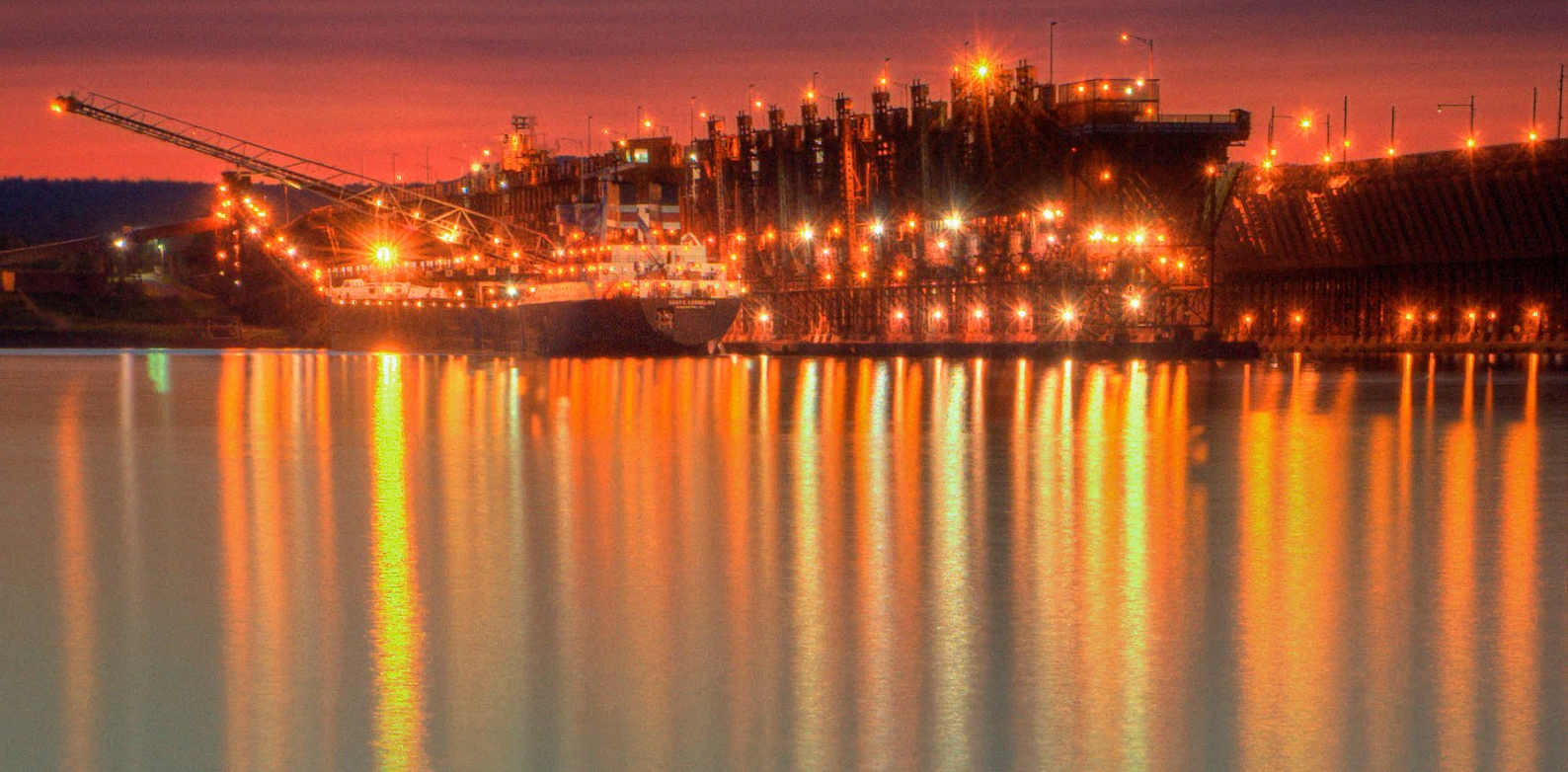


Hazard Assessment of Ores and Concentrates for Marine Transport

Guidance, 3rd Edition



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Foreword

Appropriate hazard assessment is the first step in ensuring that goods of all sorts can be safely produced, transported and used for their intended purpose. It is essential for ensuring that any potential physical, environmental and health risks can be properly managed throughout the supply chain.

Ensuring that minerals and metals are produced and used safely is part of the industry's commitment to sustainable development and is essential for building society's trust and for ensuring an ongoing license to operate. The first step in the life cycle of metals is the extraction and processing of mineral ores to create beneficiated products such as concentrates. These are refined to the metals and minerals that have always been vital for development – never more so than in the challenges we face in a transition to a more circular, decarbonized world.

In this guidance, ICMM sets out the approaches to hazard classification that leading mining and metals commodity associations have developed in collaboration with scientific experts from research institutes around the world. Over the last decade, ICMM and others have invested significantly in developing scientifically robust and consistent approaches for hazard classification of materials, including ores and concentrates. This work has positioned the industry well. Practical implementation however has led to some significant challenges:

- There are many producers of ores and concentrates around the world – from large multinationals and state-owned enterprises to smaller and even artisanal miners.

- A wide range of ores and concentrates are produced and shipped globally – and even when eventually used to produce the same metal, products from different mines may be very different in terms of their elemental and mineralogical composition and ultimately in the hazards they possess.

This makes understanding of the techniques required for accurate hazard assessment of paramount importance. This publication is an update of a document published first in 2014, at a time when the International Maritime Organization (IMO) was taking first steps to align its Codes with other UN instruments such as the Globally Harmonized System of Classification and Labelling. In the intervening years, the science has evolved, practical experience has been gained and concepts have been formally adopted and enshrined in transport codes and other regulation.

This third edition reflects all those changes, and, through its promotion and application, we hope to promote a consistent and responsible approach for assessment of materials governed within the IMO mandate and generated by the mining and metals industry. This is a key part of ensuring that mining and metals generate the positive contribution to sustainable development that they seek to do.

Introduction

The marine transport of materials in packaged and in solid bulk form is governed by various codes administered by the International Maritime Organization (IMO) and implemented by Member States. These aim to ensure safe shipment of cargoes and the protection of the marine environment from harmful pollutants.

These regulations include the International Maritime Solid Bulk Cargoes Code (IMSBC Code) and the International Maritime Dangerous Goods Code (IMDG Code), which are specialized codes mandated by the International Convention for the Safety of Life at Sea (SOLAS) under Chapter VI and VII respectively, and the Annex V of the International Convention for the Prevention of Pollution from Ships (MARPOL 73/78). These instruments have been adopted and given force of law in most jurisdictions.

All include provisions that are intended to control risks and specify the measures that must be taken by shippers depending on the physical, human health and environmental hazards of the material transported. Assessment of these hazards is based on the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

This document has been written with the specific case of ores and concentrates (O&Cs) in mind. These products of mining are solid materials that are often transported by sea, usually in bulk, but sometimes in packaged form. While the guidance here is focused on O&Cs, it could be applied to any other inorganic complex solid materials transported in bulk or packaged form.

The hazards of O&Cs must be assessed to determine whether compliance with special requirements defined in the MARPOL Convention, IMSBC Code or IMDG Code is needed.

The aim of this document is to provide an overview of:

- the GHS system and the various IMO regulations that link it to marine transport of O&Cs
- the specific hazards considered in each of the marine regulations
- the science-based hazard assessment strategy developed by the international mining and metals industry for applying the GHS to O&Cs.

This document provides general guidance for mining and metals industry personnel on the hazard classification requirements for marine transport of O&Cs. It is intended as general classification guidance and is not a substitute for expert advice. The document does not include provisions for cargoes which may liquefy, belonging to Group A (for details see Section 7 and 8 of the IMSBC Code).

