INSOLENT [LABS]

Dossier de lot : J-23-124

Beauty Cheveux

Général	
Date début de production :	06/11/2023
Date fin de production :	07/11/2023
DLUO :	26/10/2026

Préparation	
Quantité demandée :	**255 000**
Quantité total engagée :	255 000
Perte :	0 %

Contenant	
Qualité :	HPMC
Taille :	T.0
Couleur :	TR.

Composition

Ingrédient	Quantité / Unité	Perte	Quantité à produire	Quantité prélevée	N° Lot
CH-Kératine hydrolysat	125 Mg	0 %	31 875 g	14 315 g 17 560 g	K3DD2.47.01 K3DD3.05.01
EXS-Prêle 10%	20 Mg	0 %	5 100 g	4 700 g 400 g	202207191741 202309201338
EXS-Ortie piquante feuille	20 Mg	0 %	5 100 g	5 100 g	NAT20221588
CH-Cystine-L	50 Mg	0 %	12 750 g	12 750 g	C605-202212103F
CH-MSM (Méthyl-sulfonyl-méthane)	100 Mg	0 %	25 500 g	18 135 g 7 365 g	20220714 20230203
EXS-Serenoa repens 20%-25% (10/1)	40 Mg	0 %	10 200 g	7 675 g 2 525 g	C20220920 W20221101
CH-Zinc citrate (31%)	8,065 Mg	0 %	2 056,45 g	2 056,45 g	342210201
CH-Sélénométhionine (0.5%)	2,75 Mg	0 %	701,25 g	701,25 g	O-1602163-220105
VIT-Vit. B5 (Panthot. calcium) 91%	6,5 Mg	0 %	1 657,5 g	1 657,5 g	21081608
VIT-Vit. B8 (ou H- Biotine)	0,015 Mg	0 %	3,83 g	3,83 g	CS1-2110022
VIT-Vit. B6 (Pyridoxine Chlor 82%)	0,5 Mg	0 %	127,5 g	127,5 g	y03202104027
AD-Magnésium stéarate	10 Mg	0 %	2 550 g	2 550 g	O-1602244-211001
Total (Mise en Oeuvre)	**382,83 Mg**		**97 621,52 g**		

Contenant	Quantité	N Lot Fourn.
G-Vg-0-Transp	255 000	SV022121106

Fabrication

Informations	
Opérateur :	**BE**
Vitesse :	

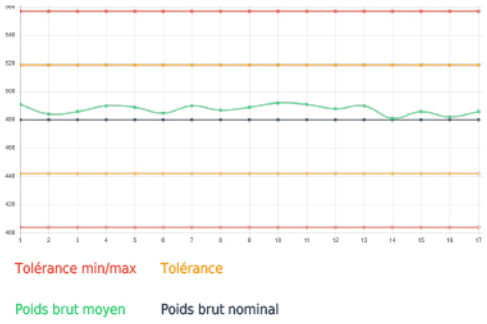
Poids	
Poids net :	383 Mg
Contenant poids :	98 Mg
Poids brut nominal :	481 Mg

Tolérance	
Tolérance / Poids net :	-10% / +10%
Soit poids unitaire brut :	>443Mg & <519Mg

Relevés

Contrôle Poids Bruts moyens (Lot de 10 gélules) : 491,484,486,490,489,485,490,487,489,492,491,488,490,481,486,482,486

INSOLENT [LABS]



Poids moyen sur 10 gélules (Mesure 17)	
Poids brut :	487 Mg
Poids net :	**389 Mg**

Contrôle Uniformité de masse : Mesures : 170	
< 443 Mg : (0 %)	**< 519 Mg : (0 %)**
< 404 Mg : (0 %)	**< 557 Mg : (0 %)**

Quantité théorique à obtenir :	250 955
Quantité unité reg. machine :	
Quantité nette à obtenir :	**250 955**

Quantité produite :	**247 240**
Rendement :	**99%**

INSOLENT [LABS]

PRODUIT
Product Details

CAS N°	69430-36-0
Scientific name	*Hydrolyzed Keratin*
Country of origin	France
Approved for human consumption	Yes
Origin	Animal
Natural from:	Poultry

DONNEES ANALYTIQUES
Analytical data

Analysis	**Specification**
Appearance	White to off-white powder : slighty odorous
Dry matter	~98.7%
Ash	NMT 10%
Free amino acids	~83.6%
Particle size	Dv(50) = 140µm
Water solubility at 20°C	200g/l
Molecular weight	<800 daltons

Microbiologie (Microbiology)

Total Plate Count	NMT 20 000cfu/g
Yeast & Mould	NMT 200cfu/g
Bile-tolerant gram - bacteria (enterobacteria)	Negative
Salmonella	Negative

Données réglementaires (regulatory data)

Ce produit est destiné à être utilisé dans des compléments alimentaires. Il appartient au client de vérifier ses conditions d'utilisation selon les règlementations en vigueur.

