

Product Technical Data Sheet

Product name: Cobamamide	AC code: AC01264b
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1. Technical Data Sheet		
Product Name	Cobamamide	
Molecular formula	C72H99CoN18O17P	
Molecular weight	1578.6	
CAS number	13870-90-1	
Item	Standard	Analysis Method
Typical Analysis		
Identification	A (IR): The infrared spectrum of the sample should be consistent with the reference.	IR
Identification	B (UV): The absorption spectrum exhibits maxima at 260, 288, 376 and 524 nm: A260/A524: 4.1-4.5 A376/A260:0.29-0.33	Titration
Identification	C (HPLC): The retention time of the major peak of the sample , solution corresponds to that of the standard solution.	HPLC
Related Substances	Total impurities:≤5.0%	USP
Related Substances	Hydroxocobalamin: ≤1.0%	USP
Related Substances	Cyanocobalamin: ≤2.0%	USP
Water	≤12%	USP
Assay on dried	96.0%–102.0%	USP
Heavy metals		
Total Heavy Metals	≤10ppm	USP
Lead (Pb)	≤2ppm	USP
Arsenic (As)	≤1.5ppm	USP
Cadmium (Cd)	≤1ppm	USP
Mercury (Hg)	≤0.5ppm	USP
Microorganism		
Total Plate Count	≤10,000 cfu/g	USP
Yeast & Mould	≤100 cfu/g	USP
E.Coli	Negative	USP
Storage & Shelf Life		
Package	1kg/tin 5kg/drum	
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 a tightly closed container in a dry place, protected from light
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2.Origin & Ingredient

Country of origin of the product: China

Origin statement: available ☒

This product is a pure material ☒		This product is a compound material ☐	
Animal origin	☐ bovine	Specific Source: /	
	☐ porcine	Specific Source: /	
	☐ avian	Specific Source: /	
	☐ Others:	Specific Source: /	
Synthetic	☐	Starting material:	origin: China
Biotechnological processing	☐ Catalysis By Enzymes	Name Of Enzyme: / Sources Of Enzymes: /	
	☒ Fermentation	Source: Propionibacterium	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild Or Cultivated:	/	
	Country Of Origin:	/	
	Solvent Used:	/	

3.Nutrition Data

Nutritional Composition	☒ Per 100g ☐ Per Serving
☒ Energy(Kj) ☐ Energy(Kcal)	0
Protein(G)	0
Fat(G)	0
Carbohydrates(G)	0
Sodium	0
Cobamamide	98-102%
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested On A Yearly Basis	

4. GMO declaration	Conforms	Not Conforms
The product does not contain or consist of GMO	☒	☐
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)	☒	☐
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,...)	☒	☐
This product is not produced with the help of enzymes, which were obtained from GMOs	☒	☐
Does the product contain any ingredients from animal?	☒	☐

If yes, are genetically modified crops contained in the feed for the animal?	☒	☐
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available	☒	

5. 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 ₂		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;

6. NON IRRADIATION

(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	☒ Conforms	☐ Not Conforms
None of the raw materials we used for this product have been treated with ionising radiation.	☒ Conforms	☐ Not Conforms
We confirm above Non-Irradiation statement is available	☒	

7.NANOMATERIAL		
(according to EU Regulation (EU) No. 1169/2011)		
This product does not contain any nanomaterials as defined in EU food legislation	☒ Conforms	☐ Not Conforms
This product has not been made with nanotechnology	☒ Conforms	☐ Not Conforms
We confirm above Non-Nanomaterial statement is available	☒	

8. 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: Ethanol Max residual level: Ethanol < 0.5%	☒ solvent used ☐ solvent not used	
We confirm solvent residual of this product complies with:	☒ EP5.4 ☒ USP <476> ☒ ICH Q3C(R7) ☒ Directive 2010/59/EU ☐ NA	
We confirm Solvent residual statement is available	☒	

