

# INSOLENT [LABS]

## THE RAPTOR COMPANY

65, rue Réaumur  
75002 PARIS

A l'attention de  
Monsieur Ismail OUSLIMANI

---

Paris, le 19 octobre 2021

**Objet : VITAMINE D**  
LIBERATION DES LOTS  
Service Qualité  
Certification

Monsieur,

Nous vous confirmons la libération du lot de VITAMINE D numéro F-21-125 en date du 19/10/2021.

Ce lot est certifié conforme en tous points, et est libéré pour sa commercialisation.

Nous attestons que l'ensemble de ce lot a été produit en France et vous remercions de bien vouloir trouver en pièce(s) jointe(s) :

- MASTER FILE PRODUIT

Nous vous remercions pour votre confiance,  
Bien cordialement,



**INSOLENT [LABS]**  
41, rue Boissy d'Anglas  
75008 PARIS  
RCS PARIS 920 229 655

Le Pharmacien Responsable Qualité

INSOLENT [LABS]

THE RAPTOR COMPANY  
RAPTOR NUTRITION  
GAMME EQUILIBRE  
VITAMINE D

# PRODUCT MASTER FILE

Paris, le 25/11/2021

**DIRECTION GÉNÉRALE DE LA CONCURRENCE,  
DE LA CONSOMMATION ET DE LA RÉPRESSION DES FRAUDES  
59 BD VINCENT AURIOL - TÉLÉDOC 223  
75703 PARIS CEDEX 13**

Bureau 4A - Nutrition et information sur les denrées alimentaires  
Tél : 01 44 97 31 51  
Mél : [bureau-4A@dgccrf.finances.gouv.fr](mailto:bureau-4A@dgccrf.finances.gouv.fr)

## **ATTESTATION DE DÉCLARATION D'UN COMPLÉMENT ALIMENTAIRE**

La Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF) atteste que :

### **THE RAPTOR COMPANY**

a effectué, le 23/11/2021, la déclaration mentionnée à l'article 15 du décret n°2006-352 du 20 mars 2006 relatif aux compléments alimentaires pour le produit :

**Vitamine D3 1000UI  
Gélule**

**Cette déclaration est enregistrée sous le numéro : 2021-11-1054**

La déclaration prévue à l'article 15 du décret n°2006-352 vise à informer l'administration de la mise sur le marché d'un complément alimentaire. Elle n'a pas pour objectif de procéder à un contrôle de la conformité du produit à l'ensemble des dispositions qui lui sont applicables, notamment en matière d'hygiène ou d'information du consommateur.

**Cette attestation ne constitue donc pas une garantie de conformité aux dispositions en vigueur.**

Conformément aux dispositions de l'article 17 du règlement (CE) n° 178/2002 établissant les principes généraux et les prescriptions générales de la législation alimentaire et à celles de l'article L. 411-1 du Code de la consommation, il incombe à l'exploitant du secteur alimentaire de veiller à ce que le complément alimentaire qu'il met sur le marché réponde aux prescriptions du droit alimentaire qui lui sont applicables.

Pour tout renseignement d'ordre général sur la procédure de déclaration des compléments alimentaires, rendez-vous sur le site de la DGCCRF à l'adresse suivante :

<http://www.economie.gouv.fr/dgccrf/Securite/Produits-alimentaires/Compléments-alimentaires>



Flasher le QR-Code ou saisir le code de vérification du document sVEKBz sur le site <https://teleicare.dgccrf.finances.gouv.fr/verif/sVEKBz>



# INSOLENT [LABS]

Général	
Date début de production :	12/07/2021
Date fin de production :	12/07/2021
DLUO :	13/07/2024

Préparation	
Quantité demandée :	150 000
Quantité total engagée :	150 000
Perte :	0 %

Contenant	
Qualité :	HPMC
Taille :	T.1
Couleur :	TR.

