

EAGOSH Meeting

Pharmaceuticals in Air Transport

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Agenda

- ❑ Classification of Pharmaceuticals: IATA vs ADR
- ❑ Safety Data Sheets for Pharmaceuticals
- ❑ Examples: Mint Oil, Akmemycin, Regaine, Amoxilin, Isoflurane, Fluoruracil
- ❑ Summary



Classification, Labelling and Marking of Pharmaceuticals

Search for „Medicine“ in IATA DGR:

Several entries of UN Numbers

Medicine,, n.o.s.
Medicine,, n.o.s.
Medicine, liquid, flammable, toxic, n.o.s....
Medicine, liquid, flammable, toxic, n.o.s....
Medicine, liquid, toxic, n.o.s....
Medicine, liquid, toxic, n.o.s....
Medicine, solid, toxic, n.o.s....
Medicine, solid, toxic, n.o.s....

**Applicable, though both expressions are not mentioned?
ID 8000 (PI Y963)**

A112 Only substances of Class 2 (non-toxic aerosols only), Class 3 (Packing Group II or III), Division 6.1 (Packing Group III only), UN 3077, UN 3082, UN 3175, UN 3334 and UN 3335, without a subsidiary hazard, are permitted to be assigned to ID 8000, Consumer commodities. Dangerous goods that are forbidden for transport aboard passenger aircraft must not be classified as consumer commodities.

Glossary

CONSUMER COMMODITY A Consumer Commodity is defined as a material which is packed and distributed in a form intended or suitable for retail sales for the purposes of personal care or household use. See Special Provision A112 for Classes and Divisions permitted under this definition.



Classification, Labelling and Marking of Pharmaceuticals

Search for „Pharmaceutical“ in ADR:

601 Pharmaceutical products (**medicines**) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR.

→ Not existing in IATA DGR !!!

Search for „Medicine“ in ADR:

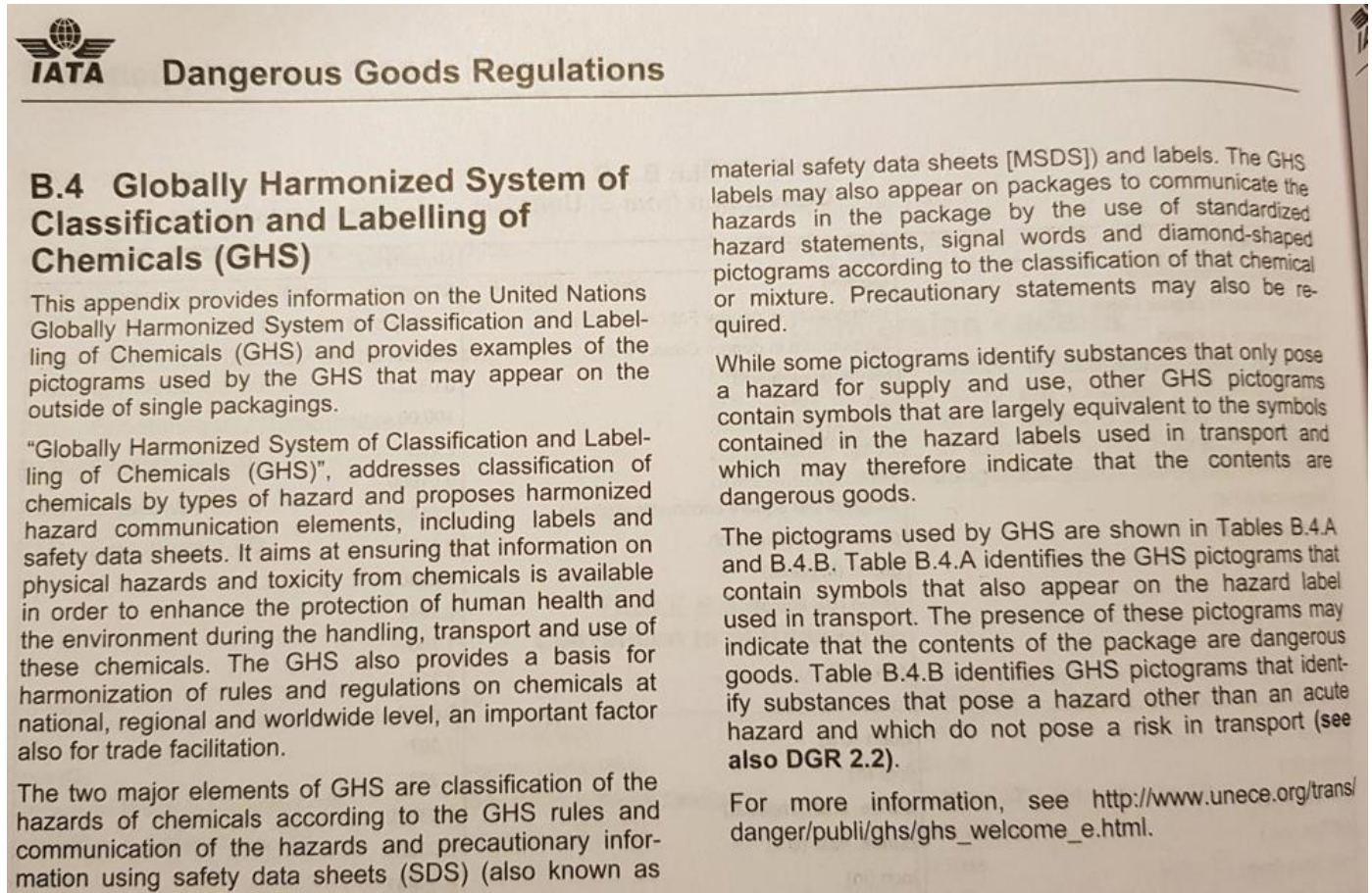
Several entries of UN Numbers (equal to IATA)



