

Allergen Checklist



Company Name: Watson Inc.
Ingredient Name: Stay Soft 75
Watson Ingredient Code: F232010

Food Ingredients that may cause allergies	Present in the Product	Present in other products mfg on same Line	Present in other products mfg in same Plant
Peanut or its derivatives e.g. peanut pieces, protein, oil, butter, & flour. Peanut may also be known as ground nut.	NO	NO	NO
Tree nuts – Cashews, Pecans, Macadamia nuts, Almonds, Pistachios, Brazil nuts, Pine nuts, Hazelnuts, Walnuts, hickory nuts, Beech nut, Butternut, Chestnut, Coconut, Ginko nut, Lychee nut, Pili nut, Sheanut, or their derivatives, e.g. nut butters & oils, protein, pieces, etc.	NO	YES	YES, almond, walnut, hazelnut
Egg or its derivatives e.g. frozen yolk, egg white, powder, egg protein isolates, albumin, etc.	NO	YES	YES
Milk or its derivatives e.g. whey, casein, caseinates, yogurt, cheese, butter, lactose	NO	YES	YES
Fish or its derivatives e.g. fresh water or saltwater, octopus, squid, fish protein & extracts, oils, etc.	NO	YES	YES
Crustaceans – including crab, crayfish, lobster, prawn, & shrimp	NO	YES	YES
Mollusks – including snails, clams, mussels, oysters, cockle & scallops or their derivatives, i.e. ingredients	NO	NO	NO
Soy or its derivatives , e.g. lecithin, oil, tofu, protein isolates, textured soy protein, etc.	NO	YES	YES
Wheat or its derivatives – spelt, semolina, durum, emmer, einkorn, kamut or their hybridized strains	YES	YES	YES
Gluten – from cereals such as wheat, rye, barley, oats, spelt, kamut or their hybridized strains	YES	YES	YES
Celery & products thereof	NO	NO	NO
Mustard & products thereof	NO	NO	NO
Sesame seeds & products thereof	NO	YES	YES
Sulfur dioxide & sulfites at concentrations of more than 10mg/kg or 10mg/litre expressed as SO	NO	NO	NO

Do you store any allergen containing raw materials at this site?	<u>YES</u>	
Do you have specific procedures to eliminate the risk of cross-contamination amongst the commodities?	<u>YES</u>	
Do you have an HACCP (Hazard Analysis Critical Control Point) plan? How is it documented?	<u>YES</u>	
Does your HACCP plan address allergens?	<u>YES</u>	
Do you identify potential sources of allergens starting in the product development stage?	<u>YES</u>	
Do you use processing aids that contain allergenic ingredients in the manufacture of the product?		<u>NO</u>
Do you identify and segregate allergenic ingredients?	<u>YES</u>	
Do you perform chemical cleaning between allergen and non-allergen products/commodities?	<u>YES</u>	
Do you schedule non-allergen products prior to allergen products?	<u>YES</u>	
Do you assure that the correct label matches the finished product?	<u>YES</u>	

Stephanie Couture

Stephanie Couture
 Regulatory Affairs Associate
 Watson Inc.
 April 23, 2018



Watson Inc.

301 Heffernan Drive · West Haven, CT 06516 · USA · (203) 932-3000 · Telex 6505312524 · Fax (203) 932-8266

Date: April 23, 2018
Re: GMO Declaration for the product titled F232010 StaySoft 275

Currently several categories exist that pertain to a GMO Declaration; Genetically Modified (GM), GMO-Free, or NON-GMO.

The Genetically Modified category refers to conformance with:

- Containing or produced from an organism whose genetic material or DNA (deoxyribonucleic acid) has been transformed via genetic engineering. Also referred to as gene splicing, this technique results in merging DNA from different species into an organism's existing DNA.

The GMO Free category refers to conformance with:

- Materials derived from a genetically modified or non-genetically modified source however no protein or DNA is present within the product after processing. This can be verified with PCR Testing.

