UN3373
Biological Substance (Cat.B)
Product Manual
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Product Introduction

UN3373 is a DG shipment classification under IATA DGR (Div 6.2) - Infectious Substances.

Infectious Substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause diseases in humans or animals.

Infectious Substances can be classified in 2 Categories – A or B according to the level of infectiousness, infectious substances normally include the followings:

- Biological Substance
- Biological Products
- Cultures
- Patient Specimens
- Medical or clinical wastes

Royale China can now provide service on handling Biological Substances- Category B (UN3373) & Exempted items

What is UN3373 - Biological Substance, Category B?

Biological Substances are divided into 2 categories – Category A & Category B.

Category A is an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

Any biological infectious substance which does not meet the criteria for inclusion in Cat.A will be assigned to Infectious Substances Category B with identification number UN 3373, unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(Please refer to IATA DG Regulations– 3.6.2.2 for more details)
What substances are Exempted from infectious category?

Any non-infectious biological substances/products or specimens with minimal likelihood that pathogens are present, will be exempted from this category.

Please refer to below IATA DG Regulations 3.6.2.2.3 for more details.

<table>
<thead>
<tr>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.6.2.2.3.1</strong> Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.</td>
</tr>
<tr>
<td><strong>3.6.2.2.3.2</strong> Substances containing micro-organisms, which are non-pathogenic to humans or animals, are not subject to these Regulations unless they meet the criteria for inclusions in another class.</td>
</tr>
<tr>
<td><strong>3.6.2.2.3.3</strong> Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.</td>
</tr>
<tr>
<td><strong>3.6.2.2.3.4</strong> Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection are not subject to these Regulations, unless they meet the criteria for inclusion in another class.</td>
</tr>
<tr>
<td><strong>3.6.2.2.3.5</strong> Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.</td>
</tr>
<tr>
<td><strong>3.6.2.2.3.6</strong> Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen,” as appropriate.</td>
</tr>
</tbody>
</table>
How to determine if a Patient Specimen is exempted from UN3373?

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious disease, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.)

Biological Products

Besides biological substances like human blood, tissue... it is also very common for sending Biological Products under UN3373 or Exempted category.

Biological Products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

Biological products are divided into the following groups:

(a) Those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to DG regulations.

(b) Those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.
Packaging Instruction

**The packaging of all Biological Substance Cat. B must comply with IATA Packing Instruction P650. Which fulfill the triple packaging principle of (1) primary receptacle, (2) leak-proof secondary container and (3) durable outer container.

Be sure to specify if the shipment is a refrigerated sample (e.g., ice packs or dry ice).

For Category B infectious substances, the maximum quantity of liquid per primary receptacle is **1 liter** and outer packaging must not contain more than **4L or 4kg**.

**Royale China can provide all standard UN3373 & temperature-controlled packaging material, to ensure safe and stable transportation.


<table>
<thead>
<tr>
<th>Shipment Type</th>
<th>Proper Shipping Name</th>
<th>UN Number</th>
<th>Hazard Class</th>
<th>Packing Group (PG)</th>
<th>Packing Instruction (PI)</th>
<th>Max. qty. per primary receptacle</th>
<th>Max. Net qty./pkg. for Passenger Aircraft</th>
<th>Max. Net qty./pkg. for Cargo Aircraft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category B infectious substance</td>
<td>Biological substance, Category B</td>
<td>UN3373</td>
<td>6.2</td>
<td>-</td>
<td>650</td>
<td>Liquids: 1 L</td>
<td>4 L or 4 kg</td>
<td>4 L or 4 kg</td>
</tr>
</tbody>
</table>
For “Exempt human specimen” or “Exempt animal specimen”, the packaging must meet the following conditions:

(a) The packing must consist of three components:
1. A leak-proof primary receptacle(s);
2. A leak-proof secondary packaging; and
3. An outer packaging of adequate strength for its capacity, mass and intended use, and with as least one surface having minimum dimensions of 100x100mm;

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release of leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

Other Packaging Requirements

Overpacks
An overpack can be used to combine several triple packages into one large package. This may be done to save on shipping charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels and proper shipping names. The outer container of the overpack must also be marked with the word, “Overpack.”

