P10

Check-In the “Infectious Baggage”

E356 – Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management

E356 Topic Tree

Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio-Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- Declaration of Pharmaceutical DG for Air Transport

Product Tracing, Recall and Disposal

- Product Tracing (anti-counterfeit technologies)
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Key Steps for shipping DG

1. Classification: Material being shipped must be categorized as a type of hazardous material
2. Identification: The shipper selects the proper shipping information from the IATA Dangerous Goods Regulations
3. Packaging: Properly packing the hazardous material for shipment
4. Marking: Writing the followings on the package: address, shipping name of hazardous material and UN code
5. Labelling: Identify the package as possessing a hazardous material and give a general indication of the type of material
6. Documenting: Filling in and signing the AWB and shipper’s declaration

Definitions for Infectious Substances

- Infectious substances are substances which are known to contain, or are reasonably expected to contain pathogens
- Pathogens are defined as micro-organisms (including bacteria, viruses) which can cause disease in humans or animals
- Cultures are the result of a process by which pathogens are intentionally propagated, and it does not include human or animal patient specimens
- Patient specimens are those collected directly from humans or animals, including but not limited to, excreta, secreta, blood, tissue and body parts being transported for purposes such as research and diagnosis

Classification of Infectious Substances

- Category A Infectious Substances are infectious substances 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. The list of Category A substances can be found in Table 3.6D of the IATA DGR Manual.

  They are assigned the following UN numbers

  and proper shipping names:

  - UN 2814 – Infectious Substance, affecting humans
  - UN 2900 – Infectious Substance, affecting animals only

IATA_DGR_3.6.2

- Category B Infectious Substances are those that do not meet the criteria for inclusion in Category A. They are assigned the following:
  - UN 3373 – Biological Substance, Category B

General Packaging Requirements for all infectious substances

- Basic triple packaging system shall be used for all infectious substances. It consists of three layers as follows:
  - Primary receptacle. A primary watertight, leak-proof receptacle containing the specimen. The receptacle is packaged with enough absorbent material to absorb all fluid in case of breakage or leakage.
  - Secondary packaging. A second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage or leakage.
  - Outer packaging. Secondary packagings are placed in outer shipping packagings with suitable cushioning material. Outer packagings protect their contents from outside influences, such as physical damage, while in transit.
  - Each completed package is normally required to be correctly marked, labelled and accompanied with appropriate shipping documents (as applicable).

Resources from: http://apps.who.int/iris/bitstream/10665/78075/1/WHO_HSE_GCR_2012.12_eng.pdf

Identification Table

Taken from IATA Dangerous Goods Regulations

Shipment Type	Proper Shipping name	UN Number	Hazard Class	Packing Group	Packing Instruction (PI)	Max Net Qty/Pkg for passenger aircraft	Max Net Qty/Pkg for cargo aircraft
Category A: Infectious Substance	Infectious Substance, Affecting Humans Affecting Animals, only	UN 2814 UN 2900	**6.2**	---	**620**	50 mL or 50 g	4 L or 4 Kg
Category B: Infectious Substance	Biological Substance, Category B	UN 3373	**6.2**	---	**650**	4 L or 4 Kg	4 L or 4 Kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN 1845	**9**	---	**954**	200 Kg	200 Kg

Packing Instruction (PI) 620

This instruction applies to UN 2814 and UN 2900

The packaging must include:

a) inner packaging comprising of

- leak-proof primary and secondary receptacle (able to withstand internal pressure of not less than 95kPa)
- absorbent materials such as cotton wool for liquids

b) Itemized list of contents, enclosed between the secondary packaging and the outer packaging; and

