



## PRODUCT QUESTIONNAIRE FOR

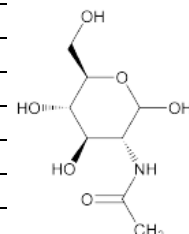
### N-acetyl D-glucosamine

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## PRODUCT QUESTIONNAIRE

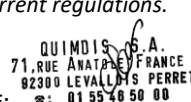
### N-acetyl D-glucosamine

SPECIFICATION DATA			
Nom chimique / <i>Chemical Name</i>	N-[(2R,3R,4R,5S,6R)-2,4,5-trihydroxy-6-(hydroxyméthyl)tétrahydro-2H-pyran-3-yl]acétamide		
Numéro CAS / <i>CAS number</i>	7512-17-6		
Numéro EINECS / <i>EINECS number</i>	231-368-2		
Masse Molaire / <i>Molecular mass</i>	221.2078 g/mol		
Formule brute / <i>Molecular Formula</i>	C <sub>8</sub> H <sub>15</sub> NO <sub>6</sub>		
Conformité / <i>Compliance</i>	USP		
Utilisation possible / <i>Use</i>			
Apparence / <i>Appearance</i>	Poudre	Powder	
Odeur et couleur / <i>Odor and Color</i>	Blanc	White	
Granulométrie / <i>Particle size</i>	≥ 90% # 100 mesh		
Solubilité / <i>Solubility</i>	Se dissout facilement dans l'eau, peu dans l'alcool	Easy to dissolve in water and a little bit dissolve in alcohol	
Densité / <i>Bulk density</i>	≥ 0.45g/mL		
Excipient / <i>Carrier</i>	Aucun	None	
	<b>Méthode d'analyses</b> <i>Analysis Method *</i>	<b>Fréquence d'analyse</b> <i>Frequency of analysis</i>	<b>Spécifications</b> <i>Specifications</i>
Teneur/ <i>Assay</i>	USP (HPLC) on dry basis	Chaque lot / Each batch	98.0 – 102.0%
Perte à la dessiccation/ <i>Loss on drying</i>	USP	Chaque lot / Each batch	≤ 0.5%
Cendres sulfuriques / <i>Sulphated ashes</i>	USP	Chaque lot / Each batch	≤ 0.1%
pH	USP	Chaque lot / Each batch	6.0 ~ 8.0
Pouvoir rotatoire / <i>Specific rotation</i>	USP	Chaque lot / Each batch	+39.0° ~ +43.0°
Point de fusion / <i>Melting point</i>	USP	Chaque lot / Each batch	196°C ~ 205°C
Identification / <i>Identification</i>	USP	Chaque lot / Each batch	Infrared absorption Optical rotation Retention time
Autres / <i>Other</i>			
<i>Absorb</i>	USP	Chaque lot / Each batch	<0.25a.u.
<i>Chloride</i>	USP	Chaque lot / Each batch	≤ 0.2%
<i>Iron</i>	USP	Chaque lot / Each batch	≤ 10 ppm
<i>Individual impurity</i>	USP	Periodically tested	≤ 0.5%
<i>Total impurities</i>	USP	Periodically tested	≤ 2.0%
<i>Limit of glucosamine</i>	USP	Periodically tested	≤ 1.0%
Métaux lourds totaux / <i>Total heavy metals</i>	USP	Chaque mois / Each month	≤ 10 ppm
Arsenic / <i>Arsenic</i>	USP	Chaque mois / Each month	≤ 1 ppm
Plomb / <i>Lead</i>	USP	Chaque mois / Each month	≤ 0.5 ppm
Cadmium / <i>Cadmium</i>	GB/T 5009.15	Chaque mois / Each month	≤ 0.5 ppm
Mercuré / <i>Mercury</i>	USP	Chaque mois / Each month	≤ 0.1 ppm
Flore totale / <i>Total Plate count (CFU/g)</i>	USP	Chaque mois / Each month	≤ 1 000
Levures et moisissures / <i>Yeast &amp; Mold</i>	USP	Chaque mois / Each month	≤ 100



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### N-acetyl D-glucosamine

<i>(CFU/g)</i>			
E. Coli	USP	Chaque mois / Each month	Absent/g
Salmonella	USP	Chaque mois / Each month	Absent/g
Staphylococcus aureus	USP	Chaque mois / Each month	Absent/10g
Enterobacteria & other gram neg	USP	Chaque mois / Each month	≤ 100 CFU/g
Conditions d'entreposage / <i>Handling and storage conditions (T°...)</i>		Stocker dans un endroit frais et sec <25°C / Keep in well-closed containers under room temperature <25°C	
Conditionnement / <i>Packaging</i>		Inner polyethylene bags – Fiber drum	
Durée de conservation / <i>Shelf life</i>		2 ans / 2 years	

