

REGULATORY INFORMATION -Colartix Bovine (B)  
Food Applications

Product Name	<b>Rousselot® Colartix Bovine (B)</b>
Company Name	<b>ROUSSELOT</b>
Rousselot office	<p><b>Rousselot</b> Kanaaldijk Noord 20-21 NL - 5691 NM SON P.O. Box 47, NL 5690 AA SON The Netherlands</p> <p>Tel.: +31 (0)499 36 41 00 Fax.: +31 (0)499 36 4972</p>
Production Site Address	<p><b>Angoulême</b> Rue St Michel à Angoulême 16000 Angoulême FRANCE</p>
Production Site Agreement Number	FR16.015.309.EC

**DATE:** VALIDITY 2022

This document is only valid for Bovine hydrolyzed cartilage manufactured by the above plant.

### 1. Ingredient breakdown

**Legal name (to be labelled): Bovine Hydrolyzed Cartilage**

No E number –Bovine Hydrolyzed cartilage is not an additive.

Composition	% Range	Raw Materials Origin	Geographical Origin*
Total collagen peptides	55-70%	Bovine cartilage	European Union (27) + UK
Chondroitin sulfate	≥ 12- 25%		

\*This list can be modified due to a modification of Rousselot's supply. However, the suppliers are exclusively selected according to the same regulatory and Rousselot requirements.

Raw materials come from bovines slaughtered in slaughterhouses and deemed fit for human consumption by official veterinarian *ante* and *post mortem* inspection.

#### Manufacturing process:

Grinding, enzymatic hydrolysis, filtration, concentration, sterilization 138°C 4s minimum, spray drying.

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**2. Conformity**

**Quality Systems:**

- Rousselot production site is IFS certified.
- Rousselot production site has implemented a HACCP system.

**International Food Regulations:**

Rousselot® Colartix Bovine (B) complies with EU food regulations as indicated below. However, we recommend that the customer ensures that these products are in compliance with local regulation in force, particularly in the countries where the finished products are to be consumed.

Rousselot® Colartix B complies with the following regulations and their further amendments:

- Regulation (EC) N°853/2004, Section XVI laying down specific hygiene rules for highly refined chondroitin sulphate, hyaluronic acid and other hydrolysed cartilage products, and its amendments e.g. Regulations (EC) N°1243/2007, N° 558/2010, N°931/2011 and (EU) 2016/355
- Regulation (EC) N° 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organization of official controls, and further amendments
- Regulation (EC) N°2073/2005 on microbiological criteria on foodstuffs

**Others:**

- Rousselot® Colartix B does not contain gluten and is **USABLE FOR CELIAC**
- Rousselot® Colartix B is **NOT SUITABLE FOR VEGETARIANS, VEGANS**
- Rousselot® Colartix B can be **HALAL** (name of product in certificate needs to be updated) & is **KOSHER** certified by Rabbi Sheinkopf

**3. Specifications**

**Appearance**

<b>Texture</b>	Powder
<b>Colour</b>	Off-White to tan
<b>Odour</b>	Characteristic to product
<b>Taste</b>	Characteristic to product

**Physical and Chemical characteristics**

Please refer to the specific product data sheet

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**Microbiological characteristics**

	Limits
Total count	< 1000 cfu/g
Total Yeast and Mould Count	< 100 cfu/g
E. Coli	Abs / 10g
Anaerobic sulphite-reducing spores	< 10 cfu/g
Salmonella	Abs / 25g

**Nutritional Information – average values per 100 g**

	Value
Protein	65 g
Total fat	1 g
Total carbohydrate	18 g
Dietary fiber	0 g
Sodium*	1730 mg
Potassium	270 mg
Calcium	270 mg
Magnesium	50 mg
Cholesterol	0 g
Vitamins	0 g
Caloric value	341 Kcal 1448 KJ

\* Sodium does not come from added salt but is a component of Colartix B.  
1730 mg of sodium \*2.5 = 4.3 g/100 Salt.