Also, this document does not cover the consequences of hazard classification under marine transport legislation. This information can be found in the respective Codes and national regulations.



The terms ‘hazard’ and ‘risk’ are fundamentally different and often confused. The hazard of a substance or mixture represents its intrinsic properties and potential effect on the environment, human health or property. The risk posed by a substance or mixture represents the likelihood and extent to which a person, the environment or property may be harmed or otherwise adversely affected when exposed to it.

1.1 The objectives of hazard classification

The hazard assessment and classification of a substance or mixture involves the evaluation of intrinsic characteristics that may result in a detrimental effect within a set of environmental, human health and physical endpoints.

The United Nations (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS) provides a standard set of endpoints, effect levels and agreed test procedures. These have been adopted as the basis for the various IMO regulations as described below.

Depending on the concentration, or dose, at which the substance causes a specific adverse effect, it is classified as hazardous or non-hazardous. If hazardous, it will be further categorized depending on the dose required to cause the effect (with thresholds defined, for example in the GHS, for each endpoint). A Category 1 implies a higher hazard level than a Category 2 and so on. This is repeated for each endpoint. This system of categorization allows chemicals that are more hazardous within a given Hazard Class to be distinguished from those that are less hazardous.

1.2 Global harmonization – the GHS

To standardize the different hazard classification and labelling systems used in various countries since the 1980s, the United Nations (UN) designed the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The aim of the GHS is to facilitate international trade by increasing consistency (or harmonization) of regulation among countries that have different hazard assessment systems and criteria. GHS also aims to provide consistency in hazard communication through standardization of safety data sheets and labelling for example. The GHS was first published in 2003 and is updated every two years. At the time of writing, the current version of this guidance is based on the 10th revision of GHS (United Nations, 2023).

All versions of GHS are available via: <https://unece.org/about-ghs>. The UN is encouraging broad international adoption of the GHS and currently more than 85 countries or regions have implemented it including Australia, Brazil, China, Europe, Japan, South Korea and the United States

Table 1: GHS Hazards

Hazard Type	Hazard Classes
Physical	<ul style="list-style-type: none"> — Explosives — Flammable gases/aerosols/liquid/solids — Oxidizing gases/liquids/solids — Gases under pressure — Self-reactive substances and mixtures — Pyrophoric liquid/solid — Self-heating substances and mixtures — Substances and mixtures which on contact with water emit flammable gases — Organic peroxides — Corrosive to metal — Desensitized explosives
Human Health	<ul style="list-style-type: none"> — Acute toxicity (via the oral, dermal, inhalation route) — Skin corrosion/irritation — Serious eye damage/eye irritation — Respiratory/skin sensitization — Germ cell mutagenicity — Carcinogenicity — Reproductive toxicity — Specific target organ toxicity (STOT) – single exposure — Specific target organ toxicity (STOT) – repeated exposure — Aspiration hazard
Environmental	<ul style="list-style-type: none"> — Hazardous to the aquatic environment — Hazardous to the ozone layer

The GHS applies to both substances and mixtures. Substances are defined in the GHS as: ‘Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.’ Mixtures are defined in the GHS as: a mixture or a solution composed of two or more substances in which they do not react.

Despite these definitions, the treatment of an O&C for the purposes of classification is sometimes less than straight forward and expert judgement may therefore be required, considering such factors as the manner of processing and the nature, availability and quality of characterization data.

The GHS covers three types of hazards: physical, human health and environment. The endpoints, or hazard classes, considered for each are shown in table 1.

Hazard classification is based on available reliable data (including animal data, in vitro data and human epidemiological data) and, in the absence of experimental evidence, expert judgement. Data should be obtained in accordance with internationally accepted test guidelines (e.g. UN, OECD) and, where possible, in laboratories that comply with Good Laboratory Practice (GLP). The GHS provides extensive guidance on how to assess relevance and reliability of data for hazard classification. The guidance is especially important for metals and their compounds. Careful evaluation of the quality and relevance of data is critical to prevent inaccurate hazard classification.

The GHS applies to substances and mixtures, among them metals, metal compounds and complex metal-containing products. Specific guidance on the environmental hazard assessment of metals and metal compounds is provided in Annex 9.7 (Classification of metals and metal compounds) and Annex 10 (Guidance on transformation/dissolution of metals and metal compounds in aqueous media). This specific treatment of metals and metal compounds is an explicit recognition by the GHS that these substances have specific characteristics that deserve special consideration in the hazard assessment process. These annexes were amended following a thorough review, with more up to date language and precise guidance on inorganic substances classification, included in the 10th edition of the GHS, published in 2023.

1.3 Basic approaches to classification

Depending on the type of information available and the nature of the product being assessed, there are several approaches to the assessment of the hazards of O&Cs.

To integrate these approaches into a common framework, a tiered approach scheme has been developed for the purposes of hazard classification of complex inorganic materials, including O&C (Figure 1). The tiers include:

- A calculation method based on a worst-case assumption of the constituents (Tier 0), where no information on speciation exists, mostly based on elemental composition and assuming full solubility.

- A calculation method based on the hazards of the individual substances or constituents of the O&C (Tier 1), where elemental and mineralogical speciation are known, but bioavailability or solubility data is unknown.
- A calculation method based on the bioaccessibility or environmental solubility of the constituents (Tier 2).
- Experimental (eco-)toxicological data that are generated with the O&C (Tier 3).

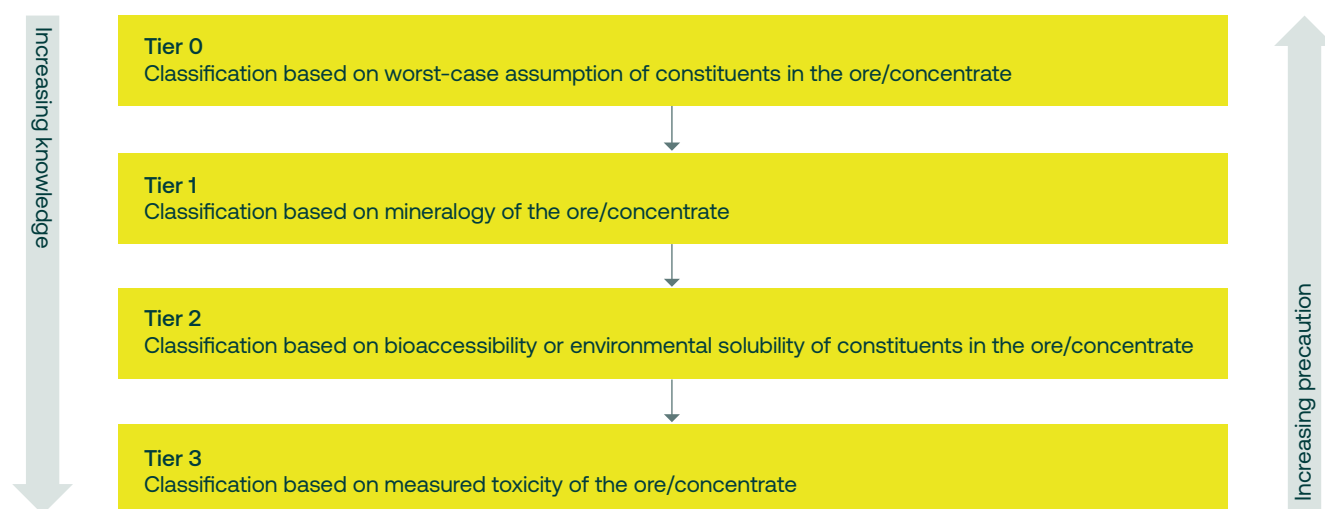
The underlying philosophy of the tiered approach is that, in the absence of data, the assessment takes precautionary (worst-case) assumptions. However, if data are available, these assumptions can be refined and made more accurate. In order to refine an assessment, the assessor can take the initiative to gather additional information in order to progress to higher tiers. The tiered approach is applied separately for each endpoint to determine the hazard profile of the O&C.

