



Infectious Substances Shipping Guidelines

Effective 1 January 2006

The Complete Reference Guide for
Pharmaceutical & Health Professionals

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Senior Vice President
Marketing and Commercial Services
International Air Transport Association
800 Place Victoria
P.O. Box 113
Montreal, Quebec
CANADA H4Z 1M1

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Preface

This seventh Edition of the IATA *Infectious Substances Shipping Guidelines* is current as of January 2006. The content of the Guidelines is based on the requirements contained in the 47th Edition (2006) of the IATA Dangerous Goods Regulations, but also includes information applicable to the transport of infectious substances by other modes of transport including sea, road, rail and through mail and courier systems. In general, the requirements for the transport of dangerous goods by air are more restrictive than the surface modes, sea, road or rail. Therefore compliance with the air regulations will, with some exceptions, be sufficient to meet other modal requirements.

While the title of the publication is the “Infectious Substances Shipping Guidelines”, the content also includes information regarding the transport of “biological products” and “clinical waste”.

In developing these Guidelines, IATA has drawn on its extensive experience to give special attention to the format and wording to ensure that the Guidelines are a readily understandable and easy-to-use guide.

Always refer to the latest edition and supplements of the relevant regulations applicable to the handling and transportation of infectious substances and diagnostic specimens, both national and international. In addition, there may be additional rules and regulations applicable including state, regional and local requirements. Your responsibility as a shipper, carrier or consignee is to become familiar with the regulations and to ensure the strictest compliance. These rules and regulations are for the protection of the shipper, acceptance staff, carrier, public, receiver and the environment during the transport of specimens from point of origin to destination.

3 Classification

3.1 GENERAL

Dangerous goods are defined as those goods which meet the criteria of one or more of nine UN hazard classes and, where applicable, to one of three UN Packing Groups according to the provisions of this section. The nine classes relate to the *type of hazard* whereas the packing groups relate to the applicable *degree of danger* within the class.

For example, Ethanol, is a flammable liquid and is therefore classified in Class 3. Some hazard classes are further subdivided into hazard divisions due to the wide scope of the class. An example of this is Class 6, which comprises Division 6.1 — Toxic substances and Division 6.2 — Infectious substances.

All nine hazard classes and the two divisions of Class 6 are listed below:

- Class 1 — Explosives
- Class 2 — Gases
- Class 3 — Flammable Liquids
- Class 4 — Flammable Solids
- Class 5 — Oxidizing Substances and Organic Peroxides
- Class 6 — Toxic and Infectious Substances
 - Division 6.1 — Toxic substances.
 - Division 6.2 — Infectious substances.
- Class 7 — Radioactive Material
- Class 8 — Corrosives
- Class 9 — Miscellaneous Dangerous Goods

Notes:

1. *The order in which the classes are numbered is for convenience and does not imply a relative degree of danger.*
2. *These Guidelines will concentrate on those substances that are classified in Division 6.2 — Infectious substances, although there is reference in Section 4.2 to substances in other classes that may be used to preserve or maintain the viability of specimens and also to*

Genetically modified organisms and micro-organisms, which are classified in Class 9.

3.2 UN NUMBERS

Dangerous goods are assigned a UN (United Nations) number or ID (Identification) number and proper shipping name according to their hazard classification and their composition. The proper shipping name is used to identify the dangerous article or substance on the outside of the package and, where required, on the “Shipper’s Declaration for Dangerous Goods”.

3.3 CLASSIFICATION CRITERIA

3.3.1 Definitions

For the purposes of these Guidelines:

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 disease in humans or animals.

Note:

Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assigned to UN 3172.

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.

Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in the paragraph below.

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

Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or from bio-research.

3.3.2 Classification of Infectious Substances

Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 or UN 3373, as appropriate.

Infectious substances are divided into the following categories:

Category A: 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. Indicative examples of substances that meet these criteria are given in Table 3.3.A.