### GENETICALLY MODIFIED ORGANISMS – GMO

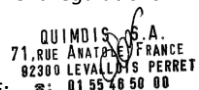
According to EU regulations EC/1829/2003 & EC/1830/2003

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.	➤ Contains ingredient(s) from Maize and/or Soya origin	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	➤ Contains no material which contains, consists of or is produced from authorized GMOs in proportion higher than 0,9 % . This presence is adventitious or technically unavoidable	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	➤ is GMO or contains or consists of GMOs	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	➤ is produced from GMOs or contains ingredients produced from GMOs	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
2.	➤ Contains ingredient(s) from other potential GMO-risk raw material(s) (rice, beet, cotton ...)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	If Yes, please specify :		
	<input type="radio"/> ingredient : <input type="radio"/> vegetable origin : <input type="radio"/> geographic origin :		
	➤ Contains no material which contains, consists of or is produced from evaluated GMOs in proportion higher than 0,5 % . This presence is adventitious or technically unavoidable	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
3.	For information about processing aids, ➤ 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)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, please specify :		

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### N-acetyl D-glucosamine

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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### 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 materials to produce the goods.

Please list all ingredients:

%	Ingredients/material composition	Country of origin
100	N-acetyl-D-glucosamine	China

### SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

According to Regulation (EU) N°1169/2011 as regards 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		x		x		x		x
Crustaceans and products thereof	Shells of crustaceans used are without meat (meat contains crustacean allergen).		x		x		x	
Eggs and products thereof		x		x		x		x
Fish and products thereof (2)		x		x		x		x
Peanuts and products thereof		x		x		x		x
Soybeans and products thereof (3)		x		x		x		x
Milk and products thereof (including lactose)(4)		x		x		x		x
Nuts (5) or products thereof		x		x		x		x
Celery and products thereof		x		x		x		x
Mustard and products thereof		x		x		x		x
Sesame seeds and product thereof		x		x		x		x
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as		x		x		x		x

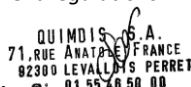
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 QUIMDIS S.A.  
 71, RUE ANATOLE FRANCE  
 92300 LEVALLOIS PERRET  
 ☎: 01 55 46 50 00

## PRODUCT QUESTIONNAIRE

### N-acetyl D-glucosamine

SO2							
Lupines and products thereof		x		x		x	x
Mollusc and product thereof		x		x		x	x
Latex		x		x		x	x

- (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;
- (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		x		x		x		x
Yeasts and hydrolysates, cardamom, vanilla, cinnamon, cocoa, leguminosae; benzoic acid, benzoate, parabens, phenylalanine, glutamate, coriander and product thereof.		x		x		x		x
Bovine, porcine, ovine, fish and by-products		x		x		x		x
Exotics fruits (kiwi, banana, mango, ...) and products thereof		x		x		x		x
Strawberry and others berries		x		x		x		x
Azo-colorants		x		x		x		x
Latex		x		x		x		x
Others: .....								

\*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:**

### NON IRRADIATION

According to UE Directive N°1999/2/CE

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

YES  NO

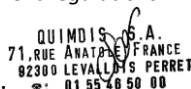
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#### NANOMATERIAL

According to Regulation (EU) N°1169/2011

- 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.

#### RESIDUAL SOLVENTS

According to UE Directive 2009/32 modified by (UE) 2010/59 and CPMP/ICH/283/95 Q3C

- Does the raw material contain any residual solvent?      YES  NO
- If yes, please give:
- percentage and name of each solvent used:
  - level of residual solvents:
- Is the product in compliance with the UE Directive 2009/32?      YES  NO
- Is the product in compliance with the ICH guidelines?      YES  NO

#### FOOD CERTIFICATE

Is the product conforming to commission regulation (EC) N° 178/2002 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?      YES  NO

Manufacturer's quality certificates:

- ISO 9001   
  ISO 14001   
  ISO 22000   
  HACCP   
  GMP   
  FAMI QS   
 Other:

Does the manufacturer make a risk analysis?      YES  NO  If yes, please specify:

CCP	Location on process	Limit	Corrective action
Crabs or shrimps' inspection	Raw material	Purchases from the qualified suppliers	Refuse to accept unqualified raw materials
Metal detector		Fe<3.0mm SUS<3.5mm Non-Fe<30.mm	1- If the metal detector is ineffective, first, we will isolate the products in this period. Then adjust metal detector and test again. 2-We conform again about the products tested by the metal detector, and find out the metal source to use it in other ways.

