

Quote Form SIIF Vitamins and food supplement insurance

Who can use this form?

- 1. An organisation or person based in the UK, manufacturing or having manufactured on their behalf food supplements (vitamins, minerals or amino acids) or herbal botanicals under their own brand name.
- 2. The projected annual income of the business for the next 12 months is no more than £500,000.
- 3. All income is generated from within the United Kingdom
- 4. There are no more than 10 employees.
- 5. You are not an existing customer of Markel International Insurance Company Limited
- 6. If you do not meet these criteria, or if you are a contract manufacturer of vitamins and food supplements, we can provide a bespoke quote. Please contact us using the information at www.vitaminsure.co.uk/contact.

How does this form work? 1.

- You can apply for cover up to 30 days before the required inception date, and we must receive a satisfactorily completed copy of this form no later than two working days before cover is required. If you can comply with the criteria and conditions stated on this form then the premium shown for your selected coverage will be confirmed in your quotation.
- 2. Cover will only start when we send you confirmation of cover. We will contact you to let you know if we are unable to offer cover but if you do not receive a response within three working days please call us as we may not have received your application.
- 3. Public and Products Liability are mandatory sections of cover, available on a standalone basis or as a package with additional cover options. The optional covers provided are not available in isolation.
- 4. A policy summary and policy wordings for each section of cover are available at www.uk.markel.com
- 5. This form expires on 01/04/2024. Please contact us for the most up to date version.

Statements of fact

If you can confirm that the statements below are true, Please complete sections 1 to 6. If these statements are not true we will not be able to offer you a quote using this Quote Form. We have relied on these facts and all the information that you or anyone on your behalf provided, in agreeing to provide this insurance and in setting the terms and premium.

You must read this document to ensure that all the facts stated below are accurate and complete. If any of the facts stated below or any of the information provided to us is not correct or needs to be changed, you must tell us before the start of the period of insurance.

If there are changes to this information during the period of insurance, you must tell us. When we are notified of a change we will tell you if this affects your policy. If you do not inform us about a change it may affect any claim you make or could result in your insurance being invalid.

- 1. The business to be insured is based in the UK and you are manufacturing or having manufactured on your behalf food supplements (vitamins, minerals or amino acids) or herbal botanicals under your own brand name.
- 2. You have no registered offices, subsidiaries or employees resident outside the UK
- 3. You are not principally a retailer or wholesale distributor of third party products.
- 4. You are not acting as a UK Responsible Person (UK REP) or an Authorised Representative (in Northern Ireland) for an imported product

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- None of the products are (or include):
 - a medicine, herbal medicine or medical device as classified by the Medicine and Healthcare products Regulatory Agency (MHRA) – see Appendix for further details;
 - a cosmetic or cosmetic device see Appendix; b.
 - a claim to treat, cure or prevent a disease or restore, correct or modify physiological c. functions;
 - d. ingredients prohibited under UK law;
 - a banned herbal ingredient or a restricted herbal ingredient as classified by the Medicine and Healthcare products Regulatory Agency (MHRA);
 - specifically marketed for use with severe acute respiratory syndrome coronavirus 2 f. (SARS-CoV-2) or coronavirus disease (COVID-19)
 - an excluded product see Appendix.
- You comply with the following regulatory and inspection requirements:
 - Food supplements comply with The Nutrition (Amendment etc.) (EU Exit) Regulations 2019, The Nutrition (Amendment etc.) (EU Exit) Regulations 2020, the food information regulations and food supplement regulations of England, Scotland, Wales and Northern Ireland and/or Directive 2002/46/EC where applicable, the Trade Descriptions Act 1968, the Food Safety Act 1990 and the Food Information Regulations of December 2014.
 - No past or present products have been subject to a voluntary or enforced recall due to risk to health; or subject to warnings or advice that they are considered unfit for human consumption.
 - c. You have procedures in place to notify your customers and recall affected products.
- 7. You have not supplied a product which has been
 - a. withdrawn or discontinued due to safety concern
 - b. subject to an enforcement notice, warning letter or other punitive, corrective or preventative action due to a safety concern
- You are unaware of any off-label use or misuse of your product.
- Any property to be insured is in good condition or repair.
- 10. Work is not undertaken at height or with animals.
- 11. Neither you, nor any director, manager, partner or trustee of yours, nor any person insured or proposing for insurance has been convicted, or charged but not yet tried, of any criminal offence other than a motoring offence.
- 12. You have never had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined, nor had similar insurance cancelled or made subject to special conditions.
- 13 within the last five years you or any person insured or proposing for insurance to which this proposal relates have not
 - had any claim, prosecution, proceedings or investigations made or instigated against them whether successful or otherwise
 - suffered any loss or made any claim (whether insured or not) which would have b. fallen within the scope of the proposed insurance irrespective of whether or not such loss or claim relates to the property insured or proposed for insurance



