P07 How can I ship them safely?

E356 – Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management (DSCM)

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

Definition of Dangerous Goods (DG)

"International standard term for goods covered under the 'UN Recommendations On The Transport Of Dangerous Goods' (see UN Recommendations). Definition of 'dangerous goods' covers articles or materials capable of posing significant risk to people, health, property, or environment when transported in quantity. It includes items of common use, such as aerosol cans, perfumes, and paints."

source: www.businessdictionary.com

DG is also known as HAZMAT or Hazardous Materials.

Definition of Dangerous Goods (DG)

https://www.youtube.com/watch?v=HpHt_c3gIt0

DG – Potential Negative Impact and Risks

- Accident and Injuries to human and living organisms
  - Chemical accidents involving flammable, toxic corrosive or reactive substances, causing harm or adverse consequences to persons
- Losses and Damage to Assets e.g. facilities, equipment and inventory
  - Forced shut down (Stop work orders) and production downtime may leads to short term to long term operational and economic losses
- Harm to environment
  - Air, Water and Land pollutions

DG in Pharmaceutical and Bio-Chem Supply Chain

- Oxygen supply apparatus may contain DG in the form of compressed or liquefied oxygen.
- Pharmaceutical and medical supplies that may include toxic, poisonous, oxidisers, organic peroxides, flammable liquids, flammable solids.

- Chemicals and reagents that are used for lab testing
- Narcotic / psychotropic drugs
- Infectious organs and blood samples infected with diseases.
- Chemicals held at cryogenic temperatures

DG- Risks Mitigation and Control

- Hazard Communication – Labelling & SDS (Safety Data Sheet)
- Specialised and specific training for personnel
- Exposure Control Measures & Personal Protection Equipment (PPE)

- Planning and Design of Storage Facility:
  - Physical Segregation, Separation of incompatible materials/ substances
  - Safety and Precautionary Features e.g. Fire Fighting measures, Spill containment Kit, Eye shower, first aid measures
- Proper Handling and Storage
- Proper Packaging and Transport
- Proper Disposal

- Regulatory Control e.g. Registrations, Licensing and Permits

Hazard Assessment/ Danger Descriptions

- Classification of DG and hazardous materials in accordance with UNRTDG and GHS
  - **UNRTDG**- a system for classification, packaging and labelling of DG to enable them to be **transported** safely published by **UN SCE TDG** (intended for safe transport of DG)
  - **GHS** – **UN** Globally Harmonised System for Classification and Labelling of Chemical (intended for health and safety at workplace)
- SDS (Safety Data Sheet)
- Use of appropriate warning labels, placards and marks.

UNRTDG - Classification of DG

- UN Recommendations On The Transport Of Dangerous Goods Classified DG in 9 Classes of DG, in 1957. These classifications apply to air, land, rail, and sea transport of dangerous goods and form the basis for the relevant uniform international regulations.
- The regulations for air, road, rail, and sea transport are not identical. Multi modal transportation of dangerous goods may fall under the regulation of different authorities.

UNITED NATIONS

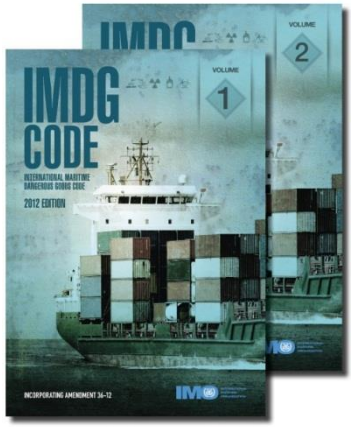
Regulation for Air Transport

- International Civil Aviation Organisation (ICAO) in UN is the international governing body for Dangerous Goods by Air. ICAO Technical Instructions are as such treated as “Law” for DG.
- International Air Transport Association (IATA) Dangerous Goods Regulations(DGR) is the international standard used by Airlines.
- Civil Aviation Authority of Singapore (CAAS) governs DG in Singapore Air. It adopts ICAO TI/IATA DGR standards.

