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REPORTS AND STUDIES

GESAMP
Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection

GESAMP HAZARD EVALUATION PROCEDURE FOR CHEMICALS CARRIED BY SHIPS, 2019

GESAMP WORKING GROUP 1

IMO FAO UNESCO IOC WMO UNIDO IAEA UN UNDP ISA UN environment

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Published by the
INTERNATIONAL MARITIME ORGANIZATION
4 Albert Embankment, London SE1 7SR
www.imo.org

Printed by CPI Colour

ISSN: 1020-4873

Cover photo: Underwater sunlight through the water surface seen from a rocky seabed with algae

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4. GESAMP wishes to draw attention to the fact that the hazard evaluation rationale was conceived for the particular purpose of the development and implementation of the International Convention for the Prevention of Pollution from Ships, MARPOL. The guidance on hazard evaluation contained in this publication is therefore intended primarily to be used for that purpose. Although it should not normally be used out of context, this guidance (or elements thereof) may be found useful for other hazard evaluation purposes provided the limitations and restrictions imposed upon such guidance by the hazard assessment rationale, as well as any associated risks, are fully appreciated.

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7. For bibliographic purposes this document should be cited as:
GESAMP (2019). GESAMP Hazard Evaluation Procedure for Chemicals Carried by Ships, 2019. Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, Rep. Stud. GESAMP No. 102.

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EXECUTIVE SUMMARY

This edition of the GESAMP Hazard Evaluation Procedure provides an updated set of criteria for evaluating the hazards of chemicals (substances and mixtures) that may enter the marine environment through operational discharge, accidental spillage, or loss overboard from ships. Hazards to both human health and the marine environment are considered and the information is collated in the form of a "hazard profile", a comprehensive but easily readable fingerprint of the hazard characteristics of each substance. The hazard profiles of substances carried by ships that have been prepared by the Evaluation of the Hazards of Harmful Substances Carried by Ships (EHS) Working Group of GESAMP are published at regular intervals and a "GESAMP/EHS Composite list of hazard profiles" is available from the International Maritime Organization (IMO) at:

http://www.imo.org/ourwork/environment/pollutionprevention/chemicalpollution/pages/chemicalsreportingforms.aspx

This document has been developed to provide a description of the basis by which chemicals are evaluated and GESAMP hazard profiles assigned ("methodology") to inform a range of audiences including:

- maritime administrations;
- companies shipping bulk liquids;
- producers of bulk chemicals;
- those required to submit data under regulative processes for bulk liquid shipments;
- first responders to maritime emergenices;
- responders to marine spills; and
- those with a general interest in hazard evaluation of chemical substances.

The purpose of this new edition is not to replace the revised GESAMP hazard evaluation procedure, but to update it with as little disruption to the user as possible, only introducing changes where necessary, in particular to ensure harmonization with IMO regulations and the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

The United Nations Globally Harmonized System of Classification and Labelling of Chemicals (United Nations, 2017) was developed to enable the global harmonization of chemical hazard classification and communication in the areas of transport, including the sea, inland waterways, road and rail, as well as consumer, worker and environmental protection. The revised GESAMP hazard evaluation procedure, although specifically developed for the maritime transport of bulk liquid chemicals, is substantially in line with the GHS.

The revised MARPOL Annex II (IMO, 2017a) entered into force on 1 January 2007. By this date, the EHS Working Group had converted more than 850 hazard profiles into a new system to allow for the recalculation of the pollution category, ship type and carriage conditions, in accordance with the new requirements. When the first edition of the GESAMP Reports and Studies 64 was published in 2002 (GESAMP, 2002a), it was based on decisions made in the period 1995 to 2000. After more than 10 years from its publication and 15 years from its inception, it was felt by GESAMP that a second edition should be prepared. This edition updated the revised hazard evaluation procedure, in the light of global developments in the understanding of chemical hazards. The implementation and further amendments of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) in particular in Europe with the CLP (EU, 2008) regulation and its guidelines provide a global standard for the hazard evaluation of substances and mixtures.

The REACH Regulation (EU, 2006) in Europe made available an increasing number of studies of relevance to the assessment of cargoes in maritime transport.

This edition updates the guidance in light of several revisions of the Globally Harmonized System of Classification and Labelling up to the 7th edition (United Nations, 2017) and introduces revisions to two hazard columns. Based on requests from IMO, a more detailed evaluation of the acute inhalation hazard onboard in particular for pure vapour exposure is also introduced. Emergency responders using the GESAMP Hazard Profile furthermore requested information on flammability for spill management which is also now included. The former rating of the potential of chemicals to taint fish and shellfish is no longer included in the profile.

The primary function of the GESAMP EHS Working Group is to evaluate the hazards of bulk liquid substances regulated under MARPOL Annex II (IMO, 2017a) and the International Code for the Construction of Ships Carrying Dangerous Chemicals in Bulk, the IBC Code (IMO, 2016a). On the basis of the GESAMP hazard profile and other properties, the pollution category and carriage requirements for the substance when carried on a ship are subsequently assigned by IMO. Thus, the evaluation addresses occupational and environmental hazards as well as ship safety.

The system for categorization of noxious liquid substances, as set out in appendix I of MARPOL Annex II, together with ship design and operational requirements, form the regulatory framework for the prevention of pollution from noxious liquid substances from ships. Relevant hazards noted in the GESAMP hazard profile may also be utilized for the classification of chemicals as a "Marine Pollutant" for packaged goods shipments, in accordance with the requirements set out in the International Maritime Dangerous Goods Code (IMO, 2016b).

Much has changed since 1972 when, at the request of IMO, GESAMP first introduced principles for evaluating hazards, based on the intrinsic properties of chemicals, in support of MARPOL. An important change is one of attitude. The public expects the seas to be kept clean, for the protection of ecosystems, for the provision of healthy, uncontaminated food and for recreational purposes. Environmental science, including hazard identification, evaluation and risk assessment of chemical substances and mixtures, has evolved considerably over the last 50 years and GESAMP has done much in light of these developments, to highlight sources of marine pollution and to assess their relative importance. Knowledge of the effects of chemical substances on human health has also advanced greatly in this time. In both fields, the routes and processes of chemical exposure and subsequent toxic effects are now better understood. Today, standardized testing is able to provide data on a wide range of both human health and environmental criteria used in hazard evaluation and risk assessment.

The large volumes of chemical substances and mixtures transported by ship still warrant special measures for the protection of the sea, just as they did when GESAMP first started its work. A single tank on board a bulk chemical tanker may hold up to 3,000 tonnes[1] of a bulk liquid chemical and the dead weight tonnage (DWT) of the ships ranges from less than 1,000 to well over 60,000 tonnes. GESAMP felt that the ecological and human health risk assessment of chemical substances and mixtures transported by ship would be too complex to be addressed under MARPOL, requiring considerably more environmental data. It was therefore decided, early on in the process, to base the revised GESAMP procedure on an expanded set of hazard end-points.

However, the distinction between hazard and risk is not always clear. The classification system to predict the behaviour of spilled chemicals while based entirely on the intrinsic properties, could be seen as a simple form of risk assessment. The aim, however, is to provide an indication of behaviour following a spill and not to provide a quantification of the risks.

The original hazard evaluation rationale was developed by the GESAMP Working Group at the request of IMO (then IMCO), in preparation for the International Conference on Marine Pollution held in 1973. It was approved in 1972 at GESAMP's fourth session as document GESAMP IV/19/ Supp.1 (GESAMP, 1972)[2]. This was superseded in 1982 by GESAMP Reports and Studies No. 17 (GESAMP, 1982), then by Reports and Studies No. 35 (GESAMP, 1989) in 1989, and again by the Revised GESAMP Hazard Evaluation Procedure, GESAMP Reports and Studies No. 64 in 2002 (GESAMP 2002a). The second edition was approved by GESAMP at its 40th session in Vienna, 2013. This third version of the Revised GESAMP Hazard Evaluation Procedure, approved at the 45th session in Rome, 2018, replaces all previous versions.

The second edition retained the revised GESAMP Hazard Evaluation Procedure with all of the main hazard end-points and criteria remaining as they were in the first edition in 2002. GESAMP has sought to introduce further refinement in the interpretation of the long-term human health effects, listed in sub-column D3, to bring it in line with developments in the GHS. In relation to sub-column C3, the application of the GESAMP inhalation toxicity extrapolation method (Höfer et al., 2011), alongside the existing set of measured data, is also described. This was first published in the Report of the 41st meeting of the EHS Working Group (GESAMP, 2005) and the inclusion of the method in the second edition of Reports and Studies No. 64 marks the completion of its implementation. It is believed that this is the first time an estimation method has been introduced into the international chemical regulations that substantially replaces the use of animals in acute lethal toxicity testing.

This edition further amends the GESAMP Hazard Evaluation Procedure reflecting recent developments. The specific rating of the potential of chemicals to taint seafood has not been used for more than 20 years as tainting had been deleted as a regulatory criterion for classifying chemicals under MARPOL. After 2000, no further evaluations related to tainting had been performed and it was decided at the 44th session of GESAMP in Geneva, 2017, to delete the information from the hazard profile. At the same meeting the introduction of a rating on flammability was accepted to provide necessary information to emergency responders. A new revised column E1 has thus been introduced. Revision of chapter 21 of the IBC Code (IMO, 2016a) which defines the criteria for assigning minimum carriage requirements, requires consideration of occupational hazards in the GESAMP Hazard Profile. Column C3 was thus amended to cover occupational exposure to vapours from cargo tanks rather than only combined mist and vapour exposure after a spill on sea.

An update of the guidance on preparing and submitting data to GESAMP, to support the evaluation of chemicals, is also included. The function of each environmental or human health end-point is separately defined and their criteria described in a short introductory section, i.e. the scale on which the end-point is measured, as well as the ranking used, is given under the heading "ratings". This is followed by a set of supporting principles, given under the heading "implementation", in order to explain how the scientific data may be applied in hazard evaluation. Finally, updated guidance is given on approved, internationally standardized, experimental and estimation methods for generating the necessary hazard data. Newer methods that avoid the use of animal testing are referenced and their interpretation briefly discussed. The annexes, containing supporting information on testing, have also been updated. Reference is made to the GHS throughout.

[1] Or possibly more, in the case of vegetable oils, which may be carried in larger quantities, subject to the provisions set out in regulation 4.1.3 of MARPOL Annex II.

[2] The report of GESAMP's 4th session held at WHO in Geneva, 1972, refers both to the original meeting document (GESAMP IV/2) and to supplement (GESAMP IV/19 Suppl.), i.e. the hazard evaluation rationale.

The “hazard profile” provides an alphanumerical fingerprint of each chemical. The numerical scales start from 0 (negligible hazard), while higher numbers reflect increasing hazard. In this way, information on chemicals evaluated by GESAMP is made available to the widest possible technical audience in an instantly readable form.

It is hoped that the revised GESAMP hazard evaluation procedure and the scientific work of GESAMP in evaluating chemicals will continue to play an important role in the protection of the marine environment.

ACKNOWLEDGEMENTS

The Working Group wishes to thank the staff of IMO who supported this work over many years: Ken McDonald, Patricia Charlebois, and Loukas Kontogiannis, Secretaries to the GESAMP EHS Working Group, are acknowledged for their contribution.