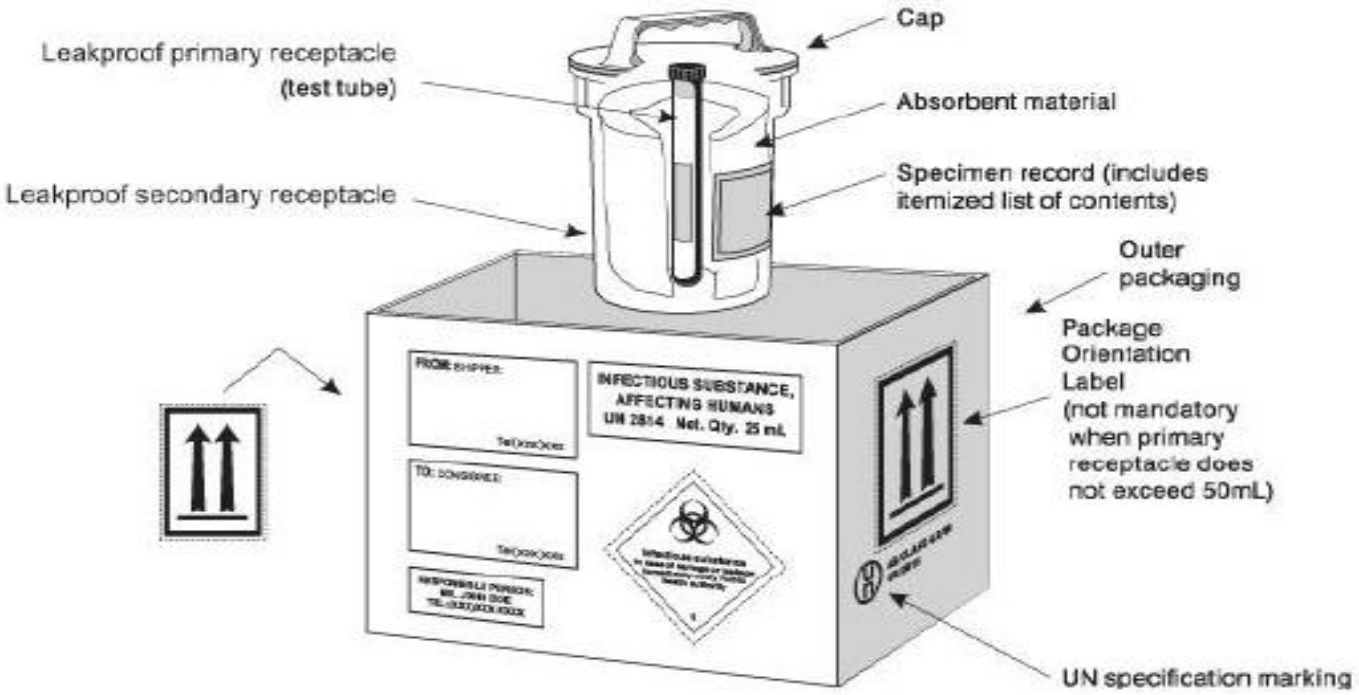
c) Rigid UN-certified outer packaging – the smallest external dimension must not be less than 100mm