Regulation for Sea Transport

- International Maritime Organisation (IMO) in UN is the international governing body of DG in the seas.
- International Maritime Dangerous Goods Code (IMDG) is guideline from IMO.
- Maritime and Port Authority of Singapore (MPA) (Dangerous Goods, Petroleum and Explosives) Regulations 2005 is Singapore's law for DG at sea in Singapore

IMO



Regulation for Land Transport

- International Carriage Of Dangerous Goods By Road is recognised generally as a guideline. However, different regulations exist in different countries.
- In Singapore, land transport of dangerous goods is governed under various Acts by several agencies including
  - National Environment Agency (NEA)
  - Singapore Police Force (SPF)
  - Singapore Civil Defence Force (SCDF)

UNRTDG - DG Classification

- Classification is based on the dangerous properties/ intrinsic hazard(s) of the various substances or articles
- The Nine classes of DG are:

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** **Class 7: radioactive material** **Class 8: corrosive substances** **Class 9: miscellaneous dangerous substances**

- The nine classes of DG are further divided into sub classifications. (referred to in IATA as “Divisions”).

  For example:

  DG Class 6 : Toxic and Infectious Substances

  Division 6.1 Toxic Substances

  Division 6.2 Infectious Substances

- The paint is classified in Class 3, Flammable Liquids.