ACRONYMS

ACC	American Chemistry Council
ATE	Acute Toxicity Estimate
BLG	Sub-Committee on Bulk Liquids and Gases[3]
CCC	Sub-Committee on Carriage of Cargoes and Containers (CCC)
CEFIC	European Chemical Industry Council
CG/HCCS	Coordinating Group for the Harmonization of Chemical Classification Systems (IPCS)
CHRIP	Chemical Risk Information Platform (see NITE)
CLP	European Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures
DSC	Sub-Committee on Dangerous Goods, Solid Cargoes and Containers[4]
DWT	Deadweight tonnage is a measure of how much weight a ship is carrying or can safely carry. The term is often used to specify a ship’s maximum permissible deadweight, when the ship is fully loaded.
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EHS	GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships
EPA	United States Environmental Protection Agency
ESPH	Working Group on the Evaluation of Safety and Pollution Hazards of Chemicals and Preparation of Consequential Amendments, a Working Group of the PPR Sub-Committee
GESAMP	Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
GHS	Globally Harmonized System of Classification and Labelling of Chemicals of the United Nations
FAO	Food and Agriculture Organization of the United Nations
HPV	High Production Volume (Chemicals Programme)
IAEA	International Atomic Energy Agency
IBC Code	International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

[3] BLG Sub-Committee was replaced by the Sub-Committee on Pollution Prevention and Response (PPR) in January 2014.
[4] DSC Sub-Committee was replaced by the Sub-Committee on Carriage of Cargoes and Containers (CCC) in January 2014.

IGC Code	International Code for the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk
ILO	International Labour Organization
IMCO	Inter-Governmental Maritime Consultative Organization (predecessor of IMO)
IMDG Code	International Maritime Dangerous Goods Code
IMO	International Maritime Organization
IMSBC Code	International Maritime Solid Bulk Cargoes Code
IOMC	Inter-Organization Programme for the Sound Management of Chemicals (sponsored by six UN agencies and the OECD)
IPCS	International Programme on Chemical Safety (sponsored by three UN agencies)
ISA	International Seabed Authority
ISO	International Organization for Standardization
JCIA	Japan Chemical Industry Association
MARPOL	International Convention for the Prevention of Pollution from Ships
MEPC	Marine Environment Protection Committee of the IMO
NITE	Japanese National Institute of Technology and Evaluation
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PCB	Polychlorinated biphenyl
PCDD	Polychlorinated dibenzodioxin
PPR	Sub-Committee on Pollution Prevention and Response
QSAR	Quantitative Structure-Activity Relationship
REACH	European Regulation concerning Registration, Evaluation, Authorisation and Restriction of Chemicals
TDG	Transport of Dangerous Goods
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO-IOC	United Nations Education, Scientific and Cultural Organization – International Oceanographic Commission
UNIDO	United Nations Industrial Development Organization
WMO	World Meteorological Organization

1 INTRODUCTION

1.1 GESAMP

GESAMP was established in 1969 as an expert group to advise its sponsoring organizations on issues related to marine pollution. Its mandate was broadened in the 1990s to address marine environmental protection. It is supervised by an Executive Committee, consisting of its Chairperson, one Vice-Chairperson, the Administrative Secretary (IMO) and Technical Secretaries representing its ten UN sponsoring agencies. It is an interagency scientific advice body of the UN system, responding to requests for advice from its sponsoring agencies. Following an external review in 2003, a renewed and revitalized GESAMP reconvened in Paris in 2006 with financial support from the Swedish International Development and Cooperation Agency and two new UN agency sponsors, UNIDO and UNDP. It currently has working groups (WGs) and task teams addressing a wide range of topics related to the protection of the marine environment, as follows:

WG 1	Evaluation of the Hazards of Harmful Substances Carried by Ships (IMO)
WG 34	Review of applications for 'Active Substances' to be used in ballast water management systems
WG 38	Atmospheric Input of Chemicals to the Ocean (WMO)
WG 39	Establishment of Trends in Global Pollution in Coastal Environments (IAEA)
WG 40	Sources, Fate and Effects of Plastics and Microplastics in the Marine Environment – a Global Assessment (UNESCO-IOC)
WG 41	Marine Geoengineering (IMO)
WG 42	Impacts of Wastes and Other Matter in the Marine Environment from Mining Operations Including Marine Mineral Mining (IMO, UNEP)
WG 43	Sea-based Sources of Marine Litter (FAO, IMO)
WG 44	Biofouling Management

The progress of the working groups is reviewed annually by GESAMP. They are led by GESAMP members and populated by specialists chosen from around the world, acting in their personal capacity as independent scientific experts.

GESAMP publishes its findings through its sponsoring agencies as Reports and Studies, of which more than 100 issues have appeared to date. Full information on GESAMP can be found at: www.gesamp.org.

1.2 Marine pollution from ships: historical background

The MARPOL Convention is the main international convention covering prevention of pollution of the marine environment by ships from operational or accidental causes. It is a combination of three treaties adopted in 1973, 1978 and 1997 respectively and updated by amendments through the years (see IMO, 2017a). It includes six annexes regulating the prevention and control of marine pollution from ships through:

Annex I	oil (regulating mineral oils);
Annex II	noxious liquid substances in bulk;
Annex III	harmful substances carried by sea in packaged form;
Annex IV	sewage from ships;
Annex V	garbage from ships; and
Annex VI	air pollution from ships.

Prior to 1973, IMO in categorizing the hazards of chemical substances carried by ships, experienced difficulties for the development of suitable control measures. It therefore requested GESAMP to consider the hazards that such substances might pose when deliberately or accidentally discharged into the marine environment. The following potential effects were to be taken into account:

- damage to living resources;
- hazards to human health;
- reduction of amenities; and
- interference with other uses of the sea.

In the light of this request from IMO for external assistance, in 1971, GESAMP agreed that an ad hoc panel of IMO and GESAMP experts should be established to develop methods for assessing the hazards of chemical substances transported by ships. The ad hoc panel met prior to the International Conference on Marine Pollution and its outcome was incorporated into MARPOL.

Following the adoption of MARPOL, GESAMP was requested to continue the task of evaluating the hazards of substances proposed for carriage by ships. In 1974, it established the EHS Working Group, which has met on an annual basis since that time. The terms of reference for the EHS Working Group are included in annex I, while the list of past and current members is given in annex II.

Harmful substances carried by ships are defined under MARPOL, article 2(2), as:

> "any substance which, if introduced into the sea, is liable to create hazards to human health, to harm living resources and marine life, to damage amenities or to interfere with other legitimate uses of the sea and includes any substance subject to control by the present Convention".

GESAMP was requested to evaluate the properties of substances transported in bulk by sea in accordance with MARPOL Annex II. Substances carried as packaged dangerous goods are defined under MARPOL Annex III (IMO, 2017a) as "those substances which are identified as Marine Pollutants in the IMDG Code".

Shippers of dangerous goods in packaged form may be required to self-classify substances based on the criteria set out in the IMDG Code for classification as a "Marine Pollutant". The CCC Sub-Committee (formerly the DSC Sub-Committee) of IMO is responsible for the official listing of cargoes in the IMDG Code. Accordingly, the EHS Working Group does not evaluate chemicals transported as packaged goods. However, where needed, the GESAMP hazard profiles are available to support self-classification by shippers.

1.3 Development of the revised GESAMP hazard evaluation procedure

By the mid 1990s, IMO's MEPC had begun to review MARPOL Annex II, which regulates the control of pollution by "noxious liquid substances" carried in bulk by ships. The intention was to simplify the text, while at the same time taking into account any new developments since its adoption.

International, non-governmental organizations, as well as government administrations, requested that, as part of the hazard evaluation procedure developed by GESAMP more than 20 years previously, additional end-points be considered, such as physical characteristics, some measure of persistence or biodegradation and chronic aquatic toxicity. The EHS Working Group members, as experts in various aspects of the hazard evaluation of chemicals, were also of the opinion that the system was in need of review, in order to take account of advances in environmental sciences in the intervening years. In response, MEPC established a panel of experts in 1995 to review the GESAMP Hazard Evaluation Procedure. This expert panel made a number of recommendations, which were endorsed in principle by GESAMP at its 26th session (March 1996). Taking these views into account, the EHS Working Group commenced the task of revising the GESAMP Hazard Evaluation Procedure.

1.4 Global harmonization of chemical classification systems

In 1992, the United Nations Conference on Environment and Development (UNCED) (United Nations, 1992), through its Agenda 21[5], Chapter 19, entitled "Environmentally Sound Management of Toxic Chemicals, Including Prevention of Illegal International Traffic in Toxic and Dangerous Products", established a programme on the "harmonization of classification and labelling of chemicals".

Its objective was to ensure that:

> "a globally harmonized hazard classification and compatible labelling system (GHS) including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000".

UNCED identified the International Programme on Chemical Safety (IPCS) as the nucleus for international cooperation on Chapter 19 activities. Following the establishment of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) in 1995, the Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS), which had already been established by ILO under the auspices of IPCS, was renamed the IOMC CG/HCCS and was given the task of promoting and overseeing the work of developing the GHS. The CG/HCCS had requested the Organisation for Economic Co-operation and Development (OECD) to act as the focal point for development of classification systems for all human health and environmental hazards. For this purpose, OECD established its Advisory Group on Harmonization of Classification and Labelling in 1994 to oversee and manage this work. These activities resulted in the establishment of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which was to be implemented by a new Sub-Committee of Experts on the GHS and a Committee of Experts on the Transport of Dangerous Goods and on the GHS under UNECE/ECOSOC responsibility. During the development of the GHS, concerns arose regarding the way in which a "harmonized" classification system might be used and whether it would meet the needs of its various end users. In this regard, attention is drawn to the following principle of the GHS:

> "harmonization means establishing a common and coherent basis for chemical hazard classification and communication, from which the appropriate elements relevant to means of transport, consumer, worker and environment protection can be selected".

[5] Agenda 21 is a non-binding voluntarily implemented action plan of the United Nations with regard to sustainable development resulting from the UN Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil, 1992.

It was also considered essential that uniform cut-off values for each hazard end-point be identified as part of the evaluation criteria, thus forming a fundamental basis for the GHS.

The activities of the OECD in developing the GHS, and those of GESAMP in developing its revised Hazard Evaluation Procedure, ran concurrently between 1995 and 1998. Representatives of IMO, as well as GESAMP experts, participated in meetings of the OECD Advisory Group on Harmonization of Classification and Labelling and, in particular, its ad hoc Working Group on the Classification of Substances Dangerous to the Aquatic Environment.

Accordingly, the revised GESAMP Hazard Evaluation Procedure was developed based on these principles of harmonization, while bearing in mind the specific needs of evaluating chemicals for transport by ship.

Any amendments made during the implementation of the GHS were closely monitored, as any change in the criteria or the cut-off values could potentially impact the existing hazard profiles or their classification under existing maritime regulations. In particular, amendments to the GHS may have necessitated an amendment to MARPOL and a revision of the GESAMP Hazard Evaluation Procedure, including potential reclassification of products. Some amendments to the GHS were introduced by six revised editions, published by the United Nations. However, due to the aforementioned requirements, not all of these could be transcribed directly into the GESAMP Hazard Evaluation Procedure.

This edition of the GESAMP Hazard Evaluation Procedure has taken into consideration the consolidated amendments to the 7th edition of the GHS (United Nations, 2017). The physical, toxicological and ecotoxicological end-points with their cut-off values have now been harmonized as far as possible with the GHS. Appropriate amendments of columns C3 and E1 resulted from this work. For transparency, Annexes VII and VIII have been introduced to facilitate the translation from GESAMP Hazard Ratings to GHS classifications and vice versa. It should, however, be kept in mind that specific GESAMP Hazard Ratings could differ from equivalent GHS classifications by industry or competent bodies as many ratings and classifications have to be based on read-across, weight of evidence approaches, or expert judgement. The limited availability of toxicological studies might influence the rating or classification further. The GESAMP Hazard Evaluation Procedure emphasizes hazards to the marine environment and thus in some cases prioritizes test data on marine organisms.

1.5 The shipping industry and the transport of bulk liquid substances

The GESAMP Hazard Evaluation Procedure is used by the GESAMP EHS Working Group for the evaluation of the hazards of chemical substances and mixtures in liquid form, as governed by MARPOL Annex II and the IBC Code (IMO, 2016a). Substances not covered by the Procedure are provided below, together with the respective regulatory instruments governing their carriage:

- packaged dangerous goods, governed by the IMDG Code (IMO, 2016b)
- solids carried in bulk, governed by the IMSBC Code (IMO, 2017b)
- gases carried in bulk, governed by the IGC Code (IMO, 2016c)
- mineral oils carried in bulk, governed by MARPOL Annex I (IMO, 2017a)
- radioactive substances (in respect to their radiation hazard).