This product is intended to be used in food supplements. It is up to the final user to determine its terms of use, according to the applicable regulations.

Conservation et durée optimale d'utilisation (Storage & Shelf life)

Packaging	Suitable for food industry
Storage	Can be stored at room temperature Need to be stored at dry place. Keep closed
Shelf life	2 years if stored in accordance with recommendations

INSOLENT [LABS]

Certificat Non OGM
GMO free certificate

Par la présente, nous certifions que la matière première ci-dessous est garantie sans OGM.

Keratin powder

The product above does not have to be declared or labelled as « GMO », containing or consisting of GMO's or produced from GMOs in accordance with Regulations (EC) No. 1829/2003 and 1830/2003 on genetically modified food and feed.

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22nd September 2003 on genetically modified food and feed
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22nd September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Certificat de Non Irradiation
Irradiated free certificate

Par la présente nous certifions que le produit ci-dessous n'a pas été irradié

Keratin powder

We hereby certify that the product above has not been irradiated.

- According to directives 1992/2/EC and 1999/3/EC

INSOLENT [LABS]

Absence de BSE – TSE *
BSE - TSE certificate

Par la présente nous certifions que le produit ci-dessous ne contient aucune trace de BSE - TSE.

Keratin powder

We hereby certify that the product above is BSE - TSE Free.

**= Encéphalopathies spongiformes transmissibles (TSE), encéphalopathie spongiforme bovine (BSE)*

Certificat nano-particules
Nano particles certificate

Par la présente nous certifions que le produit ci-dessous ne contient pas de nano-particules.

Keratin powder

We hereby certify that the product above does not contain any nano-particles

-According to EU regulation (EU) N° 1169/2011 of the European Parliament and of the council of 25 October 2011.

INSOLENT [LABS]

Product: **HORSE TAIL EXTRACT, 10% SILICA**
Product Code: N20100501
Botanical name: *Equisetum arvense L.*
Plant Part Used: Aerial parts
Excipients: Maltodextrine, Silicon dioxide
Description: Beige powder with characteristic taste and odor**

ANALYSIS	SPECIFICATION	METHODS
Assay (%)	Min. 10,0 Silica	Internal method
Loss on drying (%)	≤ 10.0	Eu. Pharm c.v. (2.8.17)
Bulk density (g/ml)	≥ 0,3	Eu. Pharm c.v. (2.9.34)
Particle size (%)	Min 95% < 200 microns	Eu. Pharm c.v. (2.9.12)
Residual solvents		
Ethanol (ppm)	< 5000	Eu. Pharm. v.v. (2.4.24)
Microbiology		
TAMC (cfu/g)	≤ 10000	Eu. Pharm. v.v. (2.6.12)
TYMC (cfu/g)	≤ 100	Eu. Pharm. v.v. (2.6.12)
Bile-tolerant gram-negative bacteria (cfu/g)	≤ 100	Eu. Pharm. v.v. (2.6.31)
Escherichia coli (1 g)	Absence	Eu. Pharm. v.v. (2.6.31)
Salmonella (25 g)	Absence	Eu. Pharm. v.v. (2.6.31)
Polycyclic aromatic hydrocarbons (PAHs) *		
Benzo(a)pyrene (ppb)	≤10	GC - MS
PAH4 (Sum of (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene (ppb)	≤ 50,0	GC-MS
Heavy metals*		
Lead (ppm)	≤ 3,0	Eu. Pharm. v.v. (2.4.27)
Arsenic (ppm)	≤ 2,0	Eu. Pharm. v.v. (2.4.27)
Mercury (ppm)	≤ 0,1	Eu. Pharm. v.v. (2.4.27)
Cadmium (ppm)	≤ 1,0	Eu. Pharm. v.v. (2.4.27)
Pesticides*	According to Regulation (EC) Nº 396/2005 and amendments	SANTE/12682/2019

Storage: Store in dry place and keep away from strong light and heat
Country of origin: Spain
Observations: * These parameters are determined in every three batches and at least once a year according to the sampling plan established in our HACCP system **This is an herbal product; therefore, it is subject to color variations from batch to batch derived from natural, raw material color deviations. Color change has no effect on the quality, purity, potency, chemical profile or efficacy of the product.

