Import Instructions – USA, Australia, Hong Kong, South Africa

You need to enclose the following:

- 1-VAT exemption certificate, signed and dated in ink available on request from Dr Binks
- 2-Proof of up-to-date rabies vaccination from applicable countries

The remaining documents are enclosed in this pdf:

- 3-Commercial invoice, signed and dated in ink with weight of parcel added
- 4-Specific import licence (attached)
- 5-Checklist (attached)

## 6-Veterinarian health letter, signed in ink on institutional headed paper, stating the following:

To whom it may concern:

I confirm that the enclosed samples are not derived from animals known or suspected to be infected with a pathogen which causes a disease that is notifiable in England, Scotland, Wales or the European Union, and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales) Order 2008, and do not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible.

Please ensure all parcels are UN3373 compliant packaged (instructions at end of pdf).

ALL DOCUMENTS MUST BE ENCLOSED IN A CLEAR PLASTIC WALLET ON THE EXTERIOR OF THE PARCEL.





COMMERCIAL INVOICE

**VAT NUMBER GB125506730** 

EORI NUMBER GB125506730065

DATE / /2025

SENDER ADDRESS

NAME OF VET

Name and address of hospital

RECEIVER ADDRESS

Dr Sophie Binks

Oxford Autoimmune Neurology Group

Nuffield Department of Clinical Neurosciences

Level 6 - West Wing

John Radcliffe Hospital

Oxford

OX3 9DU

UK

Tel: 01865 (2)34829

### PACKAGE CONTENTS

Blood and serum samples from a [insert country of origin here] domestic cat, non-infective, non-toxic

### THE EXPORTER OF THE PRODUCTS COVERED BY THIS

DOCUMENT (EORI NUMBER) DECLARES THAT,

### **EXCEPT WHERE OTHER WISE CLEARLY INDICATED**

THESE PRODUCTS ARE OF UK PREFERENTIAL ORIGIN

### AND THAT ALSO

i. the products are not derived from animals known or suspected to be infected with a pathogen which causes a notifiable disease to which the animals from which the products are derived are susceptible according to retained European Regulations or the Animal Health Regulations of the exporting country; and

ii. the products do not originate from animals in a premises or region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals are susceptible according to European or other National Animal Health Regulations.

iii. These products are category 1 as defined in Articles 8, 9 or 10 of Regulation (EC)No 1069/2009

Nominal £1 HS CODE 30029030

REASON FOR SHIPPING
For use in experimental and diagnostic testing ONLY

TOTAL WEIGHT

TERMS OF CARRIAGE C.P.T

EURO 1/T2L

THIS INVOICE SHOWS THE FULL VALUE OF THE ARTICLES AND NO OTHER

### INVOICE WILL BE ISSUED

SIGNED

### **PRINT**

NAME OF VET



Commission Regulation (EU) 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive ("Regulation 142/2011")

The Trade in Animals and Related Products Regulations 2011 Animal By-products (Enforcement) (England) Regulations 2013

### **AUTHORISATION FOR THE IMPORTATION FROM THIRD COUNTRIES OF RESEARCH AND DIAGNOSTIC SAMPLES**

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under Article 27 of Regulation (EU) 142/2011, authorises:

Sophie N M Binks Oxford Autoimmune Neurology Group Nuffield Department of Clinical Neurosciences Medical Sciences Division, University of Oxford Level 6 – West Wing, John Radcliffe Hospital Headley Way, Headington, Oxford OX3 9DU	impor	and full address of ter responsible for gnment
	Full address of destination premises (if different from importer)	
to land in England, in accordance with the conditions set out below,  Non-infectious, screened feline whole blood, serum and cerebrospinal fluid from domestic pet cats intended for particular studies or analyses only. (Not for resale).		Product
from  USA, Hong Kong, Australia and South Africa		Countries of origin
at  All ports and airports in England		Ports of entry
This authorisation does cancel and replace ITIMP24.0585. This I	icence	expires on 2 years

less one day from the date of signature. After this date the licence should have either been renewed if required and deleted or cancelled and archived.