1.5.1 *Bulk liquid cargoes*

The dead weight tonnage (DWT) of a modern chemical tanker may range from 1,000 to over 60,000 tonnes. For the purpose of carrying noxious liquid substances in bulk, most of these will be of double hull construction to prevent the release of cargo in the event of collision or grounding. Older tankers carrying less hazardous chemical substances may be single hulled. However, based on current regulations, most new chemical tankers will be of double hulled construction. A large chemical tanker may be equipped with as many as 50 separate tanks. Each tank can be filled and emptied independently via its cargo pumps and associated piping connected to a manifold, usually located amidships on deck. Some vessels may also carry additional cylindrical tanks attached to the deck, often giving the chemical tanker its characteristic profile.

At each port of call, the chemical tanker will generally load and unload several tanks at one or more chemical terminals within the harbour. This requires that the empty tanks are cleaned and that the residues are removed while in port, ready for receipt of the next cargo. There is a complex protocol for determining which cargoes may be suitably loaded in a particular tank. This depends on the tank material/lining, the adjacent cargoes (depending on their safety compatibility), and previous cargoes (to avoid contamination).

Chemical tankers are required to discharge tank washings. The designated pollution category under MARPOL Annex II will determine what the vessel operator must do with these residues. It is important for the protection of the marine environment that tanks are first stripped of their bulk liquid cargo to the maximum extent. This is also in the economic interest of the owners of both the ship and its cargo. It is generally accepted that modern chemical tankers can strip their tanks of non-viscous liquid cargo to 75 litres or less. The double bottom allows room for a small well in which the “cargo line” is placed so that only the cargo in the bottom of the pumping well remains after the tank has been emptied. Tanks containing cargoes deemed to be particularly hazardous to the marine environment or those with a high viscosity, generally require a prewash (e.g. a hot water wash) after emptying, in order to remove any clinging material. These residues are then discharged to shore.

While reception facilities are available at many major ports and harbours, they are absent in many parts of the world. It is also unlikely that the technology and facilities for dealing effectively with hazardous waste is available in every country. In the absence of port reception facilities, the tank washings from particularly hazardous cargoes may have to be transported onwards to another port where such facilities are available. The residues of hazardous substances that do not require a prewash are permitted to be discharged into the sea, but only in limited quantities as follows:

- discharge outlet below the waterline;
- not less than 12 miles from the nearest land;
- at water depth of not less than 25 metres; and
- at a speed of at least 7 knots.

The use of the GESAMP Hazard Profile for the carriage of bulk liquids is stipulated in MARPOL Annex II and chapter 21 of the IBC Code. With the revision of this chapter in 2018, a direct link to the GESAMP Hazard Ratings has been introduced. Ratings from all columns (except D2 and E3) have become part of the regulations for defining minimum carriage requirements including safety, occupational protection and pollution aspects.

1.5.2 *Cleaning additives*

Aside from bulk liquid cargoes, GESAMP Hazard Profiles have an important role in the evaluation of cleaning additives, which may be used in tank washing operations to remove cargo residues. In accordance with regulation 13 of MARPOL Annex II, which sets out the provisions for the "control of discharges of residues of noxious liquid substances", restrictions are placed on the cleaning additives permitted for use as follows:

> "13.5.2 When small amounts of cleaning additives (detergent products) are added to water in order to facilitate tank washing, no additives containing Pollution Category X components shall be used except those components that are readily biodegradable and present in a total concentration of less than 10% of the cleaning additive. No restrictions additional to those applicable to the tank due to the previous cargo shall apply."

To determine whether a cleaning additive component complies with the provisions of 13.5.2, information for sub-columns A1, A2, B1 and D3 of the GESAMP Hazard Profile is required, together with the concentration of each component (IMO, 2007).

On this basis, for cleaning additive components, it is possible to request a short GESAMP hazard profile, comprising only the above four sub-columns. However, the GESAMP EHS Working Group will evaluate all hazardous properties for which information is available and assign a full GESAMP Hazard Profile, if practicable.

2 THE GESAMP HAZARD PROFILE UNDER THE REVISED PROCEDURE

2.1 Aims of the revision

In revising its hazard evaluation procedure, GESAMP made every effort to address the following needs to:

- provide a comprehensive and practical procedure based on current knowledge of environmental science and occupational health;
- provide a set of human health and safety criteria to assist in the assignment of the "carriage requirements" for each substance, in accordance with the IBC Code, in particular, for the protection of the crew on board chemical tankers;
- help to protect the marine environment from the effects of operational discharges or accidental spillage of substances from ships;
- include hazard end-points that would assist IMO to regulate the transport of bulk chemical cargoes; and
- enhance harmonization with the GHS.

2.2 Structure of the revised GESAMP Hazard Profile

During the 1995 to 1998 review process, the familiar five-column system was retained; however, each column was divided into several sub-columns, in order to further characterize the underlying hazard information, as far as possible, and make it clearer to the end user. A summary of the end-points used today can be found in Table 1.

The revised GESAMP Hazard Profile consists of the end-points listed in Table 1. Each of the 14 sub-columns represents an environmental or human health end-point or "effect" category, although there may still be several underlying elements, e.g. toxicity to fish, crustaceans and microalgae in Sub-column B1 (acute aquatic toxicity).

A comprehensive summary of the GESAMP Hazard Profile and its ratings can be found on the inside back cover.

Table 1 – Summary of the end-points used in the GESAMP Hazard Evaluation Procedure

Title	Sub-column	Hazard criterion	Comment
A Bioaccumulation and Biodegradation			
	A1	• Bioaccumulation	Measures of the tendency of a substance to bioaccumulate in aquatic organisms.
	A2	• Biodegradation	Used to identify substances with biodegradation characteristics.
B Aquatic toxicity			
	B1	• Acute aquatic toxicity	Toxicity to fish, crustaceans and microalgae, generally measured in appropriate laboratory tests.
	B2	• Chronic aquatic toxicity	Reliable data on chronic aquatic toxicity, based on fish, crustaceans and microalgae.
C Acute mammalian toxicity			
		Distinguishes lethal toxicity as a result of exposure through the following routes:	Measured in appropriate tests with laboratory animals, based on human experience or on other reliable evidence.
	C1	• Oral toxicity	
	C2	• Dermal toxicity (skin contact)	
	C3	• Inhalation toxicity	

Title	Sub-column	Hazard criterion	Comment
D Irritation, corrosion and long-term mammalian health effects			
		Distinguishes toxicity as a result of the following:	Measured in appropriate tests with laboratory animals, based on human experience or on other reliable evidence.
	D1	• Skin irritation/corrosion	
	D2	• Eye irritation	
	D3	• Long-term health effects	Carcinogenicity, Mutagenicity, Reprotoxicity, Sensitization, Aspiration, Specific Target Organ Toxicity (including Neurotoxicity and Immunotoxicity).
E Interference with other uses of the sea			
	E1	• Flammability	Rated according to a measured flashpoint.
	E2	• Behaviour of chemicals in the marine environment	Behaviour in seawater, i.e. the tendency to form slicks or blanket the seabed, evaluated on the basis of solubility, melting point, vapour pressure, specific gravity and viscosity.
	E3	• Interference with coastal amenities	Potential need for closing beaches due to physical hazards and specific health concerns.

A hazard profile is illustrated below in Figure 1, where it can be seen that the chemical in question:

- has a high potential to bioaccumulate in aquatic organisms (A1);
- is not readily biodegradable (A2);
- has a moderate acute and a low chronic aquatic toxicity (B1 and B2);
- has a low oral, moderate dermal and a moderate inhalation toxicity to mammals (C1 to C3);
- is mildly irritating to skin and eye (D1 and D2);
- is potentially carcinogenic (D3);
- is not flammable (E1);
- is a floating substance liable to form persistent slicks on the water surface (E2); and
- has a significant impact to onshore and offshore amenities (E3).

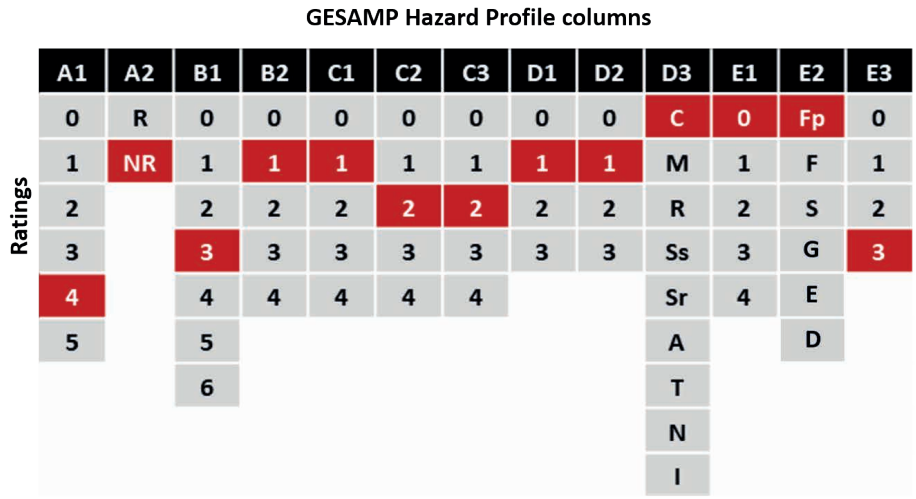

Figure 1 – *Illustration of a GESAMP Hazard Profile for a given chemical*

The explanation of the descriptive terms (columns D3 and E2) and the largely quantitative ratings are developed in detail in section 4. The quantitative rating scales range from 0 ("practically non-hazardous" or of "negligible hazard") to a maximum of 3 to 6, indicating an increasingly severe hazard. R = readily biodegradable, NR = not readily biodegradable. The descriptive terms C = carcinogenicity, M = mutagenicity, R = reproductive toxicity, Ss = skin sensitization, Sr = respiratory sensitization, A = aspiration hazard, T = specific organ toxicity, N = neurotoxicity, I = immunotoxicity are defined under column D3, see paragraph 4.4.3. The descriptive terms Fp, F, S, G, E, D are defined under column E2, see paragraph 4.5.2.

2.3 Other uses of the profile

The GESAMP hazard evaluation procedure was designed to assist with the implementation of MARPOL. However, it also provides a range of information on the properties of chemicals, with respect to the protection of the aquatic environment and human health, which may be suitable for other uses, such as:

.1 in an emergency context to help to determine the potential hazards of the chemical released, where information in:

- columns A and B may contribute to environmental impact assessments on a short or long-term basis;
- columns C and D (Human Health) can provide operational personnel with information relevant to appropriate safety precautions when responding to accidental spills (e.g. selection of protective clothing and respiratory equipment); and
- column E may assist authorities in options analysis for response during maritime emergencies. For example, a spilled chemical that floats and is not soluble could be recovered from the water surface. An evaporating flammable product may create a risk of ignition and fire. Some chemicals may present hazards on the coastline and measures to restrict access may need to be considered (e.g. evacuation of areas such as beaches, a ban on swimming);

.2 the cut-off criteria in columns A, B, C and D are harmonized with the respective building blocks of the GHS. The GESAMP Composite List which currently contains over 1000 hazard profiles can be used, therefore (with some limitations) as providing an indication of GHS classifications based on data available in the GESAMP files; and

.3 the hazard profiles may also have some use in assessing discharges of effluents into the aquatic environment on a continuous-release basis, such as from sea-based activities (e.g. offshore platforms) or from land-based activities.