INSOLENT [LABS]

Informations sur la plante
Herb specification sheet

PLANT INFORMATION

Latin Name	*Urtica dioica L.*
Used part	Leaf
Botanical family, genus and species	Urticaceae
Type of culture (wild/agricultural/industrial)	Agricultural
Is the plant concerned by the regulation 338/97/CE	No
Method of harvest (Manual/Mechanical)	Mechanical
Harvest time (month(s) of harvest)	May - August
Harvest stage (developmental stage of the plant)	Full vegetation
Has the plant been dried after harvest If so, what is the drying method	Yes Oven drying
Has the plant been treated before harvest If so, what treatment	No
Has the plant been treated after harvest If so, what treatment	No
Has the plant been crushed after harvest	Yes
Has the plant been cleaned after harvest:	No

Analysis	**Specification**
Appearance	Brown-greenish to brown Powder
Loss on Drying	NMT 5%
Sieve Analysis	90% through 300 microns
Assay	/
Testing Method	/
Métaux lourds / Pureté (Heavy Metals / Purity)	
Heavy Metals*	NMT 10ppm
Lead (Pb)*	NMT 3ppm
Arsenic (As)*	/
Cadmium (Cd)*	NMT 1ppm
Mercury (Hg)*	NMT 0.1ppm
Pesticides Residues*	Comply to Reg (EC) n° 396/2005 and amendements
HAP/PAH*	NMT 50ppb
Benzo(a)pyrene*	NMT 10ppb
Microbiologie (Microbiology)	
Total Plate Count	NMT 10 000cfu/g
Yeast & Mould	NMT 500 cfu/g
Enterobacteriaceae*	NMT 100 cfu/g
E.Coli*	Negative
Salmonella*	Negative/25g
Substance(s) à contrôler (Substance(s) to control) **Données réglementaires** (regulatory data)	
Substance to control*	/

INSOLENT [LABS]

CYSTIL002 – L-CYSTINE FERMENTED

INFORMATIONS SUR LE PRODUIT
PRODUCT INFORMATION

Scientific name	(R,R)-3,3'-Dithiobis(2-aminopropionicacid)
CAS N°	56-89-3
Molecular formula	$C_6H_{12}N_2O_4S_2$
Molecular weight	240.3 g/mol

Origin	Fermentation
Natural from	Microbiological strain used for fementation : *E. coli*
Informations	**Strains of Escherichia coli are part of the normal micro flora of intestines of all vertebrates. All strains of Escherichia coli used for the biotechnological production of commercial amino acid are classified as Escherichia coli. As such they are scientifically recognized as safe bacterial strains and harmless to impacts on human and environment*
ANALYTICAL DATA	
Appearance	White or almost white crystal, crystalline powder
Identification	IR
Assay	98.5% - 101%
Specific rotation	-218° to -224°
Loss on drying	NMT 0.2%
pH	5.0 – 6.5
Residue on ignition	NMT 0.1%
STORAGE CONDITION – SHELF LIFE	
Type of packaging	Double plastic bag, cardboard
Packaging	Suitable for food industry
Storage conditions	Store at temperature below 25°C, in a well closed bag away from moisture and direct sun light
Shelf life	3 years if stored in accordance with recommendations
Batch size	Batch size depends of our suppliers and of customer order (kg to tons)

INSOLENT [LABS]

CYSTIL002 – L-CYSTINE FERMENTED

PRODUCT IMPURITIES*

Contaminants and residues		Analysis		Not tested	Content- limit	Reference and/or method
		Each batch	Control plan			
Heavy metals	Lead (Pb)	☐	☒	☐	<3ppm	
	Cadmium (Cd)	☐	☒	☐	<1ppm	
	Mercury (Hg)	☐	☒	☐	<0.1ppm	
	Arsenic (As)	☐	☒	☐	<1ppm	
Microbiological control	Total plate count	☒	☐	☐	<20 000 cfu/g	
	Yeast & moulds	☒	☐	☐	<200 cfu/g	
	Bile tolerant gram – bacteria (enterobacteria)	☐	☒	☐	<100 cfu/g	
	E. coli	☒	☐	☐	Negative/g	
	Salmonella	☒	☐	☐	Negative/25g	
	Staphylococcus aureus	☐	☐	☐	Negative/g	
	Others ...	☐	☐	☒	-	
Contaminants control	Residual solvent ...	☐	☐	☒	-	
	Pesticides	☐	☐	☒	<MRL	
	Aflatoxin B1	☐	☐	☒	-	
	Sum of B1, B2, G1, G2	☐	☐	☒	-	
	Ochratoxin A	☐	☐	☒	-	
	Dioxins and PCBs	☐	☐	☒	-	
	Benz(o)apyrene	☐	☐	☒	<10ppb	
	Sum of PAH (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)	☐	☐	☒	<50ppb	
	Melamine and its structural analogues	☐	☐	☒	-	-
	Iodine (algae)	☐	☐	☒	-	-
	Microcystin (algae)	☐	☐	☒	-	-
	Other contaminants :					
	Pyrrolizidine alkaloids	☐	☐	☒	*On customer's request*	-
	3-MCPD (3-monochloro-propanol-1,2-diol)	☐	☐	☒	-	-