UNRTDG- DG Classification/Labels

1 EXPLOSIVES

2.1 FLAMMABLE GASES

2.2 NON-FLAMMABLE NON-TOXIC GASES

2.2 OXIDIZING GAS
SUB RISK
5.1 (NITROUS OXIDE & OXYGEN ONLY)

2.3 TOXIC GASES

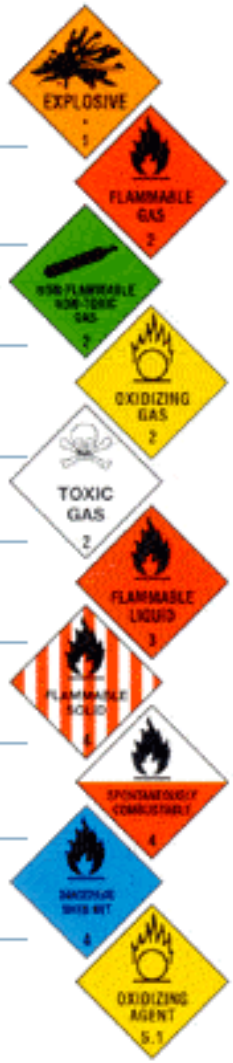
3 FLAMMABLE LIQUIDS

4.1 FLAMMABLE SOLIDS
(and other reactive substances)

4.2 SUBSTANCES LIABLE TO SPONTANEOUS COMBUSTION

4.3 SUBSTANCES THAT IN CONTACT WITH WATER EMIT FLAMMABLE GASES

5.1 OXIDIZING SUBSTANCES



5.2 ORGANIC PEROXIDES

6.1 TOXIC SUBSTANCES

6.2 INFECTIOUS SUBSTANCES

7 RADIOACTIVE MATERIAL
(CATEGORY I)

7 RADIOACTIVE MATERIAL
(CATEGORY II or III)

8 CORROSIVE SUBSTANCES

9 MISCELLANEOUS DANGEROUS GOODS AND ARTICLES

MIXED CLASS LABEL FOR ROAD AND RAIL TRANSPORT

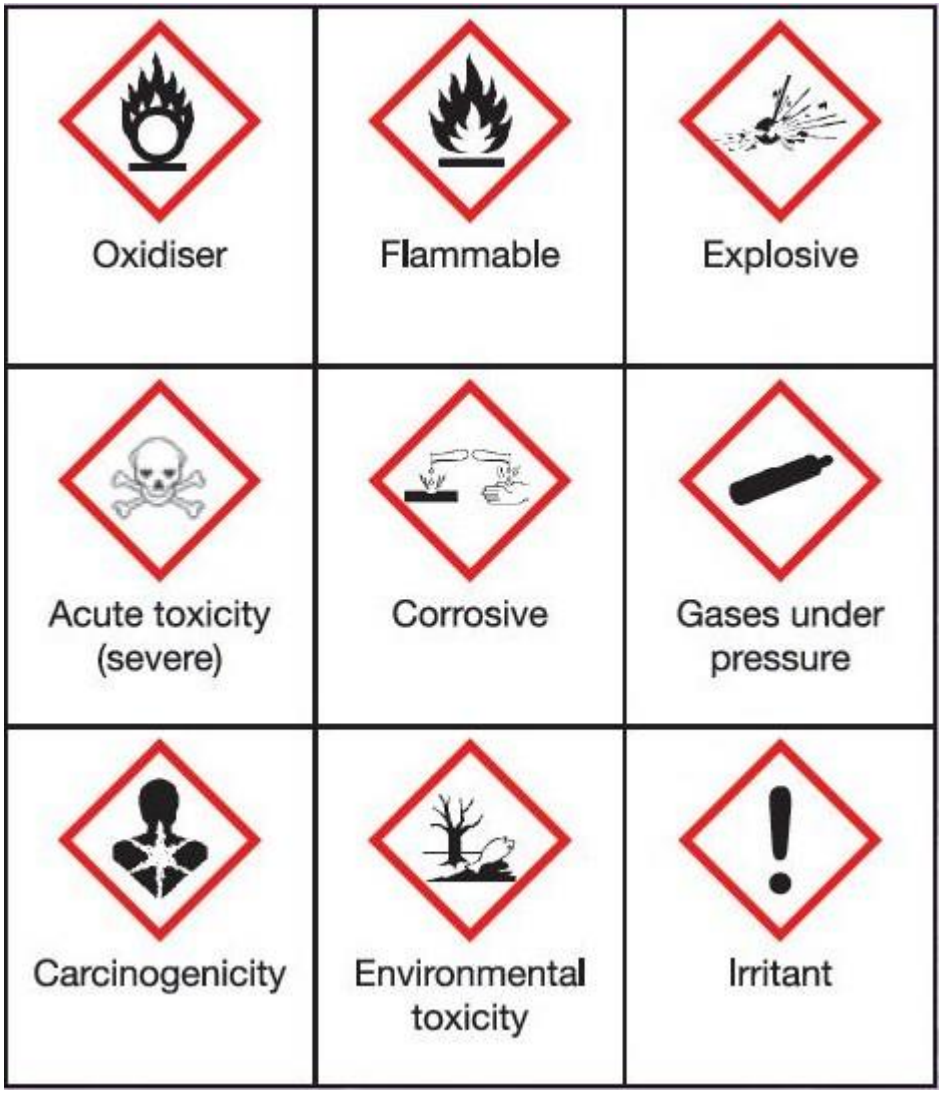
SUBSIDIARY RISK LABEL TO BE USED WITH ELEVATED TEMPERATURE SUBSTANCES

GHS

- Globally Harmonised System (GHS) for Hazard Classification and Labelling of Chemicals.
- United Nations system to identify hazardous chemicals and to inform users; including employers, workers, consumers, transport workers and emergency responder about these hazards through standard symbols and phrases on the packaging labels and SDS.
- The GHS hazard communication is the starting point and provides the necessary information for the establishment of a chemical safety programme, which forms part of the safety and health management system.
- In Singapore, the Singapore Chemical Industry Council (SCIC) has published a guidebook on GHS of Classification and Labeling of Chemicals.

GHS

- GHS Classification Criteria
  - 16 Physical Hazards e.g. Explosives, Gases under pressure
  - 10 Health Hazards e.g. Acute toxicity
  - 1 Environmental Hazard – i.e. Hazardous to the aquatic environment
- The classified chemicals are assigned a fixed set of GHS pictograms.



GHS pictograms

SDS - Safety Data Sheet

- SDS is a document that provides comprehensive information on the chemical, pharmaceutical or biochemical product
- The SDS should be updated regularly by the product steward responsible for the ethical management of the safety, health and environmental risks of chemicals.
- Under GHS, information in the SDS is presented under 16 sections/ headings as given below:

1. Identification of the substance or mixture and of the supplier
2. Hazard(s) Identification
3. Composition/ Information on Ingredients
4. First-Aid measures
5. Fire-Fighting measures
6. Accidental release measures
7. Handling and Storage
8. Exposure controls/ personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological Information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