## Composition

Ingrédient	Quantité / Unité	Perte	Quantité à produire	Quantité prélevée	N° Lot
VIT-Vit. D3 (100.000 U.I./ g)	10 Mg	0 %	1 500 g	1 500 g	5431-2012001
AD-Maltodextrine	290 Mg	0 %	43 500 g	43 500 g	E533E
<b>Total (Mise en Oeuvre)</b>	<b>300 Mg</b>		<b>45 000 g</b>		

Contenant	Quantité	N Lot Fourn.
G-Vg-1-Transp	150 000	SV121010303

## Fabrication

Informations	
Opérateur :	BE
Vitesse :	2100

Poids	
Poids net :	300 Mg
Contenant poids :	73 Mg
Poids brut nominal :	373 Mg

Tolérance	
Tolérance / Poids net :	-10% / +10%
Soit poids unitaire brut :	>343Mg & <403Mg

## Relevés

Contrôle Poids Bruts moyens (Lot de 10 gélules) : 376,378,377,374,374,375,377,380,374,376,379,378



Poids moyen sur 10 gélules (Mesure 12)	
Poids brut :	377 Mg
<b>Poids net :</b>	<b>304 Mg</b>

Quantité théorique à obtenir :	148 026
Quantité unité reg. machine :	
Quantité nette à obtenir :	148 026

Contrôle Uniformité de masse : Mesures : 120	
< 343 Mg : (0 %)	< 403 Mg : (0 %)
< 313 Mg : (0 %)	< 433 Mg : (0 %)

Quantité produite :	147 840
Rendement :	100%

# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### Product SPECIFICATION

<b>Product Name</b>	Cholecalciferol 0.1 MIU/g (VIT D3)
<b>INCI Name</b>	coleciferol
<b>EINECS Number</b>	200-673-2
<b>CAS Code</b>	67-97-0

The product meets OR exceeds:  
**USP**

<b>Name</b>	Vitamine D3 Powder
<b>Spec.</b>	100,000IU/g
<b>Type</b>	CWS(Food Grade)
<b>1. Appearance</b>	White or off-white flowing powder
<b>2. Loss on drying</b>	≤5.0%
<b>3. Vitamin D3 Content</b>	≥100,000IU/g
<b>4. Solubility</b>	Easily dispersed in cold water 15°C to form a homogeneous and stable emulsion
<b>5. Granularity: go through the sieve of 60 mesh</b>	≥90.0%
<b>6. Heavy Metal</b>	≤10ppm
<b>7. Lead</b>	≤2ppm
<b>8. Arsenic</b>	≤1ppm
<b>9. Mercury</b>	≤0.1ppm
<b>10. Cadmium</b>	≤1ppm
<b>11. Microbial Limit Test</b>	
<b>[1] Total Plate Count</b>	≤1000cfu/g
<b>[2]Yeast and Mold</b>	≤100cfu/g
<b>[3] Coliforms</b>	≤0.3MPN/g
<b>[4] E. Coli</b>	Negative/10g
<b>[5] Salmonella</b>	Negative/25g
<b>[6] S. aureus</b>	Negative/25g

### COMPOSITION

<b>ITEMS</b>	ASSAY
<b>1. Vitamin D3 Crystal</b>	0.3%
<b>2. Corn Oil</b>	1~15%
<b>3. Modified Starch</b>	35~50%
<b>4. Sucrose</b>	5~15%
<b>5. Maltodextrin</b>	25~40%
<b>6. Tocopherol</b>	0.5~2%
<b>7. Sodium Ascorbate</b>	0.5~1%
<b>8. Silicon Dioxide</b>	0~1%

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### GENERAL PRODUCT INFORMATION

Mesh of the product	Above 90% passing through 60 mesh
Water solubility	Easily dispersed in cold water 15°C to form a homogeneous and stable emulsion <0.1 g/L at 20 °C
Origin (Synthetic, Fermentation)	Synthetic
Origin (Animal, Vegetal, etc.)	N/A
Is the product and their ingredients FREE of GLUTEN?	Yes
Product is suitable for Vegans	No
Product is suitable for Vegetarians	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	USP/EP
Drug indication	N/A
Melting Point	84-85°C

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## TECHNICAL PRODUCT INFORMATION