Information may not always be available on every O&C, but in some cases relevant information may be available from a similar O&C. On the basis of that information, it may be possible to derive a classification using the principles of read-across¹ and/or bridging².

The tiered approach is implemented in MeClas (www.meclas.eu), a tool specifically developed to increase the consistency in classification of complex inorganic materials, including O&Cs.

These classification approaches and their applicability to O&Cs are explained further in Section 3 of this document.

Figure 1: General Rationale of the Tiered Approach for Environmental and Human Health Hazard Assessment of Ores and Concentrates. Adapted from Verdonck et al. (2017) and Eurometaux (2020).



1. Read-across: extrapolation of known data from one substance to another substance based on the assumption that the two substances will cause similar biological responses (ECHA, 2017).

2. Bridging principles: derivation of health or environmental classification of mixtures based on available data on similar tested mixtures and on the ingredient substances (EC, 2008).



Safety of maritime transport of goods is regulated through various international codes, treaties, and other applicable legislation. These are aimed to protect the crew, ships and the environment during maritime transport and to prevent or reduce the occurrence of accidents

Each of these regulations includes special provisions for dangerous goods (i.e. materials with certain hazardous properties) and each build upon the GHS for the hazard identification of the materials. The most relevant regulations for marine transport of solid cargoes are:

- International Maritime Dangerous Goods Code (IMDG Code).
- International Maritime Solid Bulk Cargoes Code (IMSBC Code).
- Annex V, International Convention for the Prevention of Pollution from Ships (MARPOL 73/78).

2.1 Code for marine transport of packaged goods (IMDG)

The International Maritime Dangerous Goods (IMDG) Code was developed to ensure the safe maritime transport of packaged dangerous goods, including substances, mixtures and articles. The IMDG Code became mandatory on 1 January 2004 and is updated every second year. This code is built on the UN Model Regulations also known as the ‘orange book’ (UN Recommendations on the Transport of Dangerous Goods – Model Regulations). The IMDG Code can be obtained through the IMO website: [https://www.imo.org/en/publications/Pages/IMDG Code.aspx](https://www.imo.org/en/publications/Pages/IMDG%20Code.aspx)

Substances, mixtures and articles with hazardous properties may be designated as Dangerous Goods in

the IMDG Code. These are materials that are listed in the IMDG Code’s Dangerous Goods List as well as others that meet the criteria of specific GHS hazard classes and categories. Not all substances hazardous under GHS are Dangerous Goods under the IMDG Code. Provisions of the Code include requirements related to packaging, labels and placards, container traffic and stowage, segregation of incompatible goods and transport documents.

The IMDG Code’s Dangerous Goods List is mandatory and deviations are only possible in exceptional circumstances and conditional upon specific measures being followed.

Dangerous goods are classified in nine classes corresponding to hazard endpoints. In some cases, the classes have divisions that specify varieties of hazards within the class. Most hazards are identified following GHS principles and guidance. Safety and precautionary measures, such as packing requirements, are specified for each hazard type. The nine classes and divisions are largely – but not entirely – based on the GHS system and are shown in Tables 2 and 3.

For an overview of the health, environment and some of the physical hazard endpoints, relevant to ores and concentrates, considered under the IMDG Code and how they relate to the GHS criteria, see Table 3.

Table 2: IMDG Code Hazards

Hazard Type	Class
Explosives	Class 1
Gases	Class 2
Flammable liquids	Class 3
Flammable solids; substances liable to spontaneous combustion; substances which, in contact with water, emit flammable gases	Class 4
Oxidizing substances and organic peroxides	Class 5
Toxic and infectious substances	Class 6
Radioactive material	Class 7
Corrosive substances	Class 8
Miscellaneous dangerous substances	Class 9

2.2 Code for marine transport of solid bulk cargoes (IMSBC)

The aim of the International Maritime Solid Bulk Cargoes (IMSBC) Code is to ensure safe maritime transport of solid bulk materials. The IMSBC Code is updated every second year and the current version can be ordered through the IMO website: <https://www.imo.org/en/OurWork/Safety/Pages/CargoesInBulk-default.aspx>.

The IMSBC Code specifies requirements related to the safe stowage and shipment of solid bulk cargoes that may give rise to relevant on-board risks for the crew or the ship, for example structural damage due to improper cargo distribution, loss or reduction of stability during a voyage, chemical reactions of cargoes such as spontaneous combustion, emission of toxic or explosive gases, corrosion, etc. The IMSBC Code categorizes cargoes into three groups:

- Group A – cargoes that may liquefy or undergo dynamic separation
- Group B – cargoes possessing chemical hazards.
- Group C – cargoes that are neither group A nor group B.

Cargoes can be designated as Group A, Group B, Group C, or Group A and B.

Group A cargoes that meet the criteria and provisions described in Section 7 of the IMSBC Code should be tested and certified for transportable moisture limit (TML) according to the provisions and procedures outlined in Sections 8 and certified according to Sections 4.3 to 4.6 of the Code. Group A cargoes

shall be accepted for loading only when the actual moisture content of the cargo is less than its TML. Notwithstanding this provision, cargoes having moisture content in excess of the TML may be carried on a specially constructed or fitted cargo ship for confining cargo shift as specified in Section 7.3.2, in which case the relevant requirements in Sections 4 and 8 of the Code need not apply to such cargoes.

Group B cargoes are those that meet either the IMDG Code's 'dangerous goods' hazard criteria or the IMSBC Code's 'materials hazardous only in bulk' (MHB) criteria. The MHB criteria were introduced in the IMSBC Code in 2013 and include physical hazard, acute and chronic health-related endpoints.

MHB cargoes are 'materials which may possess chemical hazards when carried in bulk other than materials classified as dangerous goods in the IMDG Code. These materials present a significant risk when carried in bulk and require special precautions' (IMSBC Code, section 9.2.3.1.1).

The MHB hazards and their corresponding notational reference are:

- Combustible solids (CB).
- Self-heating solids (SH).
- Solids that evolve flammable gas when wet (WF).
- Solids that evolve toxic gas when wet (WT).
- Toxic solids (TX).
- Corrosive solids (CR).
- Other hazards (OH).

Both sets of Group B chemical hazard endpoints are largely aligned with GHS. However, there are differences related to the cut-off values and/or testing conditions for some of the MHB endpoints. These need to be checked carefully when assessing the MHB properties of a cargo.

For an overview of the hazard endpoints relevant to ores and concentrates, considered under the IMSBC Code and how they relate to the GHS criteria, see Table 3.

Appendix 1 of the IMSBC Code is structured in the form of individual schedules. These schedules are specific to the bulk cargoes or cargo groups named, and contain information on their hazards, handling measures, loading, unloading, carriage, stowage and segregation. The IMSBC code specifies that these schedules are not exhaustive. It is the shipper's obligation to provide to the ship's master all available information on the hazards of the cargo. Where a new hazard is identified for a solid bulk cargo, the existing schedule is updated, or a new

schedule proposed for integration into the IMSBC Code, the cargo can be transported using provisions such as tri-partite agreements and exemptions (see sections 1.3 and 1.5 of the IMSBC Code).

The current IMSBC Code includes a schedule for the shipment of mineral concentrates and several schedules for metal sulphide concentrates with specific characteristics. These schedules can be applied for a wide range of ores and mineral concentrates. For specific schedules see Appendix 1, IMSBC Code.