Note: Do not consolidate infectious agents with other infectious agents

Packing Instruction (PI) 620

Example of Packing and Marking for Category A Infectious Substances

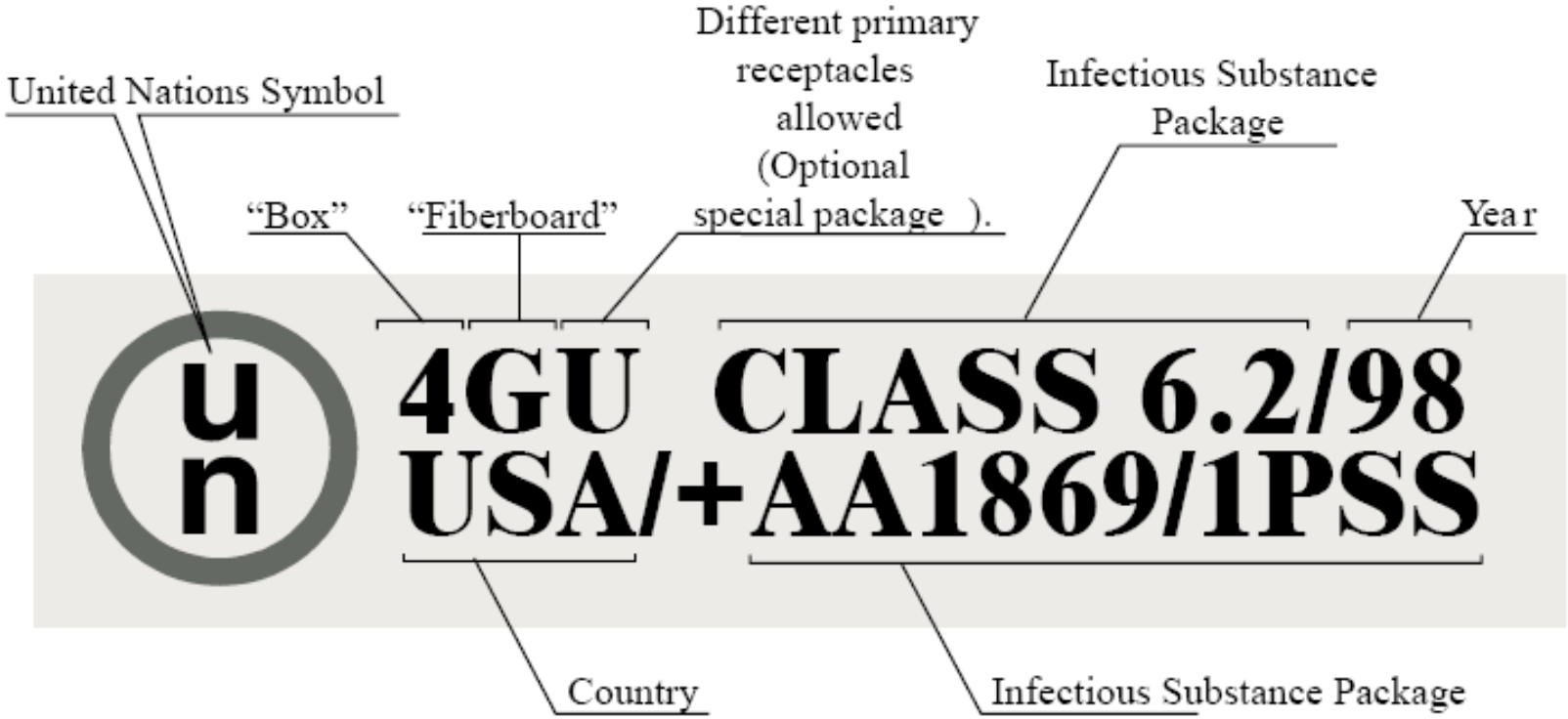
(See Packing Instruction 620 for additional requirements)



Notes:

1. The smallest external dimension of the outer packaging must not be less than 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

UN-certified box markings



The UN Packaging must therefore pass through some very rigorous testing, such as puncture and stacking test, water spray, and it has to be extensively sampled during the manufacturing phase in order to be certified UN approved packaging for DG.

Packaging Type & Material Code

Packaging Type Code

1. **Drum**
2. **Wooden Barrel**
3. **Jerrican**
4. **Box**
5. **Bag**
6. **Composite Packaging**

Therefore 4G often seen:

is a Box that is made from Fiberboard material

Material Code

A. Steel

B. Aluminum

C. Natural wood

D. Plywood

F. Reconstituted Wood

G. Fiberboard

H. Plastic Material

L. Textile

M. Paper, Multi-Wall

N. Metal (Other than steel or aluminum)

P. Glass, porcelain or stonerware

Other requirements for PI 620

- Must be marked with proper shipping name “Infectious Substance Affecting Humans” or “Infectious Substance Affecting Animals” and UN code “UN 2814” or “UN 2900”
- Must display the name and telephone number of a person responsible, on the exterior packaging, and quantity of content
- Must display the name and address of shipper and consignee on each package
- If shipping with dry ice, the dry ice should be outside of the secondary container or in an Overpack and the outer package should be marked and labelled to include the dry ice shipment

Packing Instruction (PI) 650

- This instruction applies to UN 3373 on passenger and cargo aircraft.