3 PREPARATION OF DATA – ADVICE TO MANUFACTURERS AND ADMINISTRATIONS

In accordance with MARPOL Annex II, bulk liquid substances are generally those which can be pumped into fixed tanks on board ships. They include pure substances and mixtures; however, mineral oils are excluded, as they are regulated under Annex I of MARPOL. Some bulk liquids are solid at ambient sea temperatures and the tanks are therefore heated to prevent solidification, and to ensure that they can be pumped on board and off. Bulk liquids also include a range of mineral materials carried as aqueous slurries, e.g. calcium carbonate and coal slurry. Some food grade substances, such as orange juice and concentrates, require refrigeration. Vegetable oils, one of the highest volume groups of substances transported, also fall under the umbrella of bulk liquid substances and are regulated as chemicals under MARPOL Annex II. Some mixtures of chemicals such as lube oil additives are regularly carried in mineral oil and, although mineral oils in general are carried under Annex I of MARPOL, some Annex II substances consist of hydrocarbon distillates. The range of chemistries, physico-chemical properties and environmental behaviour encountered is vast, as are the related potential hazards to the marine environment and human health. The following sections (3.1 to 3.11) provide information on assessing data quality, confidentiality, addressing data gaps, conducting read across, considering weight of evidence, as well as initial guidance on considering mixtures.

3.1 Submitting data to GESAMP

Enquiries and/or submissions on chemicals proposed for transport by ship that require evaluation by GESAMP, should be addressed to:

The Secretary of the GESAMP EHS Working Group
Marine Environment Division
International Maritime Organization
4 Albert Embankment
London SE1 7SR
United Kingdom
Email: GESAMP-EHS@imo.org

The GESAMP-EHS Product Data Reporting Form, reproduced in Annex VI of this document, may be obtained from IMO or, along with other related documents, may be accessed directly at:

http://www.imo.org/en/OurWork/Environment/PollutionPrevention/ChemicalPollution/Pages/ChemicalsReportingForms.aspx

To facilitate processing a request, an electronic submission of the GESAMP-EHS Product Data Reporting Form is requested (preferably as a Microsoft Word document).

Many of the chemical substances and mixtures proposed for carriage by ship are identified under trade names by the submitting organization. To allow clear identification, GESAMP and IMO may assign a chemical name and/or a product name to the substance. The appropriate naming of chemicals is considered further in annex III. GESAMP requires detailed information on the exact composition of a chemical substance and mixtures. If the composition of a chemical that has already been evaluated is altered, it is the responsibility of the manufacturer to inform GESAMP and IMO, accordingly.

The GESAMP EHS Working Group generally meets once each year to consider requests to evaluate new chemicals, to address correspondence with the chemicals industry or to otherwise amend existing hazard profiles based on new information. Entities planning to submit data on chemicals for evaluation by the GESAMP EHS Working Group are advised to enquire concerning the dates of the relevant meeting through the contact point listed above. If data are submitted, it is often helpful to have a representative of the company available by telephone or email during EHS meetings, in case there are questions relating to the evaluation of the chemicals. Scientists and the public are invited to submit data on chemicals to optimize or revise existing GESAMP Hazard Profiles accordingly. Such correspondence will be discussed at the subsequent meeting of the GESAMP EHS Working Group. Reports of the meetings are made publicly available (see paragraph 3.2).

3.2 Evaluation fees

Following a decision taken by the Marine Environment Protection Committee, a standard charge for the assignment of a GESAMP hazard profile for all chemicals has been introduced. This applies regardless of whether a full hazard profile or a short profile (as for cleaning additives) is requested. Details of current charges are contained in the IMO circular BLG.1/Circ.28[6] "The Introduction of Charges for Product Evaluation Undertaken by GESAMP/EHS".

[6] Available at IMODOCS or by contacting the GESAMP/EHS Secretariat.

GESAMP, through its EHS Working Group, encourages industry involvement in the preparation of the hazard profiles. The sessions of the GESAMP EHS Working Group are closed in order to preserve the confidentiality of proprietary trade information. However, representatives from chemical manufacturers, their trade associations or sector groups, as well as shipping agencies, are frequently invited to provide statements or to comment on specific items under discussion. Such contributions are particularly welcomed by GESAMP.

The results of the evaluation of chemical substances are published in the meeting reports of the GESAMP EHS Working Group. Following a decision by GESAMP at its 32nd Session[7] and in order to avoid any delay in the process of hazard evaluation and pollution categorization, the EHS Working Group notifies IMO directly of any new or revised hazard profiles, without prior approval from GESAMP. This decision was reviewed and endorsed by GESAMP at its 40th session in Vienna, in 2013 (GESAMP, 2013).

An updated list of hazard profiles, together with the report of the latest GESAMP EHS Working Group meeting, is published annually by IMO in the form of an IMO PPR.1/Circular and distributed to IMO Member States and observer organizations. The latest GESAMP Composite List can be accessed on the IMO website under the heading 'Related documents' at:

http://www.imo.org/en/ourwork/environment/pollutionprevention/chemicalpollution/pages/chemicalsreportingforms.aspx

3.3 Data recording by the EHS Working Group

In addition to retaining copies of the supporting data on each chemical, the EHS Working Group records the rationale behind its ratings for each hazard end-point (sub-column) of the hazard profile. With careful recording of all decisions on ratings, the EHS Working Group is able to respond to any queries from manufacturers and Administrations concerning its classifications. The rationale, as well as the supporting data, are added to the files for each chemical which are maintained by IMO, on behalf of the EHS Working Group.

3.4 Data confidentiality

Over 1000 chemicals, including many mixtures, have been evaluated by the EHS Working Group over the years. Original data submitted by manufacturers on these substances are stored securely at IMO and remain confidential. Such proprietary data are only made available to members of the GESAMP EHS Working Group for the purposes of establishing or reviewing a hazard profile.

3.5 Sources of data

Most GESAMP EHS Working Group evaluations are based primarily on data submitted by industry. Additional information may also be referenced. In recent years, available data on the properties and toxicity of industrial chemicals has been made publicly available by national, supranational and international agencies. The most comprehensive source of such information is the OECD Chemicals Portal[8] which links to relevant national and intergovernmental sources such as those of the European Chemicals Agency, the Canadian Chemicals Management Plan, the U.S. Environmental Protection Agency and the Japanese National Institute of Technology and Evaluation (NITE).

If parts of the product submission presented to GESAMP/EHS are reliant upon such sources, relevant study summaries should be copied from the sources concerned and appended to the submission (preferably as an electronic copy). This ensures that the specific data being proposed for review is clearly identified and not subject to being misidentified.

3.6 Data quality

While all relevant, high-quality data are acceptable for review in support of hazard profiles, GESAMP has a strong preference for experimental data generated in compliance with the OECD Principles of Good Laboratory Practice (OECD, 1997). The EHS Working Group searches for qualifying information, to complement and confirm the scientific data submitted by manufacturers. The accuracy of data contained in submissions is also cross-checked against information available in the open literature. Expert judgement is used by the EHS Working Group to evaluate the quality and interpret the results of older, often non-standard studies.

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[7] GESAMP, at its 32nd meeting, decided the following, in relation to its EHS working group:
"6.11 … it was agreed that this independence could only be maintained by the Group [EHS] being under the auspices of GESAMP which would continue to provide guidance regarding the membership of the Group, defining its method of work and reviewing the processes involved, such as the content of Reports and Studies 64.
6.12 In order to expedite the use of the Hazard Ratings by IMO, it was proposed that the hazard evaluations, developed by the Group, could be reported directly to IMO bodies at the same time as GESAMP."

[8] OECD Chemicals Portal: https://www.echemportal.org/echemportal/index.action

Box 1

Guidance on the required quality standards of test reports

With regard to laboratory testing to generate data for the GESAMP hazard evaluation procedure, there is a strong preference for studies carried out under the OECD Principles of Good Laboratory Practice (GLP) and internationally standardized test guidelines, e.g. OECD or ISO test designs.

Care should be taken to ensure that:

- laboratories carrying out such studies are certified as being "in compliance" with OECD GLP or have appropriate alternative accreditation, e.g. for analytical chemistry or testing physical properties;
- the reports of such studies contain a quality assurance statement; and
- the tests meet the stated validity criteria of the appropriate test guidelines.

With respect to the aquatic hazard environmental end-points, detailed technical guidance is contained in annex 9 of the GHS to assist in developing data for classifying substances as dangerous to the aquatic environment. The reader is referred to this document for more detailed guidance.

3.7 Complete data set

GESAMP strives to issue hazard profiles in the most complete form possible, i.e. with ratings in all of the columns appropriate for the purpose intended (i.e. carriage as a bulk liquid substance, as a component in a mixture or as a cleaning additive). This, however, depends on the suitability and reliability of the data submitted. Care should be taken to provide full supporting references and copies of the appropriate test laboratory reports in support of each submission. Submissions that are missing essential information may be rejected, pending receipt of more complete data.

When reviewing the profiles of substances where data may be lacking, the EHS Secretariat may invite the chemical industry to provide additional data. Such substances are then reviewed again, once sufficient data have become available.

In the context of bulk liquid transport by ships, it should be noted that while some of the sub-columns are not used for assigning pollution categories or for defining the tank protection standards for transport ("ship typing"), they may be needed by IMO bodies to assign carriage requirements, based on safety considerations.

3.8 Estimation techniques

Where experimental data on bioaccumulation, biodegradation, or acute aquatic toxicity are not available, then generally accepted estimation techniques may be applied, on a case by case basis. Only reliable and validated Quantitative Structure-Activity Relationships (QSARs) for estimating the acute aquatic toxicity of the chemical group in question are acceptable. The OECD principles for validating QSARs (OECD, 2004a) should be followed by the manufacturer and a suitable justification provided for the submitted data.

In the absence of measured data, estimates generated by the US EPA's K_{ow}WIN model, which estimates the log octanol-water partition coefficient of chemicals using an atom/fragment contribution method, is normally considered acceptable for organic chemicals. Results of estimation techniques for biodegradation, such as the set of six US EPA models known as BIOWIN, may also be acceptable as a basis for being considered not readily biodegradable, in order to avoid further testing.

Both of the above models are contained in the US EPA's Estimation Program Interface (EPI) SuiteTM (US EPA, online, b).

The EHS acute inhalation toxicity estimation rationale, outlined in section 4.3.4, is used in lieu of missing data. Estimations for other acute end-points may also be acceptable, provided that adequate justification is included with the submitted data.

Extrapolation techniques for estimating mammalian data on long-term toxicity and chronic aquatic toxicity are regarded generally as being inadequate. However, this is an aspect that is kept under review by the EHS Working Group.

3.9 Rating by read across

In cases where data on a structurally similar substance(s) is available, this may be used as a basis to provide a rating for one or more hazard end-points (sub-columns), whether related to the marine environment or to human health.

In such cases, convincing evidence of the structural similarity, physico-chemical properties, common molecular functional groups, metabolites, and/ or mechanism of action or other such characteristics of the analogous substance(s) should be provided to the EHS Working Group of GESAMP. Where manufacturers choose to submit data on a closely analogous substance, then the exact relationship and complete supporting information should be provided. Significant gaps in the available data on the supporting substance may lead to rejection. In such cases, estimated (non-experimental) data may be considered.

In the case of a substance belonging to a homologous series, manufacturers are encouraged to provide a comprehensive data set for the selected homologues and to clearly justify the arguments for read across of the selected hazard end-points to the target substance.

It should be borne in mind that read across needs to be approached on the basis of individual hazard criteria (end-points) and that it may not be possible to read-across data for some end-points, even where chemical structures are quite similar.

If there are any doubts, it is always advisable to contact the GESAMP-EHS Secretariat prior to making a submission on the basis of read across.

3.10 Rating of mixtures

Extensive consideration has been given to the classification of mixtures as part of the GHS. This is based on a separate consideration of each hazard end-point. The GHS defines "substances" as being:

> *"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".*

A "mixture" is defined as:

> *"mixtures or solutions composed of two or more substances in which they do not react".*

The GESAMP EHS Working Group evaluates chemicals which are defined as pure and technically pure substances as well as mixtures. The group in the past has evaluated many mixtures, including natural mixtures, such as hydrocarbon distillates, and other prepared mixtures, such as solutions, preparations, etc. To facilitate the use of this guidance by maritime administrations, the term substance in this GESAMP document refers also to mixtures, noting that this deviates from the GHS definition for substances (see Glossary).