CYSTIL002 – L-CYSTINE FERMENTED

INFORMATIONS COMPLEMENTAIRES
OTHER INFORMATION

REGULATORY STATUS

This product is approved in:

☒ French decree – Décret 2006-352

☐ French decree – Arrêté du 26 septembre 2016

☐ French doctrine – Doctrine d'avril 2016

☐ Belgian decree – Arrêté ministériel du 19/02/09 mis à jour octobre 2018

☒ Italian positive list – Liste positive de septembre 2019

☒ Other : *Croatia, Denmark, Germany, Iceland, Norway, Poland, Slovenia, Spain ans Switzerland*

Country	Source	Authorized	Minimal daily intake	Maximal daily intake	Conditions
Belgium	Indicative list of substances NOT NFS 2013	L-cysteine N-acetyl-L-cysteine			
France	Decree 2006-352, Regulation 609/2013 (replacing Regulation (EC) N° 953/2009)	L-cysteine Cystine N-acetyl-L-cysteine			
Germany	BVL 12.2016; BVL 10.2013; BVL 10.2012; BVL 02.11.2004; BVL 03.2003				
Italy	Positive list, List of other substances September 2019, Regulation 609/2013	L-cysteine Cystine N-acetyl-L-cystein			

Information given as an indication according to our current knowledge only for Belgian, German, French and Italian regulations. This product is intended to be used in food supplements. It is up to the final user to determine its terms of use, according to the applicable regulation

INSOLENT [LABS]

Dimethyl sulfone (MSM)

Product SPECIFICATION

Product Name	Dimethyl sulfone (MSM)
INCI Name	dimethyl sulphone
EINECS Number	200-665-9
CAS Code	67-71-0

The product meets OR exceeds: **USP31**	
Appearance	White crystalline powder
Residue on ignition	0.10% max.
Heavy Metals	0.001% max.
Lead (Pb)	< 3 ppm
Cadmium (Cd)	< 1 ppm
Mercury (Hg)	< 0.1 ppm
Arsenic (As)	1 ppm max
Melting point	108.0 - 110.0
Water content	0.20% max
DMSO Content	Free
Mesh size	40-60 mesh
Assay	99.90% min
Silicon Dioxide	≤0.5%
Total plate count	< 10 cfu/g
Yeast / Mold	< 10 cfu/g
Coliform	Negative
E.Coli	Negative
Salmonella	Negative
Staphylococcus	Negative

INSOLENT [LABS]

Dimethyl sulfone (MSM)

GENERAL PRODUCT INFORMATION

Mesh of the product	40-60
Taped denisty	0.07-0.8 g/ml
Bulk density	0.65-0.75 g/ml
Water solubility	150 g/L at 20 Deg C
Origin (Synthetis, Fermentation)	Synthetic
Origin (Animal, Vegetal, etc.)	From chemicals
Is the product and their ingredients FREE of GLUTEN?	Yes
Product is suitable for Vegans	Yes
Product is suitable for Vegatarians	Yes
Product is free of fructose	Yes
Is this product suitable for food?	Yes
Can be the product used in baby food (According to Directive 2006/141/CE)?	No
Has been sold this product in the EU before May 1997?	No
Pharmacopoeias that product meets	USP
Melting Point	108.5-110.5 Deg C

INSOLENT [LABS]

SAW PALMETTO EXTRACT (SERENOA REPENS) (25% FATTY ACIDS)

PRODUCT SPECIFICATION

Product Name	INCI Name	EINECS Number	CAS Code
SAW PALMETTO EXTRACT (SERENOA REPENS) (25% FATTY ACIDS)	Serenoa repens, ext.	290-312-5	90106-85-7

Used Part:	Fruit
Solvents Used	CO2
Botanical Source	Serenoa repens
General Information	
ANALYSIS ITEM	SPECIFICATION
Assay:	
Fatty Acid (GC)	≥25.0%
Extract Ratio	10:1
Appearance	Fine Powder
Color	White
Odor & taste	Characteristic
Identification	Identical to R.S. sample
Loss on Drying	≤5.0 %
Sieve analysis	100 % through 80 mesh
Bulk density	40~60 g/100mL
Tap density	60~90g/100mL
Heavy metals:	
Lead (Pb)	≤3.0 mg/kg
Arsenic (As)	≤2.0 mg/kg
Cadmium (Cd)	≤1.0 mg/kg

INSOLENT [LABS]

SAW PALMETTO EXTRACT (SERENOA REPENS) (25% FATTY ACIDS)