2.3 MARPOL Annex V and marine transport of solid bulk cargoes

The International Convention for the Prevention of Pollution from Ships (MARPOL) is the main international convention covering prevention of pollution of the marine environment by ships due to operational or accidental causes. The MARPOL Convention was adopted in 1973, whereas the actual Protocol was adopted in 1978. The combined instrument – MARPOL 73/78 – entered into force in 1983 and has been updated periodically. MARPOL 73/78 and its annexes can be ordered through the IMO website: <https://www.imo.org/en/KnowledgeCentre/ConferencesMeetings/Pages/Marpol.aspx>.

The Protocol includes six technical annexes:

- Annex I: Regulations for the prevention of pollution by oil.
- Annex II: Regulations for the control of pollution by noxious liquid substances in bulk.
- Annex III: Regulations for the prevention of pollution by harmful substances carried by sea in packaged form.
- Annex IV: Regulations for the prevention of pollution by sewage from ships.
- Annex V: Regulations for the prevention of pollution by garbage from ships.
- Annex VI: Prevention of air pollution from ships.

Substances harmful to the marine environment (HME)

Amendments to MARPOL Annex V of relevance to O&Cs were adopted in and came into force in 2013. MARPOL Annex V Implementation guidelines were adopted in 2012 and amended in 2016.

The adopted amendments prohibit the discharge of all garbage into the sea, unless explicitly permitted (Appendix 1 of Annex V MARPOL Convention as

amended in Resolution MEPC 277 (70)). Dry cargo residues and wash water containing such residues are defined as garbage and subject to the provisions of Appendix 1 of Annex V as amended. Cargo residue not classified as harmful to the marine environment (HME) can be discharged to the sea, outside special areas. The amendments specify that residues and wash waters of HME cargoes shall be discharged at adequate port reception facilities.

The criteria to identify HME cargoes are based on the GHS environmental and human health toxicity endpoints, and include:

1. Acute aquatic toxicity Category 1; and/or
2. Chronic aquatic toxicity Category 1 or 2; and/or
3. Carcinogenicity Category 1A or 1B combined with not being rapidly degradable and having high bioaccumulation; and/or
4. Mutagenicity Category 1A or 1B combined with not being rapidly degradable and having high bioaccumulation; and/or
5. Reproductive toxicity Category 1A or 1B combined with not being rapidly degradable and having high bioaccumulation; and/or
6. Specific target organ toxicity repeated exposure Category 1 combined with not being rapidly degradable and having high bioaccumulation; and/or
7. Solid bulk cargoes containing or consisting of synthetic polymers, rubber, plastics, or plastic feedstock pellets (this includes materials that are shredded, milled, chopped or macerated or similar materials).

Consistent with the principles of the GHS, Appendix 1 of MARPOL Annex V is based on self-classification of cargoes by the shipper and inclusion of a relevant statement (i.e., HME or not HME) in the mandatory Form for cargo information for solid bulk cargoes (see IMSBC Code, section 4.2.3).

It should be noted that for MARPOL HME (unlike for IMDG and IMSBC) cargoes only the oral and dermal routes are relevant or where the exposure route is not specified. Therefore, cargoes, which are classified for Carcinogenicity, Mutagenicity, Reproductive toxicity or Specific Target Organ Toxicity Repeated Exposure only by inhalation are not relevant for HME assessment. For an overview of the health- and environment-related hazard endpoints considered under MARPOL Annex V and how they relate to the GHS criteria, see Table 3.

Table 3: Overview of Hazard Endpoints and Classification Categories Relevant to the Transport of Ores and Minerals Concentrates Considered under the IMSBC Code and its Relationship with the IMDG Code and Appendix 1 to Annex V of MARPOL, and equivalent Hazard Categories of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Hazard End Point	IMSBC Code ⁽¹⁾	From IMDG Code ⁽²⁾	MARPOL Annex V	UN GHS ⁽³⁾
Physical Hazards				
Flammable solids	Group B	Class 4.1 (PG III)	N/A	Cat. 2
	Group B, MHB (CB)	Not classified	N/A	Not classified
Substances liable to spontaneous combustion (Self-heating solids)	Group B	Class 4.2 (PG III)	N/A	Cat. 2
	Group B, MHB (SH)	Not classified	N/A	Not classified
Substances which, in contact with water, emit flammable gases	Group B	Class 4.3 (PG III or PG II ⁽⁴⁾)	N/A	Cat. 3
	Group B, MHB (WF)	Not classified	N/A	Not classified
Oxidizing substances	Group B	Class 5.1 (PG III or PG II)	N/A	Cat. 3
Radioactive material	Group B	Class 7	N/A	N/A
Corrosive substances	Group B	Class 8 (PG III)	N/A	Cat. 1
	Group B, MHB (CR) ⁽⁵⁾	Not classified	N/A	Not classified
Human Health				
Oral	Group B	Class 6.1 (PG III)	N/A	Acute Cat. 3
Dermal	Group B	Class 6.1 (PG III)	N/A	Acute Cat. 3
	Group B, MHB (TX)	Not classified	N/A	Acute Cat. 4 or STOT-SE & RE Cat. 1
Inhalation	Group B	Class 6.1 (PG III)	N/A	Acute Cat. 3
	Group B, MHB (TX)	Not classified	N/A	Acute Cat. 4 or STOT-RE Cat. 1
	Group B, MHB (WT)	Not classified	N/A	Acute Cat. 4
Skin corrosion/irritation	Group B	Class 8 (PG III)	N/A	Cat. 1C
	Group B, MHB (CR)	Not classified	N/A	Cat. 2
Serious eye damage/irritation	Group B, MHB (CR)	Not classified	N/A	Cat. 1 or 2A
Respiratory sensitization	Group B, MHB (CR)	Not classified	N/A	Cat. 1
Mutagenicity	Group B, MHB (TX)	Not classified	HME ⁽⁶⁾	Cat. 1 (A or B)
Carcinogenicity	Group B, MHB (TX)	Not classified	HME ⁽⁶⁾	Cat. 1 (A or B)
Reproductive toxicity	Group B, MHB (TX)	Not classified	HME ⁽⁶⁾	Cat. 1 (A or B)
Environment				
Aquatic	Not classified ⁽⁷⁾	Class 9 UN 3077	HME	Acute Cat. 1 or Chronic Cat. 1 or 2
Other Hazards				
Miscellaneous	Group B, MHB (OH) ⁽⁸⁾	Class 9	N/A	N/A

Notes.

(1) The Materials Hazardous only in Bulk (MHB) classification procedure should be carried out as prescribed in section 9.2.3 of the IMSBC Code as amended, in some cases, test methods and cut-off values differ from those laid out in the GHS.

(2) IMDG Code Hazard classes and hazard categories (packing groups) relevant to the IMSBC Code as dangerous good possessing chemical hazards. The IMDG code considers additional hazard classes and hazard categories (packing groups) not related with the transport of bulk cargoes.

(3) GHS Hazard Categories equivalences relevant to the IMSBC Code corresponding to the acceptable IMDG Code packing group for bulk transport.

(4) In practice, Dangerous Good, Packing Group II, are acceptable for bulk transport, when the main hazard falls within packing group III and a subsidiary hazard, e.g., Class 6.1, result in the assignment of PG II in the IMDG Code.

(5) The assessment for corrosivity to metals, MHB (CR), should be conducted following paragraph 9.2.3.7.3 considering the guidance prepared by the Organization (see Guidance for conducting the refined MHB (CR) test, MSC.1/Circ.1600/Rev.1)

(6) The classification of solid bulk cargoes as Harmful to the Marine environment (HME) should be performed according to the criteria set out in Appendix 1 to de Annex V of the MARPOL convention, as amended in Resolution MEPC.277(70), adopted in October 2016. Cargoes classified as carcinogens, mutagens, reproductive toxicants, or STOT-RE are only considered HME under specific conditions – see text for details.