In the past, hazard ratings for mixtures have been developed on a case by case basis, taking into account decision rules outlined in the GHS combined with expert judgement. More specific general guidance for hazard classification for mixtures has been introduced here, as a response to a request from IMO bodies, though it should be noted that for some GESAMP Hazard Ratings, there is no GHS equivalent (e.g. for column E2 ratings). The principles of this guidance, which is outlined in specific paragraphs for the ratings for each column below are, in general, consistent with those of GHS, which specifies preference for test data on the mixture itself, followed by rating based on data on a comparable mixture for which bridging rules are specified and finally, dose addition for components.

Annex III of this report contains guidance on the naming of chemicals, particularly mixtures, for submission to the GESAMP EHS Working Group. The hazard profile provides an ideal format for a modular approach to mixtures, allowing components to be compared at a glance.

At present, the EHS Working Group rates the hazard of mixtures on a case by case basis. The rationale behind each decision is recorded in the substance file retained by IMO. It is recognized that aquatic environment data on bioconcentration and biodegradation may need to be generated separately for the significant components of a mixture, rather than for the mixture as a whole.

3.11 Weight of evidence

Specific detailed weight of evidence (WoE) approaches are followed where acute aquatic toxicity is evaluated. When only a single result for each of the different trophic levels is available, e.g. acute fish, crustacean and algal toxicity tests, then the lowest LC_{50} value of the three is used to provide a rating. However, where multiple results are available (taking into account that many substances have acquired large databases for many of the hazard end-points in recent years) a WoE approach may become necessary to ensure that the rating reflects the body of data, rather than simply the most conservative value.

For the human health criteria contained in the hazard profile, the EHS Working Group prefers the use of appropriate experimental data. However, human experience, based on instances of accidental poisoning or from epidemiological studies, is also taken into account. All available information is considered by the experts and ratings are given on the basis of the total weight of evidence, for the hazard evaluation of substances. The result of any WoE approach including the identification of relevant studies, the alternative interpretation of study results, scientific judgements by the experts, and the drawing of conclusions is recorded in the confidential files resulting from a Working Group session on a specific chemical. In general, conclusions are based on consideration and weighting of the quality of available studies addressing specific end-points, the consistency of results across studies in inducing the specified effect and observed dose-response relationships, the biological plausibility of the observed responses based on knowledge of the broader scientific database including available mechanistic data and the analogy of observed effects with those of similar chemicals. These generic considerations are applied, as appropriate, depending upon the nature of the end-

point and the extent of the available database (i.e. as a basis for weight of evidence and expert judgement as they appear throughout this document). GESAMP/EHS welcomes constructive scientific debate commenting or questioning the outcome of such determinations of WoE via correspondence, in view of the variety of approaches available to assess WoE (Rhomberg et al., 2013).

The distribution of data for a given end-point often lies across more than one rating category. In such cases, the EHS Working Group will examine the data at the upper and lower ends of the distribution to assess whether to include them or to disregard such data as outliers. Less reliable data indicating effects at lower concentrations or doses may not be weighted. Where the aquatic environment is concerned, taxonomic considerations, such as whether the organism is of marine or freshwater origin, may also be taken into account.

3.12 Rating notation and confidence in the supporting data

The GESAMP EHS Working Group assigns a rating in one of the following ways:

- a rating without qualification (i.e. without brackets), is based on a review of data specific to a product, or on adequate supporting evidence;
- a rating "in brackets" indicates that there is sufficient confidence to provide a rating, but it is based on indirect data or estimation techniques – i.e. read across to similar substances, acceptable estimation methods, classifications by other bodies or expert judgement. It should be pointed out that in defining the pollution category, ship type and carriage requirements at IMO, ratings both with and without brackets are utilized in the same way; and
- the symbol "NI" (no information) is placed in any sub-column of the hazard profile to indicate that insufficient data were available to allow a rating for that end-point. In such circumstances, it may not be possible to categorize the product under MARPOL Annex II or assign carriage requirements according to the IBC Code.

The GESAMP EHS Working Group makes every effort to list the hazards to human health including the long-term health effects covered in sub-column D3. This is based on the evidence available at the time the substance is reviewed. The absence of one of the hazards in sub-column D3 should not be considered to indicate that a particular chemical does not cause this hazard. It could reflect that there has been no positive effect based on the results of standard testing or that there is a lack of standard testing or epidemiological data (see also 4.4.3).

3.13 Review of substances by the GESAMP EHS Working Group

The revised GESAMP hazard profiles are subject to regular review, either at the request of manufacturers, or by the EHS Working Group itself, which verifies and/or updates profiles for individual substances and occasionally whole groups of chemically related substances. Re-evaluation of a profile may have implications for the assignment of carriage conditions.

4 HAZARD EVALUATION END-POINTS

This section describes the hazards arising from the intrinsic properties of chemical substances, how they are evaluated and the application to mixtures. The hazard end-points are set out below in the order of the GESAMP hazard profile columns.

In the following sections, introductions to each hazard end-point are followed by descriptions of the basis for application of the ratings. Most sections contain guidance on selecting appropriate test methods (see Boxes 2 to 9).

4.1 Column A: Bioaccumulation and Biodegradation

The tendency for substances to bioaccumulate and biodegrade is reflected in two sub-columns under column A of the hazard profile:

- A1: Bioaccumulation; and
- A2: Biodegradation.

4.1.1 *Sub-column A1: Bioaccumulation*

4.1.1.1 Introduction

Bioaccumulation is the presence of (a) substance(s) in the tissues of organisms resulting from the complex process by which chemical substances are taken up into the body through all exposure routes (water, food and sediment). In practice, bioaccumulation is estimated by exposing fish or shellfish to a chemical in water under steady state conditions, i.e. by measuring bioconcentration from the water phase only and ignoring the influence of food or sediment. GESAMP is aware that such test methods may provide an inadequate simulation of conditions in the marine environment.

However, bioconcentration tests provide a relatively reliable comparative measure of the intrinsic tendency of a given substance to accumulate in living tissues and are therefore considered appropriate for use in the GESAMP hazard evaluation procedure.

A bioconcentration test (OECD, 2012a) measures steady state concentrations of the substance in the tissue of the test organism, relative to the concentration in the water, through simultaneous uptake (e.g. by gill or epithelial tissue) and elimination. The exposure duration needed to reach steady state often depends on the hydrophobicity/lipophilicity of the test substance (see log P_{ow} below). The bioconcentration factor (BCF) can be thus established accordingly.

An alternative experimental test method is available in which the test organisms are exposed to the chemical substance through their diets. The preference of the EHS Working Group is still for bioconcentration tests relative to the water phase, unless the chemical is highly hydrophobic so as to make accurate dosing and analytical confirmation difficult.

Bioconcentration factors (BCF) can also be estimated on the basis of the n-octanol-water partition coefficient, which relates to uptake in the fatty tissues of the fish, in particular the phospholipid bilayers of the cell membranes. Usually the n-octanol-water partition coefficient is expressed as the base 10 logarithm of the concentration ratio of the substance under test in the lipophilic phase (n-octanol) and the hydrophilic phase (water). It is referred to as the log K_{ow} or log P_{ow}.

The log P_{ow} relates to the solubility of hydrophobic organic substances in n-octanol but it cannot be used to estimate bioaccumulation of highly polar substances such as inorganic chemicals.

The log P_{ow} is applied by the EHS Working Group:

- to estimate the potential of an organic chemical to bioaccumulate in fish tissues; and
- to estimate baseline toxicity of organic substances to aquatic organisms.

Baseline toxicity (Verhaar et al., 1992) data derived from the log P_{ow} are routinely used for assessing the reliability of experimentally derived ecotoxicity test data (see section 4.2.1.3). Internationally standardized methods for measuring the log P_{ow} of a chemical are OECD Guidelines for the Testing of Chemicals 107 (OECD, 1995a), 117 (OECD, 2004b) and 123 (OECD, 2006a). Additionally, there are two methods for calculating the log P_{ow} from molecular fragment values (Rekker and Mannhold, 1992; Hansch and Leo, 1979).

For values below 4, log P_{ow} data are reliable for estimating bioaccumulation. However, for values above 4 to 6, measured log P_{ow} data may underestimate bioaccumulation, whereas calculated log P_{ow} data may overestimate. Therefore, at log P_{ow} values of $\geq$4, a measured BCF is required to provide definitive information on the potential of a substance to bioaccumulate under steady state conditions. Measured BCFs may result in ratings of lower hazard than log P_{ow} values, since they take into account processes of elimination from tissues such as metabolism.

Sub-column (A1) dealing with bioaccumulation therefore contains two sets of related information:

- **A1a:** the log n-octanol/water partition coefficient (log P_{ow})
  - measured directly in the surrogate phase octanol; and/or
  - estimated from fragmental constants;
- **A1b:** the measured BCF in fish, crustaceans or molluscs as test organisms.

For inorganic substances, the octanol-water partition coefficient does not provide a reliable parameter to assess bioaccumulation, since most ions are actively regulated by specific transport proteins and are not readily soluble or partitioned between cellular membranes and the aqueous media. A label “Inorg.” (for inorganic) in the column indicates that the substance is inorganic and that no log P_{ow} data can be generated. Bioaccumulation must be assessed, therefore, based on an actual bioconcentration test data (all exposure routes considered) or bioconcentration studies using expert judgement case-by-case.

Box 2

Guidance for experimentally measuring and calculating the log P_{ow}

Several methods are available for calculating the log P_{ow}. When commissioning log P_{ow} tests, it is essential to ensure that the appropriate method for the compound in question is selected and that the detection limits of the analytical method are sufficiently low. Where very high log P_{ow} values are expected, the slow-stirring method OECD No.123 is recommended, as described below. Surface active and easily emulsified compounds are generally difficult to test experimentally.

OECD No. 107: The shake flask method

With this method, the chemical under study is placed in a two-phase octanol-water system and allowed to equilibrate by shaking. This method is suitable for compounds with a log P_{ow} of slightly below 0 (highly water soluble) to approximately 4 (moderately lipophilic). This method has the disadvantage that octanol droplets may enter the water phase, effectively emulsifying the test chemical in the wrong phase and disturbing the equilibrium.

OECD No. 117: Reversed phase High Pressure Liquid Chromatography method

This is an indirect method, where the retention time on a C18 loaded HPLC column is used to estimate the log P_{ow}. This method is particularly suitable for measuring log P_{ow} values between 4 and 6 (highly lipophilic). Provided that suitably low analytical detection levels can be achieved and that all the other validity criteria can be met, this method may be extended beyond its originally intended range by adding additional standards with log P_{ow} values above 6 to the recommended calibration series.

OECD No. 123: Slow-stirring method

The slow-stirring method of de Bruijn et al. (1989) is a direct method that uses a temperature controlled flask provided with gentle stirring to bring the chemical into equilibrium between the water and n-octanol phases. The water and n-octanol phases are periodically analysed, e.g. using appropriate HPLC or GC methods. This method has the advantage that compounds with a log P_{ow} of up to 8 can be measured, depending on the limits of analytical detection available.

Calculating the log P_{ow} using fragmental constants

In the case of surface active substances, using fragmental constants may be the only feasible way to estimate the log P_{ow}. The hydrophobic fragmental constant method of Rekker and Mannhold (1992) and a comparable method provided by Hansch and Leo (1979) are both suitable for estimating log P_{ow} values. The two methods are roughly equivalent. The US EPA EPI Suite computer based package contains a useful model (K_{ow}WIN) for calculating the log P_{ow}.

For sub-column A1b, bioconcentration data on fish are preferred, as frequently used and standardized test methods are available (see Box 3). However, data on other groups of organisms, such as crustaceans and molluscs, may be useful as additional information or where no other information is available. Although occasionally found in the literature, data on bioaccumulation in microalgae are not used by the EHS Working Group.