- Was the product used in the European food industry before May 1997?      YES  NO
- If no, could you provide an authorisation (according to Regulation 258/97/EC)?      YES  NO
- Is the raw material Food Grade?      YES  NO

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Can the product be used in babyfood (Directive 2006/141/CE)? YES  NO  No data

Does the product comply with the UE Regulation N° 231/2012 about additives? YES  NO  NOT CONCERNED

Is the product complying with a Pharmacopeia monography? YES  NO  NOT CONCERNED

Is the product complying with the UE Regulation N°1334/2008 about flavourings? YES  NO  NOT CONCERNED

Is this product (*if yes, please attach certificates*)

- Kosher certified YES  NO   
- Halal certified YES  NO

Is this product suitable for:

Vegetarians (free of all animals and fish products and derivatives thereof, except for honey, egg, milk and milk products)? YES  NO

Vegans (no product issued from animals, including honey, egg, milk, and milk products)? YES  NO

Are stability studies available? YES  NO

### ORIGIN

Is a manufacturing process available? : YES  NO

Country of origin of the product: China

#### Source of the product:

**Animal** origin, please specify:

Bovine

Porcine

Ovine

Others  Please specify: Crustaceans shell

⇒ If yes, could you confirm that the product is BSE/TSE free (according regulation (CE) 220/2009) YES  NO

⇒ If yes, does the manufacturing plant comply with UE regulation 853/2004 (laying down specific hygiene rules for food of animal origin)? YES  NO

⇒ Is the manufacturer registered to the European Commission? YES  NO

⇒ Is the health certificate available for a food use? YES  NO

**Mineral** origin, please specify species:

**Synthetic**, please specify species:

Manufactured by **biotechnological processing** (micro-organisms, enzymes...)

Medium's origin:

Processing aid type/species:

**Vegetable** origin, please specify:

Botanical name:

Is there risk of falsification?

Geographical origin of the raw materials (country and region if possible):

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 Cultivated  / Wild 

 Harvest method: manual  / mechanical 

Harvest period:

Harvest stage (age of the plant):

 Is the technical data sheet of the plant raw material available? YES  NO .

Could you precise the treatments used on the plant harvesting?

Irrigation	Fertilizers	Herbicides	Insecticides	Fungicides	Other

Could you precise the treatments / transformations after harvest?

<input type="checkbox"/> Decontaminated plant (treatment used: _____ )	<input type="checkbox"/> Undecontaminated plant
<input type="checkbox"/> Washing	<input type="checkbox"/> Drying
<input type="checkbox"/> Natural drying: _____	<input type="checkbox"/> Artificial drying, specify: _____
Other: _____	

Part of the plant:

Plant-native extract ratio:

Plant-final extract ratio:

Drug extract ratio:

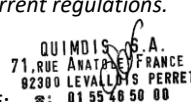
 Are there any agents responsible for adverse effects? YES  NO 

If yes, please precise:

Please precise the methods of eliminating risk constituents:

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#### CONTAMINANTS

Is the product conforming to UE regulations No 1881/2006 and No 629/2008 setting maximum levels for certain contaminants in foodstuffs, as amended? YES  NO

Contaminants	Tested?
Pesticides (please precise)?	Not tested
Dioxins and dioxin like PCBS?	Not tested
PAH's (polycyclic aromatic hydrocarbons)?	Not tested
PCB's (polychlorobifenyls)?	Not tested
Benzopyrens?	Not tested
Melamine?	Not tested
Mycotoxins and 3-MCPD?	Not tested
Doping like substances? <a href="http://list.wada-ama.org/">http://list.wada-ama.org/</a>	Not tested

Is the product conforming to UE regulations No 396/2005 about maximum residue levels of pesticides? YES  NO

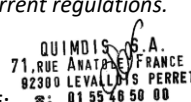
#### FOREIGN BODIES

Which material do you use in order to fight against the foreign bodies?