(7) In the IMSBC code, cargoes Class 9, specifically UN 3077 (Environmentally Hazardous Substance, Solid, N.O.S.) are not considered in the characteristics table of each schedule, therefore the class box is left blank, pursuant the exemption in paragraph 4.1.1.3.

(8) Where human experience or other factors indicate the need to consider other chemical hazards, these shall always be considered. These are recognized as Other Hazard (OH) and should be included in the “Hazard” section in the individual schedule.

N/A Indicate hazard endpoints not applicable under the given regulatory framework.





Ores and concentrates are complex inorganic materials consisting of aggregates of natural minerals. These mineral constituents can be characterized by their chemical composition and crystal structure. O&Cs are generally best described by the physical properties and chemical/mineralogical composition. Common distinguishing properties include crystal structure, hardness, specific gravity, particle size, elemental and mineralogical composition as well as the solubility of the elements in a relevant fluid under relevant conditions.

The extent to which metal ions are released to aqueous or physiological media from these complex mineral structures determines to a large extent their health and environmental hazard potential. Applying the GHS rules to O&Cs therefore requires expert knowledge and assessment of the potential for metal release.

GHS provides extensive guidance on how to assess hazards and classify metals and metal compounds for the environment (Annex 9.7) and on how to determine transformation/dissolution of metals and metal compounds in aqueous media (Annex 10). Guidance on how to classify complex materials such as O&Cs for environment or health, however, is not provided. Such guidance can be found in Risk Management of Complex Inorganic Materials (Verougstraete, 2017).

As O&Cs have an inherently variable chemical composition, each cargo must be assessed for its particular hazards. Testing every product that is shipped

in bulk for all hazard endpoints is however clearly not practical. Instead, a testing and assessment strategy based on GHS principles has been developed by the international mining and metals industry to assess the hazards of complex inorganic materials. This approach is described in the sections below and includes:

1. Characterization of the composition.
2. Hazard data collection and review.
3. A tiered classification approach based on data availability.

More detailed background, particularly on the underlying scientific principles, can be found in Risk Management of Complex Inorganic Materials (Verougstraete, 2017).

3.1 Characterization of the composition of ores and concentrates

O&Cs are naturally occurring complex materials with varying composition. Concentrates of the same metal from different mines can differ in composition so their hazard profiles may also be different. Similarly, the composition of a concentrate from a given mine will vary over time as it is extracted from different parts of the ore body, meaning that its hazard classification may change over time.

Accurate characterization of O&Cs is essential for precise hazard classification and should include collection of data on its elemental and mineralogical composition. The more data that are available on the characteristics of a complex material, the more accurate the hazard assessment will be. For classifying data-poor cargoes, conservative assumptions must be used.

A recommended characterization of an O&C should consider the following:

- The full elemental and mineralogical composition should be determined.
- Particle size distribution should be determined.
- The relevant constituent substances in an O&C are those which are classified and are present in a concentration equal to or greater than the generic cut-off values defined by GHS for each hazard endpoint, where available. If there is evidence that a constituent present at a concentration less than the generic cut-off can still be relevant for classifying an O&C it should also be included.
- Elemental and mineralogical composition data should be collected from representative samples of the O&C as shipped. Composition data should be reviewed at appropriate time intervals or when circumstances change, e.g. when moving to a different part of the ore body, on process changes, etc. These data are then used to derive typical concentration ranges for each listed mineral and to identify any trends influencing the hazard classification. Historical analytical data can also assist in establishing typical concentration ranges.
- Geological information on the ore body can facilitate the determination of the O&C composition and the interpretation of the results.

3.2 Collection of data for hazard classification

To assess the hazard and determine the classification of an O&C, all available information should be considered and assessed for quality and relevance.

Such information includes:

- The appropriate information on the composition as detailed in Section 3.1.
- The hazard classification information of similar O&Cs from which classification could be read-across.
- The hazard classification of constituent minerals; this includes both officially listed in the harmonized classifications (e.g. EU CLP [classification, labelling and packaging regulation]) and self- classifications made by industry. A good source of such information is MeClas, which contains both the latest official classifications and industry data and is available online at www.meclas.eu.
- When available, the metal release during transformation/dissolution (T/D) testing (Annex 10, GHS), of the O&C, similar O&C and/or constituent minerals.
- Information on the acute and chronic ecotoxicity of the metals in the O&Cs for which soluble inorganic compounds are classified for environmental hazard. Ecotoxicity data are typically expressed as LC₅₀ or EC₅₀ values for acute toxicity, or as NOEC or ECx values for chronic toxicity. However, for many metals, extensive ecotoxicity datasets are available, and a weight-of- evidence approach (GHS section 4.1.2.5 and A9.3.4) has been adopted which expresses the ecotoxicity in terms of the acute and chronic Ecotoxicity Reference Values (ERVs). A list of high-quality ERVs is embedded in MeClas (see above). Their use is important to ensure consistency in hazard classification.
- Acute toxicity values of constituent minerals classified for acute toxicity where available³. Bioaccessibility data on the O&C, similar O&C and/or constituent minerals and substances for the route of exposure (i.e. oral, dermal, inhalation) relevant for the health endpoint of concern.

3. For example, the Eurometaux Multi-Metallic Database for UVCBs

3.3 Tiered environmental classification approach

For most O&Cs, little or no direct acute or chronic ecotoxicity data for hazard assessment are available. Constituents of O&Cs are often highly insoluble and cannot be subjected to direct ecotoxicity testing. However, the indirect assessment of the ecotoxicity of these complex materials has been addressed with the implementation of the Dissolution Transformation Protocol (GHS, Annex 10 and OECD Guidance 29, 2001). Considering the inherent variability in composition of

O&Cs, testing every product that is shipped in bulk is not practical and may not be desirable (for reasons of animal welfare, cost and availability of test laboratory facilities). Instead, an intelligent tiered testing and assessment strategy is followed to assess the environmental hazards of O&Cs. The approach is presented in Figure 2 and summarized below. It allows the user to make an assessment based on the data available. This gives the option to develop further data and eliminate conservative assumptions in order to refine a classification if desired.

Classification using available toxicity or transformation/dissolution data on O&C

Where 7-day and 28-day transformation/dissolution (T/D) data are available for the O&C; these are used to assess the aquatic hazard classification by comparing the solubility of each relevant metal ion with their acute and chronic ERVs respectively and applying the GHS additivity method. Such assessment can be made, for example using MeClas.

Classification based on read-across from similar O&Cs

Where no T/D data are available for the O&C, but the composition is similar to a group of O&Cs for which T/D⁴ and classification data are available (e.g. it fits within a range of previously tested representative samples), the O&C can be classified by reading across from the classification from the similar group.

Classification based on data of constituent minerals

Where read-across is not possible from a group of similar O&Cs and no T/D data are available for a specific O&C under investigation, but T/D data are available for the minerals present in the specific O&C, the T/D data of the minerals⁵ and the ERVs of the relevant metal ions

is used to assess the aquatic hazard classification of the O&C. This can be done following the GHS additivity rule or the summation rule – in the latter case using the classification of the constituent minerals derived using the mineral T/D data and ERVs of the relevant metal ions in the minerals. Such assessment can also be made using MeClas.

Classification in absence of data, worst case approach

If no T/D data are available for the O&C or the constituent minerals, and read-across from a similar group of O&Cs is not possible, a worst-case classification approach may be applied, assuming all relevant metal ions present in an O&C are soluble and following the GHS summation method – using in the latter case the classification of soluble metal compounds.

