



**QUIMDIS S.A.S**

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**Chondroitin Sulphate Sodium Shark Type II**

**Product questionnaire**

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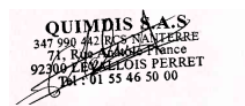
We, *QUIMDIS*, guarantee that the data provided is correct.

**DATE: 03/08/2015**

**FUNCTION: REGULATORY AFFAIRS MANAGER**

**NAME: GOLIARD AURÉLIEN**

**STAMP AND SIGNATURE:**





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**Chondroitin Sulphate Sodium Shark Type II**

**GENETICALLY MODIFIED ORGANISMS- GMO**  
According to EU Regulations Ec/1829/2003 & EC/1830/2003

According to the EU regulations concerning the traceability and labelling of Genetically Modified Organisms (GMO), and the traceability of food products produced from GMO (Regulation N°1829/2003/EC and N°1830/2003/EC and amendments), we confirm that the product :

1.	<ul style="list-style-type: none"> <li>Contains ingredient(s) from Maize and/or Soya origin</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	If Yes, Please send us an up to date IP certificate		
	<ul style="list-style-type: none"> <li>Contains material which contains, consists of or is produced from authorized GMOs in proportion higher than 0,9 % . This presence is adventitious or technically unavoidable</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> <li>is GMO or contains or consists of GMOs</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> <li>is produced from GMOs or contains ingredients produced from GMOs</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

2.	<ul style="list-style-type: none"> <li>Contains ingredient(s) from other potential GMO-risk raw material(s) (rice, beet, cotton ...)</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	If Yes, please specify :		
	<ul style="list-style-type: none"> <li>ingredient :</li> <li>vegetable origin :</li> <li>geographic origin :</li> </ul>		
	<ul style="list-style-type: none"> <li>Contains material which contains, consists of or is produced from evaluated GMOs in proportion higher than 0,5 % . This presence is adventitious or technically unavoidable</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

3.	For information about processing aids, <ul style="list-style-type: none"> <li>is produced or contains ingredient(s) produced with GMOs or Genetically Modified Microorganisms processing aids (bacteria, yeast...) or derived from GMOs or GMMs (including enzymes)</li> </ul>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	If yes, please specify :		
We confirm that the ingredient supplied is compliant in all respects with the Regulations N°1829/2003/EC and N°1830/2003/EC where applicable		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

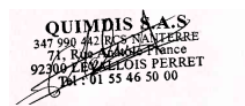
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**Chondroitin Sulphate Sodium Shark Type II**

**INGREDIENTS**

An ingredient is defined in Directive 2000/13/EC on labelling: "ingredient means any substance including additives, used in the production or preparation of a foodstuff and still present in the finished product although possibly in a modified form" i.e all raw material to produce the goods.

Please list all ingredients:

%	Ingredients/material composition	Country of origin	GMO free	
			Yes	No
100	Chondroitin Sulphate Sodium Shark	China	Yes	

**ORIGIN**

Is a manufacturing process available? Yes  No  If yes, please enclosed it

Country of origin of the product: China

Source of the product:

- Animal** origin Shark (If animal origin, please fill in TSE/BSE part)
- Vegetable** origin, please specify species:
- Mineral** origin, please specify species:
- Synthetic**
- Manufactured by **biotechnological** processing (micro-organism, enzymes...)  
Medium's origin:

Processing aid type:

- Others:** .....

**QUALITY AND REGULATORY CERTIFICATES**

The manufacturing plant is certified:

- ISO Please specify: ISO 22000
- GMP  EU-GMP Do you have a written confirmation if concerned (as per Regulation 2011/62/UE)?  No  Yes
- HACCP
- IPEC

If yes, please attach relevant certificates /documents.

The product has:

- COS (certificate of Sustainability to the Ph EUR pharmacopeia)
- DMF
- Kosher
- HALAL

If yes, please attach relevant certificates /documents. For confidential document we can sign a Non-disclosure agreement

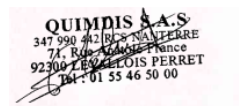
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**Chondroitin Sulphate Sodium Shark Type II****TSE/BSE**  
According to EU Regulation EC/1999/82 & EMEA regulation 410-01 rev.3

Does the product involve the use of materials of animal or human origin?