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- 14. Neither you nor any person insured or proposing for insurance is aware, after enquiry, of any circumstance or incident which they have reason to suppose might afford grounds for any future claim such as would fall within the scope of the expiring insurance or the proposed insurance which has not already been advised to Underwriters.
- 15. When trading outside the United Kingdom
 - a. You are not aware of any circumstance where
 - your products are not lawfully allowed to be sold in any of your chosen markets
 - ii. there is a connection between you and/or your business or your product and a country or person subject to trade sanctions or embargoes asserted by the United Kingdom (UK), European Union (EU), United Nations (UN) or United States of America (USA)

and

b. y	our back	office sy	ystems	would	prevent s	sales t	o these	territories.
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I confirm that I have read and comply with the	I can comply	T connet comply
statements of fact above.		I cannot comply [

Cover options C and D

- 1. Where cover for Property and Business Interruption are selected you comply with the Minimum Security Requirements see Appendix.
- 2. You have appointed a competent person to manage your health and safety
- 3. Where you have 5 employees or more, you have a written health and safety policy, which is reviewed annually and updated when required
- 4. You have undertaken a risk assessment to comply with the Management of Health and Safety at Work Regulations 1999
- You have consulted with your workers and involved them and informed them about health and safety. You have provided then with information and training about their duties regarding health and safety
- 6. Your workplace has the appropriate welfare facilities, first aid kits are provided, workers trained and first aiders appointed
- 7. You keep an accident book
- 8. You employ a process to ensure that the health and safety policy is implemented at all times

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Optional Cover — Cyber & Data Risks

Cover is available for businesses based within the UK who can confirm that

- 1. You do not collect, store or process more than
 - a. 50,000 personally identifiable information records
 - b. 5,000 patient/healthcare records



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- c. 5,000 payment card data or other personal financial information records (other than for their own employees
- You do not collect personal data from citizens resident outside the United Kingdom
- On all your computers, you
 - use anti-virus, anti-spyware and firewall protections which are set to a. automatically check for updates at least once a day
 - perform software security updates as soon as they are released by vendor b.
 - c. backup of data at least monthly
 - d. only use operating software supported by the original provider
- You have in place
 - controls to restrict unauthorised access to confidential / sensitive data within your a. network
 - b. processes to ensure all confidential data is encrypted when stored on portable devices or in transmission
- 5. If you operate websites that include E-commerce, process payments or collect confidential / sensitive data, you confirm that
 - all payments made via your website are processed through an independent third a. party site that is PCI-DSS (Payment Card Industry Data Security Standard) compliant, and no payment details are captured or recorded by you before transferring to the third party site.
 - You do not process more than £100,000 per annum b.

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& Officers Liability

Optional Cover – Directors Cover is available for businesses based within the UK who can comply with the following statements:

- You have no income derived from the USA and there are no assets, employees, subsidiaries or shares issued within the USA or Canada
- All shareholders of the company are directors of the company or members of their 2. immediate family
- You have traded continuously for at least 12 months and there has not been a management buy-out or buy-in within the last 2 years
- 4. You have not merged with or been taken over by any other company in the last 12
- You have not acquired or disposed of any companies in the last 12 months 5.
- You have no plans to trade your shares
- 7. You have not had a pre-tax loss or negative net worth (share capital plus reserves) in any of the last two financial years and you do not anticipate it in the current financial year



8.	You and your subsidiaries are solvent and able fall due, including but not limited to pension and		obligations as they
	onfirm that I have read and comply with the tements of fact above.	I can comply 🗌	I cannot comply



Section 1: Your details	Your name	
	Insured name (e.g. company name)	
	Address	
	Postcode	
	Telephone	
	Email	
	Website	
	Employer Reference Number (if applicable)	



Section 2: **Coverage options**

All the premiums are inclusive of Insurance Premium Tax.