Laboratory testing

In case of uncertainty in the outcome of the assessment, classifications can always be refined or validated by further T/D testing of O&Cs, and as a last resort through ecotoxicity tests on the O&C itself, if soluble.

4. In case of variation in T/D results within the specific group of O&Cs, the worst-case data are taken forward

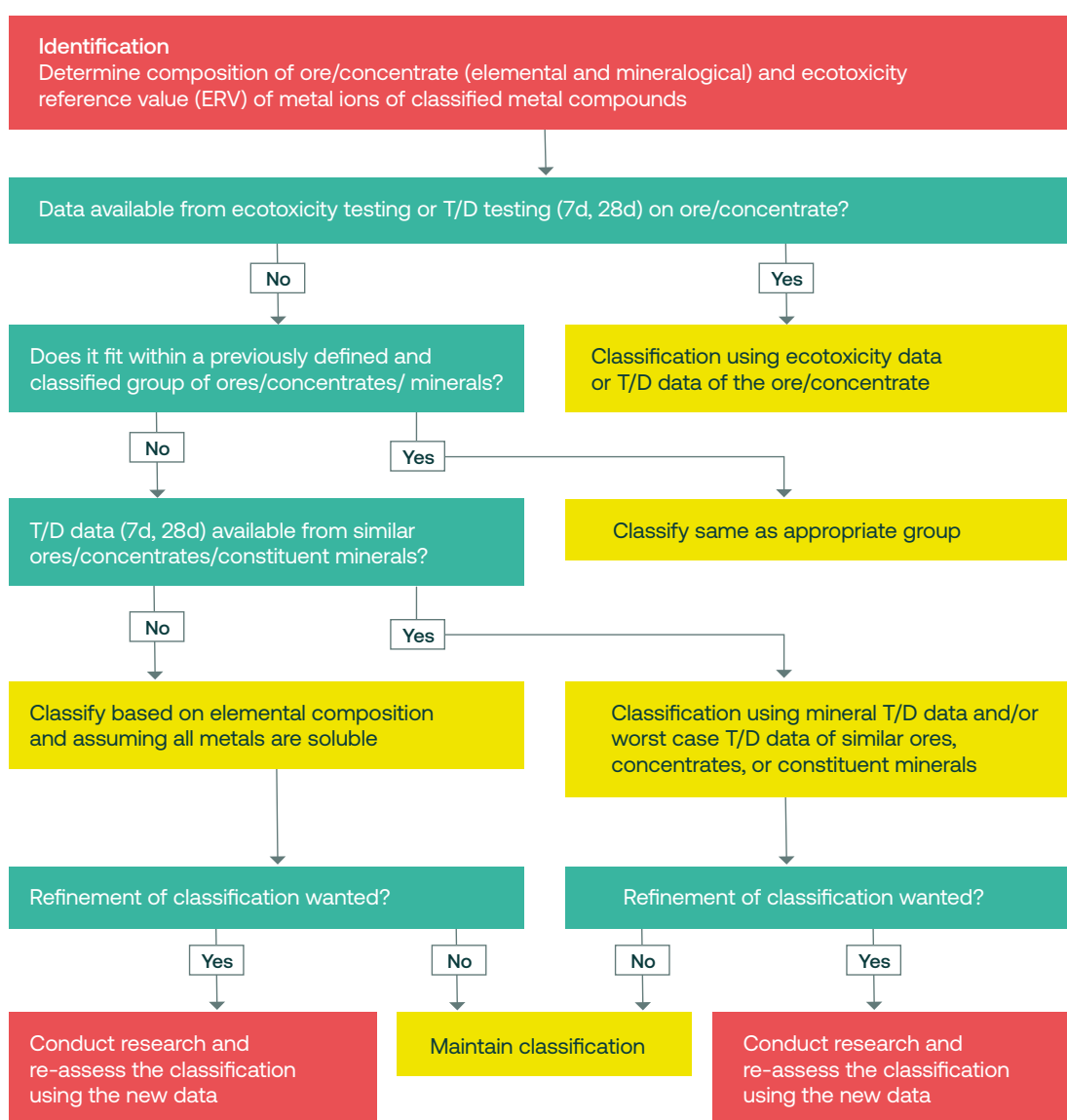
5. In case of variation in T/D results for a specific mineral, the worst-case data are taken forward

Following the above approach, under the IMDG code, O&Cs that meet the GHS criteria for acute aquatic toxicity Category 1 and/or chronic aquatic toxicity Category 1 or 2 are considered as Environmentally hazardous substances, which are grouped under Class 9.

Under MARPOL Annex V, O&Cs that meet the GHS criteria for acute aquatic toxicity Category 1 or chronic aquatic toxicity Category 1 or 2 are considered as harmful to the marine environment (HME). The IMSBC code does not indicate Class 9 for cargoes which are HME, since HME cargoes are already classified under

MARPOL. More details on the approach, research data and resulting classifications are available for various groups of ores and concentrates via the relevant metals commodity associations (see Section 5 for contact details). Some have also developed simple models, based on the approach described above, to predict the environmental classification of the O&Cs of their metal (e.g. Cu, Zn). Where these are available, the only information shippers need to make the required assessment is the elemental and mineralogical composition of their O&Cs. These models are easy to use and can avoid the need to invest in T/D testing.

Figure 2: General Approach to Assess the Environmental Hazards of O&Cs Relevant for Transport Regulations



3.4 Assessment of human health endpoints

For most O&Cs, little or no direct acute or chronic toxicity data on the O&Cs of sufficient relevance or quality for use in human health hazard assessment are available. Performing acute or chronic animal tests using O&C samples is not recommended for the reasons stated in Section 3.3. Instead, the acute and chronic health hazards of O&Cs are based on the classifications of constituents of the O&C with support from bioaccessibility tests (bioelution tests in mimetic biological fluids).

‘Bioaccessibility data can inform the assessment for those endpoints and those metal substances for which it is demonstrated that systemic absorption (i.e. dissolution of the metal ion and subsequent uptake), precede the observed effects. In practice, this includes systemic endpoints, like carcinogenicity, mutagenicity, reproductive toxicity and specific target organ toxicity with repeated exposure (STOT-RE). Acute toxicity via the oral route is also included if the effects are due to systemic absorption. Bioaccessibility data cannot be used to assess local effects, such as skin irritation after dermal exposure, or local lung effects after inhalation exposure.’ (Eurometaux, 2020)

The toxicity of metal ions present in O&Cs depends largely on the bioaccessibility of the metal ions for the associated route of exposure and the particle size distribution (critical for the inhalation route). Bioaccessibility is assessed by determining the metal released in synthetic biological fluids according to various protocols. For the oral route, bioaccessibility of metal ions is assessed in synthetic gastric fluid, for example using ASTM standard D5517-07 (ESAC, 2019). Bioaccessibility via the dermal route can be assessed in synthetic sweat, e.g. fluid composition used in EN1811:2011 + A1:2015., and bioaccessibility via the inhalation route is assessed in artificial lung fluids (e.g. lysosomal). The guidance document developed by Eurometaux (2020) is a useful reference document with further information on when and how to use bioaccessibility data.

Assessment of corrosion, irritation and sensitization related hazards is based on the guidance provided in the GHS.

3.4.1 Acute toxicity

Classification using classification data from a similar O&C

If no toxicity or bioaccessibility data are available for an O&C, another O&C (or group of O&Cs) may be identified for which an acute hazard classification has been derived based on toxicity data or bioaccessibility data. If the composition of the O&C is very similar to the other O&C (or group of O&Cs), the O&C can be classified by reading across from the classification for the similar O&C (or group of O&Cs).