The packaging must include:

- Primary receptacle(s)
- Secondary packaging
- Rigid outer packaging (need not be UN certified) – at least one surface must be minimum dimensions of 100mm x 100mm

An itemized list of contents must be enclosed between the secondary packaging and the outer packaging

Packing Instruction 650 (for liquids)

For liquid substances:

- Primary receptacle(s) must be leak proof and not contain more than 1 L
- Secondary packaging must be leak proof
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them
- Sufficient absorbent material must be placed between primary receptacle and secondary packaging to absorb the entire contents
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95kPa
- Outer Packaging must not contain more than 4 L

Packing Instruction 650 (for solids)

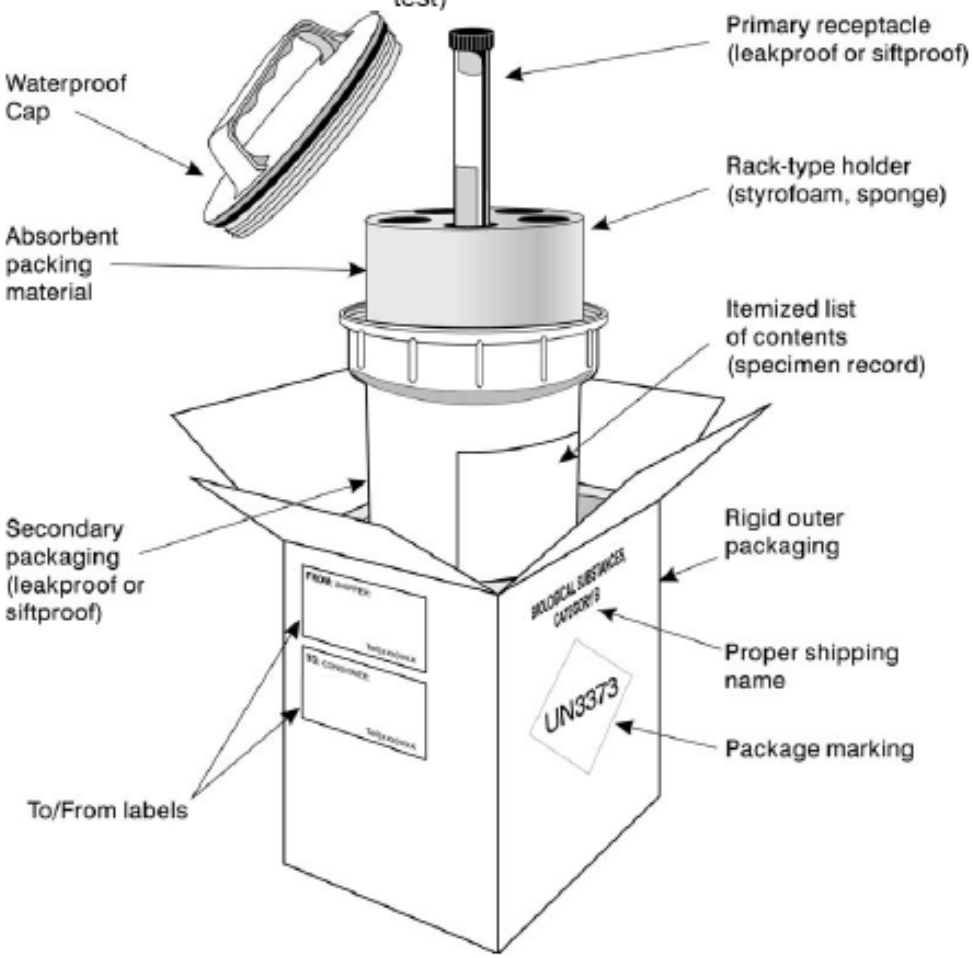
For liquid substances:

- Primary receptacle(s) must be leak proof and not contain more than 1 L
- Secondary packaging must be leak proof
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them
- Sufficient absorbent material must be placed between primary receptacle and secondary packaging to absorb the entire contents
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95kPa
- Outer Packaging must not contain more than 4 L

Packing Instruction (PI) 650

ANNEX 4 **Example of Packing and Marking for Category B Infectious Substances**

(See Packing Instruction 650 for additional requirements, e.g. drop test)



Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Other requirements for PI 650

- Must be marked with proper shipping name “Biological Substances, Category B” and UN code “UN 3373”
- Must display the name and address of shipper and consignee must be provided on each package, and quantity of content
- Completed package must be capable of successfully passing a drop test, where the height of the drop must not be less than 1.2m

Drop Test for PI 650

- Samples are subjected to free-fall onto a rigid, non-resilient, flat, horizontal surface. Since the samples are the shape of a box, five samples must be dropped once each:
  - flat onto base;
  - flat onto top;
  - flat onto longest side;
  - flat onto shortest side;
  - onto a corner.