The NON GMO category refers to conformance with:

- Is not composed of, derived from or contain genetically modified organisms (GMOs).
 - Is not manufactured using genetically modified organisms (GMOs).
 - Chemically produced products of synthetic origin.
 - Materials in which no genetic modification currently exists (E.g. palm oil).
- or
- Identity Preserve (IP)-Materials derived from traditional, non-gmo seeds with a documented traceability process in place to assure that appropriate segregation of ingredients from seeds, through harvesting and production of final product is maintained.
With a recombinant DNA threshold of no more than 0.9% the IP category is not subjected to labeling under Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003.

This product contains several categories of ingredients such as NON GMO and GMO Free ingredients however it is labeled with the lowest classification therefore the final product coded as:
F232010 StaySoft 275 is a GMO Free product.

A handwritten signature in cursive script that reads "Stephanie Couture".

Stephanie Couture
Regulatory Affairs Associate
Watson Inc.



WATSON INC.
301 Heffernan Drive, West Haven, CT 06516
Tel: (203) 932-3000, Fax: (203) 932-8266

Johnpaul Tata
Regulatory Affairs Specialist
Phone: 800 388 3481
e-mail : johnpaul.tata@watson-inc.com

July 21, 2017

PRODUCT STATEMENT

StaySoft-275, F232010 contains the following ingredients:

<u>Ingredient</u>	<u>Range</u>	<u>Function</u>
Calcium Sulfate	60 – 80%	Diluent
Enzymes	20 – 40%	Dough Improvement/Carrier

Johnpaul Tata

Johnpaul Tata
WATSON INC.



Product Information

StaySoft™ 275

Watson Code: F232010
(Formerly WT-3443B)

Description: StaySoft™-275, F232010 is a blend of fungal and bacterial enzymes that improves crumb grain and texture and extends stale-free shelf life. StaySoft-275, F232010 is supplied in 10 g (net weight), water soluble, edible film packets (Sol-U-Paks™).

Ingredients: Calcium sulfate, enzymes.

Specifications:

Fungal Alpha Amylase (SKB/g)*:	6600 to 7400 with a target of 7000	By Calculation
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Additional Information:

Recommended Usage	For bread and rolls: 1 Sol-U-Pak (10 g. net weight) per 100 lbs. of flour. For sweet goods: use up to 3 Sol-U-Pak's (30 g net weight) per 100 lbs. of flour. Lower use levels are recommended during the summer months.
GMO Status:	GMO-free
Irradiation/Ethylene Oxide:	This product is not irradiated or treated with ethylene oxide.
Kosher:	This product is certified Kosher Pareve by the Union of Orthodox Jewish Congregations of America.
Country of Manufacturing:	United States
Allergen Statement:	This product does contain allergens. <input type="checkbox"/> Milk <input checked="" type="checkbox"/> Wheat <input type="checkbox"/> Peanuts <input type="checkbox"/> Tree Nuts <input type="checkbox"/> Eggs <input type="checkbox"/> Soy <input type="checkbox"/> Fish <input type="checkbox"/> Shellfish

Nutritional per 100 grams (typical):

Nutrient		Unit	Nutrient		Unit
Calories	93.7		Total Carbohydrate	16.7	g
Calories from Fat	1.5		Dietary Fiber	0.37	g
Total Fat	0.43	g	Sugars	0.32	g
Saturated Fat	0.02	g	Protein	8.04	g
Trans Fat	0.00	g	Vitamin A	0.00	IU
Cholesterol	0.00	mg	Vitamin C	0.00	mg
Sodium	0.37	mg	Calcium	15935	mg
			Iron	32.0	mg
This information is compiled from information from one or more of the following; our suppliers, USDA Handbook #8, our own analysis					

Watson, Inc.

301 Heffernan Drive, West Haven, CT06516, Telephone (203) 932-3000

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Product Information

StaySoft™ 275
Watson Code: F232010
(Formerly WT-3443B)

Packaging: 10 g. (net weight) Sol-U-Paks™, 1200 paks per carton.

Storage and Handling: Store in a clean, cool and dry place in the original sealed container. Preferred storage conditions: 20°C and 50% R.H. Expected shelf life: 12 months; Re-certification recommended after 12 months.