Name of the product	Cholecalciferol 100,000IU/g
IUPAC name	N/A
ATC Code	N/A
Molecular Formula	C <sub>27</sub> H <sub>44</sub> O
Stereochemistry	N/A
Molecular mass	384.64
Raw materials used and their function	Modified Starch, Malt dextrin, Vitamin D3 Oil, Vegetable Oil
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Every batch, Every batch
Frequency of analysis of each heavy metals?	Every batch, Every batch

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## FOREIGN BODIES

Explanation about control of the foreign bodies during the manufacturing process:

Metal detector	Yes	Detection limit: Non-Fe/Stainless steel 1.2mm Fe 0.7mm
Sieve	Yes	60mesh US standard sieve.
Filter	No	
X-Ray	No	
Other	No	

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## INGREDIENTS

In accordance with the Directive 2003/89/EC We confirm this is the ingredients and their content in %

Vitamin D3 Crystal (Main Ingredient)	0.3%
Corn Oil (Carrier)	1~15%
Modified Starch (Carrier)	35~50%
Sucrose (Carrier)	5~15%
Maltodextrin (Carrier)	25~40%
Sodium Ascorbate (Antioxidant)	0.5~1%
Tocopherol (Antioxidant)	0.5~2%
Silicon Dioxide (Anti-caking)	0~1%

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## 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.

---

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## PESTICIDES

To our actual knowledge of production process, raw materials and equipment used potential pesticide residues in the above mentioned product comply with the European legislation on pesticide residues, esp. Regulation (EC)None. 396/2005. However, we do no test for pesticide residues on a routine basis.

## RESIDUAL SOLVENTS

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

## CONTAMINANTS

The product is in accordance and meets with the commission regulation (EC) No.629/2008 of 2 July 2008 amending regulation (EC) No.1881/2006 setting maximum levels for certain contaminants in foodstuffs.

## PCBS and MELAMINE

The product is in accordance and meets with the commission regulation (EU) No.594/2012 of 5 July 2012 amending regulation (EC) No.1881/2006 as regards the maximum levels of the contaminants Ochratoxin a, non dioxin-like PCBS and melamine in foodstuffs.

## ANTI-DOPING

As per the list of 2012 of the world anti-doping agency the ingredient is not a doping substance and not a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

As per the list of 2016 of the world anti-doping agency the ingredient is not a doping substance and not a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

## NANOMATERIALS

According to the the definition of 'nanomaterials' of the UE REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers , we hereby attest that no nanomaterials are used in the formulation nor in the packaging materials of our product.

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## PACKING

We confirm that the packing used is in compliance with:

- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

---

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## ALLERGENS

In accordance with the Directive 2003/89/EC and Council amending Directive 2000/13/EC and taking Directive 2005/26/EC, Directive 2005/63/EC and Directive 2006/142/EC of 22.12.2006 into consideration. We confirm the following information:

Note: Does the raw material CONTAIN or is it DERIVED from or could it be CROSS-CONTAMINATED by any of the following.

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof	No
Milk and products thereof (including lactose)	No
Nuts (i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO <sub>2</sub>	No
Lupine and products thereof	No
Molluscs and products thereof	No

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## ALBA LIST (ALLERGENS)

When it is written 'No' means that there's no contamination in:

Contain in recipe, Handled on same production line or Handled at same side.

Where: 1) Contain in recipe 2) Handled on same production line 3) Handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	Yes	Contain in recipe
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## NUTRITIONAL INFORMATION

The values given are approximate

### NUTRITIONAL INFORMATION (PER 100G OF RAW MATERIAL)

1. Energy KJ 1576
2. Protein g 0
3. Total Fat g 2.7
4. Carbohydrates g 86.3
5. Sodium mg 184

---

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## RESIDUE LIMITS

For the products/s mentioned above We herewith certify that the ingredient mentioned is in compliance with: commission regulation (EU) 2016/355 of 11 march 2016 amending Annex III to regulation (EC) No. 853/2004 of the European parliament and of the council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

## HYGIENE OF FOODSTUFFS

For the products/s mentioned above We herewith certify that the production complies with regulation (EC) No. 852/2004 of the European parliament on the hygiene of foodstuffs and all its amendments.