SDS – Source of information on

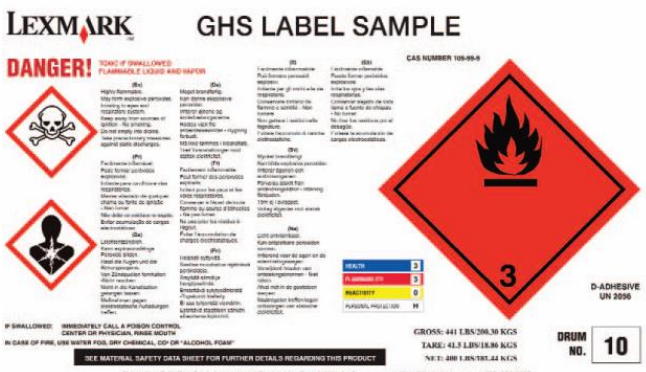
- Proper warning labels to use for hazard identification – **section 1, 2**
- First-Aid Treatment - **section 4**
- Storage and handling of DG
  - Physical Segregation, Separation and Zoning - **section 7**
  - Safety Features & Emergency Response Planning e.g. exposure controls, fire fighting and spill containment equipment - **section 5, 6 and 8**
- Exposure control using PPE – **section 8**
- Proper Disposal – **section 13**
- Transport , **UNRTDG** classification (proper shipping name and UN number) and UN Packing group – **section 14**
- Regulations specific for the product – **section 15**

GHS Label

A GHS label provides a summary of the chemical's hazard and warns the users to take precautions if necessary.

All containers / packages of classified chemicals must be affixed with a GHS label. Information required on a GHS label include pictograms, signal words, hazard statements, precautionary statements, product identifier and supplier information.

Sample GHS Label



1 Sulfuric Acid

3 Danger! May be harmful if swallowed. Causes sever skin burns and eye 4 damage. Fatal if inhaled. Harmful to aquatic life.

Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection.

5

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

In case of fire Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

See Material Safety Data Sheet for further details regarding safe use of this product.

6 Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA Telephone : +18003255832

1 Product Identifier
2 Pictograms
3 Signal word, "Danger!"
4 Hazard Statements
5 Precautionary Statements
6 Supplier Information

Placards, Labels and Marks

- Effective method of communicating
  - any dangers associated with a substance and
  - The appropriate handling procedures to follow for that substance
- Can be used at workplace, for transport, by consumers and by emergency responders.
- Minimum size are as follows:
  - Placard 250 mm x 250 mm
  - Label 100 mm x 100 mm
  - Mark Depending on specific marks

DG Handling - Specialized and Specific Training

- Chemical Safety induction program and training course mandatory by NEA, SCDF, MOM under the various Acts and regulations.
- First-Aid Training

- Specific Training required for personnel transporting DG
  - IATA DG awareness and training course for air shipment
  - IMDG for sea shipments
- To handle or transport DG, you must be properly certified by the proper accreditation authorities, like IATA, IMO, NEA recognized training centers.

Dangerous Goods Segregation Table

Class or Division	1.3	1.4	1.5	1.6	2.1	2.2	2.3 Zone A	2.3 Zone B	3	4.1	4.2	4.3	5.1	5.2	6.1 PGI Zone A	7	8 Liquids
Explosives - 1.3	*	*	*	*	X		X	X	X		X	X	X	X	X		X
Explosives - 1.4	*	*	*	*	O		O	O	O		O				O		O
Very Insensitive Explosives - 1.5	*	*	*	*	X	X	X	X	X	X	X	X	X	X	X	X	X
Extremely Insensitive Explosives - 1.6	*	*	*	*													
Flammable Gases - 2.1	X	O	X				X	O							O	O	
Non-Toxic, Non-Flammable gases - 2.2			X														
Toxic Gas Zone A - 2.3	X	O	X		X				X	X	X	X	X	X			X
Toxic Gas Zone B - 2.3	X	O	X		O				O	O	O	O	O	O			O
Flammable Liquids - 3	X	O	X				X	O					O		X		
Flammable Solids - 4.1			X				X	O							X		O
Spontaneously Combustible Materials - 4.2	X	O	X				X	O							X		X
Substances which, in contact with water, emit flammable gases - 4.3	X		X				X	O							X		O
Oxidizers - 5.1	X		X				X	O	O						X		O
Organic Peroxides - 5.2	X		X				X	O							X		O
Toxic Liquids PGI Zone A - 6.1	X	O	X		O				X	X	X	X	X	X			X
Radioactive Materials - 7			X		O												
Corrosive Liquids - 8	X	O	X				X	O		O	X	O	O	O	X		

(X): These materials may not be loaded, transported, or stored together in the same transport vehicle or storage facility during the course of transportation. Both main hazard risks and subsidary risks need to be taken into account.