Classification – worst case approach in absence of data (Tier 0)

If insufficient data are available for the specification of the composition of the O&C other than elemental, and read- across from a similar group of O&Cs is not possible, a worst-case classification approach is applied, assuming all relevant metal ions present in an O&C are soluble and following the GHS summation method – using in the latter case the classification of soluble metal compounds.

Classification using composition data (Tier 1)

If no toxicity or bioaccessibility data are available for the O&C nor for similar O&Cs, then the composition of the O&C should be used to assess the acute toxicity of the O&C. This can be done based on the concentrations of the various constituents and their corresponding classification for acute toxicity. Assessment of the acute toxicity of O&Cs on this basis can be carried out efficiently using the GHS mixtures approach, as is applied in MeClas.

Classification using available bioaccessibility data on the O&C (Tier 2)

Where O&Cs contain metals that are classified for acute toxicity endpoints, either on their own or in the form of certain inorganic metal compounds, and these effects are due to systemic absorption, the bioaccessibility of the ion of concern from the O&C may be further investigated as its solubility will influence potential absorption and effects. Bioaccessibility tests in the relevant media may be conducted, and the acute hazards of the O&C then assessed using the bioaccessibility data⁶. More guidance on how to conduct these tests and how to use the resultant data for hazard classification is available in

6. Relative bioaccessibility is determined by comparing under similar test conditions the release of metal ion from the O&C in question with the release from appropriate reference substances (e.g. specific minerals or compounds known to be contained in the O&C).

guidance document 'Guidance on the classification of inorganic UVCB substances for human health hazards' (Eurometaux, 2020). Information on the acute hazard classification of metals and inorganic metal compounds can be found in the MeClas tool.

Classification using available toxicity data on the O&C (Tier 3)

Where acute toxicity data are available for an O&C and meet the GHS quality and relevance criteria, they should be used to determine the acute hazard classification of the O&C.

Laboratory testing

In case of uncertainty in the outcome of the assessment, classifications can always be refined or validated by further bioaccessibility testing of O&Cs, and as a last resort through toxicity tests on the O&C itself.

Classification in IMDG, IMSBC and MARPOL Annex V

Under the IMDG Code, O&Cs that meet the GHS criteria for acute toxicity Category 1–3 are considered as dangerous goods Class 6.1.

Under the IMSBC Code, O&Cs that meet the GHS criteria for:

- Acute toxicity Category 1–3 are considered as Group B – Class 6.1 cargoes.
- Acute toxicity Category 4 by the dermal or inhalation route or STOT – single exposure (STOT-SE) Category 1 by the inhalation or dermal route, are considered as Group B – MHB (TX). Cargoes which evolve toxic gas when wet are considered as Group B – MHB (WT).

These GHS hazards are not relevant to HME MARPOL Annex V classification.

3.4.2 Skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitization

The assessment of skin corrosion, skin irritation, serious eye damage, eye irritation and respiratory sensitization for an O&C should be made following the guidance provided in GHS using available test data on the O&C or on similar O&Cs. Where data are only available for the constituents this information is used to assess the above hazard endpoints for the O&C. In the latter case, the assessment can be made very efficiently with MeClas.

Laboratory testing

In case of uncertainty in the outcome of the assessment, classifications can always be refined or validated by further research.

Classification in IMDG, IMSBC and MARPOL Annex V

Under the IMDG Code, O&Cs that meet the GHS criteria for skin corrosion Category 1A, 1B or 1C are considered as dangerous goods Class 8.

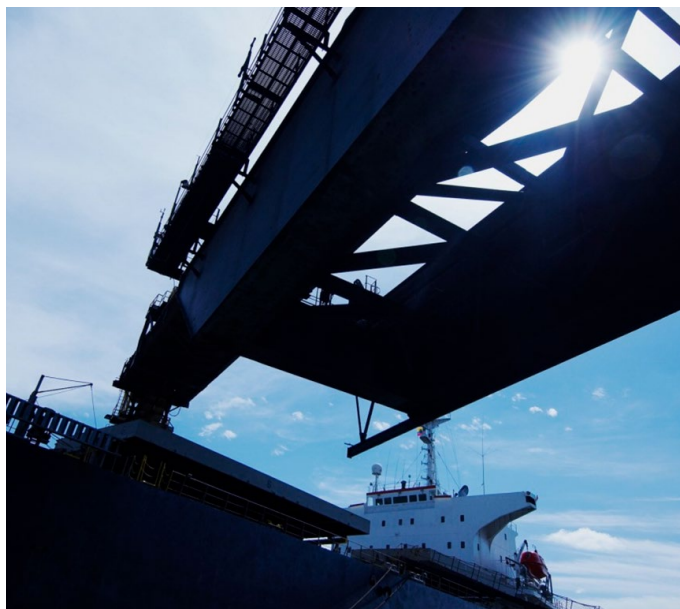
Under the IMSBC Code, O&Cs that meet the GHS criteria for:

- Skin corrosion Category 1A, 1B or 1C are considered as Group B – dangerous goods Class 8.
- Skin corrosion/irritation Category 2, serious eye damage Category 1, eye irritation Category 2A or respiratory sensitization Category 1 are considered as Group B – MHB (CR) cargoes.

These GHS hazards are not relevant to HME MARPOL Annex V classification.

3.4.3 Chronic toxicity

The chronic hazard endpoints for human health include carcinogenicity, mutagenicity, reproductive toxicity, and STOT-RE (see Table 3). For the assessment of these endpoints, a similar approach to that described for the acute hazard endpoints (Section 3.4.1) can be followed, with more detail available in Eurometaux (2020).



Classification in IMDG, IMSBC and MARPOL Annex V
The IMDG code does not consider chronic toxicity.

Under the IMSBC Code, O&Cs that meet any of the criteria for STOT-RE Category 1 by the inhalation and/or dermal route, carcinogenicity Category 1A, 1B, mutagenicity Category 1A, 1B, or reproductive toxicity Category 1A, 1B, are considered as Group B – MHB (TX).

Under appendix 1 of MARPOL Annex V, O&Cs that meet certain criteria for chronic hazard endpoints must be assessed further to determine whether a HME classification should apply. This further assessment is described in Section 3.4.4.

3.4.4 MARPOL health-related HME criteria

For specific application to Annex V of the MARPOL Convention (Appendix 1 to Annex V of the MARPOL convention, as amended in Resolution MEPC.277(70)), a testing and assessment strategy to assess human health related HME hazards of O&Cs is summarized below. The approach is similar for the oral and dermal routes.

Where an O&C contains metals that, either on their own or in the form of certain inorganic minerals or compounds, are classified as carcinogenic Category 1A/1B, mutagenic Category 1A/1B, reproductive toxicant Category 1A/1B or as STOT-RE Category 1 for the oral or dermal route or without specification of the exposure route⁷, the properties ‘high bioaccumulation’ and ‘not rapidly degradable’ need to be assessed for these metal ions.

Table 4: Example of Metal Ions in Compounds Classified under GHS as a Category 1 (A or B) Carcinogen, Mutagen, Reproductive Toxicant or STOT-RE Relevant to Maritime Transport Regulations.

Substances	Hazard Endpoint			
	Mutagen	Carcinogen	Reproductive Toxicant	STOT-RE
Pb compounds			Category 1	Category 1
Ni in e.g. NiSO ₄		Category 1*	Category 1	Category 1*
Cd in e.g. CdCl ₂	Category 1	Category 1	Category 1	Category 1
Co in e.g. CoCl ₂		Category 1*	Category 1	

*By inhalation only (not relevant to MARPOL Annex V)

Bioaccumulation

The assessment of the potential for high bioaccumulation and of the rapid degradability of metal ions, is complex and requires specific considerations for inorganic substances. The GHS and the European Chemicals Agency’s (ECHA) CLP guidance (ECHA, 2017) provide guidance on this.