## FULL TRACEABILITY

For the products/s mentioned above We herewith the full traceability as mentioned in regulation (EC) No. 178/2002 of the European parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.

---

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

## FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 14001	Yes
ISO 22000	Yes
HACCP	Yes
GMP	No
FAMI QS	No

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

NON ANIMAL TESTING

We certify that the product has not been tested on animals for cosmetic purposes.

---

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### MSDS (Material Safety Data Sheet)

#### Section 1: Product and Company Identification

Product Name: Cholecalciferol 0.1 MIU/g (VIT D3)

CAS Number: 67-97-0

#### Section 2: Hazards Identification

##### 2.1. Classification of the substance or mixture

Classification according to Directive 2006/121/EC or 1999/45/EC

Indications of danger: T - Toxic, Xn - Harmful

R phrases:

Toxic by inhalation.

Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Classification according to Regulation (EC) No.

1272/2008 [CLP]

Hazard categories:

Acute toxicity: Acute Tox. 4

Specific target organ toxicity - repeated exposure:

STOT RE 2

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful if inhaled.

May cause damage to organs through prolonged or repeated exposure.

Harmful to aquatic life with long lasting effects.

##### 2.2. Label elements

Hazardous components which must be listed on the label

Vitamin D3, cholecalciferol

Signal word:

Pictograms:



Warning

Hazard statements

H332 Harmful if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P260 Do not breathe dust.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of this material and its container to hazardous or special waste collection point.

# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### MSDS (Material Safety Data Sheet)

#### Section 3: Composition and Information on Ingredients

##### 3.2. Mixtures

##### Hazardous components

Chemical name Vitamin D3, cholecalciferol

EC No 200-673-2

CAS No 67-97-0

Index No 603-180-00-4

Classification according to Directive 2006/121/EC: T+ - Very toxic, T - Toxic R26-24/25-48/25

Classification according to Regulation (EC) No. 1272/2008 [CLP]: Acute Tox. 2\*, Acute Tox. 3\*, Acute Tox.

3\*, STOT RE 1; H330 H311 H301 H372 \*\*

Quantity: 0.25%-<1%

#### Section 4: First Aid Measures

##### 4.1. Description of first aid measures

##### Eye contact

Rinse immediately with tap water for 10 minutes - open eyelids forcibly.

##### Skin contact

Remove immediately contaminated clothes, wash affected skin with water and soap- do not use any solvents.

##### Inhalation

Remove the casualty to fresh air and keep him/her calm; get medical treatment.

##### Note to physician

Ample supply of liquids, low calcium diet, in severe cases corticosteroids and/or Plicamycin (15-25 µg/d on up to 4 consecutive days, daily checking of serum calcium level), if necessary also administration of ascorbic acid 4x500 mg/d.

##### ON ALL OF THE ABOVE

Consult a physician if symptoms persist.

#### Section 5: Firefighting measures

##### 5.1. Extinguishing media

##### Suitable extinguishing media:

Water spray. Foam. Extinguishing powder. Carbon dioxide (CO<sub>2</sub>). Sand.

##### 5.2. Special hazards arising from the substance or mixture

Dust explosive. In case of fire and/or explosion do not breathe fumes.

Slightly flammable to flammable in presence of open flames and sparks, of heat.

Non-flammable in presence of shocks.

Risks of explosion of the product in presence of mechanical impact: Not available.

Risks of explosion of the product in presence of static discharge: Not available.

##### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

##### Additional information

Dispose of waste according to applicable legislation.

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: >350°C

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbón oxides (CO, CO<sub>2</sub>).



# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### MSDS (Material Safety Data Sheet)

#### Section 6: Accidental Release Measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

Avoid dust formation.

Use personal protective equipment.

##### 6.2. Environmental precautions

Do not discharge into the drains or bodies of water.

Do not discharge into surface waters/groundwater.

Do not discharge into the subsoil/soil.