Signed: Sean Moore (APIA) Dated: 21/02/2025

Name: Sean Moore Officer of the Animal and Plant Health Agency authorised by the Secretary of State.

Authorisation No: | ITIMP25.0215

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### **CONDITIONS ATTACHED TO THIS AUTHORISATION**

1. This authorisation is valid for multiple consignments and the net weight per consignment must not exceed 1 Kg.

2. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.

### **Packaging**

- 3. The material must be packed in leak-proof sealed containers.
- 4. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.
- 5. Irrespective of the mode of transport, all specimens must be packaged so that they fully comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.
- 6. The packaging must be clearly labelled to indicate the nature of the product, that this is intended for *in vitro* use for research and that it is **not** for human or animal consumption.

### **Import Documentation**

- 7. Each consignment must be accompanied by a copy of this import authorisation and a commercial document which must confirm:
  - i. The description of the material and the animal species of origin;
  - ii. The category, 1, 2 or 3, of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009<sup>1</sup>;
  - iii. The quantity of the material;
  - iv. The place of origin and the place of despatch of the material;
  - v. The name and the address of the consignor;
  - vi. The name and address of the consignee and/or user;
- 8. Each consignment must be accompanied by a signed and dated declaration completed by a veterinarian, on official paper, confirming that:
  - i. the products are **not** derived from animals known or suspected to be infected with a pathogen which causes a notifiable disease to which the animals from which the products are derived are susceptible according to retained European Regulations<sup>2</sup> or the Animal Health Regulations of the exporting country; and
  - ii. the products **do not** originate from animals in a premises or region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals are susceptible according to European or other National Animal Health Regulations.
  - iii. n/a

<sup>&</sup>lt;sup>1</sup> https://www.legislation.gov.uk/eur/2009/1069/title/I/chapter/I/section/4

<sup>&</sup>lt;sup>2</sup> https://www.legislation.gov.uk/eudr/1982/894

Authorisation No: | ITIMP25.0215

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### **Transportation**

- 9. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address on page 1.
- 10. The material must be transported, handled and labelled in accordance with the Animal Byproducts Regulations.
- 11. The transporter and destination address must be registered or approved (see note E) in accordance with the relevant Animal By-Products (Enforcement) Regulations, (ABPE) before commencing operations.
- 12. The products must remain in their original wrapping at all times until their arrival at the destination address on page 1.

### Storage, Use and Handling

- 13. Users shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.
- 14. The samples and material derived from the samples shall be for in vitro use only.
- 15. Samples must be handled and stored under containment level conditions which are appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002.
- 16. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.
- 17. Any subsequent use of these products for purposes other than those referred to in point 38 of annex 1 of Regulation (EU) No 142/2011, is prohibited.
- 18. Importers shall keep a register of consignments of samples imported under this authorisation, which should contain the information referred to in condition 7 above as well as the date and method of disposal.
- 19. Unless they are kept for reference purposes, transferred or re-dispatched to the third country of origin, research and diagnostic material, products derived from their use and waste shall be disposed of appropriately, in accordance with The Waste (England and Wales) Regulations 2011/The Waste (Scotland) Regulations 2012 or Animal By-Product Regulations (Regulation (EC) 1069/2009 and Regulation (EU) 142/2011).

### Transfer of Material

20. Any transfer of material from the authorised user to any other user must be pre-authorised by APHA.

Authorisation No: | ITIMP25.0215

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### **NOTES**

- A. When expired or exhausted this authorisation is to be deleted or cancelled and archived.
- B. Please note that while this authorisation was current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with Animal and Plant Health Agency, Imports Team, Carlisle, at the address below.
- C. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.
- D. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 24 months for presentation to the competent authority.
- E. For information on registration/approval, please see the website: <a href="https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered">https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered</a>
- F. References to European Union (EU) legislation within this document are references to direct EU legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023), and can be viewed on the UK legislation website (legislation.gov.uk)

Further information regarding changes to the import controls from an EU country from 31 January 2024 can be found on GOV.UK at:

https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain

### **CAUTION**

It is the importer's responsibility to ensure that any import covered by this authorisation complies with the terms and conditions as set out. If you cannot comply with any of the conditions above, please contact the APHA Imports Team.