4.1.1.2 Ratings

For bioaccumulation, a rating scheme has been developed for sub-column A1 as shown in Table 2, below. Ratings which are estimated by expert judgement are shown in brackets “( )”. The overall rating for column A1 is extracted from the information obtained in sub-columns A1a and A1b. When data on BCF (A1b) is available, it is preferred to that for log P_{ow} for the final rating.

Table 2 – Rating scheme for bioaccumulation (A1)

Rating	Description	Sub-column A1a	Sub-column A1b
		Criteria for log P_{ow}	Criteria for BCF
0	No potential to bioaccumulate	$<$1, or $>$ ca.7, or Mol. Wt. $>$ 1000	No measurable BCF
1	Very low potential to bioaccumulate	$\geq$1 and $<$2	$\geq$1 and $<$10
2	Low potential to bioaccumulate	$\geq$2 and $<$3	$\geq$10 and $<$100
3	Moderate potential to bioaccumulate	$\geq$3 and $<$4	$\geq$100 and $<$500
4	High potential to bioaccumulate	$\geq$4 and $<$5	$\geq$500 and $<$4000
5	Very high potential to bioaccumulate	$\geq$5 and $\leq$ ca.7	$\geq$ 4000

The substances most likely to pose a hazard to aquatic organisms through bioaccumulation typically have log P_{ow} values ranging from 4 to approximately 7.

From Table 2 above, it can be seen that a log P_{ow} of $>$ ca.7 would generally lead to a "0" rating. The EHS Working Group considered that available evidence indicates that the majority of organic chemicals carried by ships with log P_{ow} values of $>$ ca.7 would have little potential to bioaccumulate. However, while this is generally true for the particular set of chemicals transported in bulk by ships, it is recognized that many groups of highly persistent, bioaccumulative and toxic substances, e.g. PCBs and PCDDs, as well as other halogenated groups, constitute well-known exceptions to this rule of thumb. Van Leeuwen and Vermeire (2007) discuss this topic in some detail in relation to log P_{ow} estimation methods. Log P_{ow} values of as high as 8.25 and associated bioaccumulation have been measured. These are also often some of the most persistent substances in the environment.

Assessing the bioaccumulation or the bioconcentration of inorganic substances (e.g. metal compounds) in the aquatic environment presents challenges. Various factors such as the water chemistry (hardness, pH, organic matter and others) affect the bioavailability of the substance influencing the test results. Furthermore, the cellular metal uptake is actively controlled by specific proteins (transporters) in the epithelial membranes in contact with the media, particularly in the case of metals that are essential for the cellular metabolism (e.g. Fe, Cu, Zn and others). The tight control of the tissue concentration of these substances makes it difficult to interpret the bioconcentration test results, since the bioconcentration factors depend on the exposure concentrations. Data from either standard freshwater or marine aquatic tests are used to assign ratings. However, marine data are preferred for assessment, if available, as bioaccumulation in marine organisms may differ from freshwater organisms.

Most of the ecotoxicity data available have been derived from the testing of water soluble metal salts. However, such data may not be applicable for assessing the bioaccumulation potential of sparingly soluble metal compounds. Suitable guidelines for assessing the aquatic toxicity of insoluble metals and metal compounds have been developed by the OECD and recognized by the GHS, as set out in its annexes 9 and 10 (United Nations, 2017). The environmental hazard of metals posed by bioaccumulation and toxicity remains difficult to estimate or interpret and case-by-case expert judgement is required.

For the case of organometallic substances (e.g. methyl-mercury, dimethyl-mercury, tributyl tin and the like) since they are highly hydrophobic and behave chemically as canonical organic substances, potential for bioaccumulation can be assessed on the basis of log P_{ow} and BCF.

4.1.1.3 Application

Where the log P_{ow} exceeds a value of 4, the substance is considered to "bioaccumulate to a significant extent" unless the measured bioconcentration factor (BCF) can be shown experimentally to be less than a value of 500. Substances with BCF values in excess of 500 are also considered to bioaccumulate to a significant extent. Cut-off values for the GHS are similar.

In general, measured BCF data, where available, overrule log P_{ow} data, provided that the study is scientifically sound and well documented. In the absence of a measured BCF value, the log P_{ow} is used directly to provide a rating which obviates the need for extrapolation of the log P_{ow}.

Box 3

Guidance for measuring bioconcentration in fish

The bioconcentration factor (BCF) is defined as the ratio (on a wet weight basis, normalized to a 5% fish fat content) between the concentration of the chemical in biota and the concentration in the surrounding water, at steady state. The BCF is experimentally derived under steady state conditions, on the basis of measured concentrations. However, it can also be calculated as the ratio between the first-order uptake and elimination rate constants; a method which does not require equilibrium conditions. Different test guidelines for the experimental determination of bioconcentration in fish have been documented and adopted. These have been consolidated in OECD No. 305, entitled "Bioconcentration in fish: aqueous and dietary exposure" (OECD, 2012a).

In measuring the BCF, the focus is generally on the parent compound but in some cases, the metabolites may also be relevant. The use of radiolabelled test substances can facilitate the analysis of water and fish samples at low test substance concentrations. However, unless combined with a specific analytical method, the total radioactivity measurements potentially reflect the presence of the parent substance, as well as possible metabolite(s) and metabolized carbon, which have been incorporated in the fish tissue in organic molecules. As a result, BCF values determined by the measurement of radioactivity alone, tend to overestimate the presence of the parent compound in the fish tissues. Therefore, the use of specific analytical methods (with radiodetection) is strongly recommended. When using radiolabelled substances, the stable part of the molecule is most often radiolabelled, which accounts also for the BCF of the metabolites.

Occasionally, it is the metabolite(s) which are most toxic and have the highest bioconcentration potential. For such substances, measurements of the parent substance, as well as the metabolites, may be important for the interpretation of the aquatic hazard (including the bioconcentration potential).

The latest version of the OECD No. 305 (OECD, 2012a) includes bioconcentration via the dietary route, which may be more suitable for determining the bioaccumulation potential of substances with very low water solubility. Additionally, the traditional aqueous exposure method has been simplified by using only one concentration and less data points, provided certain criteria can be met. This contributes to objectives to reduce animal testing, as it requires fewer fish.

The majority of substances in bulk liquid maritime transport with very high log P_{ow} values (>7) are generally presumed to be so insoluble in water as to pose no potential for bioaccumulation. However, where there is evidence to the contrary, the default "0" rating will be overridden and a measured or estimated log P_{ow} will be used to derive a rating. This cut-off point is included to avoid classifying non bioaccumulating substances with high log P_{ow} values, such as vegetable and animal oils (triglycerides).

Substances with molecular weights of >1,000 in bulk maritime transport are also assumed not to bioaccumulate (Newsome et al., 1996; ECHA, 2017), as the molecular size is generally too large to pass through cell membranes.

4.1.1.4 Application to mixtures

Where mixtures are concerned, and consistent with the summation method of the GHS (United Nations, 2017), the rating of a mixture is the sum of the concentrations of the individual components weighted by their concentration and rating, where the cut-off limit is set at 25% as w/w%. For example, a chemical where the sum of the components rated as 5 under sub-column A1a or A1b is equal to or greater than 25%, would result in a rating of 5 for the whole mixture in column A1, as indicated in Table 3. For components for which both A1a and A1b ratings are available, only the A1b rating is taken into account for assigning a mixture classification. An example of the mixture calculation is outlined under Annex IX.

Table 3 – Classification of mixtures for Bioaccumulation

Classification of mixtures for Bioaccumulation, using log P_{ow} (or log K_{ow}) (A1a) and/or Bioconcentration factors (A1b) data, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the ingredients i=1 to n and where R for columns A1a and/or A1b goes from 0 to 5.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\,(R=5)}$	≥ 25%	5
$\left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=4)}$	≥ 25%	4
$\left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=3)}$	≥ 25%	3
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=2)}$	≥ 25%	2
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	≥ 25%	1

Sum of concentrations (in %) of ingredient in the mixture rated as:	If	Mixture is rated as:
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$< 25\%$	0

4.1.2 *Sub-column A2: Biodegradation*

4.1.2.1 Introduction

Knowledge of the rate at which organic substances degrade in the aquatic environment is of great importance in determining their impact and ultimately in assessing its long-term biological effects. Metabolism by microbes is an important route of degradation of organic substances. Other routes, e.g. abiotic; through hydrolysis and photolysis may also contribute to degradation for some chemicals. With the exception of agricultural pesticides, there are few data available on the degradation rates of most chemicals in relevant environmental compartments, such as water and aquatic sediments, while data for degradation in the marine environment are particularly sparse as outlined in Box 4 and further described in Annex IV, to this date there are only two specific marine ready biodegradation test designs, though biodegradation in freshwater can vary considerably from that in the marine environment.

The approach to assess environmental degradation of organic substances cannot be applied directly to inorganic compounds such as metals. Metals are substances that are persistent in the marine environment. In contrast to most organic compounds, the toxicity of metals is modulated by environmental conditions. The bioavailability and therefore the toxicity of metals is a complex function of the water chemistry (e.g. pH, hardness, organic carbon content and other variables). As IMO uses biodegradation (sub-column A2) for bulk liquid classification purposes, both organic and inorganic compounds are rated under this hazard profile sub-column. The latter are labelled as "inorganic" (abbreviated to "Inorg.") in the GESAMP Composite List.

4.1.2.2 Ratings

The rating notations for sub-column A2 are presented in Table 4 and the pass and fail conditions in section 4.1.2.3 below. Ratings which are estimated by expert judgement are shown in brackets "()".

Table 4 – Rating scheme for ready biodegradability (A2)

Rating	Description (organic substances)
R	readily biodegradable
NR	not readily biodegradable

4.1.2.3 Application to organic substances

The biodegradation sub-column A2 refers to substances that are considered to be "readily biodegradable" if, in 28-day biodegradation studies, the following end-points of degradation are achieved:

.1 in tests based upon dissolved organic carbon (DOC) degradation $\geq$70%; or

.2 in tests based upon oxygen depletion or carbon dioxide generation: $\geq$60% of the theoretical maxima; or

.3 where only chemical oxygen demand (COD) and biochemical oxygen demand (BOD_5) data are available, the ratio of BOD_5/ COD $\geq$0.5; or

.4 where other convincing scientific evidence is available to demonstrate that the substance can be degraded biotically and/or abiotically in the aquatic environment to a level of >70% within a 28-day period. The exact values of percentage biodegradation within 28 days should be reported, together with the test method.

Evidence from recognized estimation methods, which indicate that a compound may not be readily biodegradable, may provide sufficient evidence to avoid testing, in which case a (NR) rating may be assigned. Data generated by well-known estimation methods, such as the US EPA's BIOWIN set of models, may in some cases be acceptable for assigning the rating "readily biodegradable" (R), provided that this is supported by the structure of the chemical and unequivocal results of BIOWIN's component (aerobic) models.

Box 4

Guidance for measuring ready biodegradability

Biodegradation testing is complicated by considerable variability in microbial populations and the wide variety of freshwater test guidelines. Annex IV contains an overview of the marine "ready" biodegradation test methods, and one freshwater method, which could be adapted to marine conditions. The terminology is further explained in the glossary.

Marine tests, e.g. OECD No. 306 (OECD, 1992a) are preferred. There is evidence to show that biodegradation proceeds less rapidly in marine waters compared to freshwater environments (ECETOC, 2009). This may vary widely from location to location, e.g. chemicals may be readily biodegraded in polluted harbours and coastal waters, while such processes may be much slower under pristine oceanic conditions. The above method uses natural seawater as the only source of microorganisms. However, as nutrients are added to sustain microbial growth, this cannot be considered as a simulation of the natural environment.