##### 6.3. Methods and material for containment and cleaning up

Collect solids (avoid dust formation) and hand over to waste removal.

#### Section 7: Handling and Storage

##### 7.1. Precautions for safe handling

Ensure thorough ventilation of stores and work areas. Keep locked up Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes In case of insufficient ventilation, wear suitable respiratory equipment If ingested, seek medical advice immediately and show the container or the label.

##### 7.2. Conditions for safe storage, including any incompatibilities

Store in the original container, protected from light, in a dry place below 25°C. Once it opened, please use it up in a short time.

#### Section 8: Exposure Controls/Personal Protection

##### 8.1. Exposure controls

Respiratory protection

Environment-independent breathing apparatus. In case of dust formation wear micro dust mask. Short term: filter apparatus, combination filter A-P3

Hand protection

Protective gloves

Eye protection

Protective goggles

Skin protection

Protective clothing

General protective measures

Avoid contact with eyes and skin. Avoid explosion-before application obtain special instructions.

Hygiene measures

Remove soiled or soaked clothing immediately. Keep divorced from food and feed. Wash hands and skin before breaks and after work.

#### Section 9: Physical and Chemical Properties

For this information, please, refer directly to the Certificate of Analysis OR Specifications

#### Section 10: Stability and Reactivity

##### 10.2 Chemical Stability

The product is stable. When exposed to light and heat, potency will deteriorate.

# INSOLENT [LABS]

## Cholecalciferol 0.1 MIU/g (VIT D3)

### MSDS (Material Safety Data Sheet)

#### 10.3 Possibility of Hazardous Reactions

Polymerization :Not determined nor anticipated under normal handling & storage conditions.

#### 10.4. Conditions to avoid

Moisture, direct sunlight, heat, conditions that might generate heat.

#### 10.5. Incompatible materials

Strong oxidizing agents. Acid, concentrated. Alkalis (alkalis), concentrated.

#### 10.6. Hazardous Decomposition Products

Not Determined.

### Section 11: Toxicological Information

#### 11.1. Information on toxicological effects

##### Routes of Entry

Eye contact. Inhalation. Ingestion.

##### Acute toxicity

LD50 3360mg/kg (oral, rat)

LD50 4880mg/kg (dermal, rat)

LC50 10.4 to 30.4 mg/l (inhal., rat, 4 h)

Acute overdosage leads to nausea, vomiting, headache, weakness, strong thirst, abdominal pain and loss of appetite (man).

##### Local effects

Skin: slightly irritating (rabbit)

Eye: non-irritant (rabbit)

##### Sensitization

Non-sensitizing (guinea pig)

##### Chronic toxicity

Chronic overdosage may lead to formation of renal calculi, bone demineralisation and formation of calcination foci in lung and kidneys up to renal insufficiency (man)

##### Mutagenicity

Not mutagenic.

### Section 12: Ecological Information

#### 12.1. Toxicity

Barely toxic for fish:(nominal concentration = 100 mg/l) (zebrafish)

LC50 (96 h) > 100 mg/l (nominal concentration)

NOEC (96 h) 100 mg/l (nominal concentration)

(OECD No. 203, semi-static) \*1

barely toxic for planktonic crustaceans: (nominal concentration= 100 mg/l), test performed with water accommodated fractions(Daphnia magna)

EC50 (48 h) > 100 mg/l (nominal concentration)

NOEC (48 h) 0.69 mg/l (average measured concentration)

(OECD No. 202) \*1

barely toxic for algae: (nominal concentration = 100 mg/l), test performed with water accommodated fractions, due to possible light sensitivity of the test substance the algae were exposed to it first for 24 hours in the dark and only subsequently for the regular 72-hour period under illumination (Selenastrum capricornutum)

EC50 (96 h) > 100 mg/l (nominal concentration)

NOEC (96 h) 0.17 mg/l (average measured concentration)

(OECD No. 201) \*1



# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

MSDS (Material Safety Data Sheet)

## 12.2. Persistence and degradability

Product is not easily biodegradable.

