

Proper Shipment of Patient Specimens and Infectious Substances

Shipping Classification Definitions

Patient Specimens

Specimens collected from humans or animals including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

Note: If specimen has a high likelihood that it contains a human or animal pathogen, then it should be shipped as an Infectious Substance. An element of professional judgment is required when making such a decision. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, and endemic local conditions.

Infectious Substances

Substances which are known or 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 disease in humans or animals.

- Category A Infectious Substances: 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. See page 2 for a list of example agents.
- Category B Infectious Substances: An infectious substance which does not meet the criteria for inclusion in Category A.

Genetically Modified Microorganisms (GMMO) and Organisms (GMO)

Microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.



Example List of Category A: Infectious Substances

UN # and Proper Shipping Name	Micro-organism	
UN 2814 Infectious Substances Affecting Humans	Bacillus anthracis cultures Brucella abortus cultures Brucella melitensis cultures Brucella suis cultures Burkholderia mallei & Pseudomonas mallei cultures Burkholderia pseudomallei cultures Pseudomonas pseudomallei cultures Chlamydia psittaci – avian strains cultures Clostridium botulinum culture- Coccidioides immitis cultures Coxiella burnetii cultures Crimean- Congo hemorrhagic fever virus Dengue virus cultures Eastern equine encephalitis virus cultures Escherichia coli, verotoxigenic cultures Ebola virus cultures Flexal virus Francisella tularensis cultures Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus cultures Herpes B virus cultures	Human immunodeficiency virus cultures Highly pathogenic avian influenza virus cultures Japanese Encephalitis virus cultures Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Mycobacterium tuberculosis cultures Nipah virus Omsk hemorrhagic fever virus Poliovirusa cultures Rabies virus cultures Rickettsia prowazekii cultures Rickettsia rickettsia cultures Rift Valley fever virus cultures Russian spring-summer encephalitis virus Sabia virus Shigella dysenteriae type 1 cultures Variola virus Venezuelan equine encephalitis virus cultures West Nile virus cultures Yellow fever virus cultures
UN 2814 Infectious Substances Affecting Humans	African swine fever virus cultures Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus cultures Classical swine fever virus cultures Foot and mouth disease virus cultures Lumpy skin disease virus cultures Mycoplasma mycoides – Contagious bovine pleuropneumonia cultures	Peste des petits ruminants virus cultures Rinderpest virus cultures Sheep pox virus cultures Goatpox virus cultures Swine vesicular disease virus culture Vesicular stomatitis virus cultures



Shipping Information Summary

Shipment Type	Shipping Name	Proper UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Hazard Label(s)	Max. Net qty./ pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft	Special Provisions **
Category A infectious substance, affecting humans	Infectious substance, affecting humans*	UN 2814	6.2	-	602	Infectious substance	50mL / 50g	4L / 4kg	A81, A140
Category A infectious substance, affecting only animals	Infectious substance, affecting animals*	UN 2900	6.2	-	602	Infectious substance	50mL / 50g	4L / 4kg	A81, A140
Category B infectious substance	Biological substance, category B	UN 3373	6.2	-	650	UN 3373	4L / 4kg	4L / 4kg	-
Category B infectious substance	Biological substance, category B	UN 3373	6.2	-	650	UN 3373	4L / 4kg	4L / 4kg	
Genetically modified micro- organisms & organisms (non- infectious)	Genetically modified micro- organisms	UN 3245	9		913	Miscellaneous	No Limit	No Limit	A47
Patient Specimens (minimal likelihood that pathogens are present)	N/A	N/A	N/A	N/A	See Checklist on Pg.6	N/A	N/A	N/A	N/A

^{*} Identify technical name of agent in parenthesis

** Special Provisions:

- A81 The maximum quantity of infectious substance that can be shipped by air in one package is 4L or 4kg. The maximum quantity that may be shipped via passenger aircraft is 50mL or 50g. The Special Provision A81 allows the shipment of body parts, organs or whole bodies to not be restricted based on quantity limits, however the shipment must still comply with Packing Instruction 602. Specimens transported in accordance with this Special Provision must be noted on the Shipper's Declaration of Dangerous Goods in the "Authorization" column of the Declaration form.
- A48 Packaging tests are not considered necessary.
- A47 Genetically modified micro-organisms and genetically modified organisms, which meet the definition of an infectious substance and the criteria for inclusion in Division 6.2 (Category A or Category B Infectious Substances), must be transported as UN 2814, UN 2900 or UN 3373, as appropriate.
- A140 For the purposes of documentation, the proper shipping name must be supplemented with the technical name. Technical names need not be shown on the package. When the Infectious Substances to be transported are unknown, but suspected of meeting the criteria of Category A, and assigned to UN 2814 or UN 2900, the words "Suspected Category A Infectious Substance" must be shown in parenthesis following the proper shipping name on the Shipper's Declaration of Dangerous Goods, but not on outer package.