Any breach of any conditions attached to this Authorisation will constitute an offence against regulation 39 of the Trade in Animals and Related Products Regulations 2011 or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013.

### CONTACT FOR FURTHER INFORMATION

Animal and Plant Health Agency, Imports Team Centre for International Trade – Carlisle Eden Bridge House, Lowther Street,

Carlisle, CA3 8DX Tel: 03000 200 301 Email: imports@apha.gov.uk

## Inventory form for importation of samples into the UK

This consignment contains the	e following (delete as applicable):	
(a) Description:		
Animal species of origin	n: DOMESTIC CAT	
Material: BLOOD / SE	RUM / CSF	
(b) The material is Category found in Regulation (EC) No 1	1. More information on sample Categories of 1069/2009.	an be
(c) There ares	samples with a total weight of	_grams
[Note: net (total) weight include	ding packaging must not exceed 15000g]	
(d) Place of origin		
(,, , , , , , , , , , , , , , , , , , ,		
Place of dispatch		
(e) Name and address of con	signor (sender)	

I confirm that the enclosed samples are not derived from animals known or suspected to be infected with a pathogen which causes a disease that is notifiable in England, Scotland, Wales or the European Union, and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales) Order 2008, and do not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible

(f) Name and address of consignee (recipient)

Sophie Binks
Nuffield Department of Clinical Neurosciences
Level 6 – West Wing
John Radcliffe Hospital
Oxford
OX3 9DU
UK

Signed \_\_\_\_\_\_\_
Date \_\_\_\_\_\_

□ Each individual consignment does not exceed 15kg
□ Samples contained within a leak-proof sealed container
☐ All inner and outer packaging swabbed with a suitable disinfectant before leaving the exporting address
□ All specimens are packaged so that they comply with requirements of Post Office or International Air Transport Association (IATA) regulations
☐ The packaging is clearly labelled with the <b>nature of the product</b> , that it is <b>intended for in vitro use for research or diagnostic purposes</b> and that it is <b>not for human or animal consumption</b>
□ Documents for each individual consignment include:
□VAT EXEMPTION CERTIFICATE
□COMMERCIAL INVOICE
□VETERINARIAN LETTER (USA, AUSTRALIA, HONG KONG, SOUTH AFRICA)
□IMPORT LICENCE (IMP/GEN/2024/13) (EU COUNTRIES); ITIMP25.0215 (USA, AUSTRALIA, HONG KONG, SOUTH AFRICA)

Check-list





# Packaging UN 3373 Shipments

## **Packaging UN 3373 Shipments**

Follow these instructions for packaging, marking, and labeling Biological Substance, Category B (UN 3373) shipments for FedEx Express® services.

## Requirements for Biological Substance, Category B (UN 3373) Shipments

This guide outlines the requirements for shipping with FedEx Express. In addition, all shipments must comply with all applicable local, state, and federal laws governing packing, marking, and labeling. Blood, urine, fluids, and other specimens containing or suspected of containing infectious substances must be shipped according to applicable government, International Air Transport Association (IATA), and International Civil Aviation Organization (ICAO) regulations.

Customers who ship Biological Substance, Category B (UN 3373) shipments must comply with local, state, and federal laws governing identification, classification, packaging, and package markings (which may be in label form). FedEx Express strictly adheres to the IATA, ICAO, and U.S. government guidelines for materials categorized as Biological Substance, Category B (UN 3373).