Following the test, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging

Packing Instruction 954 – Dry Ice

- Previously named as PI 904.This instruction applies to UN 1845 on passenger and cargo aircraft. The maximum amount of dry ice that can be shipped is 200 kg.
- Carbon dioxide, solid (dry ice) in packages, when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.
- The following must be clearly marked:
  - Proper Shipping Name
  - UN number & Class Number
  - Net Weight of Dry Ice in package
  - Full name and address of shipper and consignee

Packing Group

- Dangerous Goods are assigned to the relevant packing group according to the degree of danger they present:

  Packing group I – High Danger

  Packing group II – Medium Danger

  Packing group III – Low Danger

Packing group only applies to some of the DG classification / division. e.g Division 6.2 has no Packing Group.

Labeling

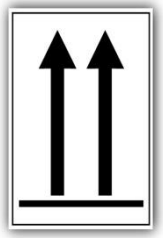
- **Labels may not overlap, be obscured or folded over a corner of package.**
- **There are two types of labels:**

  1) Hazard Labels (Diamond Shape) must also be clearly visible

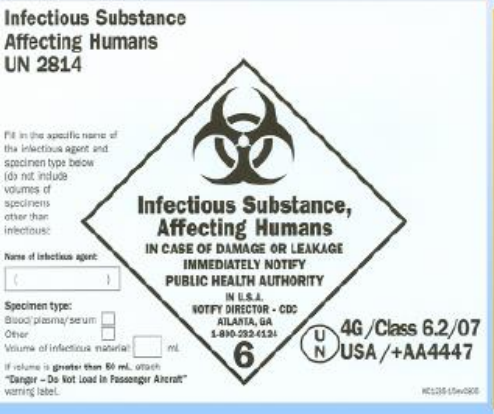
  2) Handling Labels (Square Shape) - Proper indication of Handling

  e.g. Cargo Aircraft Only must be present for shipment using PI that is only for cargo aircraft.

