U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

Pipeline and Hazardous Material Administration (PHMSA)

Department of Transportation

AN ICCVAM UPDATE

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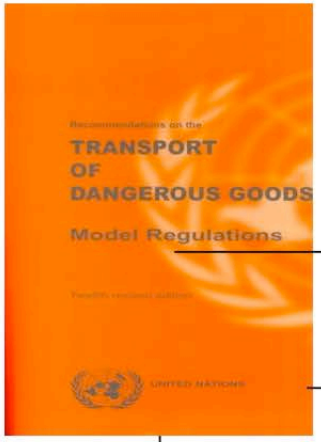
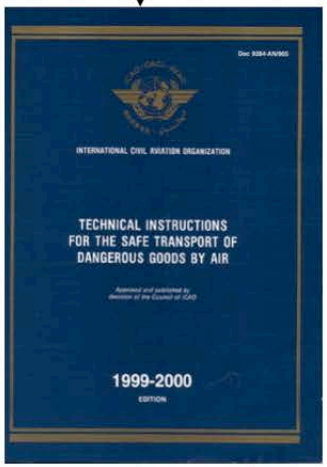
International Regulatory Structure



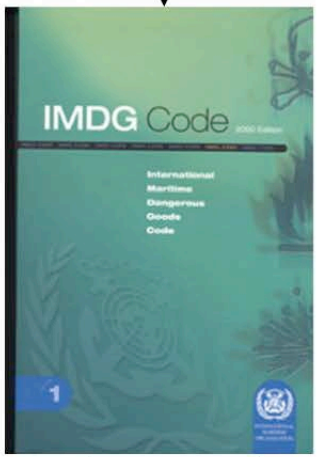
The UN Model Regulations serve as the basis for transport regulations

Canadian TDGR&Mexican Standards

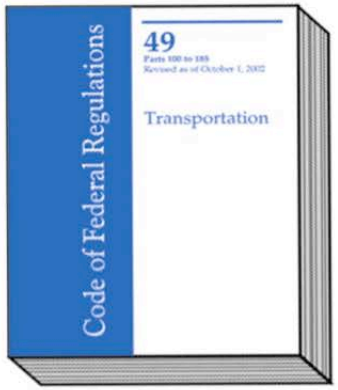
Other National Regulations



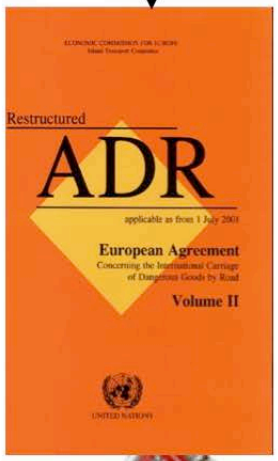
Air



Ocean



US HMR



Europe

Regulatory Classification

- Acute Toxicity
- Skin Corrosivity
- Infectious Substances

ACUTE TOXICITY

	Inhalation	Dermal	Oral
Gas	√		
Dust & Mists	√		
Liquids	√	√	√
Solids		√	√

CLASSIFICATION

Gas	Division 2.3	Hazard Zone A Arsine	Hazard Zone B Chlorine	Hazard Zone C Sulfur Dioxide
Dust & Mists	Division 6.1	Packing Group I	PG II	PG III
Liquids	Division 6.1	PG I Hazard Zone A Hazard Zone B	PG II	PG III
Solids	Division 6.1	PG I	PG II	PG III

SKIN CORROSIVITY

Classification - Class 8, and further subdivided into PG I PG II PG III.

Corrosive Substances – substances which, by chemical action, will cause severe damage when in contact with living tissue, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

PG I - Materials that cause full thickness destruction of intact skin tissue within an observation period of up to 60 minutes starting after the exposure time of three minutes or less.

PG II – Materials other than those meeting PG I criteria that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes.

PG III - Materials other than those meeting PG I or II criteria that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hr.

Infectious Substances

Classification 6.2
Category A: UN2814, UN2900
Category B: UN3373

WHO RISK GROUPs

WHO Risk Group 1 (no or low individual and community risk). A microorganism that is unlikely to cause human disease or animal disease

WHO Risk Group 2 (moderate individual risk, low community risk). A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited.

WHO Risk Group 3 (high individual risk, low community risk). A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

WHO Risk Group 4 (high individual and community risk). A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

TEST GUIDELINES FOR ACUTE TOXICITY

- Inhalation

  Test Method not specifically specified

  OECD TG 403 (Dusts and Aerosol) – Acute Inhalation Toxicity Acceptable

  OECD TG 436 (Acute Toxic Gas Method)

- Oral

  OECD TG 423 – Acute Oral Toxicity – Acute Toxic Class Method

  OECD TG 420 - Fixed Dose Procedure

  OECD TG 425 – Acute Oral Toxicity : Up-and-Down Procedure

  No In-Vitro Method at this point.

TEST GUIDELINES FOR CORROSIVITY

DOT E-10904 – An In Vitro alternative to the In Vivo method.

OECD TG 404 – In Vivo method

OECD TG 435 – "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006

OECD TG 430 – "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

OECD TG 431 – "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

In Vitro Corrosivity Test Methods

Performance Standards for DOT E-10904 call for an in vitro testing system that mimics the effect of corrosives on living skin and classifies the level of corrosivity in chemicals, formulations, and waste.

Taken together, these observations suggest that the Corrositex® test, as defined by the parameters embodied in DOT E-10904, is a very suitable and safe *in vitro* alternative to the *in vivo* methods that are employed to assess the dermal corrosivity of hazardous materials.

A substance which is determined not to be corrosive in accordance with the OECD TG 430 or 431 may be considered not to be corrosive to skin without further testing.

A substance which is determined to be corrosive in accordance with the OECD TG 430 or 431 must be further tested using TG 435 or TG 404 for the PG assignment.