Certificate of Analysis: All ingredients meet the specifications of the FCC or USP/NF where such specifications are listed. Watson Inc. guarantees this product meets the above minimum specifications and issues a certificate of analysis for each production lot. . * - Asterisk indicates a specification derived by calculation, not by assay. All calculated specifications will be checked for accuracy, through reference to our supplier's certificates for lot numbers of ingredients used and by a review of the weight tapes and batch sheets for each production lot, but cannot be guaranteed. Nutrient levels in final products are not guaranteed. The user is responsible for compliance with the final goods specifications and/or labels.

Technical Support: For technical assistance, please contact Watson, Inc. Technical Service Department at 1-800-388-3481.

Watson, Inc.

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Nutritional Information

StaySoft™ 275 F232010

Total Weight: 100.00 g (3.53 oz-wt)			
Nutrient	Amount Per 100 g	Nutrient	Amount Per 100 g
Calories	93.65	Calories from Saturated Fat	0.23
Calories from Fat	1.5	Water	16.0 g
Total Fat	0.43 g	Ash	59.1 g
Saturated Fat	0.02 g	Phosphorus	0.0 mg
Trans Fat	0.00 g	Potassium	15.5 mg
Polyunsaturated Fat	0.12 g	Magnesium	217.2 mg
Monounsaturated Fat	0.02 g		
Cholesterol	0 mg		
Sodium	0.37 mg		
Total Carbohydrate	16.65 g		
Dietary Fiber	0.37 g		
Sugars	0.32 g	Added Sugars	0.00 g
Protein	8.04 g	Vitamin D	0.00 mcg
Vitamin A	0 IU		
Vitamin C	0 mg		
Calcium	15935 mg		
Iron	32 mg		

This information is compiled from information from our suppliers, USDA Handbook #8 and our own analysis.

Ingredients: Calcium sulfate, wheat flour, enzymes.

F232010

Watson Inc.

301 Heffernan Drive, West Haven, CT 06516, Telephone: (203) 932-8266 or (800) 388-3481

Fax: (203) 932-8266, e-mail: order@watson-inc.com

Version (10387)(JPT)



Watson Inc.

301 Heffernan Drive · West Haven, CT 06516 · USA · (203) 932-3000 · Telex 6505312524 · Fax (203) 932-8266

Date: November 13, 2017
From: Johnpaul Tata
Re: Vegetarian/Vegan Statement for F232010 Stay Soft 275

This is to certify that:

F232010 Stay Soft 275 does not contain any animal product or derivative and is thus can be considered vegetarian/vegan.

A handwritten signature in blue ink, appearing to read "Johnpaul Tata".

Johnpaul Tata
Regulatory Affairs Specialist
Watson Inc.



SAFETY DATA SHEET

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StaySoft 275; F232010

1. IDENTIFICATION OF SUBSTANCE/MIXTURE AND MANUFACTURER IDENTIFICATION

Product Name: **StaySoft 275**
Synonyms: **StaySoft 275**
Product Code: **F232010**
CAS-No.: **N/A**
Manufacturer: **Watson, Inc.**
Address: **301 Heffernan Dr., West Haven, Connecticut 06516 USA**

Emergency Phone: **(800) 424 9300 ChemTrec**

Information Phone: **203/932-3000**
Information Fax: **203/932-8266**
Information E-Mail: **order@watson-inc.com**
Date prepared: **January 9, 2017**

2. HAZARDOUS IDENTIFICATION

Physical and Chemical Hazards: **Not Applicable**
Human Health: **Not Applicable**
Environment: **Not Applicable**
Hazardous Symbol: **Not Applicable**
Risk Phrases: **Not Applicable**
Safety Phrases: **Not Applicable**

3. PRODUCT INGREDIENT(S) COMPOSITION / INFORMATION

<u>Hazardous Component</u>	<u>Approx. %</u>	<u>CAS #</u>	<u>EINECS #</u>
NO Hazardous Components	N/A	N/A	N/A

4. FIRST AID MEASURES

Routes of entry: Signs / Symptoms - First Aid Measures

EYES: **For eye irritation, Flush eyes with water for 15 minutes.**

SKIN: **For skin irritation, Wash affected area with soap and water.**

INGESTION (large) **Ingestion of large doses may cause gastrointestinal disturbances. If needed get medical attention.**