  Package orientation labels must be applied to two opposite sides

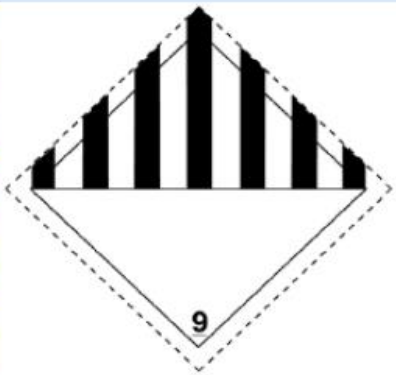


Class 6 Hazard Label

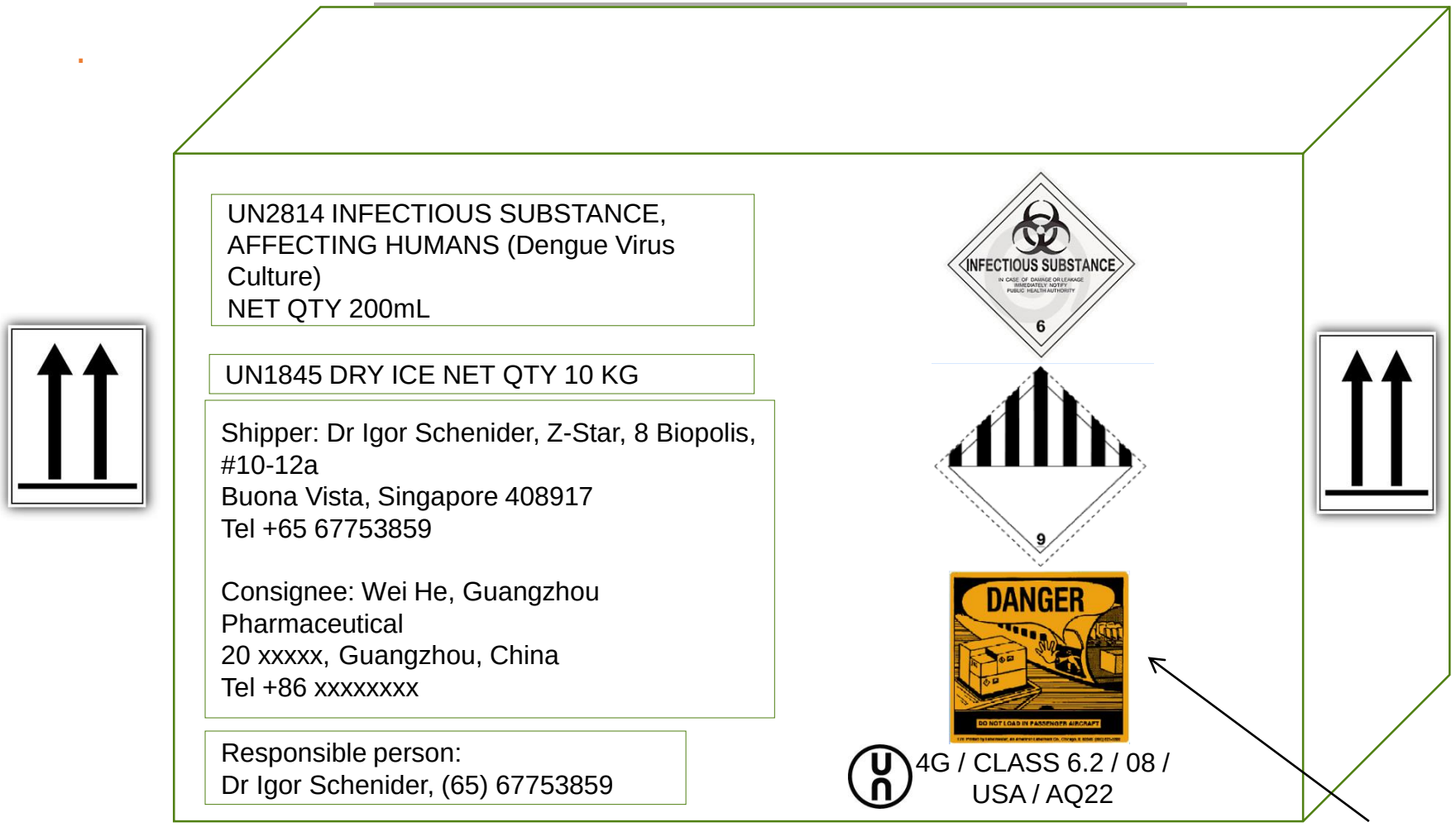


Cargo Aircraft-Only Label

Dry Ice: Hazard Class 9 diamond