## 12.3. Bioaccumulative potential

No data available

## 12.4. Mobility in soil

No data available.

## 12.6. Other adverse effects

Product may not be released into water without pre-treatment.

\*1 referring to: Vitamin D3

## Section 13: Disposal Considerations

### 13.1. Waste treatment methods

Storage and disposal must be in accordance with applicable local, state & federal disposal regulations.

Characterization and compliance with applicable laws

Waste code No. Name of waste

07 05 99 Wastes not otherwise specified

16 05 03 Other waste containing organic chemicals e.g. lab chemicals not otherwise specified

18 02 04 Discarded chemicals

are the responsibility solely of the generator.

Recommendations for the product

Dispose of as hazardous waste.

Recommendations for packaging

Packaging that cannot be cleaned should be disposed of like the product.

## Section 14: Transport Information

DOT classification

Not a DOT controlled material (United States).

Land and inland navigation transport

(ADR/RID/GGVS/GGVE/ADNR).

No hazardous material as defined by the transport regulations.

IATA Classification

They are considered to be non-dangerous by the 59th IATA Dangerous Goods Regulations and it is not restricted as per SPECIAL PROVISION A3

Suggestion according to IMO IMDG Code

The substance is not subject to IMO IMDG Code.

## Section 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EINECS

This product is on the European Inventory of Existing Commercial Chemical Substances.

Protective equipment

Gloves, lab coat, dust respirator, be sure to use an approved/certified respirator or equivalent, safety glasses.

## Section 16: Other Information

Revision date: 03.01.2018

# INSOLENT [LABS]

Cholecalciferol 0.1 MIU/g (VIT D3)

MSDS (Material Safety Data Sheet)

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

# INSOLENT [LABS]

## Maltodextrin

### Product SPECIFICATION

<b>Product Name</b>	Maltodextrin
<b>INCI Name</b>	Maltodextrin
<b>EINECS Number</b>	232-940-4
<b>CAS Code</b>	9050-36-6

<b>Aspecto Limpieza Producto   Aspect Cleaning Product</b>	Conforme / Conform
<b>Perdida a la desecacion   Loss on drying</b>	%
<b>Dextrosa Equivalente   Dextrose Equivalent</b>	
<b>Aspecto en Solucion   Appearance in solution</b>	Conforme / Conform
<b>Dióxido de Azufre   Sulfur Dioxide</b>	mg/kg
<b>Part. Sup. A 250 Micras   Part. Over. At 250 Microns</b>	%
<b>Part. Sup. A 40 Micras   Part. Over. At 40 Microns</b>	%
<b>Densidad sin asentar   Density unsettled</b>	kg/l
<b>pH en Solución   pH in Solution</b>	
<b>Recuento de aerobios totales   Total viable count</b>	/10g
<b>Escherichia Coli   Escherichia Coli</b>	AUS/10g
<b>Salmonela   Salmonella</b>	AUS/25g
<b>Mohos   Molds</b>	/10g
<b>Levaduras   Yeasts</b>	/10g
<b>Esporas de anaerobios S.R.   S.R. anaerobic spores</b>	/10g

The information contained herein is, to the best of our knowledge, correct. Part or total information as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you evaluate the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

### GMO Statement

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 Statement

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.

### NANOMATERIALS Statement

# INSOLENT [LABS]

According to the the definition of 'nanomaterials' of the UE REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers , we hereby attest that no nanomaterials are used in the formulation nor in the packaging materials of our product.

# INSOLENT [LABS]

## Maltodextrin

### ALLERGENS Statement

In accordance with the Directive 2003/89/EC and Council amending Directive 2000/13/EC and taking Directive 2005/26/EC, Directive 2005/63/EC and Directive 2006/142/EC of 22.12.2006 into consideration. We confirm the following information:

Note: Does the raw material CONTAIN or is it DERIVED from or could it be CROSS-CONTAMINATED by any of the following.

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof	No
Milk and products thereof (including lactose)	No
Nuts (i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO <sub>2</sub>	No
Lupine and products thereof	No
Molluscs and products thereof	No