Freshwater tests, e.g. the OECD No. 301 A–F series (OECD, 1992b), ISO 9439 (ISO, 1999a), ISO 10707 (ISO, 1994) or EPA OPPTS equivalents, are acceptable, with limitations. All of these tests are inoculated with activated sludge from sources such as wastewater treatment plants (receiving domestic and not industrial effluent) and are thus expected to encourage biodegradation to a greater extent than the seawater design described above.

An acceptable alternative to the OECD No. 306 is the aerobic mineralization in surface water – simulation biodegradation test, OECD No. 309 (OECD, 2004c) carried out with natural seawater. This method allows testing of very low concentrations, under relatively natural conditions.

Inherent biodegradation tests, or wastewater treatment simulation tests, using microorganisms which have been pre-adapted to biodegrade chemical substances, are not considered to be sufficiently representative of the marine environment.

4.1.2.4 Application to mixtures

To assess the biodegradation rating of a mixture, where not readily biodegradable (NR) and readily biodegradable (R) ingredients are present, the rating is calculated as the sum of the concentrations of the individual components, weighted by their concentration and rating, where the cut-off limit is set at 25% as w/w%. For example, a chemical where the sum of the components rated as NR under column A2 is equal to or greater than 25%, would result in a rating of 'NR' for the whole mixture, as indicated in Table 5. An example of the mixture calculation is outlined under Annex X.

Table 5 – Classification of mixtures for biodegradation

Classification of mixtures for biodegradation, column A2, based on the summation of components rated by GESAMP as not readily biodegradable (NR) or readily biodegradable (R). Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for rating in column A2 is NR or R.

Sum of concentrations (in %) of ingredient in the mixture rated as:	If	Mixture is rated as:
$\sum_{i=1}^{n} \%C_{R=NR}$	$\geq$ 25%	NR
$\sum_{i=1}^{n} \%C_{R=NR}$	$<$ 25%	R

4.2 Column B: Aquatic Toxicity

Column B has two sub-columns, one for acute aquatic toxicity (B1), and the other for chronic aquatic toxicity (B2).

The acute and chronic GESAMP aquatic toxicity scales are independently rated (similar to the GHS) and are treated as separate effects.

Aquatic toxicity is generally expressed as LC_{50}, EC_{50}, IC_{50} or NOEC. In acute tests, the LC_{50} is usually determined for fish and crustaceans, the EC_{50} (immobility) for the commonly used freshwater crustacean *Daphnia sp.*, while the IC_{50} or EC_{50} (reproduction and/or growth) generally applies to microalgae. In chronic tests, the end-point is given as a NOEC value.

Most test guidelines describe how water-soluble substances should be tested. However, many substances carried in bulk by ship are poorly soluble, defined for this purpose as having a water solubility of $<$1 mg/L, for which two relevant approaches are available.

With poorly soluble, pure substances, the water solubility is first determined accurately. The substance is then tested using a concentration series at and below the saturation level in water. Where no acute toxicity can be measured below the limit of solubility of the substance in water, the result of the test is expressed as being:

"greater than x mg/L and therefore above the limit of solubility in water"

and a rating of '0' is given, where x is the solubility concentration of the substance in the test water. Should toxicity be observed, then the result is calculated and expressed in the normal way as an LC/EC/IC_{50} and an appropriate rating assigned. Confirmation of the exposure concentrations using chemical analysis is essential.

For mixtures, differential solubility of the components may make conventional testing and analysis difficult, necessitating an alternative approach. A series of water accommodated fractions (WAFs, see annex V) are prepared by stirring excess amounts of the test substance separately in water (at a uniform speed) for a period of 16 to 24 hours to allow an equilibrium to be achieved (in reality, a true equilibrium is seldom demonstrated). The phases are allowed to separate for approximately 4 hours and the test water (less the test substance) is tapped directly into the test vessels and the test organisms immediately introduced. In such cases, the test results are expressed as the "loading rate" (LL_{50}/EL_{50} and IL_{50}), rather than the exposure concentration. Critics of this method note that the toxicity of the most potent component may be underestimated by the integral result derived for the mixture as a whole. The EHS Working Group considers that the methodology provides sufficient indication of the intrinsic hazard of mixtures.

In general, data from freshwater aquatic toxicity tests are acceptable for evaluation by GESAMP. The molecular (partitioning) processes governing bioaccumulation and non-specific "baseline toxicity" effects are generally the same for marine and freshwater organisms. However, there are some differences in the effects caused by specific groups of chemicals, e.g. for organometallic compounds, metal ions, ammonia, amines and acids in seawater, as opposed to freshwater. Toxicity of dissociating/reactive substances may be influenced by pH and the buffering capacity of seawater may reduce exposure and thereby the potential for aquatic toxicity. Marine data are preferred and may provide a more realistic assessment of the toxicity of substances to marine organisms.

4.2.1 *Sub-column B1: Acute aquatic toxicity*

4.2.1.1 Introduction

In order to rate the acute hazard posed by chemical substances to aquatic organisms, the use of acute toxicity test data is still preferred. Data relates to organisms representing the lower to middle trophic levels of an aquatic food chain, e.g. crustaceans and fish, in addition to microalgae, which represent primary producers at the base of the food chain, are preferred.

It is recognized that the standardized tests carried out according to international guidelines may not simulate conditions when substances of low solubility, low density and high volatility are spilled or discharged at sea. However, it is important that the intrinsic toxicity of all substances be considered on the same basis, under standardized and controlled conditions.

Table 6 – GESAMP rating scheme for acute aquatic toxicity (B1)

Rating	Description	LC/LL_{50}, EC/EL_{50}, IC/IL_{50} (mg/L)
0	Non-toxic	>1000
1	Practically non-toxic	>100 and ≤1000
2	Slightly toxic	>10 and ≤100
3	Moderately toxic	>1 and ≤10
4	Highly toxic	>0.1 and ≤1
5	Very highly toxic	>0.01 and ≤0.1
6	Extremely toxic	≤0.01

4.2.1.2 Ratings

The ratings for acute toxicity address a range of observed toxicity values from >1000 mg/L down to <0.01 mg/L, as shown in Table 6. The ranges for each of the ratings distinguish the toxicity of groups of substances on a log scale, in order to reflect the hazards associated with:

- substances with limited toxicities, that may have a significant volume in an accidental release (e.g. LC/EC_{50} 100–1,000 mg/L);
- the ranges of acute toxicity values of the GHS (10–100, 1–10 and ≤1 mg/L);[9]
- substances which due to very high (0.1–0.01 mg/L) or extreme (≤0.01 mg/L) acute toxicity may be hazardous when discharged in small quantities.

All of these ranges of toxicity are used in regulating substances under MARPOL Annex II (bulk liquid substances). Ratings which are estimated by expert judgement are shown in brackets "( )".

[9] Acute class I of the GHS contains all substances with an LC/EC_{50} of ≤1 mg/L. The revised GESAMP hazard evaluation procedure adds three extra hazard bands. Apart from the reasons given above, this is intended to enable IMO to consider in detail the categorization of mixtures. The GHS uses M-factors (M for mixture) to achieve the same purpose.

Box 5

Guidance for measuring acute aquatic toxicity

Testing strategies for acute aquatic toxicity studies should be able to address difficult substances transported in bulk by sea (e.g. those that are poorly soluble, highly volatile, tending to solidify at ambient temperatures, etc.).

Fish

The appropriate test for measuring the acute aquatic toxicity to marine fish is OECD No. 203 (OECD, 1992C). This is an established and flexible guideline allowing the use of many freshwater and marine species. A small estuarine fish, the sheepshead minnow Cyprinodon variegatus, has generally been found suitable. Other fish species are also acceptable, as indicated in the above guideline. The deleted (2014) OECD No. 204, 14-day prolonged toxicity study, is not recommended, as it is too long for an acute study and too short for a chronic study.

As alternative methods to reduce animals in testing become internationally standardized, the EHS Working Group may also consider data generated with fish embryos.

Crustaceans

Tests with marine crustaceans can be carried out according to the ISO 14669 guideline (ISO, 1999b). The recommended species are the copepod *Acartia tonsa* and the mysid shrimp *Mysidopsis bahia* (US EPA, 1996a). Other well-established guidelines, covering additional marine crustaceans, may also be acceptable. Existing freshwater data is already available, data on the water flea Daphnia magna according to OECD No. 202 (OECD, 2004d) is generally acceptable.

Microalgae

Microalgal toxicity tests can best be carried out under the ISO 10253 (marine) (ISO, 2016), ISO 8692 (freshwater) (ISO, 2012) or OECD No. 201 (freshwater) (OECD, 2011a) guidelines. The ISO standards generally provide more practical guidance. All of the above guidelines have been updated relatively recently. In addition, advice on the toxicity testing of difficult substances using microalgae, including volatile and poorly soluble chemicals, is given in ISO Test No.10634 (ISO, 1995).

Testing poorly soluble pure substances and mixtures

Annex V to this document contains guidance on methods for exposing organisms to poorly soluble mixtures, with components of different behaviours in water. For further advice on this topic, the reader is referred to the guidance provided by organizations such as ISO, European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) (1996) and OECD (2000a).

Analytical determination of exposure concentrations

Acute aquatic toxicity tests should be accompanied by analytical evidence showing that exposure to a particular concentration of the test substance has occurred and has been appropriately maintained. This may present some challenges for mixtures. Total Organic Carbon analysis of the test media may be appropriate. The reader is referred to the specific guidance contained in the relevant OECD guidelines and to the above guidance documents for additional information.

4.2.1.3 Application

Data from the following three standard tests will generally be used:

- 96 h LC/LL_{50} fish tests;
- 48 to 96 h $LC/LL_{50}/EC/EL_{50}$ crustacean tests; and
- 72 to 96 h $EC/EL_{50}/IC/IL_{50}$ microalgal growth inhibition tests.

Where only one result each for the three groups of organisms is available and the data are of acceptable quality, the lowest LC_{50} or EC_{50} (i.e. from the test showing the highest acute toxicity) will be used to assign the toxicity rating. The use of a weight of evidence approach for larger data sets for assignment of ratings by read across is considered in section 3.11 and is applied by the EHS Working Group, as appropriate.

Data from either standard freshwater or marine aquatic toxicity tests are used for assigning ratings. The processes governing the expression of toxicity in freshwater and marine organisms are generally similar. Baseline data on toxicity of exposure to non-polar organic substances, i.e. the accumulation of substances in the phospholipid bilayer of the cell membrane until saturation is reached and the cell dies, is relevant to both freshwater and marine organisms. This also probably holds true for polar organic substances. However, the toxicity of reactive substances in seawater may vary considerably to that in freshwater. In such cases, marine data are preferred and may provide a more realistic assessment of the toxicity of substances to marine organisms.

Toxicity data generated with organisms other than fish, crustaceans and microalgae, in particular other marine taxa, may also be acceptable.

4.2.1.4 Application to mixtures

To assess the acute aquatic toxicity of a mixture, the rating is calculated as the sum of the concentrations of the individual components, weighted by their concentration and rating, where the cut-off limit is set at 25% as w/w%. For example, a chemical where the sum of the components rated as 6 under column B1 is equal to or greater than 25%, would result in a rating of 6 for the whole mixture, as described in Table 7. An example of the mixture calculation is outlined under Annex XI.

Table 7 – Classification of mixtures for short-term (acute) aquatic hazard

Classification of mixtures for short-term (acute) aquatic hazard, column B1, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for ratings in column B1 ranges from 0 to 6.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\,(R=6)}$	$\geq$ 25%	6
$\left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=5)}$	$\geq$ 25%	5
$\left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=4)}$	$\geq$ 25%	4
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[10x \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=3)}$	$\geq$ 25%	3
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=2)}$	$\geq$ 25%	2
$\left[100000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$\geq$ 25%	1
$\left[100000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$<$ 25%	0

4.2.2 *Sub-column B2: Chronic aquatic toxicity*

4.2.2.1 *Introduction*

Chronic toxicity addresses the impacts of long-term exposure of aquatic organisms and is a core component of hazard evaluation in the marine environment, as it considers the influence of:

- operational discharges from ships in heavily used shipping lanes, particularly near specially protected marine areas; and
- accidental spills from ships, where the timescales involved may be longer than expected, e.g. where the substances form slicks that do not break up and readily disperse (see section 4.5), bearing in mind the potentially large volumes involved.