	Presence?	Test frequency	Where is it located on the process line?
<b>Magnet</b>	Magnet power: Gauss		
<b>Metal detector</b>	Precise the lowest detection limit:		
	<b>Iron</b> <b>Non-ferrous</b> <b>Stainless</b>		
<b>Sieve</b>	Grid size: 100 mesh		
<b>Filter</b>			
<b>X-ray detection</b>			
<b>Other (please specify)</b>			

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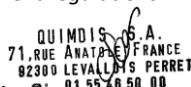
### N-acetyl D-glucosamine

### NUTRITIONAL VALUES

Items	Values
Energy (kJ/kcal)	
Total Fat (g)	
Saturate Fat (g)	
Mono-unsaturated Fat (g)	
Polyunsaturated Fat (g)	
Total Carbohydrate (g)	
Sugars (g)	
Polyols (g)	
Starch (g)	
Fibre (g)	
Protein (g)	
Salt (g)	
<b>Vitamins:</b>	
Vitamin A (µg)	
Vitamin D (µg)	
Vitamin E (mg)	
Vitamin K (µg)	
Vitamin C (mg)	
Thiamin (mg)	
Riboflavin (mg)	
Niacin (mg)	
Vitamin B6 (mg)	
Folic acid (µg)	
Vitamin B12 (µg)	
<b>Minerals:</b>	
Pantothenic acid (mg)	
Potassium(mg)	
Chloride (mg)	
Calcium (mg)	
Phosphorus (mg)	
Magnesium (mg)	
Iron (mg)	
Zinc (mg)	
Copper (mg)	
Manganese ( mg)	
Fluoride (mg)	
Selenium (µg)	
Chromium (µg)	
Molybdenum (µg)	
Iodine (µg)	

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#### TRACEABILITY

Batch size	1000kg
Batch definition	Serial number + YYYYMMDD
Signification of the batch number by an example	Ex: 0420140907
Marking method (labelling...)	Label

#### PACKAGING

	YES	NO
Is the packaging material approved as food grade according to regulations 1935/2004, 10/2011 and 1282/2011?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Do you guarantee the packaging traceability according to regulation 1935/2004 (art 17)?	<input type="checkbox"/>	<input type="checkbox"/>
Can you guarantee that the product and its packaging supplied to QUIMDIS do not contain Phtalates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Can you guarantee that the product and its packaging supplied to QUIMDIS do not contain ITX? (A packaging contaminant: Isopropylthioxanthone (ITX) found in dairy products)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Can you guarantee that the product and its packaging supplied to QUIMDIS do not contain Bisphenol A (BPA)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Do you add desiccant bags during packaging process? If so, where do you mention it: .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Can you provide migration test in order to guarantee packaging safety?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

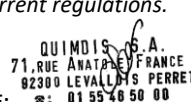
#### WASTE DISPOSAL

What is your waste disposal method? NA

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

*These data are based on our present knowledge and on the provided information by the manufacturer. The customer is responsible for the use of the product and has to refer to the current regulations.*

DATE: 20/10/2017  
NAME: JULIE SOULIÉ

  
 STAMP AND SIGNATURE: \_\_\_\_\_  
 FONCTION: REGULATORY AFFAIRS MANAGER

## PRODUCT QUESTIONNAIRE

### N-acetyl D-glucosamine

#### DISTRIBUTOR/MANUFACTURER CHANGE CONTROL STATEMENT OF COMMITMENT

Name of the product: N-acetyl D-glucosamine

Commercial name: N-acetyl D-glucosamine

Distributor's name: Quimdis

Manufacturer's name: Confidential

Manufacturing site's address: Confidential

We will notify you of any changes which may have an impact on the quality of the product, when the supplier/manufacturer informs us:

- Supplier, manufacturer or raw material origin change /
- Raw material quality change
- Manufacturing process change
- Manufacturing site change
- Equipment and/or critic premise change
- Subcontractor set up
- Subcontractor change
- Method of analysis change
- Release specifications change
- Raw material reference change
- Identification change
- Packaging unit and/or labelling and/or packaging change
- Appearance and/or content of certificate of analysis change /
- Supplying stop

*These data are based on our present knowledge and on the provided information by the manufacturer. The customer is responsible for the use of the product and has to refer to the current regulations.*

DATE: 20/10/2017

NAME: JULIE SOULIÉ

STAMP AND SIGNATURE:

FONCTION: REGULATORY AFFAIRS MANAGER

QUIMDIS S.A.  
71, RUE ANATOLE FRANCE  
92300 LEVALLOIS PERRET  
☎: 01 55 46 50 00