Checklist for Shipping: Patient Specimens

For which there is minimal likelihood that pathogens are present

Specimen Packaging

Specimen in leakproof primary container

Absorbent material is sufficient to absorb entire contents of primary container(s)

Primary containers are wrapped individually

Leakproof secondary container

Labeling Outer Container

Statement: "Exempt human specimen" or "Exempt animal specimen"

Miscellaneous Class 9 label(2) if shipment contains dry ice, "UN 1845" and amount used in kg

Completing the Airbill

Name and address of shipper and recipient

Check "Saturday Delivery" box if applicable

In Section 6 (Special Handling) of the airbill, indicate that the shipment is NOT a dangerous good

Check the "Dry Ice" box if applicable and indicate "UN 1845" and the quantity of dry ice in kg

Shipper's signature (optional)

Note: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required. That judgment should be based on the known medical history, symptoms, and individual circumstances of the source and endemic local conditions.



Checklist for Shipping: Category A Infectious Substances

Specimen Packaging

Specimen in leakproof primary container

Absorbent material is sufficient to absorb entire contents of primary container(s)

Primary containers are wrapped individually

Leakproof secondary container

Itemized list of contents placed between secondary and outer container

Labeling Outer Container

Infectious Substance, Class 6 label

"Infectious Substance Affecting Humans", "UN 2814", or "Infectious Substance"

Affecting Animals, "UN 2900", and net quantity of infectious substance Miscellaneous Class 9 label if shipment contains dry ice, "UN 1845" and amount used in kg

Name and telephone number of the responsible party, knowledgeable of the package contents and available 24 hours a day

If a shipment includes >50mL or 50g of a Category A infectious substance, then add a "Danger, do not load in passenger aircraft" label to the outer container

Dangerous Goods Declaration Form

Name, address and phone number of shipper and recipient

Mark out non-applicable "Aircraft Box"

Mark out non-applicable "Radioactive" box

24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents

Name and title of signatory, place, and date

Shipper's signature

"Nature and Quantity of Dangerous Goods" section of the Declaration Form

Complete this section using the information provided on Pages 3, 7, and 8 of this Guide



Checklist for Shipping: Category B Infectious Substances

Specimen Packaging

Specimen in leakproof primary container

Absorbent material is sufficient to absorb entire contents of primary container(s)

Primary containers are wrapped individually

Leakproof secondary container

Itemized list of contents placed between secondary and outer container

Labeling Outer Container

UN 3373 label(1)

"Statement: "Biological Substance, Category B" adjacent to UN 3373 (2) label

Miscellaneous Class 9 label(1) if shipment contains dry ice, "UN 1845"(1) and amount used in kg

Completing the Airbill

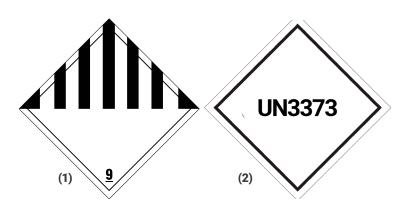
Name and address of shipper and recipient

Check "Saturday Delivery" box if applicable

In Section 6 (Special Handling) of the airbill, indicate that the shipment is a dangerous good, which does NOT require a Shipper's Declaration

Check the "Dry Ice" box if applicable and indicate "UN 1845"(1) and the quantity of dry ice in kg

Shipper's signature (optional)





Checklist for Shipping: Genetically Modified Microorganisms & Organisms

Specimen Packaging

Specimen in leakproof primary container

Absorbent material is sufficient to absorb entire contents of primary container(s)

Primary containers are wrapped individually

Leakproof secondary container

Itemized list of contents placed between secondary and outer container

Labeling Outer Container

Miscellaneous Class 9 label

"Genetically modified micro-organism" or "Genetically modified organism", "UN 3245"

If shipment contains dry ice, "UN 1845" and amount used in kg

Name and telephone number of the responsible party, knowledgeable of the package contents and available 24 hours aday