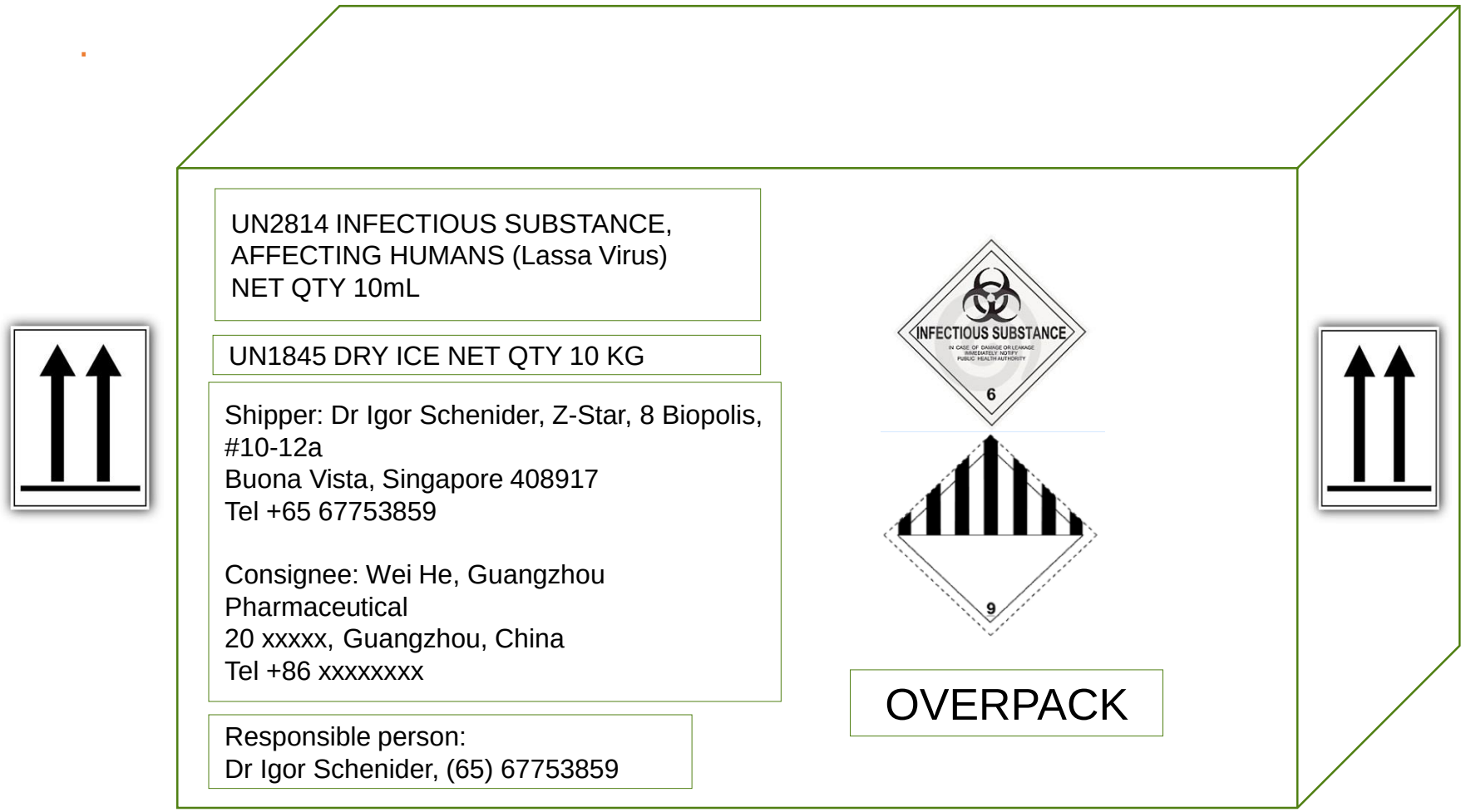
Marking and labeling for 200ml of Dengue virus (Culture), packed with dry ice in one UN certified box – Scenario 1



Cargo aircraft is needed to ship this content.