PRODUCT SPECIFICATION	
Mercury (Hg)	≤0.1 mg/kg
Benzo(a)Pyrene	≤10μg/Kg
PAH4	≤50μg/Kg
PAs	≤400 μg/kg
ETO	≤0.1mg/kg
Residual solvents	Meet Eur.Ph. <5.4>
Residual pesticides	Meet Eur.Ph. <2.8.13>
Non irradiated	≤700
Microbiology	
Total Plate Count	≤10000 cfu/g
Yeast &Mold	≤1000 cfu/g
E.Coli.	Negative
Salmonella	Negative

SAW PALMETTO EXTRACT (SERENOA REPENS) (25% FATTY ACIDS)

BSE/TSE

This product does not contain and is not derived from Specified Risk Material as defined in European Commission Directive (and its amendments) and is therefore conform with the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

The following EU regulations have been published in the Official Journal of the European Union in this subject:
- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, we confirm that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.

INSOLENT [LABS]

Zinc citrate trihydrate

Product SPECIFICATION

Product Name	Zinc citrate trihydrate
INCI Name	trizinc dicitrate
EINECS Number	208-901-2
CAS Code	546-46-3

Appearance	White powder
Zinc (as dry base), ≥%	31.1
Identification	Passes test for Zinc and Citrate
Solubility	Slightly soluble in water
Loss on drying (105□,2h), ≤%	2.0
Chloride, ≤%	0.05
Sulfate, ≤%	0.05
Lead (Pb), ≤mg/kg	3
Cadmium (Cd), ≤mg/kg	1
Arsenic (As), ≤mg/kg	1
Mercury (Hg), ≤mg/kg	0.1

GENERAL PRODUCT INFORMATION

Mesh of the product	85% min pass through 100 mesh sieve
Taped denisty	0.7-0.8
Bulk density	0.6-0.7g
Watter solubility	Slightly soluble in water
Origin (Synthetis, Fermentation)	Synthetic
Origin (Animal, Vegetal, etc.)	Synthetic
Is the product and their ingredients FREE of GLUTEN?	Yes
Product is suitable for Vegans	Yes
Product is suitable for Vegatarians	Yes
Product is free of fructose	Yes
Is this product suitable for food?	Yes
Can be the product used in baby food (According to Directive 2006/141/CE)?	Yes
Has been sold this product in the EU before May 1997?	No
Pharmacopoeias that product meets	USP
Drug indication	Zinc Citrate can be used as a dietary supplement and as a nutrient. This product known to be used in oral care products. Zinc is an important antioxidant nutrient. It is necessary for protein synthesis, wound healing, for blood stability, normal tissue function, and aids in the digestion and metabolism of phosphorus. It also governs the contractility of muscles and maintains the body's alkaline balance.

INSOLENT [LABS]

Sélénomethionine L Poudre Se 0.5% - Origine synthétique
Selenomethionine L Powder Se 0.5% - Synthetic origin
Code : 1602163

SPECIFICATION DATA SHEET – FICHE TECHNIQUE

Manufacturing	
Product name	2-amino-4-methylselanyl-butanoic acid
Molecular formula	C5H11NO2Se
Molecular weight	196.106 g/mol
CAS N°	3211-76-5
Origin	Synthetic
Carrier	Calcium carbonate > 90%
Properties	**Specifications**
Organoleptic	
Appearance	White crystalline powder to off white powder
Chemical	
Se content	≥ 0.5% (5000ppm)
Physical	
Loss on drying	≤ 10.0%
Particle size	≥ 90% pass through #40 mesh
Microbiological	
Total plate count	≤ 3000 CFU/g
Yeast & Mold	≤ 300 CFU/g
E.coli	Absence
Salmonella	Absence
Staphylococcus aureus	Absence
Heavy metals	
Lead	≤ 3ppm
Arsenic	≤ 1ppm
Cadmium	≤ 1ppm
Mercury	≤ 0.1ppm
Shelf life	2 years

**According to a control plan*

Remarks: To be stored in original tightly closed package away from moisture and sunlight

Abbreviations: ND: not determined / NA: not applicable

INSOLENT [LABS]

Sélénomethionine L Poudre Se 0.5% - Origine synthétique
Selenomethionine L Powder Se 0.5% - Synthetic origin
Code : 1602163

ATTESTATION DE NON IRRADIATION / NON IONIZED STATEMENT

Le produit et les matières qui le composent n'ont pas été soumis à des rayonnements ionisants conformément aux Directives 1999/2/CE et 1999/3/CE.

According to Directives 1999/2/EC and *1999/3/EC, we confirm that the product and the ingredients used in it have not been subjected to ionizing radiation.*

ATTESTATION OGM / GMO STATEMENT

Conformément aux Règlements 2001/18/CE, 1829/2003/CE et 1830/2003/CE, nous déclarons que le produit ci-dessus n'est pas génétiquement modifié puisqu'il :

- Ne provient pas de substances génétiquement modifiées
- Ne contient pas de supports ou d'additifs génétiquement modifiés.

