



Product Specification	
Product name: L-5-Methyltetrahydrofolate Calcium	AC code: AC30045b

1. Technical Data Sheet			
Chemical Name		CALCIUML-5-METHYLTETRAHYDROFOLATE	
CAS number		151533-22-1	
Molecular weight		497.5	
Molecular Formula		C20H23CaN7O6	
Compliance (Food / Pharmacopoeia / FCC / Feed)		Food Grade / US Pharmacopeia	
Source (animal, plant, mineral, petrochemical)		Chemical	
Brief introduction:			
This product is the calcium salt of L-5-methyltetrahydrofolate, belonging to folic acid vitamins (vitamin B9, folic acid), which is a coenzyme form of folic acid. L-5-methyltetrahydrofolate calcium (5-mthf) is a naturally produced salt forming methyl derivative form of folic acid. 5-mthf is also called L-methylfolic acid. It is the most biologically active and functional form of folic acid and is easier to absorb than ordinary folic acid. Our product is crystal 1 type.			
Item	Standard	Analysis Method	Test Frequency
Sensory			
Appearance	White to light yellowish crystalline powder		
Typical Analysis			
Identification	The retention time of the principle peak should conform with standard		
Assay (HPLC)	95.0% ~ 102.0%	USP43	Every Batch
Calcium	7.0% ~ 8.5%	USP43	Every Batch
Enantiomeric Impurity (D-5-methyltetrahydrofolate)	≤1.0%	USP43	Every Batch
Total Related Compounds	≤2.5%	USP43	Every Batch
4-Aminobenzoylglutamic Acid	≤0.5%	USP43	Every Batch
4a-Hydroxy-5-Methyltetrahydrofolic Acid	≤1.0%	USP43	Every Batch
(6R and 6S) – Mefox	≤1.0%	USP43	Every Batch
Tetrahydrofolic Acid	≤0.5%	USP43	Every Batch
7,8-Dihydrofolic Acid	≤0.5%	USP43	Every Batch
Folic Acid	≤0.5%	USP43	Every Batch
5,10-Methylenetetrahydrofolic Acid	≤0.5%	USP43	Every Batch
5-Methyltetrahydropteroic Acid	≤0.5%	USP43	Every Batch
Dimethyltetrahydrofolic Acid	≤0.15%	USP43	Every Batch
2-Propanol	≤0.5%	USP43	Every Batch
Ethanol	≤0.5%	USP43	Every Batch



Physical Analysis			
Water Content	6.0% ~ 17.0%	USP43	Every Batch
Chemical Analysis			
Total Heavy Metals (ppm)	≤10 ppm	USP 43	Every Batch
Boron (ppm)	≤50 ppm	USP 43	Every Batch
Chloride	NMT 0.5%	USP 43	Every Batch
Platinum (ppm)	NMT 10 ppm	USP 43	Every Batch
Arsenic mg/kg	≤1.0 ppm	USP 43	Every Batch
Lead mg/kg	≤1.0 ppm	USP 43	Every Batch
Total Mercury mg/kg	≤0.1 ppm	USP 43	Every Batch
Cadmium mg/kg	≤0.5 ppm	USP 43	Every Batch
Microorganism			
Total Plate Count CFU/g	≤1,000	USP 43	Every Batch
Yeasts & Mold	<100	USP 43	Every Batch
E.Coli	Negative	USP 43	Every Batch
Salmonella	Negative	USP 43	Every Batch
S.Aureus	Negative	USP 43	Every Batch
Pseudomonas Aeruginosa	Negative	USP 43	Every Batch
Candida Albicans	Negative	USP 43	Every Batch
Clostridia	Negative	USP 43	Every Batch
Package	1kg per bag		
Shelf life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is opened.		
Storage	Store in unopened original package under clean and dry condition, away		

2. GMO declaration	YES	NO
The product does not contain or consist of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced by means of GM microorganism including precursor substances, e.g. with GMOs or Genetically Modified microorganisms processing aids(bacteria, yeast,..)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the product contain any ingredients from animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, are genetically modified crops contained in the feed for the animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available	<input checked="" type="checkbox"/>	

### 3. Allergen declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	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		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO <sub>2</sub>		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

- (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;

### 4. NON IRRADIATION

(According to EU directive 1999/2/EC & 1999/3/EC)

This product has not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
None of the raw materials we used for this product have been treated	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO



with ionising radiation.		
We confirm above Non-Irradiation statement is available		<input checked="" type="checkbox"/>

5.NANOMATERIAL		
(according to EU Regulation (EU) No. 1169/2011)		
This product does not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
We confirm above Non-Nanomaterial statement is available	<input checked="" type="checkbox"/>	

6. Residual solvents	
(according to UE Directive 2009/32 modified by(UE)2010/59; EP5.4;USP476;ICH Q3C(R7))	
For this product following solvents are used during production process: Solvent A:                      max residual level:	<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used
We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> EP5.4 <input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> ICH Q3C(R7) <input checked="" type="checkbox"/> Directive 2010/59/EU <input checked="" type="checkbox"/> NA
We confirm Solvent residual statement is available	<input checked="" type="checkbox"/>

7.Pesticide residual	
(according to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm pesticide residual of this product complies with:	<input checked="" type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide residual statement available	<input checked="" type="checkbox"/>

8.BSE/TSE information	
(according to EU legislation 999/2001; EP general chapter 5.2.8)	
<p>Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as "ESE-relevant animal species"</p> <p>Pigs and birds are not naturally susceptible to infection via the oral route; therefore, they are not TSE-relevant animal species. Dogs, rabbits and fish are not TSE-relevant animal species."</p>	
the product contains no ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	<input type="checkbox"/> NA
In the manufacturing of this product, there is no any raw or source material and /or reagent used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 & <input type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

### 9. Contaminants information

(according to UE regulation NO.1881/2006 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)

<ul style="list-style-type: none"> <li>● Aflatoxin B1 &lt;5ppb</li> <li>● Aflatoxins B1 + B2 + G1 + G2 &lt;10ppb</li> <li>● Ochratoxin A &lt;15ppb</li> </ul>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
● Melamine	<input checked="" type="checkbox"/> YES
For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> : <ul style="list-style-type: none"> <li>● Maximum level of 10 µg/kg of benzo(a)pyrene</li> <li>● 50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements</li> </ul>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	<input checked="" type="checkbox"/> YES

## Flow Chart