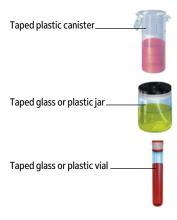
## **General Packaging Requirements**

For Biological Substance, Category B (UN 3373) shipments, cushioning material is required for both liquid and dried specimens. You must include four layers of packaging:

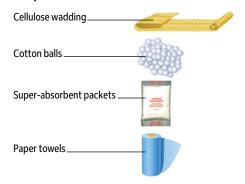
- 1. Primary watertight inner receptacle. Use primary receptacles made of glass, metal, or plastic with a positive means of ensuring a leakproof seal; a skirted stopper or metal crimp seal must be provided; screw caps must be reinforced with adhesive tape. For liquid specimens, the primary receptacle must not contain more than 1 L. For dried specimens, the primary receptacle must not exceed the outer packaging weight limit.
- 2. Absorbent material. Place absorbent material between the primary and secondary receptacles, using enough material to absorb the entire contents of all primary receptacles. Absorbent material is required for Biological Substance, Category B (UN 3373) shipments containing liquids. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets, and paper towels.

- 3. Secondary watertight inner receptacle. Use a secondary container that is leakproof for liquid specimens or siftproof for dried specimens. Choose only secondary containers certified by the manufacturer for Biological Substance, Category B (UN 3373) prior to use. Either your primary or secondary receptacle must be able to withstand, without leakage, an internal pressure differential of not less than 95 kPa in the range of -40°C to 55°C (-40°F to 130°F). To prevent contact between multiple fragile primary receptacles, individually wrap or separate them inside the secondary container.
- 4. Sturdy outer packaging. Use rigid outer packaging constructed of corrugated fiberboard, wood, metal, or plastic, or other equally strong material, including cylinders made of such materials and appropriately sized for the contents. Chipboard or paperboard boxes are unacceptable outer packaging. The completed packaging must be of good quality, strong enough to withstand the normal rigors of transportation without loss of contents as a result of vibration, changes in temperature, humidity, or pressure. Limit the total volume for liquid samples to 4 L and the total weight of dried samples to 4 kg per outer container. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (4" x 4"). Completed packages must be able to withstand a 4' (1.2-m) impact test. Before sealing the outer packaging, you must make an itemized list of the contents of the package and enclose the list between the secondary packaging and outer packaging.

### **Acceptable Primary Receptacles**



#### **Acceptable Absorbent Materials**



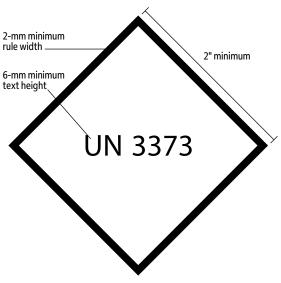
### **Acceptable Secondary Receptacles**



# Biological Substance, Category B (UN 3373) Marking Requirements

- Clearly mark "Biological Substance, Category B" in 6-mm-high text on the outer package adjacent to a properly sized UN 3373 diamond-shaped marking. If you prefer, package markings may be in the form of a label.
- If you use any of the following clinical or Temp-Assure® boxes to ship samples classified as Biological Substance, Category B (UN 3373), you must add a properly sized UN 3373 diamond-shaped marking; if you prefer, package markings may be in the form of a label:
   FedEx® Medium Clinical Box; FedEx® Large Clinical Box; Small Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Extended Duration (48 Hours); Large Cold Box (2–8°) Standard Duration (48 Hours); and Large Cold Box (2–8°) Extended Duration (96 Hours).
- If you use the FedEx® UN 3373 Pak, duplicate all required dangerous goods markings on each package inside the overpack. Do not place dry ice inside the pak.
- The name and telephone number of a person responsible must be marked on the package or provided on the airbill.
- The name and address of the shipper and recipient must be marked on the package.

#### Biological Substance, Category B (UN 3373) Marking Requirements



"Biological Substance, Category B" must appear in 6-mm-high text on the outer package adjacent to a diamond-shaped mark like the one shown here. The UN 3373 marking must be in the form of a square set at an angle of 45 degrees. Each side of the UN 3373 diamond should measure a minimum of 2" (50 mm). The width of the diamond rule line must be a minimum of 2 mm, and the letters and numbers must be at least 6 mm high.

## FedEx UN 3373 Packaging Options

For your convenience, we offer the FedEx UN 3373 Pak, the FedEx Medium Clinical Box, and the FedEx Large Clinical Box as packaging options for your Biological Substance, Category B (UN 3373) shipments. We recommend the FedEx UN 3373 Pak for use when the sturdy outer packaging of your properly packaged shipment is smaller than 7" x 4" x 2" (minimum acceptable size).