SDS in air transport regulations

A SDS can be asked to clarify a classification or provide data. (see 9.1. Note 1)

But available only for those products, for which a SDS is legally required by national or regional regulations!



The image shows a page from the IATA Dangerous Goods Regulations document. At the top left is the IATA logo, and to its right is the title "Dangerous Goods Regulations". The main heading is "B.4 Globally Harmonized System of Classification and Labelling of Chemicals (GHS)". Below this heading is a paragraph of text explaining the purpose of the appendix. To the right of this text is another paragraph of text. At the bottom of the page, there are three small images: a cargo plane, a globe with hazard symbols, and a cargo ship.

IATA Dangerous Goods Regulations

B.4 Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

This appendix provides information on the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and provides examples of the pictograms used by the GHS that may appear on the outside of single packagings.

"Globally Harmonized System of Classification and Labelling of Chemicals (GHS)", addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. It aims at ensuring that information on physical hazards and toxicity from chemicals is available in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals. The GHS also provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level, an important factor also for trade facilitation.

The two major elements of GHS are classification of the hazards of chemicals according to the GHS rules and communication of the hazards and precautionary information using safety data sheets (SDS) (also known as

material safety data sheets [MSDS]) and labels. The GHS labels may also appear on packages to communicate the hazards in the package by the use of standardized hazard statements, signal words and diamond-shaped pictograms according to the classification of that chemical or mixture. Precautionary statements may also be required.

While some pictograms identify substances that only pose a hazard for supply and use, other GHS pictograms contain symbols that are largely equivalent to the symbols contained in the hazard labels used in transport and which may therefore indicate that the contents are dangerous goods.

The pictograms used by GHS are shown in Tables B.4.A and B.4.B. Table B.4.A identifies the GHS pictograms that contain symbols that also appear on the hazard label used in transport. The presence of these pictograms may indicate that the contents of the package are dangerous goods. Table B.4.B identifies GHS pictograms that identify substances that pose a hazard other than an acute hazard and which do not pose a risk in transport (see also DGR 2.2).

For more information, see http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.



SDS in air transport regulations

To what extent are safety data sheets for pharmaceuticals or substances helpful as a source of information for risk assessment?

No. 3.1 para. 2 TRGS 525 mentions, among other things, safety data sheets as a source of information for risk assessment. **Manufacturers and suppliers of pure medicinal substances are obliged to provide users with up-to-date safety data sheets.**

However, this does not apply to medicinal products that are delivered ready-to-use by the pharmaceutical industry (finished medicinal products). Insofar as the finished medicinal products are supplied to the consumer or patient unchanged, a hazard cannot be assumed and therefore no risk assessment is necessary. However, if ready-to-use medicinal products are used, e.g. in the preparation of formulations, employees may be at risk.

In this case, other sources must be used to determine the information (see No. 3.1 para. 2 TRGS 525). The ingredients are usually visible from the package leaflet, but databases such as

the database modules of the ABDA (Federal Association of German Pharmacists' Associations) or the "ChemIDplus" database of the U.S. National Library of Medicine, as well as the classification of the substances under hazardous substances law in the existing lists of hazardous substances.



Example Japanese Mint Oil 100ml



E1 → 30ml !

