marketed on the basis of a number of stated benefits including:

- “Stress-relief formula with isoflavones incorporated to aid collagen production and control of the visible signs of skin aging.”
- “Skin rejuvenation for mature and sun-damaged skin” (said to improve elasticity and to smooth wrinkles).
- Anti-aging formulae for “positive collagen and hyaluronic acid enhancing effects”, or “to increase skin density”.
- Combination products said to be designed to benefit the skin in relation to all four stated causes of skin aging, i.e. environment, hormonal changes, physiology and UVB irradiation.

Summary

Results of the research described above indicate that the most effective isoflavone products for use in skincare applications are those that are naturally high in genistein. The application of isoflavones to skincare, however, is still very new, and their full potential is yet to be realised.

References:

1. B. Armstrong, R. Doll, Environmental factors and cancer incidence and mortality in different countries with specific reference to dietary practices. *Int. J. Cancer*, 1975, 15, 617-631.
2. D.M. Tham, Potential health benefits of dietary phytoestrogens: a review of the clinical, epidemiological, and mechanistic evidence. *J. Clin. Endocrinol. Metab.*, 1998, 83, 2223-2235.
3. D.L. Miller, M.A. Weinstock, Non-melanoma skin cancer in the US: incidence. *J. Am. Acad. Dermatol.*, 1994, 30, 774-778.
4. H. Wei, R. Bowen, Q. Cai, et al., Antioxidant and anti-promotional effects of the soybean isoflavone genistein. *Proc. Soc. Exp. Biol. Med.*, 1995, 208 (1), 124-30.
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6. H. Wei, Q. Cai, R.O. Rahn, Inhibition of UV-light and Fenton reaction-induced oxidative DNA damage by the soybean isoflavone genistein. *Carcinogenesis*, 1996, 17 (1), 73-77.
7. Y. Wang, X. Zhang, et al., Inhibition of UVB-induced *c-fos* and *c-jun* expression *in vivo* by a tyrosine kinase inhibitor genistein. *Carcinogenesis*, 1998, 19 (4), 649-654.
8. Y. Wei, J. Spencer et al., The isoflavone genistein: a new agent in dermatology? *Cosmetic Dermatol.*, 2001, Feb, 13-19.
9. S. Kang, Y. Wan, J. Lee, et al., Isoflavone genistein blocks UV irradiation-induced epidermal growth factor-receptor activation, mitogen-activated protein kinase activity and matrix metalloproteinase gene expression in human skin *in vivo*. *J. Invest. Dermatol.*, 2000, 114, 153.

Sicherheitsdatenblatt gemäß EG-Richtlinie 91/155/EWG

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Seite 1/2

1. Stoff-/Zubereitungs und Firmenbezeichnung

1.1 Angaben zum Produkt

Handelsname:	NovaSoy 400
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1.2 Angaben zum Hersteller/Lieferanten

- 1.2.1 Lieferant GUSTAV PARMENTIER GmbH
Eichendorffstraße 37
D-60320 Frankfurt am Main
Telefon: 069 / 56 10 34
Telefax: 069 / 56 85 18
- 1.2.2 Auskunftgeber: Dr. Wolfgang Parmentier
Mathias Parmentier
Telefon: 069 / 56 10 34
- 1.2.3 Notfallauskunft (7.00 - 22.00 h): 069 / 56 10 34

2. Zusammensetzung/Angaben zu Bestandteilen

2.1 Chemische Charakterisierung

- 2.1.1 Bezeichnung: **Extrakt aus Sojabohnen**
- 2.1.2 Identifikationsnummer CTFA Nr: 4637
INCI-Name: Soy Isoflavones

3. Mögliche Gefahren

- 3.1 Gefahrenbezeichnung **ungefährlich**
- 3.2 Besondere Gefahrenhinweise für Mensch und Umwelt **keine**

4. Erste-Hilfe-Maßnahmen

- 4.2 nach Hautkontakt **Hautstellen abspülen**
- 4.3 nach Augenkontakt **Augenspülung**

5. Maßnahmen zur Brandbekämpfung

- 5.1 geeignete Löschmittel **Wasser, Schaum und CO². Trockenlöschmittel geeignet**

6. Maßnahmen bei unbeabsichtigter Freisetzung

- 6.1 Personenbezogene Vorsichtsmaßnahmen **Staubmaske (bei >15 mg/m³)**
- 6.2 Umweltschutzmaßnahmen **nicht in Gewässer oder Kanalisation gelangen lassen**
- 6.3 Verfahren zur Reinigung/Aufnahme **aufkehren**

7. Handhabung und Lagerung

- 7.1 Handhabung
- 7.1.1 Hinweise zum sicheren Umgang **keine besonderen Maßnahmen**
- 7.2 Lagerung
- 7.2.1 Anforderung an Lagerräume und Behälter **keine**

8. Expositionsbegrenzung und persönliche Schutzausrüstung

8.3 Persönliche Schutzausrüstung

8.3.1 Allgemeine Schutz- und Hygienemaßnahmen	keine speziellen Schutzmaßnahmen
8.3.2 Atemschutz	Atemschutz empfohlen (bei >15 mg/m ³)
8.3.3 Handschutz	Handschuhe empfohlen
8.3.4 Augenschutz	Schutzbrille empfohlen
8.3.5 Körperschutz	keine speziellen Schutzmaßnahmen

9. Physikalische und chemische Eigenschaften

9.1.1	Form	Pulver
9.1.2	Farbe	gelblichbraun
9.1.3	Geruch	charakteristisch
9.1.4	Dichte	0,35 g/cm ³
9.10.2	Löslichkeit (in Wasser)	teilweise löslich
9.10.3	Flammpunkt:	n.a.
9.10.4	Zündtemperatur:	n.a.
9.10.5	Schmelztemperatur:	über 100°C

10. Stabilität und Reaktivität

10.1	Zu vermeidende Bedingungen	nicht zutreffend
10.2	Zu vermeidende Stoffe	stark oxidierende Produkte

11. Angaben zur Toxikologie

ungefährlich. LD₅₀ bei Ratten größer als 3 g/kg Körpergewicht

12. Angaben zur Ökologie

12.3.2 Bemerkung	<i>Produkt nicht in größeren Mengen in Gewässer oder Kanalisation gelangen lassen.</i>
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13. Hinweise zur Entsorgung

13.1	Produkt	<i>aufkehren</i>
13.1.1	Empfehlung:	<i>auf normaler Deponie entsorgen, bzw. verbrennen</i>

14. Transportvorschriften

14.1	Landtransport ADR/RID und GGVS/GGVE (grenzüberschreitend/Inland)	
14.1.6	Bemerkungen	nicht kennzeichnungspflichtig
14.2	Binnenschifftransport ADN/ADR	
14.2.5	Bemerkungen	nicht kennzeichnungspflichtig
14.3	Seeschifftransport IMDG/GGVSee	
14.3.8	Bemerkungen	nicht kennzeichnungspflichtig
14.4	Lufttransport ICAO-TI und IATA-DGR	
14.5	Bemerkungen	nicht kennzeichnungspflichtig

15. Vorschriften

15.1 Kennzeichnung nach EWG-Richtlinien

15.1.1	Kennbuchstabe und Gefahrenbezeichnung des Produktes	nicht zutreffend
15.1.3	R-Sätze	nicht zutreffend
15.1.4	S-Sätze	nicht zutreffend

15.2 Nationale Vorschriften

15.2.8 Wassergefährdungsklasse: **1** (Selbsteinstufung)

16. Sonstige Angaben

INCI: Isoflavones