

## Description

**Origin:** Tryptone V is a pancreatic hydrolysate of casein of Oceanic (NZ or AUS) origin produced according to proprietary process developed by SOLABIA.

**Context :** this peptone is produced from alimentary or food-grade casein, with enzymes of porcine origin. It is therefore compliant with the Note for Guidance EMEA/410/01 – Rev. 3 of March 2011 (2011/C 73/01 of the Official Journal of the European Union) but can not be considered allergen-free due to the presence of milk proteins (Annex IIIa of the EU directive 2003/89/EC, updated with 2006/142/EC).

**Application :** developed primarily as a product destined for bacterial vaccine production, Tryptone V is particularly well adapted for the culture of *Clostridium tetani* in the production of tetanus toxin. In light of its similarity to standard Tryptone, it will also naturally favor the growth of a wide variety of microorganisms, including lactic acid bacteria, yeasts and molds.



## Physical properties

**Appearance :** white cream powder  
**Stability (2% in solution) :** stable  
**Solubility in water at 2% :** total

## Microbiological controls

Total aerobic mesophilic flora ≤ 5000 cfu/g

## Chemical analysis

Total Nitrogen (NT) : 12.6%  
 $\alpha$ -amino Nitrogen (N $\alpha$ ) : 3.8%  
 N $\alpha$  / NT : 0.30  
 Total carbohydrates : 0.5%  
 pH (2% solution) : 7.0  
 Sulfuric ash : 13.4%  
 Chlorides (as NaCl) : 0.3%  
 Loss on drying ≤ 6.0%

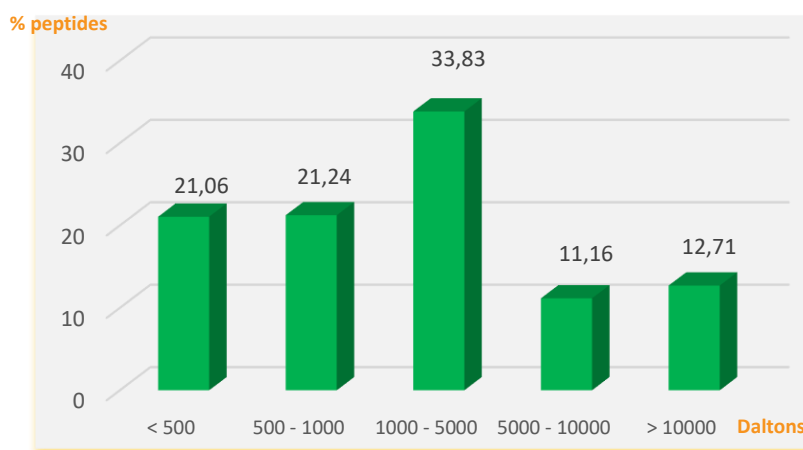
## Chemical characteristics

Nitrites : absent  
 Non-digested proteins : negative  
 Proteoses : positive  
 Tryptophan : positive

## Amino acid (AA) distribution (mg/g)

	Total AA		Total AA
Aspartic acid	69.0	Methionine	20.0
Threonine	46.0	Isoleucine	37.0
Serine	51.0	Leucine	78.0
Glutamic acid	154.0	Tyrosine	12.0
Proline	93.0	Phenylalanine	42.0
Glycine	15.0	Histidine	29.0
Alanine	24.0	Lysine	57.0
Cysteine	-	Arginine	26.0
Valine	44.0	Tryptophan	-

## Molecular weight distribution (Daltons)



## Storage

Keep in original packaging when not in use, in a dry area ideally between 10 and 35°C. Avoid direct sunlight.  
 Hygroscopic product.  
 Expiry date : 5 years from date of manufacture.

## Standard packaging

25 kg carton ; other formats inquire.  
 Delivered with Certificate of Analysis, Certificate of Origin.