SECTION 2 : Hazard Identification

2.1 GHS Classification of the substance / preparation

Flam. Liq. 4	H227: Combustible liquid
Acute Tox. Oral 4	H302: Harmful if swallowed
Skin Irrit. 2	H315: Causes skin irritation
Skin Sens. 1	H317: May cause an allergic skin reaction
Eye Irrit. 2A	H319: Causes serious eye irritation
Asp. Tox. 1	H304: May be fatal if swallowed and enters airways
Aquatic Acute 2	H401: Toxic to aquatic life
Aquatic Chronic 2	H411: Toxic to aquatic life with long-lasting effects

2.2 GHS Label Elements

GHS Signal Word

Danger

Hazard Pictograms



GHS07



GHS09



GHS08

Hazard Determining components of Labeling

l-Menthol; *l*-Menthone; *d,l*-Isomenthone; Pulegone

14.1 Land Transport (ADR/RID/GGVSE)

UN Number	3082
DG Class	9
Packing Group	III
Proper Shipping Name	Environmentally Hazardous Substance, Liquid
Classification code	3Z

14.2 Sea Transport (IMDG-Code/GGVSE)

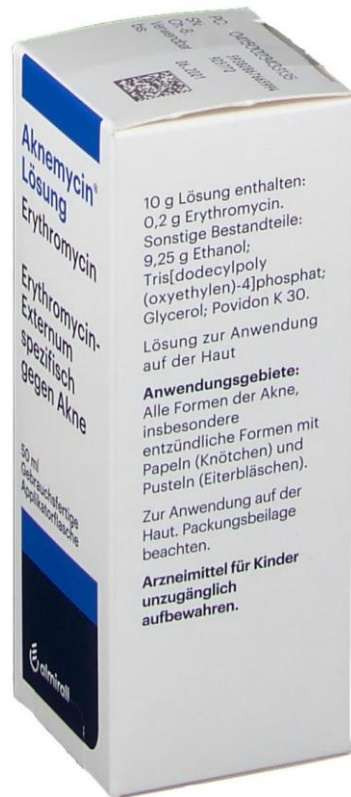
UN Number	3082
DG Class	9
Packing Group	III
Proper Shipping Name	Environmentally Hazardous Substance, Liquid
Marine Pollutant	Yes

14.3 Air Transport (ICAO-TI/IATA-DGR)

UN Number	3082
DG Class	9
Packing Group	III



Example Aknemycin 50ml



92,5% Ethanol in 50 ml solution
Fp EtOH 12°C
estimated PG II, E2 → 30ml !



Source: shopapotheke

Example Regaine

ECOLAB SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

REGAIN

Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name : REGAIN

Product code : 116831E

Use of the Substance/Mixture : Floor Cleaner

Substance type: : Mixture

For professional users only.

Product dilution information : 1.0 % - 2.0 %




Transport : 8 Verpackungsgruppe : III
 Umweltgefahren : No
 Lufttransport (IATA)
 UN-Nummer oder IDnummer : 2491
 ordnungsgemäße Versandbezeichnung :
 Ethanolamine solution

Gefahr

H314 Verursacht schwere Verätzungen der Haut und schwere Augenschäden.

EUH071 Wirkt ätzend auf die Atemwege.

Sicherheitsdatenblatt
 gemäß 1907/2006/EG, Artikel 31

Druckdatum: 01.08.2023 Versionsnummer 1.00 überarbeitet am: 01.08.2023

1 Bezeichnung des Stoffs beziehungsweise des Gemischs und des Unternehmens

· Produktidentifikator

· Handelsname: Minoxidil, API

· Artikelnummer: 5310

· CAS-Nummer: 38304-91-5

· EG-Nummer: 253-874-2

· Registrierungsnummer Der Stoff ist von der REACH-Registrierungspflicht ausgenommen.

· Relevante identifizierte Verwendungen des Stoffs oder Gemischs und Verwendungen, von denen abgeraten wird

· Verwendung des Stoffes / des Gemisches
 Rezeptursubstanz für pharmazeutische Rezepturen oder pharmazeutischer Wirkstoff.

· Verwendungen, von denen abgeraten wird Keine Informationen verfügbar.




14 Angaben zum Transport

· UN-Nummer oder ID-Nummer	Unterliegt nicht den Transportvorschriften
· ADR, IMDG, IATA	entfällt
· Ordnungsgemäße UN-Versandbezeichnung	
· ADR, IMDG, IATA	entfällt
· Transportgefahrenklassen	
· ADR, ADN, IMDG, IATA	
· Klasse	entfällt
· Verpackungsgruppe	
· ADR, IMDG, IATA	entfällt
· Umweltgefahren:	Nicht anwendbar.

Source: caelo/ecolab/desertcart.ae



Example Amoxillin



Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Cayman Chemical Co.
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
USA

Product identifier

Trade name: **Amoxicillin (hydrate)**

Article number: 19188

CAS Number:

61336-70-7

EC number:

612-127-4

Application of the substance / the mixture

This product is for research use - Not for human or veterinary diagnostic or therapeutic use.