Note:

An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

- (a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.
- (b) Assignment to UN 2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Notes:

1. *The proper shipping name for UN 2814 is **Infectious substance, affecting humans**. The proper shipping name for UN 2900 is **Infectious substance, affecting animals** only.*
2. *The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.*
3. *In the following table, the micro-organisms written in italics are bacteria, mycoplasma, rickettsia or fungi.*

TABLE 3.3.A
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.3.2)

UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substance affecting humans	<i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only) <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only) <i>Chlamydia psittaci</i> – avian strains (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Coxiella burnetii</i> (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i> , verotoxigenic (cultures only) Ebola virus Flexal virus <i>Francisella tularensis</i> (cultures only)

TABLE 3.3.A
Indicative Examples of Infectious Substances Included in Category A in Any Form
Unless Otherwise Indicated (3.3.2) (Cont'd)

UN Number and Proper Shipping Name	Micro-organism
	Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus <i>Mycobacterium tuberculosis</i> (cultures only) Nipah virus Omsk hemorrhagic fever virus <i>Poliovirus</i> (cultures only) Rabies virus (cultures only) <i>Rickettsia prowazekii</i> (cultures only) <i>Rickettsia rickettsii</i> (cultures only) Rift Valley fever virus (cultures only) <i>Russian spring-summer encephalitis virus</i> (cultures only) Sabia virus <i>Shigella dysenteriae type 1</i> (cultures only) <i>Tick-borne encephalitis virus</i> (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) <i>West Nile virus</i> (cultures only) <i>Yellow fever virus</i> (cultures only) <i>Yersinia pestis</i> (cultures only)
UN 2900 Infectious substances affecting animals	African swine fever virus (cultures only) Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) <i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only)

TABLE 3.3.A
Indicative Examples of Infectious Substances Included in Category A in Any Form
Unless Otherwise Indicated (3.3.2) (Cont'd)

UN Number and Proper Shipping Name	Micro-organism
	Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.

Note:

*The proper shipping name of UN 3373 is **Diagnostic specimens, Clinical specimens or Biological substance category B**. From 1 January 2007, it is anticipated that the use of the shipping names *Diagnostic specimens* and *Clinical specimens* will no longer be permitted.*

Exceptions

Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Guidelines unless they meet the criteria for inclusion in another class.

Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Guidelines unless they meet the criteria for inclusion in another class.

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 Guidelines unless they meet the criteria for inclusion in another class.

Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection are not subject to these Guidelines, unless they meet the criteria for inclusion in another class.

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 Guidelines.

3.3.3 Biological Products

For the purposes of these Regulations, 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 these 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.

Note:

Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

3.3.4 Genetically Modified Micro-organisms and Organisms

Genetically modified micro-organisms not meeting the definition of an infectious substance must be classified according to Subsection 3.3.9

3.3.5 Medical and Clinical Waste

Medical or clinical wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900, as appropriate. Medical or clinical wastes containing infectious substances in Category B, must be assigned to UN 3291.

Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances must be assigned to UN 3291.

Note:

*The proper shipping name for UN 3291 is **Clinical waste, unspecified, n.o.s. or (Bio) Medical waste, n.o.s. or Regulated medical waste, n.o.s.***

Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.3.6 Infected Animals

A live animal that has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be transported under terms and conditions approved by the appropriate national authority.

Unless an infectious substance cannot be consigned by any other means, live animals must not be used to consign such a substance.

Animal carcasses affected by pathogens of Category A or which would be assigned to Category A in cultures only, must be assigned to UN 2814 or UN 2900 as appropriate. Other animal carcasses affected by pathogens included in Category B must be transported in accordance with provisions determined by the competent authority.

3.3.7 Patient Specimens

Unless patient specimens comply with the following requirements, they must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Guidelines 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. The packaging must meet the following conditions:

- (a) The packaging 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 at least one surface having minimum dimensions of 100 mm × 100 mm;
- (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 or 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.

Note:

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 diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

3.3.8 Carbon Dioxide, Solid (Dry Ice)

Carbon dioxide, solid (dry ice), UN 1845, is classified as a dangerous goods in Class 9—Miscellaneous Dangerous Goods. The packing requirements for dry ice are outlined in Packing Instruction 904 (see 5.7—Packing Instructions). Packaging used for the transport of dry ice must allow for the continuous release of carbon dioxide gas (no pressure build-up).

3.3.9 Genetically Modified Micro-Organisms (GMMOs) or Genetically Modified Organisms (GMOs)

Genetically modified organisms and micro-organisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction. They must be assigned to UN 3245.