Coverage options	A	В	С	D
Public and Products Liability	£1 million	£2 million	£2 million	£5 million
Product Withdrawal Expenses	£25,000	£25,000	£25,000	£25,000
Employers Liability	Nil	Nil	£10 million	£10 million
Property	Nil	Nil	£25,000	£50,000
Business Interruption	Nil	Nil	£50,000	£100,000
Premium	£739.00	£862.00	£986.00	£1,109.00
Optional coverage		_		_
Optional coverage	A	В	С	D
Optional coverage Cyber and Data Risks	£100,000	£100,000	£100,000	£100,000
	7-			
Cyber and Data Risks Premium	£100,000	£100,000	£100,000	£100,000
Cyber and Data Risks	£100,000	£100,000	£100,000	£100,000
Cyber and Data Risks Premium	£100,000	£100,000 £93.00	£100,000	£100,000 £93.00
Cyber and Data Risks Premium Optional coverage Directors & Officers	£100,000 £93.00 □	£100,000 £93.00 □	£100,000 £93.00 C	£100,000 £93.00 □

Please note that alternative levels of cover for Property and Business Interruption are available upon request.



Section 3: Additional information	How long has the business traded?		
	Who is manufacturing your products?		
	Do you have a current insurance policy	in place?	Yes 🔲 No
	What date is cover required from?		
	Are you a member of any professional Manufacturers Association (HFMA)?	associations, such as the Health Food	Yes No

Section 4: Select your payment option

Credit or debit card	
We will contact you by telephone to collect the card details.	
Bank Transfer Bank transfer details will be issued with the quotation invoice.	
Monthly Direct Debit	
We are able to offer a 10-month premium finance plan with Premium Credit for this contract of insurance. Please see your quotation document for full details	

Section 5: **Important information**

Specified Products and/or Specified Product Categories

This insurance product uses a policy wording designed to meet the demands and needs of the Biomedical and Life Sciences sector and therefore the insurance certificate excludes a number of products and product categories with historic safety issues. These products are mainly medicines, medical devices and cosmetic products. We do not expect that you will have any past, present or planned future dealings with any of these products however, it is important that we bring these exclusions to your attention.

For more information please refer to the definition of Specified Products and the definition of Specified Product Categories for more information.

Products Liability excess

The insurers shall only be liable for that part of each and every loss which exceeds £1,500.

Section 6: Declaration and signature

Important information concerning your personal information

Please carefully read the following before you sign and date the declaration.

Your insurance cover includes cover for individuals who are either insureds or beneficiaries under the policy (individual insureds). We collect and use relevant information about individual insureds to provide you with your insurance cover and to meet our legal obligations.

This information includes individual insureds' details such as their name and address [and may include more sensitive details such as information about their health and criminal convictions].

We will process individual insureds' details, as well as any other personal information you provide to us in respect of your insurance cover, in accordance with our full Markel privacy notice, a copy of which is available online at

http://www.markelinternational.com/foot/privacy-policy/ or on request.

Information notices

To enable us to use individual insured's details in accordance with current data protection laws, we need you to provide those individuals with certain information about how we will use their details in connection with your insurance cover.

You agree to provide to each individual insured this short form information notice on or before the date that the individual becomes an individual insured under your insurance cover or, if earlier, the date that you first provide information about the individual to us.

Minimisation and notification

We are committed to using only the personal information we need to provide you with your insurance cover. To help us achieve this, you should only provide to us information about individual insureds that we ask for from time to time.

You must promptly notify us if an individual insured contacts you about how we use their personal details in relation to your insurance cover so that we can deal with their queries.

Fair presentation

Before the insurance policy takes effect, you have a duty to make a fair presentation of the risks to be insured. A fair presentation of the risk is one:

- which discloses to us every material circumstance which you know or ought to know of,
- gives us sufficient information to put us on notice that we will need to make further enquiries for the purpose of revealing those material circumstances, and
- which makes that disclosure in a manner which is reasonably clear and accessible to us, and
- in which every material representation as to a matter of fact is substantially correct and every material representation as to a matter of expectation or belief is made in good faith.

A material circumstance is one that would influence our decision as to whether or not to agree to insure you and, if so, the terms of that insurance. If you are in any doubt as to whether a circumstance is material you should disclose it to us. Failure to make a fair presentation of risk could prejudice, reduce or modify your rights under the policy.

Declaration

I declare that:

- I am authorised to complete this proposal on behalf of the proposer
- Every statement and particular within this proposal



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- o which is a statement of fact, is substantially correct, and
- o which is a matter of expectation or belief, is made in good faith

If any such facts, expectations and/or beliefs materially change before the insurance policy takes effect I will undertake to provide details of all such changes to you in order to comply with my obligation to provide a fair presentation of the risk to be insured under the insurance

Name	Position
Signature	Date

Please return the signed and dated form to us:

Email : enquiries@knighthoodcorporate.com

Post: Knighthood (Advisory Insurance Brokers Ltd t/a), Knighthood House, Imberhorne Lane, East Grinstead, West Sussex, RH19 1LB



What is a medicine?