Dry Ice
If a shipment includes dry ice the outer packaging must allow for the release of carbon dioxide gas when the solid sublimes. Dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant sublimes. Dry ice is considered a miscellaneous hazard (Class 9). Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number, and net quantity, (e.g., Dry Ice, UN1845, 3 kg). Packages designed for dry ice often are pre-labeled and marked. A Shipper’s Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on declarations for shipments that include other hazardous materials such as infectious substances.

Liquid Nitrogen
Biological materials can be shipped refrigerated with liquid nitrogen in dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material.
Labeling

The outer container of Category B Infectious Substance shipment must display the following information:

- The sender and recipient’s full name and address;
- The words “Biological Substance, Category B”
- UN3373 label (Ref. to Figure A)
- The text “Person responsible: name and phone number” and
- Class 9 label (if packaged with dry ice) (Ref. to Figure B)

Other labels if applicable

- This End Up Labels
- Exempt Specimen
- Overpack Labels
Exporting from China / Importing into China

All UN code identification, packaging and labeling instructions are the guidelines given by IATA and Airlines to ensure all shipments are travelling and being handled in safe and stable condition. Besides fulfilling requirements of airline, shipper and consignee are also required to provide appropriate documents for exporting and importing biological substances from and into China, according to local governmental organization’s requirement.

Depending on the nature of the shipment, a China permit maybe required when sending your package. If your shipment requires an import or export permit, **it must be completed and approved by the related government authority prior to shipment.**

All genetic materials such as human organs, tissues, cells, blood specimens, preparations of any types or recombinant DNA constructs, which contain human genome, genes or gene products as well as to the information related to such genetic materials, will be considered as “Human Genetic Resources”

All “Human Genetic Resources” to be exported or imported by means of hand carrying, mailing and transporting should be truthfully declared to the China Customs. China Customs will give clearance to those accompanied by the Import/Export Permit issued by the Human Genetic Resources Administration of China (HGRAC).

HKRAC was established and in charged by the Administrative Department of Science and Technology and the Administrative Department of Public Health. Which carry out routine duties of review and approve applications for exportation of human genetic resources.

Sending any other biological substances for medical production, treatment or research purposes...etc, shall also submit application to local administrative departments and relevant departments under the State Council for approval.

**Gateways for Export/Import**

- **Beijing**
- **Shanghai**
Documents

Shipper’s Declaration for Dangerous Goods is **NOT** required for shipment of Category B Infectious Substances assigned to UN3373 or Exemption. However, shipper/consignee still need to provide appropriate documents for Airline and China Customs. Here are some examples of documents required:

**Documents for Airline:**
- Packing list (with shipper & consignee’s detail address, packing & pieces, detail commodity description, weight, value...etc)
- Export permit or declaration (if required)
- DGM
- A courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious.

**Documents for Import & Export clearance:**
- Commercial Invoice
- Packing List
- Bill of Customer Declaration
- Customs Power of Attorney (POA)
- Description of commodity/HS code
- Customs Inspection Power of Attorney
- Customs clearance of Exit Commodity (issued by CIQ)
- Export and Entry Certification (issued by MOH)
- Other permit issued by relevant governmental organization subject to shipment content

One of the common required documents (Permit) for sending biological substance & products is the approval of Import/Export Special Articles for Verification of Health and Quarantine.

Royale International Freight Forwarding Agency (Shenzhen) Ltd.
Tel: + (86)-755-8394 3033
Website: www.royaleinternational.com
What Information do we need for quotation?

- Detail commodity description (with HS CODE)
- Full shipper and consignee detail
- Availability of Import /Export Right & necessary documents
- Quantity
- Packing
- Temperature requirement
- Transit time requirement
Operations Workflow – Export

1. Inquiry Received
2. Confirm shipment details & requirements
3. Contact shipper for necessary export documents
4. Confirm with airline & broker if shipment can be sent
5. Provide Quotation & Schedule
6. Shipment packing & labeling according to IATA requirement
7. Transport with temperature-controlled facilities (if required)
8. Export Clearance
9. Flight Departure

Operations Workflow – Import

1. Inquiry Received
2. Confirm shipment details & requirements
3. Contact consignee for necessary import documents
4. Confirm with broker if documents sufficient for clearance
5. Provide Quotation & Schedule
6. Overseas consign shipment & send pre-alert
7. Customs Clearance & Inspection (if required)
8. Delivery (with Temperature-Controlled facilities if required)
Contact

Royale China has a dedicate Hazmat/UN3373 technical team to provide professional advice and solution for your shipments.

For any product inquiry and quotation request, please contact:

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