9.Pesticide residual		
(according to EC 396/2005; EP07; USP <561>)		
This product is of vegetable origin	☒ Conforms	☐ Not Conforms
We confirm pesticide residual of this product complies with:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP<561> ☐ N/A	
Pesticide residual statement available	☒	

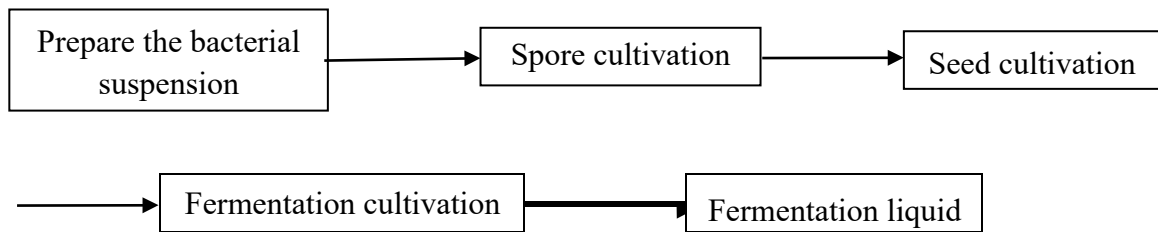
10.BSE/TSE information		
(according to EU legislation 999/2001; EP general chapter 5.2.8)		
Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as “ESE-relevant animal species Pigs ad 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 TES-relevant animal species.”		
the product contains no ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine for Transmitting	☒ Conforms	☐ Not Conforms

Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	☐ 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	☒ Conforms ☐ Not Conforms
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)	☒ Conforms ☐ Not Conforms
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin	☒ Conforms ☐ Not Conforms
We confirm this product complies with:	☒ EU legislation 999/2001 & ☒ EP general chapter 5.2.8
We confirm BSE/TSE statement is available	☒ Conforms