YES  NO

*If yes, please attach relevant certificate about conformity with TSE/BSE legislation*

If any material or finished product is animal origin or contains raw material(s) derived from animal origin, or if the manufacturing process uses raw material(s) of animal origin, please indicate:

Raw material name: Shark Bones  
 From (animal species): Shark.

**FOOD SAFETY**  
According to EU Regulation EC/1881/2006

CAS Number: 12678-07-8

Heavy metals:

	Content	Remark
Lead	NMT 3ppm	
Arsenic	NMT 1ppm	
Mercury	NMT 0.1ppm	
Cadmium	NMT 1ppm	
Total heavy metals (as Pb)	NMT 20ppm	

4

**CONTAMINANTS**  
According to EU Regulation EC/466/2011 & EC/2375/2001

Does the product contain:

	Not tested	YES	NO	if yes, please precise the level
Pesticides(please precise) ?			NO	
Dioxins?			No	
PAH's (polycyclic aromatic hydrocarbons)?			NO	
PCB's (polychlorobifenylys) ?			No	
Mycotoxin			No	
Aflatoxine			No	
Benzopyrens			No	
3-MCPD			No	
Phtalates			No	

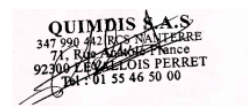
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**Chondroitin Sulphate Sodium Shark Type II**

**RESIDUAL SOLVENTS**  
According to CPMP/ICH/283/95

Are solvents listed in the Note of guidance Ref. CPMP/ICH/283/95 used during the manufacturing of the product?

Yes  No

✓ If yes, please list the solvents concerned and their maximum concentration in the material:

Name of solvent	Class	Maximum concentration (ppm)

✓ If yes, does the CEP for chemical quality include data concerning residual solvents?

Yes  No

✓ If no, please enclosed the statement

**METAL CATALYSTS**  
According to ICH Guideline Q3D for "elemental impurities"

Is the raw material produced in the presence of metal catalysts or metal reagents that could lead to metal residues?

Yes  No

Statement on the identity and specification of each metal residue present in the substance, according to section 4.6 of the above mentioned guideline:

Metal	Classification (according to section 4 of the guideline: 1, 2A, 2B, 3)	Manufacturer's specification (ppm)	Meets Option 1 limit for			
			Oral use	Parenteral use	Inhalation use	none
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**DISPOSAL WASTE**

What is your disposal waste method? N/A

Please indicate waste code (according to OJ 2006/1013 on the July 12th, 2006): .....

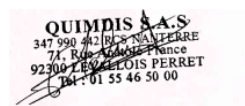
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**SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES**  
 According Regulation (EU) N°1169/2011 as regards indication of ingredients present in foodstuffs

The modification of the 2000/13 European directive about the labelling aims at the obligation of labelling clearly the allergen below used in food products production and still present in the product, even in a modified form, including additives and processing aids.

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		<b>NO</b>		No		No		No
Crustaceans and products thereof		No		No		No		No
Eggs and products thereof		No		No		No		No
Fish and products thereof (2)	Yes							
Peanuts and products thereof		No		No		No		No
Soybeans and products thereof (3)		No		No		No		No
Milk and products thereof (including lactose)(4)		No		No		No		No
Nuts (5) or products thereof		No		No		No		No
Celery and products thereof		No		No		No		No
Mustard and products thereof		No		No		No		No
Sesame seeds and product thereof		No		No		No		No
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO2		No		No		No		No
Lupines and products thereof		No		No		No		No
Mollusc and product thereof		No		No		No		No
Latex		No		No		No		No

(1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;

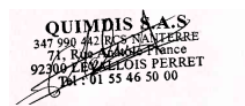
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- (3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;
- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