According to Regulations 2001/18/EC, 1829/2003/EC and 1830/2003/EC and its modifications, we declare that the product above is not genetically modified as it:

- *Does not come from genetically modified raw material*
- *Does not contain any carrier or additive coming from genetically modified organisms.*

ATTESTATION NANOMATERIAUX / NANOMATERIALS STATEMENT

Nous certifions que ce produit est conforme au Règlement n°1169/2011 du Parlement européen et du conseil du 25 octobre 2011 sur la fourniture d'information sur les aliments pour les consommateurs.

We certify that this product is in compliance with Regulation n°1169/2011 of the European parliament and the council of October the 25th 2011, on the provision of food information to consumers.

ATTESTATION EST-ESB / TSE-BSE STATEMENT

Nous certifions que notre produit est conforme à la réglementation européenne relative au risque d'Encéphalopathie Spongiforme Transmissible (EST).

We certify that this product is conform to the European legislation relative to the risk of Transmissible Spongiform Encephalopathy (TSE).

ATTESTATION CONFORMITE EMBALLAGES / PACKAGING STATEMENT

Nous certifions par la présente, que le conditionnement de ce produit satisfait aux législations suivantes :

- Règlement n°10/2011/CE de la Commission du 14 janvier 2011 concernant les matériaux et objets en matière plastique destinés à entrer en contact avec les denrées alimentaires
- Règlement n° 1935/2004/CE du Parlement européen et du conseil du 27 octobre 2004 concernant les matériaux et objets destinés à entrer en contact avec des denrées alimentaires et abrogeant les Directives 80/590/CEE et 89/109/CEE

Hereby, we certify that the packaging used complies with:

- *Commission Regulation n°10/2011/EC dated January the 14th 2011, on plastic materials and articles intended to come into contact with food and its modifications*

INSOLENT [LABS]

D-Calcium pantothenate

Product SPECIFICATION

Product Name	D-Calcium pantothenate
INCI Name	calcium pantothenate , D-form
EINECS Number	205-278-9
CAS Code	137-08-6

The product meets OR exceeds: **USP**	
Appearance	White powder
Identification A, Infrared Absortion	Match up with the spectrum of USP calcium pantothenate RS
Identification B, identification of Calcium ion	Normal reaction
Identification C, Specific rotation (Dried Basis)	+25.0°---+27.5°
Alkalinity	No Pink reaction within 5 minutes
Loss on drying	≤5.0%
Heavy metal	≤0.002%
Lead (Pb)	< 3 mg/kg
Arsenic (As)	< 1 mg/kg
Mercury (Hg)	< 0.1 mg/kg
Cadmium (Cd)	< 1 mg/kg
3-aminopropionic acid	≤0.5%
Residual Solvent (Methanol)	≤0.3%
Calcium content	8-2 -8.6%
Assay (On Dried Basis)	98.0-102.0%
Total Plate Count cfu/g	< 1,000 cfu/g
Yeast and Mold cfu/g	< 100 cfu/g
Salmonella	Negative
E.Coli	Negative
Staphylococcus Aureus	Negative
Nitrogen content	5.7% ~ 6.0%

INSOLENT [LABS]

D-Calcium pantothenate

GENERAL PRODUCT INFORMATION

Mesh of the product	40
Bulk density	0.6~0.7g/ml
Water solubility	Soluble
Origin (Synthetis, Fermentation)	Synthesis
Origin (Animal, Vegetal, etc.)	Synthesis
Is the product and their ingredients FREE of GLUTEN?	Yes
Product is suitable for Vegans	Yes
Product is suitable for Vegatarians	Yes
Product is free of fructose	Yes
Is this product suitable for food?	Yes
Can be the product used in baby food (According to Directive 2006/141/CE)?	Yes
Pharmacopoeias that product meets	EP USP FCC
Drug indication	NA
Melting Point	NA

INSOLENT [LABS]

D-Calcium pantothenate

BSE/TSE

The product does not contain and is not derived from Specified Risk Material as defined in Commission Directive European and it is conform to the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

Following EU regulations have been published in the Official Journal of the European Union:
- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22nd September 2003 on genetically modified food and feed
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22nd September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, We confirm is not made from irradiated/ionized raw materials or was irradiated/ionized the product.