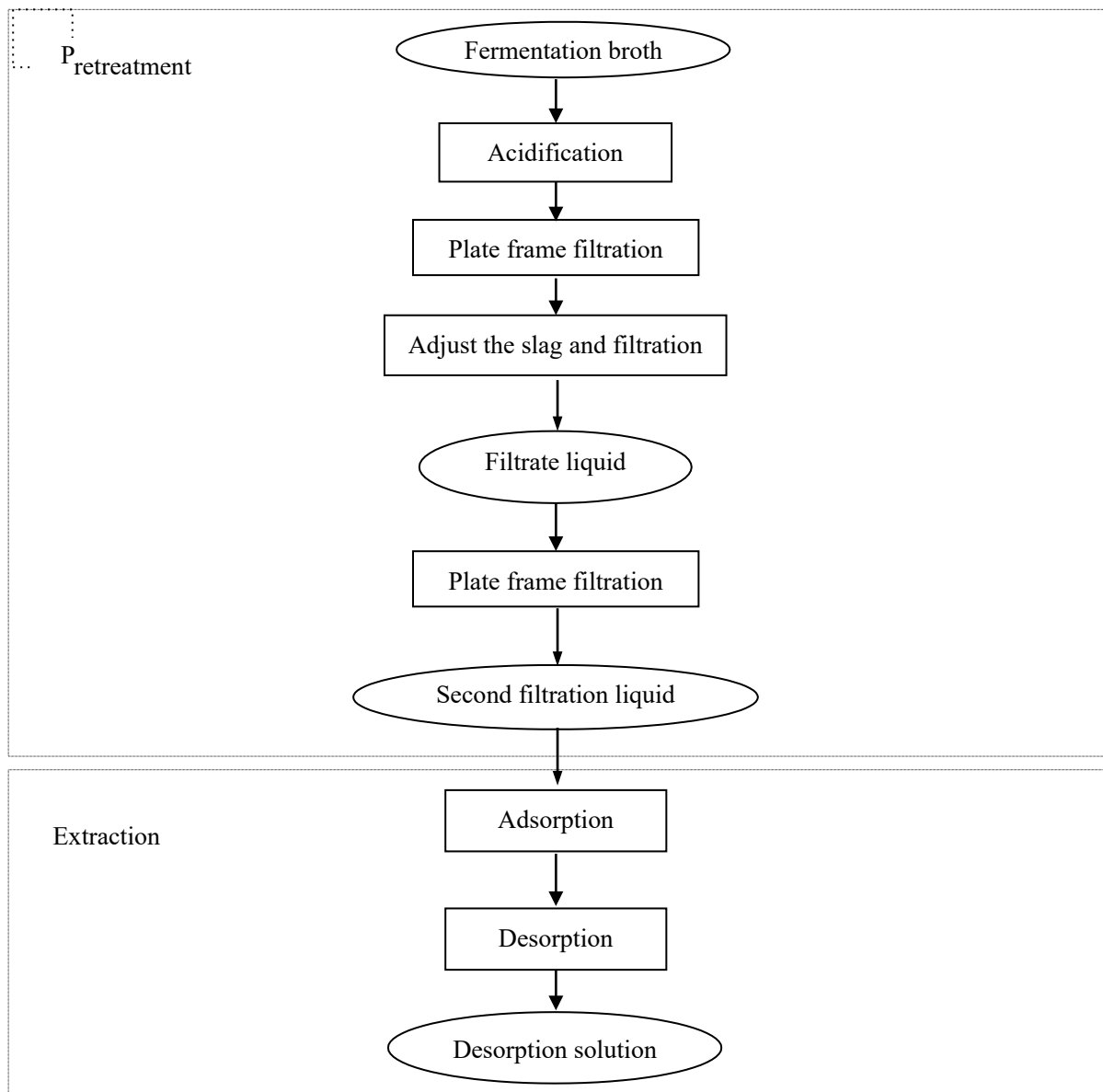
11. Contaminants information (according to EU Regulation No 915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
- Food supplements containing $\geq 80\%$ peanuts or oilseeds Aflatoxins B1 ≤ 2.0 ppb Aflatoxins B1+B2+G1+G2 ≤ 4.0 ppb - Other food supplements Aflatoxins B1 ≤ 5.0 ppb Aflatoxins B1+B2+G1+G2 ≤ 10.0 ppb - Food supplements, cocoa fibre, banana chips, dried herbs and dried spices Ochratoxin A ≤ 5.0 ppb	☒ Conforms ☐ Not Conforms ☐ NA
Melamine	☒ Conforms
Applicable to: food supplements, cocoa fibre, banana chips, dried herbs and dried spices - Benzo(a)pyrene ≤ 1.0 ppb - The sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) ≤ 10.0 ppb	☒ Conforms ☐ Not Conforms ☐ NA
We confirm this product complies with Regulation (EU) 915/2023 and NO.629/2008 and keep compliance statement available	☒ Conforms