Dangerous Goods Declaration Form

Name, address and phone number of shipper and recipient

Mark out non-applicable "Aircraft Box"

Mark out non-applicable "Radioactive" box

24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents

Name and title of signatory, place, and date

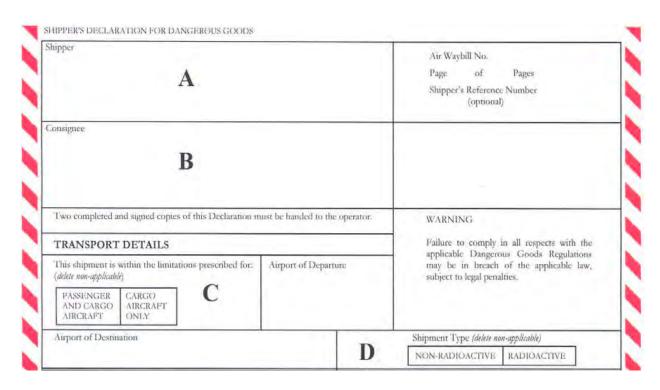
Shipper's signature

"Nature and Quantity of Dangerous Goods" section of the Declaration Form"

Complete this section using the information provided on Pages 3, 7, and 8 of this Guide



Completing the Top-half of a Dangerous Goods Declaration



Remember, FedEx requires all dangerous goods declaration forms to be typed or computer generated!

- A Shipper: Enter your full name, address and telephone number.
- B Consignee: Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible:" plus his/her name and phone number at the bottom of "Consignee" box.
- C Transport Details: Indicate here if your shipment is restricted to cargo aircraft only (if it is > 50ml or 50g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
- D Shipment Type: Cross out "radioactive" to indicate you are shipping a non-radioactive substance.



Completing the Bottom-half of the Dangerous Goods Declaration

	Dangerous Goods Identification					
UN or ID No.	Proper Shipping Name	Class	Packing	Quantity and Type of Packing	Packing Instructi ons	Authorization
E	F	G	H	Ι	J	K
Additional Hans	lling Information L	1				
described above marked and labe transport accord	that the contents of this consignment are fully by the proper shipping name, and are classif elled/placarded, and are in all respects in prope ing to the applicable international and national clare that all of the applicable air transport requ	red, packaged, r condition for governmental irrements have Signa	e/Title of Sign and Date ture rming above)	M	1	

- E UN or ID Number: Enter appropriate UN number (i.e. UN 2814 or UN 3245).
- F Proper Shipping Name: Enter the proper shipping name with the technical name in parentheses i.e. "Infectious substance, affecting humans (Hepatitis B virus)".
- G Class or Division: Enter appropriate hazard class (i.e. 6.2 or 9).
- H Packing Group: For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.
- I Quantity and Type of Packaging: Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages. If multiple packages are packed in one overpak state ("All packed in one fibreboard box."). Do not spell like "fiberboard." If using an overpack, indicate here with "Overpack Used."
- J Packing Instructions: Enter appropriate packing instruction number. The Packing Instruction for infectious substances is 602. The Packing Instruction for dry ice is 904. The Packing Instruction for genetically modified micro-organisms or organisms is 913.
- K Authorization: Note any Special Provisions, if applicable (i.e. if you choose to not include the technical name on outer package, you must list A140 in this column).
- L Additional Handling Instructions: The statement "Emergency Contact:" followed by a 24-hour emergency telephone response number where the shipper can be reached.
- M Sign and date each copy of your Shipper's Declaration.

A statement must appear on the Shipper's Declaration. The statement reads as follows: "I declare that all of the applicable air transport requirements have been met." This statement is often pre-printed on the form (see above). If this statement does not appear on the form then it should be typed in the "Additional Handling" section of the form.



Packed in Compliance with IATA Packing Instruction 602 (Category A Infectious Substances)

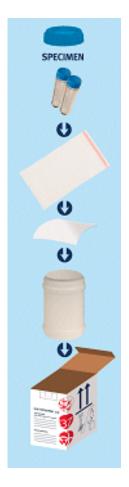
An Introduction to the Classifications and Packing Guidelines

Packaging for Infectious Substances Category A & B must comprise of three packaging layers.