*The values given above are based on our best knowledge at the time of printing. They are calculated on the basis of average values obtained from own measurements or from the literature. These values are given for information only and are not to be considered as specifications. They do not constitute a guarantee as to the properties of the product.*

**4. Allergen information**

**EU list, Regulation (EU) N°1169/2011  
US Food Allergen Labelling and Consumer Protection Act (FALCPA),  
2004**

Allergenic substance or product thereof	Presence	Absence
Cereals containing gluten		X
Crustaceans		X
Egg		X
Fish		X
Peanuts		X
Soybeans		X

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Milk		X
Tree nuts		X
Celery		X
Mustard		X
Sesame seeds		X
Sulphur dioxide and sulphites > 10ppm		X
Lupin		X
Molluscs		X

### 5. GMO

Rousselot® Colartix B is not produced from Genetically Modified Organisms (GMO), and there is no risk of cross-contamination.

*GMO status according to the European Regulation (EC) N°1829/2003 and (EC) N°1830/2003*

- The product is NOT genetically modified
- Genetically modified organisms have not been used in its production
- The product does NOT contain an ingredient that contains a GMO or is a GMO in its own
- GM materials are NOT used on production site
- The product does NOT have to be labelled according to Regulation (EC) N°1829/2003 or (EC) N°1830/2003.

### 6. Residue information

Residue	Limits	Test method
Cd	≤ 0.5 ppm	GME
Pb	≤ 1 ppm	GME
As	≤ 1 ppm	GME
Hg	≤ 0.1 ppm	GME
Cr	≤ 10 ppm	GME
Cu	≤ 30 ppm	GME
Zn	≤ 50 ppm	GME
SO <sub>2</sub>	≤ 50 ppm*	GME
H <sub>2</sub> O <sub>2</sub>	≤10 ppm	Rousselot
Pesticides	Conform to Regulation (EC) N°396/2005	
Toxins, mycotoxins	Conform to Regulation (EC) N°1881/2006 and amendments	
Dioxins and PCBs	Conform to Regulation (EC) N°1881/2006 and (EU) N°1259/2011	
Veterinary medicinal products	Conform to Regulations (EC) N°37/2010 & N°470/2009	

\* 853/2004 limit is 50 ppm however a tighter limit is applied (see allergens)

**Rousselot® Colartix B does NOT contain any preservatives.**

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### **WADA**

Cfr. Rousselot statement Contaminant Policy: Colartix B does NOT contain nor has been manufactured by a process involving any of the components listed in the current Prohibited List of the World Anti-Doping Code (WADA).

### **Metal Catalysts**

The manufacturing process does NOT involve any metal catalyst.

### **Solvents**

In accordance with Directive 2009/32/EC on extraction solvents used in the production of foodstuffs the manufacturing process of Colartix B does NOT involve any solvent except water.

### **Irradiation / Ionizing radiation**

Rousselot® Colartix B has NOT been irradiated in conformity with European Directives 1999/2/EC and 1999/3/EC and further amendments.

## 7. Packaging / Storage

### **Labelling:**

**Best Before Date:** 3 years when stored in the storage conditions mentioned below and in its original unopened packaging.

**Lot Number description:** unique 7-digit number

All packaging/bags used for Rousselot® Colartix B are labelled with the following information:

- Name of product
- Lot Number
- Best before date
- Date of preparation
- Food agreement number of production site
- Net weight

### **Packaging Conformity:**

All materials intended to pack Rousselot® Colartix B conform to the following regulations:

- European Parliament and Council regulation (EC) N°1935/2004 relating to materials and articles intended to come into contact with foodstuffs, and further amendments;
- Council regulation (EC) N°2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, and further amendments;
- Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food and further amendments;

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- Regulation (EU) N°10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs, and further amendments;
- European Parliament and Council directive 94/62/EC on packaging and packaging waste, and further amendments;
- Packaging material does not contain restricted substances or SVHC's (Substances of Very High Concern) in a concentration exceeding 0.1% (w/w) nor are the substances used in the production process (Regulation (EC) No. 1907/2006 - REACH);
- US FDA 21 CFR part 170 to part 190;
- Does not contain GMO's and allergens nor are they used in the production process of the packaging;
- Does not contain MOSH (Mineral OH Saturated Hydrocarbon), MOAH (Mineral OH Aromatic Hydrocarbon) or PAH (Polyaromatic Hydrocarbons) nor are they used in the production process of the packaging.

### **Storage conditions:**

Store away from heat and moisture in its original unopened packaging.

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*For additional information, please contact your current ROUSSELOT Sales Manager or ROUSSELOT corporate office with Telephone Numbers indicated on the first page.*

[www.rousselot.com](http://www.rousselot.com)