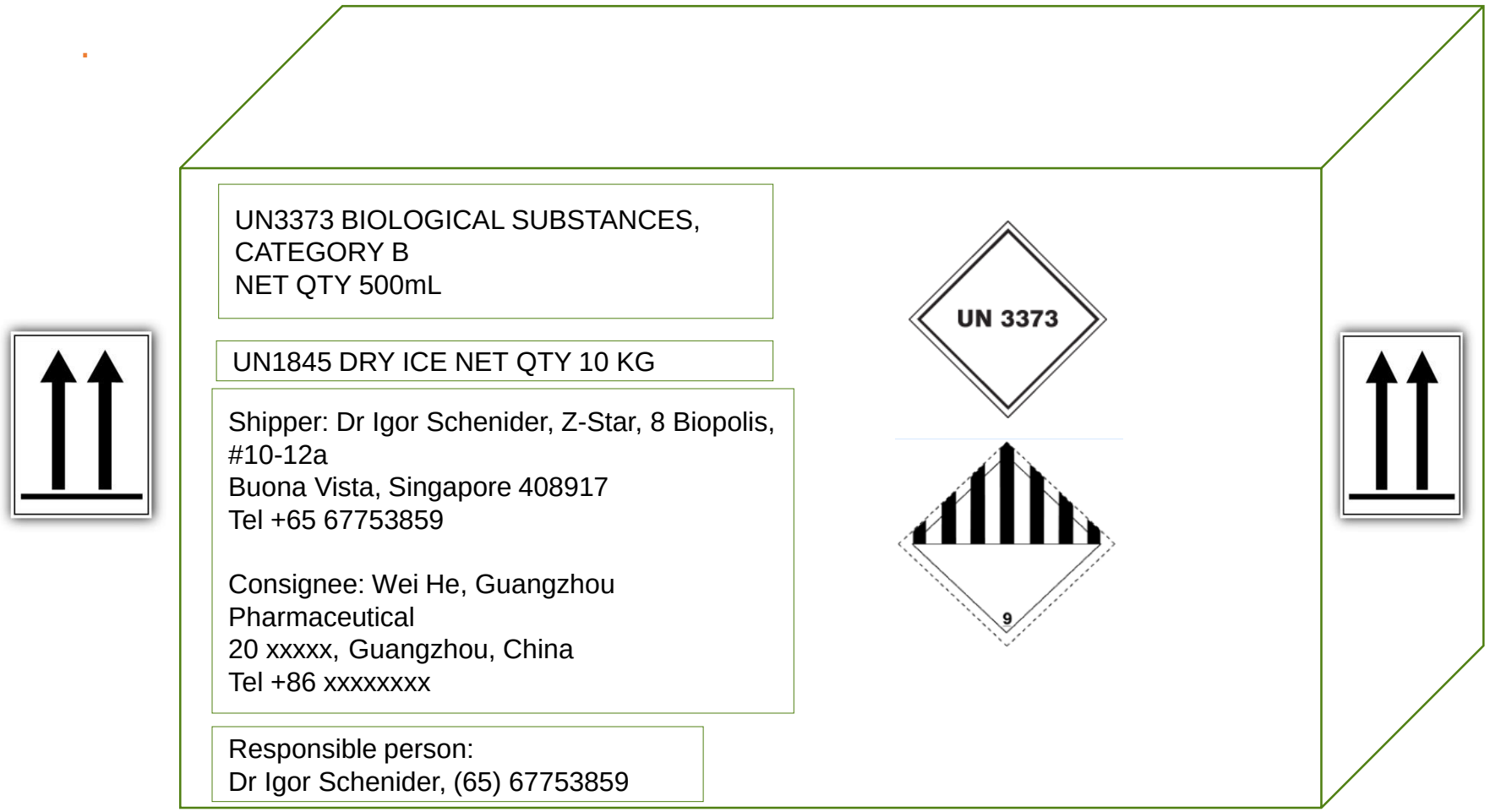
Cargo Aircraft label necessary as volume exceeds 50ml limit for passenger aircraft

Marking and labeling for 10ml of Lassa virus in UN certified box, with dry ice in an overpack – Scenario 2



Cargo/passenger aircraft is needed to ship this content.

Marking and labeling for 500ml of Dengue Virus Infected blood sample packed with dry ice – Scenario 3



Cargo/passenger aircraft is needed to ship this content.

Marking and labeling for 2.0 liters of Dengue Virus Infected blood sample packed with dry ice – Scenario 4

The 2.0L of blood sample has to be packed in 2 primary receptacles, each contains 1 L of blood sample

Cargo/passenger aircraft is needed to ship this content.

Today's Problem

- The classification of the 2 items are:

Materials	Infectious Substance, Category A	Infectious Substance, Category B
Cultured Dengue Virus	X	
Tube of blood infected with Cultured Dengue Virus		X

- Thus, PI 620 and PI 650 have to be complied with when packing and shipping these 2 items to Guangzhou by air
- PI 954 is used when shipping dry ice
- The maximum amount of each shipment type is regulated by IATA DGR
  - The 200ml of cultured dengue virus (using one UN-certified box only) cannot be shipped using passenger aircraft, cargo aircraft is needed to ship this content.
  - The 2.0L of blood sample has to be packed in 2 primary receptacles, each contains 1 L of blood sample.

Learning Outcomes

- Classify pharmaceutical items under Division 6.2 Infectious Substance of the UNRTDG.
- Select the appropriate packaging instructions (PI) and packaging types for different pharmaceutical, bio-chemical product and hazardous material.
- Demonstrate the packaging set up for different categories of infectious substances.