GMMOs or GMOs are not subject to these Guidelines when authorised for use by the appropriate national authorities of the States of origin, transit and destination.

3.3.10 Other Dangerous Goods

Shippers in the medical field must also be aware of other substances and materials which are dangerous goods, some examples include:

- Cryogenic liquids, such as refrigerated liquid nitrogen (Class 2 Division 2.2 Non-flammable non-toxic gas);
- Ethanol solution (Class 3 Flammable liquid);
- Methanol (Class 3 Flammable liquid);
- Pyridine (Class 3 Flammable liquid);
- Strong formaldehyde solutions (Class 8 Corrosive material);
- Hypochlorite solutions (Class 8 Corrosive material);
- Aviation regulated liquid, n.o.s. (Class 9 Miscellaneous Dangerous Goods) ⁽¹⁾;
- Iodine.

Note:

More information on these substances, including the specific Packing Instructions, can be found in the IATA Dangerous Goods Regulations.

3.4 CLASSIFICATION SCENARIOS

The recent changes in the classification criteria for infectious substances and removal of the risk groups has raised some uncertainties on just how specimens should be classified. The following scenarios and the flowchart shown in Figure 3.4.A are provided as guidance on the correct classification.

1. A blood sample known or reasonably suspected to contain EBOLA VIRUS.
Appropriate classification: Infectious substances, affecting humans UN 2814.
2. A culture of FOOT AND MOUTH DISEASE.
Appropriate classification: Infectious substances, affecting animals, UN 2900.
3. A blood sample taken from a patient known or suspected to have a category B pathogen, such as HEPATITIS B or HIV.
Appropriate classification: Biological substance, category B ⁽²⁾, UN 3373.
4. Culture of BOVINE TUBERCULOSIS.
Appropriate classification: Biological substance, category B ⁽²⁾, UN 3373.
5. Laboratory stock culture of a pathogen in category B, e.g. INFLUENZA VIRUS.
Appropriate classification: Biological substance, category B ⁽²⁾, UN 3373.

⁽¹⁾ Formaldehyde solutions containing less than 25%, but 10% or more formaldehyde must be shipped under this Proper Shipping Name.

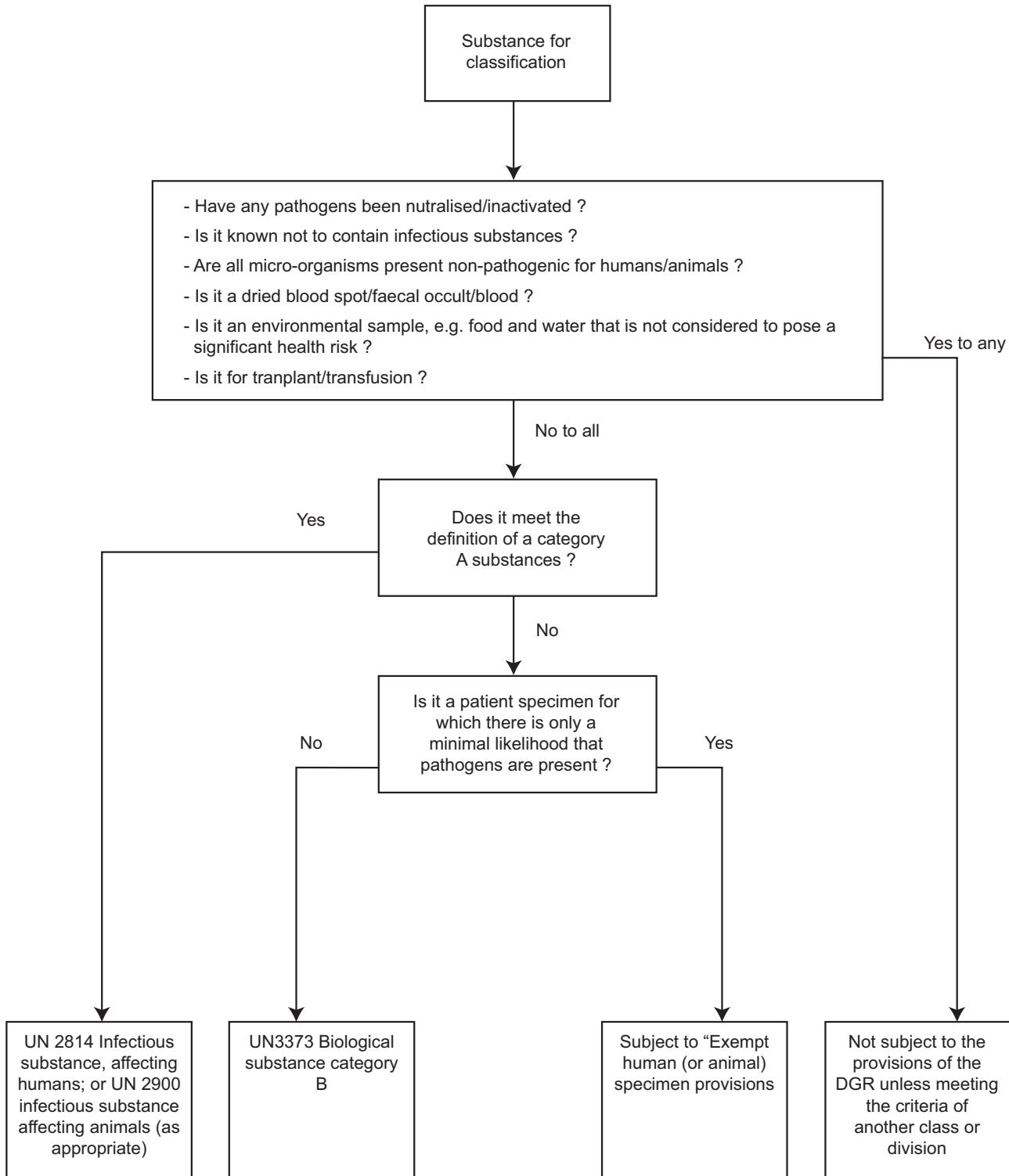
⁽²⁾ The shipping names "Diagnostic Specimens" or "Clinical Specimens" may be used until December 31, 2006.