INSOLENT [LABS]

D-Calcium pantothenate

FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 14001	Yes
HACCP	Yes
GMP	No
FAMI QS	Yes

INSOLENT [LABS]

Vitamin B8 – Biotin – VITB8001

INFORMATIONS SUR LE PRODUIT
PRODUCT INFORMATION

Scientific name	Biotin
CAS N°	58-85-5
Molecular formula	$C_{10}H_{16}N_2O_3S$
Origin	Synthetic
Natural from	/
Melting point:	229-232°C
ANALYTICAL DATA	
Appearance	White to off-white crystalline powder
Identification	Match with reference IR spectrum
Assay	97.5-101%
Individual impurity	NMT 1.0%
Total impurities	NMT 2.0%
Loss on drying	NMT 0.1%
Sulphated ash	NMT 0.1%
Specific rotation	+89 - +93°
Particle size	NLT 50% <10µm NMT 90% <20µm NLT 98% <30µm
STORAGE CONDITION – SHELF LIFE	
Type of packaging	Not Specified
Packaging	Suitable for food industry
Storage conditions	Store at temperature below 25°C, in a well closed bag away from moisture and direct sun light
Shelf life	3 years if stored in accordance with recommendations
Batch size	Batch size depends of our suppliers and of customer order (kg to tons)
Stability data	Not Specified

INSOLENT [LABS]

Vitamin B8 – Biotin – VITB8001

PRODUCT IMPURITIES*

Contaminants and residues		Analysis		Not tested	Content- limit	Reference and/or method
		Each batch	Control plan			
Heavy metals	Lead (Pb)	☒	☐	☐	<3ppm	USP/EP
	Cadmium (Cd)	☒	☐	☐	<1ppm	USP/EP
	Mercury (Hg)	☒	☐	☐	<0.1ppm	USP/EP
	Arsenic (As)	☒	☐	☐	<2ppm	USP/EP
Microbiological control	Total plate count	☒	☐	☐	<20 000 cfu/g	
	Yeast & moulds	☒	☐	☐	<200 cfu/g	
	Bile tolerant gram – bacteria (enterobacteria)	☒	☐	☐	<100 cfu/g	
	E. coli	☒	☐	☐	Negative/g	
	Salmonella	☒	☐	☐	Negative/25g	
	Staphylococcus aureus	☐	☐	☐	Negative/g	
	Others ...	☐	☐	☒	-	
Contaminants control	Residual solvent ...	☐	☐	☒	-	
	Pesticides	☐	☐	☒	<MRL	
	Aflatoxin B1	☐	☐	☒	-	
	Sum of B1, B2, G1, G2	☐	☐	☒	-	
	Ochratoxin A	☐	☐	☒	-	
	Dioxins and PCBs	☐	☒	☐	NMT 0.75 ng/kg	Dir. 2002/70/EC
	Benz(o)apyrene	☐	☐	☒	<10ppb	
	Sum of PAH (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)	☐	☐	☒	<50ppb	
	Melamine and its structural analogues	☐	☐	☒	-	-
	Iodine (algae)	☐	☐	☒	-	-
	Microcystin (algae)	☐	☐	☒	-	-
	Other contaminants :					
	Pyrrolizidine alkaloids	☐	☐	☒	*On customer's request*	-
	3-MCPD (3-monochloro-propanol-1,2-diol)	☐	☐	☒	-	-

**Information given by our supplier on the date of updating of data sheet*

Vitamin B8 – Biotin – VITB8001

ATTESTATIONS - *STATEMENTS*

GMOs FREE STATEMENT

According to the manufacturer's declaration and to the European Regulations:
- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
- Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning tractability and labelling on GMOs and tractability of food and feed products produced from GMOs and amending Directive 2001/18/EC

GMOs FREE	☒ **Yes**	☐ **No**

If no, name and quantity (%):

NON-IRRADIATION STATEMENT

According to the manufacturer's declaration and to the European Directive 1999/2/EC and 1999/3/EC of the European Parliament and of the Council:

NON-IRRADIATION	☒ **Yes**	☐ **No**

BSE/TSE FREE STATEMENT

According to the manufacturer's declaration:

BSE/TSE FREE	☒ **Yes**	☐ **No**

NANOMATERIALS FREE STATEMENT

According to the manufacturer's declaration and to the EU Regulation No 1169/2011 of the European Parliament and of the Council of 25 October 2011:

NANOMATERIALS FREE	☒ **Yes**	☐ **No**

INSOLENT [LABS]

azinvit®

VITAMIN B6, PYRIDOXINE HCl

Product information:

Product name	Vitamin B6, Pyridoxine HCl
Chemical formula	$C_8H_{12}ClNO_3$
Cas number	58-56-0
Reference	BP/EP

Test parameter:	**Specification:**
Appearance	White or almost white crystalline powder or small granule
Appearance of solution	Clear, not more intense than Y_7
Identification	IR absorption: concordant with the reference spectrum
	Responds to the test for chloride (USP39)
Assay	99,0% – 101%
Loss on drying	Max. 0,5 %
Residue on ignition	Max. 0,1 %
pH	2,4 – 3,0
Chloride content	16,9 – 17,6%
Related substances (disregard limit 0,05%)	
Impurity B	Max. 0,15%
Unspecified impurity	Max. 0,1%
Total impurities	Max. 0,2%