The Medicines and Healthcare products Regulatory Agency (MHRA) defines a medicinal product as; any substance or combination of substances presented as having properties for treating or preventing disease in human beings or any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis. All medicines placed in the UK market require a Marketing Authorisation (MA) from the Medicines and Healthcare products Regulatory Agency (MHRA).

What is a herbal medicine?

The World Health Organisation defines a herbal medicine as plant-derived materials or products with therapeutic or other human health benefits which contain either raw or processed ingredients from one or more plants. Herbal medicines placed in the UK market are required to have either a Traditional Herbal Registration (THR) or a Marketing Authorisation (MA) from the Medicines and Healthcare products Regulatory Agency (MHRA).

What is a medical device?

The Medical Devices Regulations 2022 defines a medical device as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which—

- (a) is intended by the manufacturer to be used for human beings for the purpose of-
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
 - (iv) control of conception; and
- (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

What is a cosmetic?

The UK Cosmetics Regulation (UKCR) defines a cosmetic product as any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours

Excluded products

- 1,3 -dimethylamylamine (DMAA)
- 1,3-dimethylbutylamine, amp citrate [4-amino-2-methylpentane citrate] (DMBA)
- 1,4 butanediol (BD)
- 2-aminoisoheptane, octodrine (DMHA)
- anabolic steroids (natural or synthetic)
- appetite suppressants
- aristolochic acids
- bismacine
- cannabidiol (CBD)



- ephedra or ephedrine or ephedrine derivatives
- gamma butyrate (GBL)
- germander
- germanium
- jin bu huan
- kava-kava (piper methysticum)
- larrea tridentata (chaparral)
- lobelia
- I-tryptophan (only when used for or as part of a physically ingestible product)
- magnolia
- mitragyna speciosa (kratom)
- pyrrolizidine alkaloids (comfrey)
- stephania tetrandra
- thimerosal
- yohimbe
- supplements specifically designed for animals;
- product of animal origin (POAO) imported from outside the European Union

Minimum security requirements

Where property and business interruption are selected:

- 1) the buildings at the premises are in a good state of repair and are constructed of brick, stone or other non-combustible materials and roofed with slates, tiles, metal, concrete, asphalt, asbestos or other non-combustible materials
- 2) the premises are not in an area troubled by flooding
- 3) you have not sustained any loss, damage or claim
- 4) the following minimum level of security must be in full and proper use at all times when the premises are closed for business or left unattended and are maintained in proper working order throughout the currency of the insurance
 - a) all external doors (and any internal doors leading to any part of the buildings not in your sole occupation) are secured with either
 - i) if an aluminium door: a cylinder mortice deadlock to EN1303, or
 - ii) if an armoured plate door: the door manufacturer's locks as supplied, or
 - iii) if a upvc door: a multi-point locking system incorporating a minimum of 3 deadbolts
 - iv) if any other type of single leaf door
 - (1) where the door thickness is at least 4.5 cm: a five-lever mortice deadlock to at least British Standard 3621 together with a 17.5 cm boxed steel striking plate
 - (2) where the door is less than 4.5 cm thick: a deadlocking rim latch keyed into the deadlock position or a mortice deadlock and two key operated security bolts engaging with the door frame and with internal operation only
- 5) if double leaf doors
 - a) the standing leaf secured with internal surface mounted key operated security bolts or concealed flush bolts sited top and bottom engaging with the door frame and the floor, and
 - b) the final closing leaf secured with either a lock fitted as above dependent on door type or both leaves fitted with a coach-bolted locking bar secured with a close shackle padlock (or, if the locking bar is sited internally, either a close or open shackle padlock) having at least five levers
- 6) if a designated fire door: either
 - a) a panic bar locking system incorporating bolts which engage both the head and sill of the door frame, or
 - b) a mortice lock having specific application for emergency exit doors and which is operated from the inside by means of a conventional handle and/or thumb turn mechanism.



- 7) all external ground floor windows, accessible windows and/or skylights, originally designed to open are secured by
 - a) key operated window locks, or
 - b) adequately secured metal bars or grilles, external or internal metal shutters or internal collapsible metal security grill, or screwed shut.