Downloads

Gebrauchsinformation

Amoxicillin-ratiopharm® 1000 mg Filmtabletten (in Deutsch),
PDF 119 KB >

Fachinformation

Amoxicillin-ratiopharm® 1000 mg Filmtabletten,
PDF 182 KB >

2 Hazard(s) identification

Classification of the substance or mixture



GHS08 Health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS09 Environment

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

14 Transport information

UN-Number

DOT, IMDG, IATA

UN3077

UN proper shipping name

DOT, IATA

Environmentally hazardous substance, solid, n.o.s.
(Amoxicillin (hydrate))
ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (Amoxicillin (hydrate))

IMDG

Transport hazard class(es)

DOT, IMDG



Class

Label

9 Miscellaneous dangerous substances and articles
9

IATA



Class

Label

9 Miscellaneous dangerous substances and articles
9

Packing group

DOT, IMDG, IATA

III

Source: ratiopharm, Cayman



Example Fluoruracil



100ml bottle
 5g API/100ml
 LD50 230mg/kg
 →presumably no 6.1

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.8
 Revision Date 20.02.2024
 Print Date 21.02.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : 5-Fluorouracil for synthesis

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008 as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567

Pictogram



Signal Word

Danger

Hazard Statements

H301

H351

Toxic if swallowed.

Suspected of causing cancer.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 2811

IMDG: 2811

IATA: 2811

14.2 UN proper shipping name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (5-fluorouracil)

IMDG: TOXIC SOLID, ORGANIC, N.O.S. (5-fluorouracil)

IATA: Toxic solid, organic, n.o.s. (5-fluorouracil)

SOLID !

14.3 Transport hazard class(es)

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

14.4 Packaging group

ADR/RID: III

IMDG: III

IATA: III

14.5 Environmental hazards

ADR/RID: no

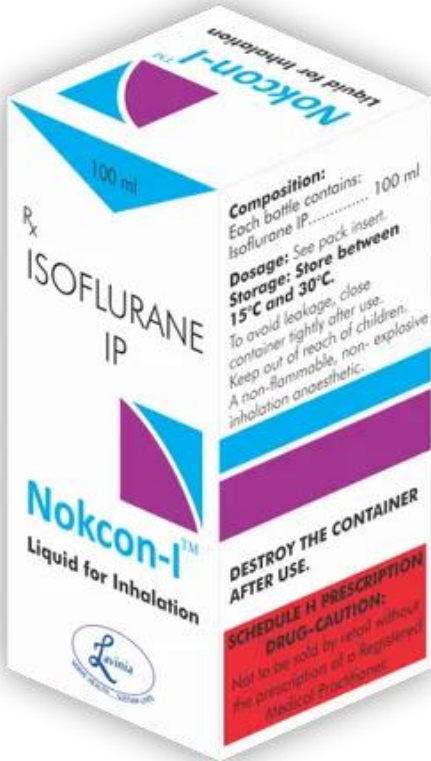
IMDG Marine pollutant: no

IATA: no

Source: exportersindia.com, Merck



Example Isoflurane



Source: scopeheal.com



Example Isoflurane

Sigma-Aldrich. www.sigmaaldrich.com

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Version 6.10
Revision Date 02.06.2023
Print Date 16.04.2024
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers
Product name : Isoflurane

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Specific target organ toxicity - single exposure (Category 3), Central nervous system, H336

Pictogram



Signal Word

Warning

Hazard statement(s)
H336

May cause drowsiness or dizziness.

Precautionary statement(s)

P261

Avoid breathing mist or vapors.

P271

Use only outdoors or in a well-ventilated area.

P304 + P340 + P312

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P403 + P233

Store in a well-ventilated place. Keep container tightly closed.

P405

Store locked up.

P501

Dispose of contents/ container to an approved waste disposal plant.



SECTION 14: Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA: 3334

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Aviation regulated liquid, n.o.s. ((±)-Isoflurane)

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: 9

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: III



Source: Sigma Aldrich

Summary

- DG classification rules differ between the modes, only ADR provides a full exemption for ready-to-use pharmaceuticals (SP 601). Same product might require labeling/marketing for air transport (UN XXXX, ID 8000, LQ/EQ).
- SDS are not mandatory for ready-to-use pharmaceuticals, hence information about classification can often be retrieved only directly from the producer.
- If SDS are made for the active pharmaceutical ingredient, not for the final consumer good, it needs expertise to check classification.
- If no SDS is available, safety officers need to investigate safety data for the case of emergency response, as instruction leaflets usually aren't accessible.
- Risk of undeclared dangerous goods as shippers apply road exemption to all modes.



Thanks for your attention

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