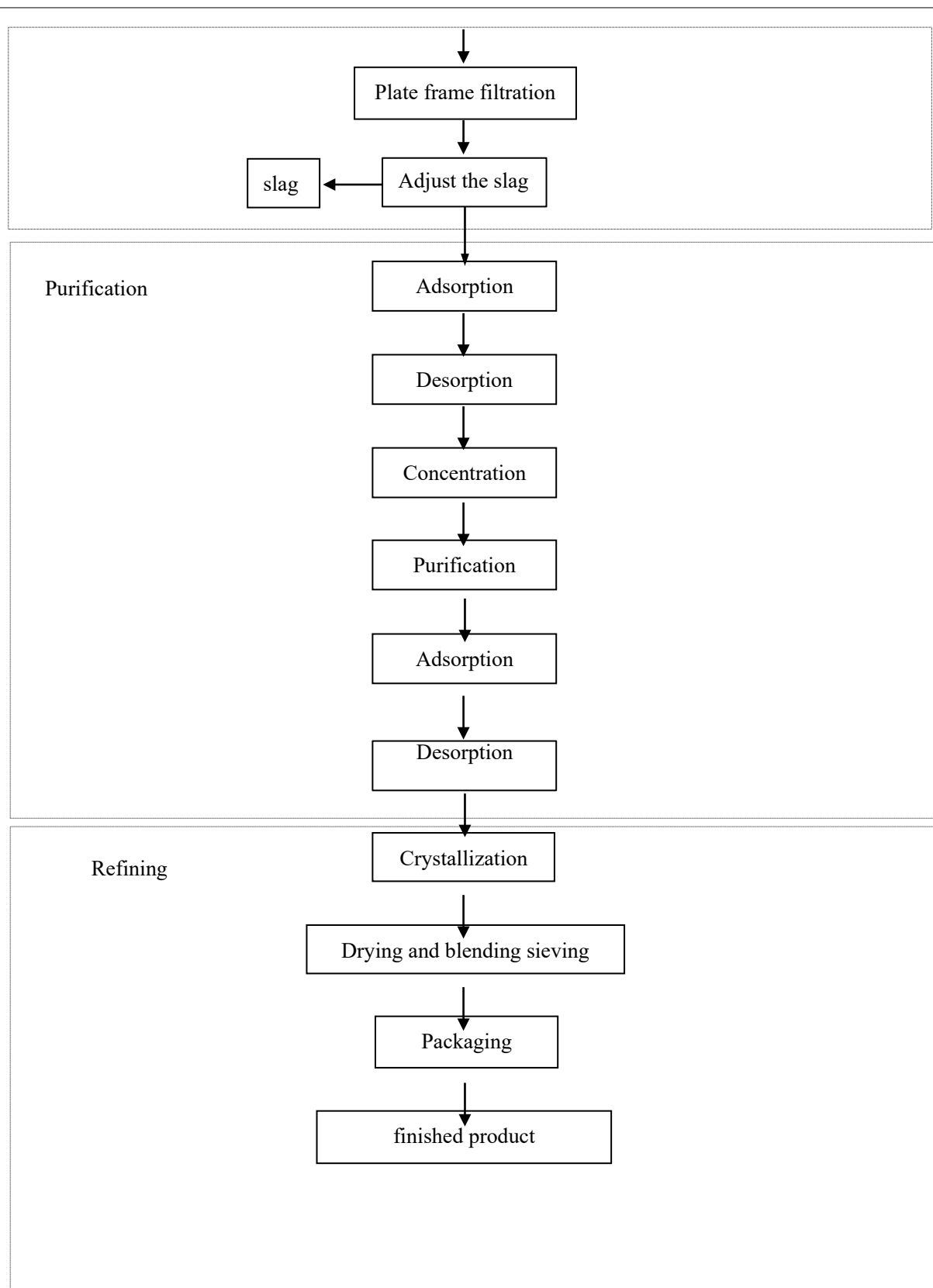
12. Others
We confirm we could meet with the requirement on hygiene of foodstuffs according to Reg 852/2004. We confirm we could meet with the requirement on general principles and requirements of food law according to REGULATION (EC) No 178/2002

Flow chart for fermentation process:



Flow chart for refining process:





Material Safety Data Sheet (MSDS)