- Primary/Inner Packaging (e.g. evacuated tubes; sample pouch; universal pots): Primary must be leak-proof and primary or secondary must withstand an internal pressure of 95kPa.
- Absorbent (e.g. absorbent material, 4 bay pouch): For liquids, there must be absorbent sufficient to absorb entire contents contained in primary packaging. Multiple primaries must be individually wrapped or separated in order to prevent contact between them.
- Secondary Packaging (e.g. pouch/bag, container): Secondary must be leak-proof and secondary or primary must withstand an internal pressure of 95kPa.
- Outer Packaging (e.g outer box): Rigid outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100mm x 100mm. Also to contain suitable cushioning material and be clearly marked appropriately



Note: Shipments that include > 50mL or 50g of Category A Infectious Substances must have the danger label attached to the outer container.





Does your shipment need a permit?

CDC Import Permit

Is required if you import:

- · Any etiologic agent
- Any arthropod or other animal host or vector of human disease
- Any exotic living arthropod or other animal capable of being a host or
- Vector of human disease

CDC: Etiologic Agent Import Permit Program

Website: cdc.gov/cpr/ipp

Telephone: 404.718.2077; FAX: 404.471.8333

Permit Program details: cdc.gov.

cpr/ipp/etool.htm

USDA/ APHIS Permit

May be required for all imports/exports, and interstate transport of:

- Animal or plant pathogens
- Specimens reasonably believed to contain animal or plant pathogens
- Any pest or vector of animal or plant disease
- Potentially hazardous animal or plant products

APHIS: Imports and Exports

Website: aphis.usda.gov/aphis/home

Telephone: 301.734.3277 (primary contact: Dr. Waleid Muhmed)

Imports and exports details: aphis.usda. gov/aphis/ourfocus/importexport

Department of Commerce (DOC) Export License

May be required when exporting:

- Infectious agents of human, plant, and animal diseases
- Genetic material, and products which might be used for culture of large amounts of agents

DOC: Bureau of Industry and Security (BIS)

Website: bis.doc.gov

Telephone: 202.482.4811

Review list of biological materials which may require an export license on pages 12-13 of this guide.

For questions about import or export requirements, contact Biological Safety at 909.60.0160.



List of biological materials that may require a DOC Export License

Contact Biological Safety at 909.607.8698 prior to Shipment or Receipt of the following human pathogens and toxins:

Bacteria

- · Bacillus anthracis
- · Brucella abortus
- · Brucella melitensis
- Brucella suis
- Burkholderia mallei (Pseudomonas mallei)
- Burkholderia pseudomallei (Pseudomonas pseudomallei)
- · Chlamydia psittaci
- Clostridium botulinum
- Clostrium perfringens, epsilon toxin producing types
- Enterohaemorrhagic Escherichia coli, serotype O157, and other verotoxin producing serotypes
- · Francisella tuarensis
- · Salmonella typhi
- · Shigella dysenteriae
- · Vibrio cholerae
- · Yersinia pestis

Toxins

- Abrin
- Aflatoxins
- Botulinum toxins
- · Cholera toxin
- · Clostridium perfringens toxin
- Conotoxin
- Diacetoxyscirpenol toxin

- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- Staphylococcal aureus toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum albumin lectin 1 (Viscumin)

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- · Hantaan virus
- Hendra virus (Equine morbillivirus)
- · Japanese encephalitis virus
- Junin virus
- · Kyasanur forest virus
- · Lassa fever virus
- Louping ill virus

- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- · Murray Valley encephalitis virus
- Nipah Virus
- · Omsk haemorrhagic fever virus
- Oropouche
- Pulmonary and renal syndromehaemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- · Rabies virus cultures
- · Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-bourne encephalitis virus (Russian Spring-Summer encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox virus
- · Yellow fever virus



Contact Biological Safety at 909.607.8698 prior to Shipment or Receipt of the following animal pathogens and toxins:

Animal Bacteria

· Mycoplasma mycoides

Animcal Viruses

- African horse sickness virus
- · African swine fever virus
- Avian influenza virus (highly pathogenic strains
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- · Lumpy skin disease virus
- Lyssa virus
- Newcastle disease virus
- Peste des petis ruminants virus
- Porine enterovirus type 9 (Swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)

- Rinderpest virus
- Sheep pox virus
- Wine fever virus (Hog cholera virus)
- Teschen disease virus
- · Vesicular stomatitis virus

Plant Fungi

- Colletotrichum coffeanum var. virulans (C.kahawae)
- Coochliobolus miyabeanus (Helminthosporium oryzae)
- Magnaporthe grisea (pyricularia grisea/pyricularia oryzae)
- Microcyclus ulei (Dothidella ulet)
- Puccinia graminis (Puccinia graminis f. sp. tritici)
- Puccinia striformis (Puccinia glumarum)