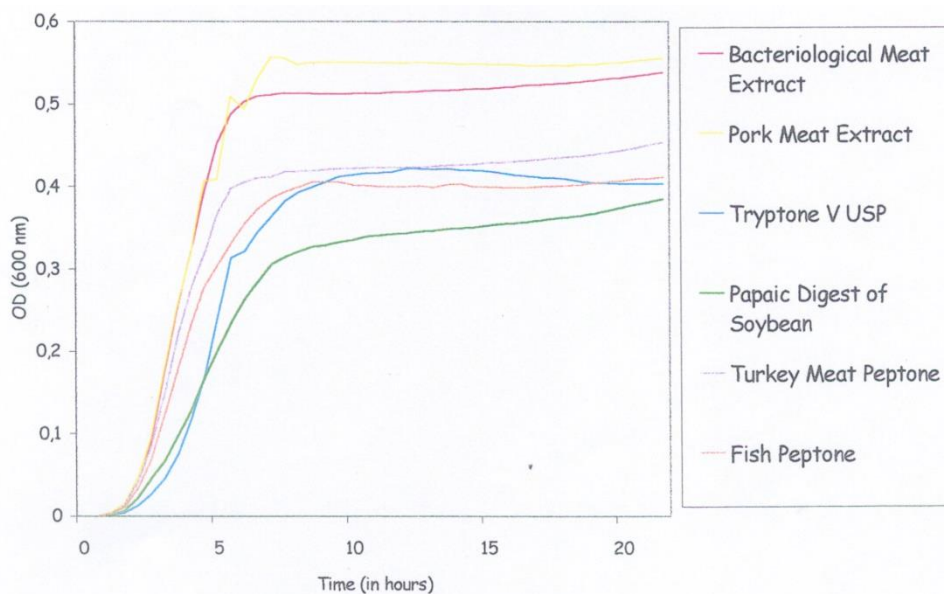
## Sanitary Attestation

Given the origins and processing of this product, it remains outside of the scope of European Pharmacopoeia directives 1999/82/EC, 1999/104/EC, 2000/418/EC & 2011/C 73/01, as well as the Note for Guidance EMEA/410/01 Rev. 3. The casein used as a starting material is sourced from animals in good health and the milk declared fit for human consumption. Geographical origin is New Zealand.

To the best of our knowledge it is GMO free (according to the European Directive 2001/18/CE defining legislation for labeling ; absence = less than 0.9%).

## OBSERVED MICROBIAL GROWTH POTENTIAL :

*Escherichia coli* ATCC® 23716 – K12



Inoculum  $10^6$  cfu / mL  
Growth medium: modified Luria broth  
37°C, aerobic incubation.

This peptone demonstrates excellent growth of a wide variety of microorganisms, particularly toxin producing and pharmaceutically relevant strains. Performance characteristics lend themselves to varied applications as an all-purpose substrate as well. Results may differ depending on individual laboratory conditions and for other genera, species and strains.



### Certifications profile :

Produced under **ISO 9001 v 2015** certification



Manufacturing site and quality system  
open to audits by qualified customers\*.

CoA available online : use product code **A144300** + lot number  
<https://www.solabia.com/coa>

Allergen considerations : **YES** (casein)      GMO issues : **NO**

**Kosher certification : No** 

Orthodox Union ; New York, NY USA.  
Rabbi Menachem Adler, Administrator

**Halal certification : No**



HFFIA ; The Hague, Netherlands.  
Inquire with Solabia for more information

V. 02/2021

The information presented in this document is submitted in good faith based on internal testing performed at Solabia S.A.S. and represents the best of our knowledge at the present time. It is provided as a guide and no warranty, implied or otherwise is associated with this data, nor is any liability assumed for patent infringement. All data represents typical analyses not to be taken for exact specifications. \*Audits may involve fees dependent on volume of business.

End-users are directed to perform proprietary tests to determine suitability and performance for specific applications. The information and results contained in this technical data sheet are susceptible to modification at any time, without warning.

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