1.	IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY	
	COMMON NAME	Cobamamide
	BOTANICAL SOURCE	Propionibacterium
	COMPANY NAME	Confidential
2.	INFORMATION ON SUBSTANCE	
	PRINCIPAL-HAZARDOUS COMPONENT (S)	Non
	CAS No	13870-90-1
	APPEARANCE	Dark red crystals or powder
3.	HAZARDS INFORMATION ON SUBSTANCE	
	HEALTH HAZARDS	No data available yet
	FIRE AND EXPLOSION HAZARDS	No data available yet
	ENVIRONMENTAL HAZARDS	No environmental hazards as far as to our knowledge.
4.	FIRST-AID MEASURES	
	INHALATION	Remove to well-ventilated area. Seek medical attention.
	SKIN CONTACT	Washed by soap water or clear water if it comes into contact with skin.
	EYE CONTACT	Washed by clear water if contacting with eyes. Sent to hospital if having excessive intake by mistake.
	INGESTION	Wash out mouth with water if conscious. Seek medical attention.
	PROTECT MEASURES	Wearing protective clothes and safety gloves when operating.
5.	FIRE-FIGHTING MEASURES	
	EXTINGUISHER MEDIA	Water Spray, Carbon Dioxide, Dry Chemical Powder or other appropriate form.
	SPECIAL FIRE FIGHTING PROCEDURES	Wear self-containing breathing apparatus against toxic fumes and protective clothing.
	FIRE & EXPLOSION HAZARDS	Not combustible, flammable or explosive. Emits toxic fumes under fire conditions.

6.	ACCIDENTAL RELEASE MEASURES	
	STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED	Wear protective equipment. Sweep up, place in proper container for waste disposal, do not get water inside container. Avoid raising dust. Ventilate area & wash site after material pickup is complete.
	CLEANING METHODS	Wash premises, equipment and working surfaces with water.
	WASTE DISPOSALS METHODS	Dispose of as solid organic waste in accordance with national and local regulations
7.	HANDLING & STORAGE	
	HANDLING&STORAGE	Keep far away from kindled material, heat source and direct light. Keep the container airtight. Should be separately stored form oxidant and edible chemical compound.
8.	EXPOSURE CONTROLS / PERSONAL PROTECTION	
	OCCUPATIONAL EXPOSURE LIMITS	
	GB TWA:	Not established
	D TWA:	Not established
	USA TWA/TLV:	Not established
	USA TWA/STEL:	Not established
	VENTILATION	Local exhaust may be needed.
	PERSONAL PROTECTIVE EQUIPMENT	Protective goggles, gloves. Coveralls, apron, boots. Respiratory protection with dust-filter may be needed.
9.	PHYSICAL AND CHEMICAL PROPERTIES	
	APPEARANCE	Off-white fine powder
	BOILING POINT	n.a.
	MELTING POINT	n.a.
	AUTO-IGNITION TEMP.	n.a.
	WATER SOLUBILITY	Part of water soluble
	FLASH POINT	n.a.
	EXPLOSIVE LIMITS IN AIR	n.a.
10.	STABILITY & REACTIVITY	
	STABILITY & REACTIVITY	The compound is stable at room temperature in closed containers.
	CONDITIONS TO AVOID	Incompatible materials, light, dust generation,

		moisture, excess heat, strong oxidants.
	MATERIALS TO AVOID	Oxidizing agents
	HAZARDOUS DECOMPOSITION PRODUCTS	Carbon monoxide, carbon dioxide.
11.	TOXICOLOGICAL INFORMATION	
	ACUTE ORAL LD50 (MICE/RATS)	Not known
	IRRITATION TESTS (EYES)	Not known
	INHALATION	Not known
12.	ECOLOGICAL INFORMATION	
		No Data available yet.
13.	DISPOSAL CONSIDERATIONS	
14.	TRANSPORT INFORMATION	
	UN UN No.	Not classified as dangerous goods
	ADR	Not restricted
	DGR	Not restricted
	IMDG	Not restricted
15.	REGULATORY INFORMATION	
		Data not available
16.	OTHER INFORMATION	
	Cobamamide has been proved no offensive smell, no infective danger or any other danger when transported. The information (including data and statements) in this Material Safety Data Sheet (MSDS) is based on experimental data and believed to be true and accurate as of the date issued. But all recommendations or suggestions are made without guarantee, since the conditions and methods of using the product and information referred to herein beyond the control of us. It is our policy, to assist our customers and to help solve particular problems, which may arise in applying our products.	