**ALLERGENS & FOOD INTOLERANCE**

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes* (precise nature)	No	Yes* (precise the nature)	No	Yes* (precise the nature)	No	Yes* (precise the nature)	No
Gluten		No		No		No		No
Yeasts and hydrolysates, cardamom, vanilla, cinnamon, cocoa, leguminosae; benzoic acid, benzoate, parabens, phenylalanine, glutamate, coriander and product thereof.		No		No		No		No
Bovine, porcine, ovine, fish and by-products	Yes							
Exotics fruits (kiwi, banana, mango, ...) and products thereof		No		No		No		No
Strawberry and others berries		No		No		No		No
Azo-colorants		No		No		No		No
Latex		No		No		No		No
Others: .....		No		No		No		No

\*If Yes :

- could you please send us your risk assessment and/or your Allergens policy?
- Procedure in place to prevent or control cross-contacts: specify the procedures:

- Validated cleaning procedure (s)
- Raw material segregation / specific label
- Specific production scheduling
- Dedicated equipment / production areas
- Other: please specify .....

**Attach documents describing these procedures.**

**- Please specify below the name of the source of allergen and its quantity:**

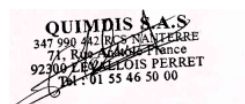
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**Chondroitin Sulphate Sodium Shark Type II**

**PACKING CERTIFICATE**  
According to EU Regulation EC/10/2011

Can you certify that the packaging of this product is safe for use in contact with food stuffs ?

Not concerned  YES  NO

Do you add desiccant bags during packaging process?

If so, where do you mention it?

Please specify the following information and provide specification sheet:

PRIMARY PACKAGING		SECOND PACKAGING		THIRD PACKAGING	
Type	Size	Type	Size	Type	Size
Bag	25 kg ( standard package)	Drum	25kg (standard package)		

**COMPLEMENTARY INFORMATION**

**Pharmacopeia:**

Does this product comply with a pharmacopoeia?

Yes  No

If Yes, which one(s)?

- European Pharmacopoeia
- French Pharmacopoeia
- British Pharmacopoeia
- US Pharmacopoeia

Other:.....

**Irradiation:**

Has this raw material or one of its ingredients been irradiated or ionised?

If yes, specify which one..... Yes  No

**Size batch:**

Please indicate the size batch: 1,000kgs

**Nanomaterial:**

Does this raw material contain or can be considered as engineered nanomaterial\*? Yes  No

Does this raw material have been made with nanotechnology? Yes  No

Does the product contain nanotechnology as defined by the French decree n°2012-232? Yes  No

'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

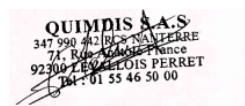
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# DISTRIBUTOR / MANUFACTURER CHANGE CONTROL

## STATEMENT OF COMMITMENT

Name of the product:...Chondroitin Sulphate Sodium Shark Type II.....  
*Nom du produit*

Commercial name.....Chondroitin Sulphate Sodium Shark Type II  
*Nom Commercial*

Distributor's name:.....QUIMDIS SAS

Manufacturer's name:...Yantai Ruikangda Biochemical Products Co.,LTD  
*Nom du Fabricant*

We will notify you of any changes which may have an impact on the quality of the product :

*Nous engageons à vous faire connaître tout changement susceptible d'interférer sur la qualité et la stabilité de la matière que nous vous fournissons :*

- Supplier, manufacturer or rawmaterialorigin change /*Changement de fournisseur, fabricant ou origine de matières premières /*
- Rawmaterialquality change/ *Changement de la qualité des matières premières*
- Manufacturingprocess change/ *Changement dans le procédé de fabrication*
- Manufacturing site change / *Changement du site de production*
- Equipment and/or criticpremise change / *Changement d'équipements et/ou de locaux critiques*
- Subcontractor set up / *Mise en place d'une sous-traitance*
- Subcontractor change / *Changement de sous-traitant*
- Method of analysis change / *Changement des techniques de contrôle*
- Release specifications change / *Changement des spécifications libératoires*
- Rawmaterialreference change / *Changement de référence de la matière première*
- Identification change / *Changement d'identification*
- Packaging unit and/or labelling and/or packaging change /*Changement de conditionnement et/ou d'étiquetage et/ou emballage*
- Appearance and/or content of certificate of analysis change /*Changement de la présentation et/ou contenu des différents certificats*
- Supplying stop / *Arrêt de commercialisation*

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