Additional information:

Shelf life	3 years
Storage	Preserve in tight closed container, protected from light
Packaging	25kg carton
Application	Nutritional ingredient

INSOLENT [LABS]

Stéarate de Magnésium E470b - Origine végétale
Magnesium stearate E470b - Vegetal origin
Code: 1602244

SPECIFICATION DATA SHEET – FICHE TECHNIQUE

Manufacturing	
Product name	Magnesium stearate
Chemical name	Magnesium distearate
CAS N°	557-04-0
EINECS N°	209-150-3
Composition	Magnesium salt of vegetable fatty acids consisting mainly of stearic acid and palmitic acid.
Additives / Carrier	None
Origin	Synthetic from palm oil
Compliance	E470b, FCC, FDA (GRAS)
Properties	**Specifications**
Organoleptic	
Appearance	A white or almost white, very fine, light powder, greasy to the touch
Physico-chemical	
Identification A Solubility	passes test : Insoluble in water, partially soluble in ethanol and ether
Identification B Positive test	passes test
Free Alkali	≤ 0.1%
Unsaponifiables	≤ 2%
Free fatty acid	≤ 2%
Bulk density tapped	0.27 - 0.37
Solidification point	≥ 54°C
Loss on drying	≤ 4%
Particle size	≥ 90% pass thru #200 mesh
Assay	
Content	≥ 95%
MgO content	6.8% - 8.3%
Contaminants	
Heavy metals (as Pb)	≤ 5ppm
Cadmium	≤ 1ppm
Lead	≤ 2ppm
Mercury	≤ 1ppm
Arsenic	≤ 3ppm
Microbiological	
Arobic microbial count	≤ 1000 CFU/g
Yeast & Mould	≤ 100 CFU/g
E.coli	Absence / g
Salmonella spp	Absence / 10g
Shelf Life	2 years

**According to a control plan*

Remarks: To be stored in original tightly closed package away from moisture and sunlight.

ND: not determined

NA: not applicable

INSOLENT [LABS]

Stéarate de Magnésium E470b - Origine végétale
Magnesium stearate E470b - Vegetal origin
Code: 1602244

ATTESTATION DE NON IRRADIATION / NON IONIZED STATEMENT

Le produit n'a pas été soumis à des rayonnements ionisants conformément aux Directives 1999/2/CE et 1999/3/CE.

According to Directives 1999/2/EC and *1999/3/EC, we confirm that the product has not been subjected to ionizing radiation.*

ATTESTATION NANOMATERIAUX / NANOMATERIALS STATEMENT

- Nous certifions qu'il n'y a pas de nanomatériaux dans le produit.

- *We certify that there is no nanomaterial in this product.*

ATTESTATION OGM / GMO STATEMENT

Conformément aux Règlements 2001/18/CE, 1829/2003/CE et 1830/2003/CE, nous déclarons que le produit ci-dessus n'est pas génétiquement modifié puisqu'il :

- Ne provient pas de substances génétiquement modifiées
- Ne contient pas de supports ou d'additifs génétiquement modifiés.

According to Regulations 2001/18/EC, 1829/2003/EC and 1830/2003/EC and its modifications, we declare that the product above is not genetically modified as it:

- *Does not come from genetically modified raw material*
- *Does not contain any carrier or additive coming from genetically modified organisms.*

ATTESTATION EST-ESB / TSE-BSE STATEMENT

Nous certifions que notre produit est conforme à la réglementation européenne relative au risque d'Encéphalopathie Spongiforme Transmissible (EST).

We certify that this product is conform to the European legislation relative to the risk of Transmissible Spongiform Encephalopathy (TSE).

ATTESTATION CONFORMITE EMBALLAGES / PACKAGING STATEMENT

Nous certifions par la présente, que le conditionnement de ce produit satisfait aux législations suivantes :

- Règlement n°10/2011/CE de la Commission du 14 janvier 2011 concernant les matériaux et objets en matière plastique destinés à entrer en contact avec les denrées alimentaires
- Règlement n° 1935/2004/CE du Parlement européen et du conseil du 27 octobre 2004 concernant les matériaux et objets destinés à entrer en contact avec des denrées alimentaires et abrogeant les Directives 80/590/CEE et 89/109/CEE

Hereby, we certify that the packaging used complies with:

- *Commission Regulation n°10/2011/EC dated January the 14th 2011, on plastic materials and articles intended to come into contact with food and its modifications*
- *Regulation n°1935/2004/EC of the European Parliament and of the Council dated October the 27th 2004, on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC*