

## MANUFACTURING STATEMENT

MANUFACTURER'S CERTIFICATE, CERTIFICATE OF ALIMENTARITY,  
HEALTH CERTIFICATE, SANITARY CERTIFICATE, QUALITY CERTIFICATE

We hereby certify that the above mentioned product: Is legally manufactured for Nova Panamedical, S.A. / ACTIRENT, S.A. nova **+QSO®** according to production recommendations and sanitary measures and complies with the purity specifications of the Food Chemical Codex (FCC). Does not contain any harmful ingredients or additives injurious for the health of the consumer and is fit for food applications. Local legislation should be consulted before use of product.

Is free for sale. The manufacturing premises are operated according to good manufacturing practices as described in the FDA 21CFR110. Procedures for the prevention of cross contamination of products are installed together with the state-of-the art quality control measures. This document is drawn up at the request of the interested party in order to be submitted to the appropriate authorities.

### Statement on GMO status for **+QSO®**

Nova Panamedical, S.A. / ACTIRENT, S.A. nova **+QSO®** is aware of the existence of legislation<sup>1</sup> on Genetically Modified (GM) Food in various countries and wants to be transparent in the information supplied to our customers about our products.

Regarding the product with the above mentioned brand name we can inform you that: This product is not a GMO and does not contain a GMO or recombinant DNA material; The micro-organism used in the process and all formulating agents (such as carriers or diluents) are of non-GM origin.

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<sup>1</sup> Most relevant: Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed.

## Stability statement +QSO®

Regarding the products with the above mentioned brand name we can inform you that:

+QSO® has a recommended storage temperature of 4-8°C whatever the presentation is. When stored under these conditions and during the shelf life period, as defined on the Product Specification Sheet of the product, the +QSO® intrinsic formulation inhibits the growth of the majority of microorganisms. The expected enzymatic activity loss during the shelf life period and under the recommended storage conditions is recorded on each product specification sheet. When the product is stored at conditions deviating from the recommended storage conditions, the expected enzymatic activity loss will be higher than the one recorded on each product specification sheet.

As indication, the loss of activity at different temperatures is estimated to be:

At 20°C the enzymatic activity loss is expected to be less than 0.1% per day.

At 30°C the enzymatic activity loss is expected to be less than 0.3% per day.

In our experience, the freezing of the product (for example at -25°C) has no negative effect on the Enzymatic activity of the product.

*Although diligent care has been used to ensure that the information provided herein is accurate, nothing contained herein can be construed to imply any representation or warranty for which we assume legal responsibility, including without limitation any warranties as to the accuracy, currency or completeness of this information or of non-infringement of third party intellectual property rights. The content of this document is subject to change without further notice. Please contact us for the latest version of this document or for further information. Since the user's product formulations, specific use applications and conditions of use are beyond our control, we make no warranty or representation regarding the results, which may be obtained by the user. It shall be the responsibility of the user to determine the suitability of our products for the user's specific purposes and the legal status for the user's intended use of our products.*

## SAFETY DATA SHEET **+QSO®**

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Product name: **+QSO® 100**

Internal code: **740117140001 0**

Synonyms: Granulated enzyme (enzyme protein) in tablet form; rennet tablet

Chemical formula: Not applicable.

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: **This product is an enzymatic preparation used in the food industry.**

#### 1.3 Details of the supplier of the safety data sheet:

Supplier:

**Nova Panamedical, S.A. / ACTIRENT, S.A. nova +QSO®**

**Avenida Petapa 52-80 zona 12 Ofibodega Petapa #40**

**Guatemala, Guatemala 01012**

Telephone no.: **+502 22958680**

e-mail address: [novamasqueso@actirent.net](mailto:novamasqueso@actirent.net)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Product definition: **Mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Resp. Sens. 1, H334

See Section 16 for the full text of the R-phrases declared above.

Classification according to Directive 1999/45/EC [DPD]

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

**Classification: R42**

See Section 16 for the full text of the R-phrases declared above

## 2.2 Label elements

Hazard pictogram:

Signal word: Danger

Hazard statements: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled



## Precautionary statements

Prevention: In case of inadequate ventilation wear respiratory protection. Avoid breathing dust.

Response: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician.

Storage: Not applicable.

Disposal: Not applicable.

Hazardous ingredients: endopeptidase

## 2.3 Other hazards

Hazard statements: Not available

## SECTION 3: Composition/information on ingredients

Powder preparation of microbial proteases extracted from *Rhizomucor miehei* containing microcrystalline cellulose (cspt); magnesium stearate, vegetal grade USP; silicate dioxide.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

IUB number: endopeptidase: 3.4.2x.xx. There is no general IUB number for proteinases. But all these enzymes fall under the 3.4.2x.xx category.

Occupational exposure limits, if available, are listed in Section 8.

## SECTION 4: First aid measures

### Wash out mouth with water

Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

#### Skin contact

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

### 4.1 Description of first aid measures

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In the event of any complaints or symptoms, avoid further exposure.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

### 4.2 Most important symptoms and effects, both acute and delayed

#### Potential acute health effects

Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion: No known significant effects or critical hazards.

Skin contact: No known significant effects or critical hazards.

Eye contact: No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

Skin contact: No specific data.

Ingestion: No specific data.

Inhalation: Adverse symptoms may include the following: wheezing and breathing difficulties; asthma

Eye contact: No specific data.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

##### Small fire

Suitable: Use dry chemical or CO<sub>2</sub>.

Not suitable: None known.

##### Large fire

Suitable: Use extinguishing media suitable for surrounding materials.

Not suitable: None known.

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

Hazards from the substance or mixture: Fine dust clouds may form explosive mixtures with air.

Hazardous combustion products: In case of fire, may produce toxic and/or corrosive decomposition products.

#### 5.3 Advice for firefighters

Special protective actions for fire fighters: Firewater contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Special protective equipment for fire fighters: Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for firefighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions:

Use suitable protective equipment (section 8). Avoid direct contact with liquid. After a leak avoid inhaling the fumes or the dry product powder. Avoid high-pressure washing and squirts (Aerosol formation). Keep down leaking liquid. Pick up the leaked liquid with mechanical tools. Wash the remaining product with plenty of water. Air out the room. Remove and wash contaminated clothes.

## 6.2 Environmental precautions:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

## 6.3 Methods and materials for containment and cleaning up

Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, watercourses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Note: see section 1 for emergency contact information and section 13 for waste disposal.

Large spill:

Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Small spill:

## 6.4 Reference to other sections:

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

## SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 7.1 Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. Persons with a history of asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous.

Do not reuse container.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

## 7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 4 to 8°C (39.2 to 46.4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Keep in a cool and dry place. The product must be stored in the original, sealed containers

Packaging materials Suitable: Polyethylene containers.

## 7.3 Specific end use(s)

Recommendations: Not available

Industrial sector specific solutions: Not available.

## SECTION 8: Exposure controls/personal protection

Exposure limit: Non-set

Breathing apparatus protection: Wear a suitable protection in case of aerosol formation

Hand protection: Practical experience shown protection gloves supply a sufficient protection.

Eyes protection: Protection glasses or face mask

Skin protection: Protective clothes

Environment rules: Do not throw out in the environment

## SECTION 9: Physical and chemical properties

Physical state: Solid. [Granular]

Color: White to brown. (Product color may vary from batch to batch)

Solubility in water: Easily soluble in cold water.

Odor: Slight fermentation odor.

pH: Not available.



## SECTION 10: Stability and reactivity

- 10.1 Reactivity: No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability: The product is stable.
- 10.3 Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid No specific data.
- 10.5 Incompatible materials: No specific data.
- 10.6 Hazardous decomposition products: No specific data.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### **Acute toxicity**

Product/ingredient name: endopeptidase

Result: LD50 Oral

Species: Rat

Dose: >5000 mg/kg

Exposure: -

Conclusion/Summary: Not available.

#### **Irritation/Corrosion** Conclusion/Summary

Skin: Not available.

Eyes: Not available.

Respiratory: Not available.

#### **Sensitization** Conclusion/Summary

Skin: Not available.

Respiratory: Not available.

Conclusion/Summary **Carcinogenicity**: Not available.

Conclusion/Summary **Teratogenicity**: Not available.

Conclusion/Summary **Reproductive toxicity**: Not available.

Specific target organ toxicity (single exposure): Not available.

#### Potential acute health effects

**Inhalation**: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Ingestion**: No known significant effects or critical hazards.

**Skin contact**: No known significant effects or critical hazards.

**Eye contact**: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Skin contact: No specific data.

Ingestion: No specific data.

Inhalation Adverse symptoms may include the following: Wheezing and breathing difficulties; asthma

Eye contact: No specific data.

General: Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity: No known significant effects or critical hazards.

Mutagenicity: No known significant effects or critical hazards.

Teratogenicity: No known significant effects or critical hazards.

Developmental effects: No known significant effects or critical hazards.

Fertility effects: No known significant effects or critical hazards.

Mutagenicity

## SECTION 12: Ecological information

### 12.1 Toxicity

Conclusion/Summary: Not available

### 12.2 Persistence and degradability

Conclusion/Summary: Not available

### 12.3 Mobility in soil

Soil/water partition coefficient (KOC): Not available.

Mobility: Not available.

### 12.4 Results of PBT and vPvBs assessment

PBT: Not applicable.

vPvBs: Not applicable.

12.6 Other adverse effects: No known significant effects or critical hazards.

Remarks: The preparation is believed not to be dangerous to the environment with respect to mobility, persistence and degradability, bio-accumulative potential, aquatic toxicity and other data relating to eco-toxicity.

## SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 13.1 Waste treatment methods

#### Product

Methods of disposal:

The generation of waste should be avoided or minimized wherever possible. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Waste packaging should be recycled.

Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

#### Packaging

Methods of disposal: The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

#### Special precautions:

This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

#### SECTION 14: Transport information

No special precaution has to be used for transport of this product

#### SECTION 15: Regulatory information

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorization

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

##### 15.2 Chemical Safety

Assessment: Not applicable.

#### SECTION 16: Other information

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

##### Full text of abbreviated H statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

##### Full text of classifications [CLP/GHS]:

Eye Irrit. 2, H319 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2

Resp. Sens. 1, H334 RESPIRATORY SENSITIZATION - Category 1

Skin Irrit. 2, H315 SKIN CORROSION/IRRITATION - Category 2

STOT SE 3, H335 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)

##### Full text of abbreviated R phrases:

R36/37/38- Irritating to eyes, respiratory system and skin.

R42- May cause sensitization by inhalation.

Full text of classifications [DSD/DPD]: Xi - Irritant

Abbreviations and acronyms:

ATE = Acute Toxicity Estimate

CLP = Classification, Labeling and Packaging Regulation [Regulation (EC) No. 1272/2008]

DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement

PNEC = Predicted No Effect Concentration

RRN = REACH Registration Number

Sources of key data: Literature data and/or investigation reports are available through the manufacturer.

Internal code: **740117140001 0**

Training advice: Handling of this substance or preparation is restricted to skilled personnel only. Safe handling of enzymes is detailed in 'AMFEP Guide to the Safe handling of Enzymes' ([www.amfep.org](http://www.amfep.org)).

**Notice to reader**

The information contained in the Safety Data Sheet is based on our data available on the date of publication. The information is intended to aid the user in controlling the handling risks; it is not to be construed as a warranty or specification of the product quality. The information may not be or may not altogether be applicable to combinations of the product with other substances or to particular applications.

The user is responsible for ensuring that appropriate precautions are taken and for satisfying them that the data are suitable and sufficient for the product's intended purpose. In case of any unclarity we advise consulting the supplier or an expert.

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