The bioaccumulation of metals and inorganic metal compounds is a complex process and the experimental data should be used with care. For most metals, the relationship between aqueous concentration and the bioconcentration factor (BCF) in aquatic organisms is inverse, meaning that, since it is a function of experimental conditions, ‘bioaccumulation’ is not an intrinsic property. The ‘bioaccumulation’ criterion is

therefore not applicable to essential elements as their content in the organism is actively regulated through homeostatic processes.

Assessing bioaccumulation for non-essential metals should be conducted carefully, based on a weight of evidence approach, using BCF studies performed in environmentally relevant concentrations in the test media.

Degradability

As stated in the current GHS Annex 9, ‘For inorganic compounds and metals, clearly the concept of degradability, as it has been considered and used for organic substances, has limited or no meaning’. The method for assessment of the degradability of chemicals has limited or no relevance for metals and inorganic

7. It should be noted that only the oral and dermal routes are relevant. Therefore, metals and metal compounds which are classified for the above listed endpoints, but only by inhalation, are not relevant for HME assessment..



compounds as it is focused on the decomposition of organic molecules. An alternative method has therefore been developed. ‘Degradation’ of metals and their inorganic compounds is evaluated by assessing the rate at which the reactive functional groups (the soluble metal ions) are removed from the water column through partitioning, precipitation and speciation processes. A detailed assessment for a range of metal ions has been made by Radar et al. (2013), Burton et al. (2019) and Huntsman et al. (2019). Additional information is available from the metal commodity associations listed in Section 5.

The assessment of the bioaccumulation potential and rapid degradability of metal ions has been made under the EU-REACH and CLP regulations – of which the guidance is in line with that of GHS Annex 9. The results of these assessments can be found via <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>. Where this information is not available for a specific metal on this website, the relevant commodity association can be contacted directly (see Section 5 for contact details).

Human health endpoints assessment relevant to HME status

Under MARPOL Annex V, O&Cs that meet all the three following criteria are considered HME:

- Classified as carcinogenicity Category 1A/1B, mutagenicity Category 1A/1B, reproductive toxicity Category 1A/1B or STOT-RE Category 1 via the oral or dermal route or without specification of the exposure route.
- Having high bioaccumulation potential.
- Not being rapidly degradable.

More details on the approach, research data and resulting classifications are available for various groups of O&Cs via the relevant metal commodity associations (see Section 5 for contact details). Some have also developed simple models, based on the approach described above, to predict the health classification of the O&Cs of their metal (e.g. Cu, Zn). Where these are available, the only information a shipper needs to make the required assessment is the elemental and mineralogical composition of their O&C. These models are easy to use and can obviate the need to invest in bioaccessibility testing.

3.4.5 Physical hazards

Physical hazard endpoints are assessed by testing the O&C, according to the test guidelines of the UN’s Recommendations on the Transport of Dangerous Goods:

- Manual of Tests and Criteria (7th rev, 2019, Amend.1 (2021)) and the OECD test guidelines recommended in the UN’s Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UN GHS 10th Rev., 2023). Test methods and cut-off values in the IMSBC Code (section 9.2.3) should be checked carefully for several of the MHB endpoints as they may differ from those in the test guidelines recommended in the GHS. This means that a product may not be classified according to the GHS endpoint, but can be classified as Group B – MHB under the IMSBC Code.

Classification in IMDG, IMSBC and MARPOL Annex V

Under the IMDG and IMSBC code, O&Cs that meet the GHS physical hazard criteria for:

- Explosive substance Div 1.1-1.6 are considered as Class 1.
- Flammable solids – readily combustible Category 1-2 or flammable solid – self-reactive Type A-G are considered as Class 4.1.
- Flammable solids – pyrophoric are considered as Class 4.2
- Flammable solids – solids that evolve flammable gas when wet Category 1-2 are considered as Class 4.3.
- Oxidizing solids Category 1-3 are considered as Class 5.1.
- Corrosive to metals Category 1 is considered as Class 8.

The IMDG Code specifies the measures associated with each Class of Dangerous Good.

Under the IMSBC Code, O&Cs that meet the criteria for the various endpoints listed in Section 9.2.3 are considered as Group B – MHB (various notational references). For further detail see Table 3.

Under MARPOL, Appendix 1 to Annex V, physical hazards are not considered.



Conclusions

Several International Maritime Organization (IMO) regulations require mandatory hazard assessment and declaration of solid cargoes, including ores and concentrates, transported in packaged form (IMDG Code) or in bulk (IMSBC Code and Annex V MARPOL Convention).

Fortunately, the hazard assessment required by the IMO is based largely on the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS), of which the mining and metals industry has significant experience. The GHS, however, contains limited guidance for complex materials, and its application to O&Cs requires expert approaches, developed by the industry.

An overview of these approaches has been presented in this guidance document, which stresses that assessment requires careful consideration of data in order to achieve consistent outcomes. One resource that has been developed to assist with consistency in classification is MeClas, which contains much of the

required reference data and applies the GHS classification rules for mixtures to the data provided for each constituent and for each endpoint. MeClas allows efficient assessment of the classification at the various tiers of assessment described above. Its use helps ensure reliability and consistency of assessment in line with industry good practices and responsible product stewardship.

Finally, robust programs of work have been undertaken by the commodity associations listed in Section 5. Companies are recommended to contact the relevant association for support in the assessment of their cargoes.

Further Information

Acknowledgments and contact points

The following associations have worked collaboratively in developing the science and data on which the concepts outlined here are based. Their contribution to this document is much appreciated.

For further information on specific cargoes:

- Cobalt Institute: advocacy@cobaltinstitute.org
- International Aluminium Institute: imo@world-aluminium.org
- International Copper Association: info@copperalliance.org
- International Iron Metallurgy Association: info@metallurgy.org
- International Lead Association: enq@ila-lead.org
- International Manganese Institute: imni@manganese.org
- International Molybdenum Association: info@imoa.info
- International Zinc Association: contact@zinc.org
- Nickel Institute: communications@nickelinstitute.org
- World Coal Association: info@worldcoal.org

Acronyms

BCF	Bioconcentration factor
CLP	EU Regulation (EC) No 1272/2008 on classification, labelling and packaging
CMR	Carcinogenic, Mutagenic, or Reprotoxic
ECHA	European Chemicals Agency
ERV	Ecotoxicity Reference Value
GHS (UN-GHS)	United Nations Globally Harmonized System of Classification and Labelling of Chemicals
GLP	Good Laboratory Practice
HME	Harmful to the Marine Environment (a MARPOL Annex V cargo criterion)
IMDG	International Maritime Dangerous Goods Code
IMSBC	International Maritime Solid Bulk Cargoes Code
LC₅₀	Lethal Concentration 50% (the statistically derived concentration that can be expected to cause death in 50% of the animals in an experimental group)
MARPOL	International Convention for the Prevention of Pollution from Ships
MeClas	Metals Classification tool (online at: www.meclas.eu)
MERAG	Metals Environmental Risk Assessment Guidance
MHB	Material Hazardous only in Bulk (an IMSBC Code hazard criterion)
NOEC	No Observed Effect Concentration
O&C	Ore and/or ore Concentrate
OECD	Organisation for Economic Co-operation and Development

REACH	EU Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT-RE	Specific Target Organ Toxicity (Repeated Exposure)
STOT-SE	Specific Target Organ Toxicity (Single Exposure)
T/D	Transformation Dissolution
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological Materials

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