To help increase your operational efficiencies and clearly identify this type of shipment, the FedEx UN 3373 Pak is preprinted with the required IATA UN 3373 marking, the proper shipping name, and the OVERPACK marking.

The FedEx UN 3373 Pak can only be used to ship Biological Substance, Category B (UN 3373) shipments. If you need an overwrap for exempt clinical and environmental test sample shipments, use the FedEx® Clinical Pak.

To order the FedEx UN 3373 Pak, go to **fedex.com** or call 1.800.GoFedEx 1.800.463.3339.

#### FedEx UN 3373 Pak



FedEx Large Clinical Box, FedEx Medium Clinical Box





## FedEx UN 3373 Packaging Options for Purchase

FedEx offers five cold shipping boxes as part of the FedEx Temp-Assure portfolio of products **for purchase**. These boxes can be used as outer packaging to ship temperature-sensitive specimens designated as Biological Substance, Category B (UN 3373) with FedEx Express services.

Each box includes a chilling unit activated by the shipper and placed in the box with the shipment. The unit continuously evaporates small amounts of water at low pressure, keeping the shipment at 2°C to 8°C for up to 48 or 96 hours,\* depending on the packaging option chosen.



<sup>\*</sup>Actual cooling duration varies, depending on external temperatures.

### **Packaging Restrictions**

- Plastic bags and paper envelopes are unacceptable outer containers.
- The FedEx® Envelope, FedEx® Tube, FedEx® Pak, FedEx® Padded Pak, and FedEx boxes, including FedEx brown packaging offered at FedEx shipping locations, are not acceptable as outer containers for Biological Substance, Category B (UN 3373) shipments.
- The FedEx Small Clinical Pak and FedEx Large Clinical Pak cannot be used to ship Biological Substance, Category B (UN 3373) shipments.
- Only shipments classified as Biological Substance, Category B (UN 3373) can be shipped in the FedEx UN 3373 Pak.
- Biological Substance, Category B (UN 3373) shipments that are shipped refrigerated, frozen, on dry ice, or in liquid nitrogen must comply with current IATA and ICAO regulations.

If you have questions about whether your shipments require a biohazard label, consult the Occupational Safety and Health Administration (OSHA) for the applicable regulations.

The FedEx Medium Clinical Box, the FedEx Large Clinical Box, and the following Temp-Assure cold shipping boxes may be used to ship either non-infectious clinical samples or samples classified as Biological Substance, Category B (UN 3373), but they must be properly labeled: Small Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Extended Duration (96 Hours); Large Cold Box (2–8°) Standard Duration (48 Hours); and Large Cold Box (2–8°) Extended Duration (96 Hours). The shipper assumes sole responsibility for compliance with all applicable governmental regulations.

**NOTE:** Biological Substance, Category B (UN 3373) shipments are accepted at FedEx Express® Drop Box locations in the U.S. and Puerto Rico. Refer to the current online Service Guide, Terms and Conditions, Dangerous Goods section for current limitations on locations that cannot accept UN 3373.

## **FedEx Packaging Services**

FedEx Packaging Services offers package development consultation services. The FedEx Packaging Lab does not test packaging containing Biological Substance, Category B (UN 3373) materials.

### **Contacts and Resources**

- How to Pack guidelines at fedex.com/packaging.
- FedEx portfolio of temperature-controlled solutions at fedex.com/us/temp-assure.
- FedEx Dangerous Goods/Hazardous Materials
   Hotline, 1.800.GoFedEx 1.800.463.3339; press "81"
   or say "dangerous goods," then press "4" for the next
   available dangerous goods agent.
- FedEx Dangerous Goods seminars and job aid at fedex.com/dangerousgoods.

### **NOTICE:**

FedEx Express will refuse to accept packages that do not meet FedEx Express, government, or IATA and ICAO requirements. This brochure is in no way intended to replace requirements mandated by 49CFR and IATA. This is for informational purposes only.