INGESTION (small) **Inhalation of the dust may irritate respiratory tract. Remove affected person to fresh air. If needed get medical attention.**

5. FIRE FIGHTING MEASURES

Conditions of Flammability: **Not Applicable**

Unusual explosion and fire hazards: **Possible dust explosions when uniform mixture of dust and air (50 g per cubic meter of air) is ignited in a confined space.**

Extinguishing media: **Water fog, water spray, carbon dioxide**

Special fire-fighting procedures: **Evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.**



6. ACCIDENTAL RELEASE MEASURES

Steps to be taken if material is spilled or released:	Avoid dusting during cleanup.
Personal precautions, protective Equipment and emergency Procedures:	Use Personal Protective equipment as required, goggles, mask, gloves, lab coat, contact emergency personnel as appropriate.
Environmental precautions:	Not Applicable
Methods for material containment: and cleaning up	Sweep or scoop up and remove into container for waste disposal in accordance with government regulations. Flush with water.

7. HANDLING AND STORAGE

Precautions for safe handling:	Avoid contact with eyes, skin, and breathing dust. This material should be handled per label instructions to insure product integrity.
Conditions for safe Storage:	Store in closed containers. This material should be stored per the label instructions.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Hazardous Component	OSHA PEL mg.m3	ACGIH TLV mg.m3	DFG MAK mg.m3	OTHER mg.m3
NONE	Not Applicable	Not Applicable	Not Applicable	Not Applicable

c. respirable dust
q. total dust
N.A – Not available

Personal Protection:

Respiratory:	Disposable dust respirators, when needed.
Ventilation:	Local exhaust recommended.
Gloves:	Rubber, when needed.
Eyes:	Safety goggles or glasses, when needed.
Other:	Protective clothing, eye fountain, normal GMP.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	powder in an edible film packet
Odor and appearance:	slight but distinctive odor, off white in color
Boiling range:	N/A
Relative Density:	N/A
Freezing range:	N/A
Percent volatile by weight:	N/A
Flash Pont:	N/A
Lower Explosive Limit:	N/A
Upper Explosive Limit:	N/A
Vapor pressure:	N/A
Evaporation rate:	N/A
Specific Gravity:	N/A
pH value:	N/A
Viscosity:	N/A
Solubility in water:	pak contents dispersible, pak soluble in water



10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to avoid:	Heat, open flames, sparks, heavy dusting.
Incompatibility:	None known
Hazardous polymerization:	Will not occur
Hazardous decomposition:	None known

11. TOXICOLOGICAL INFORMATION

Acute effects:	Persistent cough, possible difficulty in breathing.
Chronic effects:	No evidence of adverse effects from available information.
Carcinogenicity:	No evidence of adverse effects from available information.
Reproductive toxicity:	No evidence of adverse effects from available information.
Teratogenicity:	No evidence of adverse effects from available information.
Mutagenicity:	No evidence of adverse effects from available information.
Toxicologically Synergistic products:	None known.

12. ECOLOGICAL INFORMATION

This product has not been evaluated for its ecotoxicity.

13. DISPOSAL CONSIDERATIONS

Follow Local, Provincial and Federal regulation.

14. TRANSPORTATION INFORMATION

RID/ADR:	Not known to be regulated.
IMDG division number:	Not known to be regulated.
IMDG code page number:	Not applicable.
ICAO number:	Not applicable.
UN number:	Not applicable.
UN class, packaging grade:	Not applicable.

15. REGULATORY INFORMATION

Follow Local, Provincial and Federal regulation.

16. OTHER INFORMATION

This product should be stored, handled and used in accordance with Good Manufacturing Practices and in conformance with any Local, Provincial, and/or Federal legal regulations.

The information contained in this MSDS is based on data from sources considered to be reliable but since Watson Inc. can not guarantee the accuracy or completeness thereof, Watson Inc. urges each customer or recipient of this SDS to become aware or understand the hazards associated with this product. The reader should consider consulting reference works or individuals who are experts in ventilation, toxicology or fire prevention as necessary or appropriate to use and understand the data in this SDS.