(O): These materials may not be loaded, transported, or stored together in the same transport vehicle or storage facility during the course of transportation **unless separated** from each other (Usually **>=3 meters**). However, Class 8 (corrosive) liquids may not be loaded above or adjacent to Class 4 (flammable) or Class 5 (oxidizing) materials except that the mixture of contents would not cause a fire or a dangerous evolution of heat or gas;

(*) Segregation among different Class 1 (explosive) materials is governed by the compatibility table. Exception: ammonium nitrate (UN 1942) and ammonium nitrate fertilizer may be loaded or stored with Division 1.1 (Class A explosive) or Division 1.5 (blasting agents) materials.

(Blank): The absence of any hazard class or division or a blank space in the table indicates that no restrictions apply.

https://www.chemsafetypro.com/Topics/TDG/Dangerous_goods_segregation_hazardous_chemicals_segregation.html

Today's Problem

- Jun Sheng can find comprehensive information from the SDS of Argon (compressed) that states:

  - Hazards identification
    UNRTDG classification - Class 2.2, Non-flammable non-toxic gas
  - Proper shipping name – ARGON, COMPRESSED
  - Advices on safe handling, storage and transport of DG
- Liquid Nitrogen that states:
  - Hazards identification
    UNRTDG classification - Class 2.2, Non-flammable non-toxic gas
  - Proper shipping name – NITROGEN, REFRIGERATED LIQUID
  - Advices on safe handling, storage and transport of DG

Today's Problem

- In order to handle, store and transport DG, Jun Sheng can engage a carrier company which must possess the followings:
  - Knowledge of DG to ensure proper hazard communication and mitigate risks and exposure
  - Facility with safety equipment and resource support required
  - Personnel with specialised and specific training competent to handle DG during storage and transport

- Based on Dangerous Goods Segregation Table
- It is safe to store both types of DG together and during transportation.

GHS Label for Argon, compressed

Argon, compressed 1

3 **Danger**

Contains gas under pressure; may explode if heated
May displace oxygen and cause rapid suffocation. 4

2

Use and store only outdoors or in a well ventilated place
Use backflow preventive device in piping
Use only with equipment rated for cylinder pressure
Close valve after each use and when empty
Response: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical attention/advice.
Storage: Protect from sunlight when ambient temperature exceeds 52°C/125°F

5

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Company: Linde Malaysia Sdn Bhd (100783-W)
Address: No 13, Jalan 222,46100 Petaling Jaya,Selangor,Darul Ehsan, Malaysia
Emergency Tel: 1800 883 888 (Toll Free)

1 Product Identifier
2 Pictograms
3 Signal word, “Danger!”
4 Hazard Statements
5 Precautionary Statements
6 Supplier Information

GHS Label for Liquid Nitrogen

Nitrogen, Refrigerated Liquid 1

3 **Danger**

Contains refrigerated gas; may cause cryogenic burns or injury.
May displace oxygen and cause rapid suffocation. 4

2

Use and store only outdoors or in a well ventilated place
Wear cold insulating gloves/face shield/eye protection
Use backflow preventive device in piping
Do NOT change or force fit connections
Close valve after each use and when empty
Always keep container in upright position
Response: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical attention/advice.
IF ON SKIN:. Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

5

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Learning Outcomes

- Define DG / HazMat and recognize the importance of mitigating any negative impact on safety, health and environment
- Classify bio-chemical and pharmaceutical products under the appropriate DG (Dangerous Goods) / HAZMAT (Hazardous Materials) classification.
- Describe and classify the UNRTDG classification and GHS classification of DG
- Interpret relevant information from the SDS that is critical for proper DG handling, storage and transport
- Prepare GHS label based on information from SDS
- Identify the various authorities governing hazardous material transportation and storage.