Plant Bacteria

- Xanthomonas albilineans
- Xanthomonas campestris pv. citri types A, B, C, D, E or otherwise classified as X.
- citri, X campestris pv. aurantifolia or X.
- · campestris pv. Citrumelo
- Xanthomonas oryzae
- Clavibacter michiganenis subspecies sepedonicus
- Ralstonia solanacearum Races 2 & 3

Plant Viruses

- Potato Andean latent tymovirus
- Potato spindle tuber viroid

Genetic Elements/Genetically Modified Organisms

Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms. Genetic elements that contain nucleic acid sequences coding for any controlled "toxins" or "subunits of toxins".

Technical Note: Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms. Genetically modified organisms that contain nucleic acid sequences coding for any controlled "toxins"



HHS AND USDA SELECT AGENTS AND TOXINS 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

Botulinum neurotoxins

Botulinum neurotoxin producing species of Clostridium

Cercopithecine herpesvirus 1 (Herpes B virus)

Clostridium perfringens epsilon toxin

Coccidioides posadasii/Coccidioides immitis

Conotoxins

Coxiella burnetii

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol

Eastern Equine Encephalitis virus

Ebola virus

Francisella tularensis

Lassa fever virus

Marburg virus

Monkeypox virus

Reconstructed replication competent forms of the 1918

pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed

1918 Influenza virus)

Ricin

Rickettsia prowazekii

Rickettsia rickettsii

Saxitoxin

Shiga-like ribosome inactivating proteins

Shigatoxin

South American Haemorrhagic Fever viruses

Flexal

Guanarito

Junin

Machupo

Sabia

Staphylococcal enterotoxins

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses

Central European Tick-borne encephalitis

Far Eastern Tick-borne encephalitis

Kyasanur Forest disease

Omsk Hemorrhagic Fever

Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

Yersinia pestis

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei (formerly Pseudomonas mallei)

Burkholderia pseudomallei (formerly Pseudomonas

pseudomallei)

Hendra virus Nipah virus

Rift Valley fever virus

Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

Ehrlichia ruminantium (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever virus

(Alcelaphine herpesvirus type 1)

Menangle virus

Mycoplasma capricolum subspecies capripneumoniae

(contagious caprine pleuropneumonia)

Mycoplasma mycoides subspecies mycoides small

colony (MmmSC) (contagious bovine pleuropneumonia)

Peste des petits ruminants virus

Rinderpest virus

Sheep pox virus

Swine vesicular disease virus

Vesicular stomatitis virus (exotic): Indiana subtypes

VSV-IN2, VSV-IN3

Virulent Newcastle disease virus¹

USDA PLANT PROTECTION AND QUARANTINE (PPQ) **SELECT AGENTS AND TOXINS**

Peronosclerospora philippinensis (Peronosclerospora

Phoma glycinicola (formerly Pyrenochaeta glycines)

Ralstonia solanacearum race 3, biovar 2

Rathayibacter toxicus

Sclerophthora rayssiae var zeae

Synchytrium endobioticum

Xanthomonas oryzae

Xylella fastidiosa (citrus variegated chlorosis strain)

11/17/2008

¹ A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (<u>Gallus</u> gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.



Manufacturers of Certified Shipping Containers for Infectious Substances, Patient Specimens, and Dry Ice

Source Packaging of New England, Inc.

405 Kilvert St.

Warwick, RI 02886

800.200.0366

sourcepakaging.com

Therapak Corporation

1440 Arrow Highway, Unit A

Irwindale, CA 91706

888.505.7377

therapak.com

CARGOpak Corporation

3215-A Wellington Court

Raleigh, NC 27615

800.266.0652

cargopak.com

Inmark, Inc.

220 Fisk Drive S.W.

Atlanta, GA 30336-0309

800.646.6275

inmarkinc.com

EXAKT Technologies, Inc.

7416 N Broadway Ext.,

Suite E

Oklahoma City, OK 73116

800.923.9123

exaktusa.com

HAZMATPAC, Inc.

5301 Polk St., Bldg. 18

Houston, TX 77023

800.347.7879

hazmatpac.com

Sonoco Thermosafe

3930 N. Ventura Dr.

Suite 450

Arlington Heights, IL 60004

800-232-7442

thermosafe.com