6. Specimen containing a category A or B infectious substance, treated so as to inactivate or neutralise the pathogens such that they no longer pose a health risk.

Appropriate classification: Not subject to the transport requirements for dangerous goods, unless meeting the criteria for another class or division.

7. Patient specimens other than those known or reasonably suspected to contain a category A infectious substance. e.g. those sent for testing for Cholesterol (blood), diabetes (urine), bowel cancer (faecal). The classification will depend on professional judgement:
 - (i) if a professional judgement is made that there is only a minimal likelihood that pathogens are present, the specimen is not subject to the provisions of these Guidelines, provided they are packed in accordance with the provisions detailed under Patient Specimens in subsection 3.3.7;
 - (ii) if no professional judgement is made, the specimen must be classified as UN 3373.

**Figure 3.4.A
Classification Flowchart**



4 Identification

4.1 GENERAL

Dangerous goods must be properly identified by UN or ID number, proper shipping name, class or division and packing group (if applicable) and infectious substances are no exception. The relevant identification information from the IATA Dangerous Goods Regulations is shown in Figure 4.2.A. The list is divided into 14 columns as follows:

4.1.1 Column A

UN or ID (identification) number — Contains the 4-digit number assigned to the article or substance under the United Nations classification system. When this number is used, it must be prefixed by the letters “UN”. If the substance has not been assigned a number in the UN classification system, a temporary identification number in the 8000 series has been assigned and is indicated where appropriate. Numbers in the 8000 series must be identified with the “ID” prefix instead of when UN is indicated for markings and documentation in these Guidelines. For example, the number would appear as UN 1950 or ID 8000 and not as 1950 or 8000.

4.1.2 Column B

Proper Shipping Name/Description — Contains an alphabetical listing of dangerous goods articles and substances identified by their proper shipping names together with qualifying descriptive text. The proper shipping name is shown in bold (dark) type whereas the descriptive text is shown in light type. See 8.1.3 for additional information concerning proper shipping names. Where applicable, cross-references from other names by which a substance or article is commonly known to the correct proper shipping name are given. The following symbols appear against some of the entries in this column:

Symbol — Meaning

★ — Addition of technical name(s) in parentheses following the proper shipping name is required.

† — Additional information can be found in the Glossary.

Note:

The “★” and “†” symbols are not part of the proper shipping name.