The GHS relies on measured chronic aquatic toxicity data by preference. However, in order to classify in GHS, chronic toxicity data are combined with evidence of non-rapid or rapid degradation. Alternatively, in the absence of measured chronic data, acute data are combined with evidence of non-rapid degradation or significant bioaccumulation. By contrast, for the GESAMP hazard profile, these hazard end-points are considered separately, consistent with the task of the EHS Working Group to evaluate intrinsic hazard rather than classifying products. However, the separate GESAMP ratings can be combined to classify substances under the GHS as shown in Annex VII.

Box 6

Guidance for measuring chronic aquatic toxicity

Fish

Suitable tests for measuring chronic toxicity to fish include the fish early life stage test (OECD No. 210) (OECD, 2013) and the 28d fish juvenile growth test (OECD No. 215) (OECD, 2000b). Equivalent national or regional test guidelines may also be acceptable. It should be noted that the OECD No. 212 (OECD, 1998) test with egg and sac-fry stages may not provide enough information for the purpose of providing a chronic rating. For investigating such specific end-points as endocrine disruption or reproductive disturbance in fish, recent test guidelines such as the OECD Nos. 229 (OECD, 2009a), 230 (OECD, 2009b) and 234 (OECD, 2011b) may be used. For the purposes of assigning a rating for chronic aquatic toxicity, the latter is the most suitable.

Crustaceans

A suitable standardized test for determining chronic toxicity to marine crustaceans is described in the US EPA 850.1350 guidelines (US EPA, 1996b) for *Mysidopsis bahia*. An equivalent test is a reproduction test with the calanoid copepod *Acartia tonsa* (ISO, 2015). Further information on reproduction and developmental testing with calanoid and harpacticoid copepods can be found in the report of an OECD validation study (OECD, 2007). Data from freshwater species, e.g. the 21d *Daphnia magna* reproduction test (OECD No. 211) (OECD, 2008a) is also commonly used. Chronic tests with crustaceans generally begin with juveniles and continue through maturation and reproduction. For mysid shrimp, 28 days are sufficient for maturation and the production of broods. Observational test end-points include time to first brood, number of offspring produced per female, growth and survival.

Microalgae

Microalgal toxicity tests can best be carried out under the ISO 10253 (marine) (ISO, 2016), ISO 8692 (freshwater) (ISO, 2012) or OECD No. 201 (freshwater) (OECD 2011a) guidelines. The ISO standards generally provide more practical guidance. In addition, advice on the toxicity testing of difficult substances using microalgae, including volatile and poorly soluble chemicals, is available in ISO Test No. 10634 (ISO, 1995).

Analytical determination of exposure concentrations

Chemical analysis to measure the exact exposure concentrations is essential in the case of all chronic tests to show that exposure to a particular concentration of the test substance has occurred and has been appropriately maintained. Where mixtures are concerned, this may be problematic. The reader is referred to the specific guidance contained in the relevant OECD guidelines and to the above guidance documents.

Annex V to this document contains guidance on methods for exposing organisms to poorly soluble mixtures, with components of different behaviours in water. For further advice on this topic, the reader is referred to the guidance provided by organizations such as ISO, European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) (1996) and OECD (2000a).

Analytical determination of exposure concentrations

Acute aquatic toxicity tests should be accompanied by analytical evidence showing that exposure to a particular concentration of the test substance has occurred and has been appropriately maintained. This may present some challenges for mixtures. Total Organic Carbon analysis of the test media may be appropriate. The reader is referred to the specific guidance contained in the relevant OECD guidelines and to the above guidance documents for additional information.

4.2.2.2 Ratings

The ratings for chronic aquatic toxicity are included in a separate sub-column, using a log scale based primarily on the 10% Effect concentration (EC10) (preferred) or alternatively the "No Observed Effect Concentration" (NOEC) as shown in Table 8 below. The EC10 is defined as the concentration where 10% of the effect is achieved. Where an EC10 is not available, a NOEC value may be used. Box 6 lists suitable test methods, including exposure times and end-points. As with the GHS, substances with a chronic NOEC of >1 mg/L are not considered to be chronically toxic. Ratings which are estimated by expert judgement are shown in brackets "( )".

Table 8 – Ratings for chronic aquatic toxicity (B2)

Rating	Description	EC_{10} or NOEC (mg/l)
0	Negligible	>1
1	Low	>0.1 and ≤1
2	Moderate	>0.01 and ≤0.1
3	High	>0.001 and ≤0.01
4	Very high	≤0.001

4.2.2.3 Application

If chronic aquatic toxicity data are not available, the EHS Working Group may request such data in the following cases:

- for poorly soluble substances where the acute toxicity is difficult to estimate accurately, or where it is reported that the substance is “not acutely toxic” within the limits of solubility in water;
- where definite chronic effects are suspected, e.g. on growth, development or reproduction, e.g. from structural alerts, or from mammalian toxicity data;
- where a specific mechanism of toxicity is expected, e.g. with pesticides; or
- for substances that are known to degrade slowly and/or bioaccumulate.

The choice of test organism will generally be based on the most sensitive group among the available chronic test results.

4.2.2.4 Application to mixtures

Long term toxicity of mixtures (chronic toxicity) with known components rated by GESAMP, is calculated as the sum of the concentrations of the individual components weighted by the concentration and rating, where ingredients with a high toxicity rating contribute to the rating of the lower mixture toxicity rating. Consistent with the GHS (United Nations, 2017) the cut-off limit is set at 25% as w/w%. For example, a chemical where the sum of the components rated as 4 under column B2 is equal to or greater than 25%, would result in a rating of 4 for the whole mixture, as indicated in Table 9. An example of the mixture calculation is outlined under Annex XII.

Table 9 – Classification of mixtures for long-term (chronic) aquatic hazard

Classification of mixtures for long-term (chronic) aquatic hazard, column B2, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for ratings in column B2 ranges from 0 to 4.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\,(R=4)}$	$\geq$ 25%	4
$\left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=3)}$	$\geq$ 25%	3
$\left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=2)}$	$\geq$ 25%	2
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$\geq$ 25%	1
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$<$ 25%	0

4.3 Column C: Acute Mammalian Toxicity by ingestion, skin contact and inhalation

4.3.1 *General remarks*

Acute toxicity refers to adverse effects that occur following a single oral or dermal administration of a chemical substance, or uninterrupted inhalation exposure of less than 24 hours, usually for 4 hours.

Column C addresses the potential acute toxicity of chemicals to humans. The hazards related to ingestion, skin contact and inhalation exposure routes are considered under the three sub-columns C1, C2 and C3.

LD_{50} or LC_{50} values have been used for many decades to indicate the dose leading to severe, life threatening or acutely toxic effects. Such data usually form the basis by which chemicals are compared regarding acute hazards for human health.

With the introduction of the GHS and more recent test guidelines by the OECD, the term Acute Toxicity Estimate (ATE) is now used instead, referring to a range of test results or extrapolations equivalent to LD_{50}/LC_{50} values. The rating system is therefore based on estimated or measured numerical dose or concentration values in animal tests, expressed as ATE values.

The limitations of using data from acute toxicity tests with mortality as the single end-point without information on other end-points are recognized. These issues have been extensively discussed in a variety of fora and publications. While most toxicological knowledge on this topic derives from animal experiments, human experience, e.g. instances of accidental poisoning, should also be taken into account. All available information is considered by the experts and ratings determined on the basis of the total weight of evidence.

There has been growing public concern about the use of laboratory animals for lethal dose testing for many years. The OECD has published alternative guidelines to the classic LD_{50} tests, aimed at a reduction in both the numbers used and the suffering of test animals. Alternatives to *in vivo* animal testing based on Quantitative Structure-Activity Relationships (QSAR) or the use of *in vitro* test systems have been published in the scientific literature, but as yet they are either insufficiently effective or have not been sufficiently validated. The development of such alternative methods will be closely monitored by GESAMP.

4.3.1.1 Ratings

The ratings, based on ranges of ATEs for oral, dermal and inhalation exposures are shown in Table 10 below. Specific details for the inhalation ratings are given in paragraph 4.3.4.2. Ratings which are estimated by expert judgement are shown in brackets "( )". The GESAMP ratings are consistent with acute toxicity hazard categories 1 to 4 of chapter 3.1 of the GHS (for equivalents see Annex VIII).

Table 10 – Rating system for acute mammalian toxicity by ingestion, skin contact and inhalation (sub-columns C1, C2 and C3)

Rating	Relative Hazard	C1 Oral ATE (mg/kg)	C2 Dermal ATE (mg/kg)	C3 Inhalation ATE (mg/L/4 hr)
0	Negligible	>2000	>2000	>20
1	Slight	>300 and ≤2000	>1000 and ≤2000	>10 and ≤20
2	Moderate	>50 and ≤300	>200 and ≤1000	>2 and ≤10
3	Moderately high	>5 and ≤50	>50 and ≤200	>0.5 and ≤2
4	High	≤5	≤50	≤0.5

4.3.1.2 Application

The quality and consistency of the underlying data are of great importance. Generally, reliable data from human exposure will be given precedence over animal data. Negative evidence from human exposure will not normally be used to override positive data from standard tests in experimental animals. However, for some well-studied chemicals, there may be scientific evidence that the test animal toxicity may not be relevant to humans (e.g. based on species-specific metabolism or toxicodynamics).

Values from mammalian species and the most susceptible sex are used, except where there is convincing evidence that toxicity in humans may vary from that observed in test organisms.

The revised GESAMP Hazard Evaluation Procedure does not include a separate toxicity class for ATEs in the range from 2000 to 5000 mg/kg, as provided by the GHS, as this is neither currently required under MARPOL for categorizing chemical substances nor under the IBC Code for assigning carriage requirements.

The ratings for acute inhalation toxicity are based on animal experiments using atmospheres consisting of pure vapour or vapour and mist phases together. For high quality inhalation studies, conducted with pure mists/aerosols without any exposure to vapour, cut-off values for mists/aerosols, as presented in the GHS, may be applied, e.g. as suitable for substances which have a very low vapour pressure.

4.3.1.3 Interpreting acute hazard data

The rating of a hazard should not be interpreted as a risk assessment. Risk must take into consideration the potential toxicity (hazard) and the exposure in a specific situation. The acute toxicity rating defines, in effect, the relative potential for severe poisoning. In this way, the oral toxicity is evaluated, although swallowing of chemicals carried as cargo is not foreseen as an exposure route on board ships. Likewise, for inhalation risk, more factors than just the ATE or LC_{50} need to be taken into account, including, for example, the saturated vapour concentration. Risk must determine whether hazards alone, or risks including consideration of exposure, need to be taken into account, as a basis for decision on appropriate management action. Several regulatory systems for transport and plant licensing are based on hazard evaluation only (Steinhäuser and Höfer, 2000).

Under accidental conditions on board ships, bursting pipes could create aerosols, while in the aftermath of an accidental discharge, mist may be generated by waves on the sea surface. In such cases, the estimated hazard could take into account the situation specific potential exposure. On the other hand, under normal operational conditions, an aerosol may not be generated in tanks, nor will there be vapours associated with liquids with very low vapour pressure. Under such circumstances, the inhalation risk could be significantly less than that indicated by hazard identification and further data may need be taken into consideration, e.g. vapour pressure of the cargo at the transport temperature or the saturated vapour pressure.

4.3.1.4 Application to mixtures

Acute toxicity ratings are based on guideline test data on the mixture itself, or where not available, expert application of GHS "bridging" principles for similar mixtures with known toxicologically active ingredients. Alternatively, where the acute toxicity of some or all components of a mixture are known, GHS allows for the estimation of acute toxicity based on concentration addition of components (the GHS "additivity formula"):

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{\mathrm{ATE}_i}$$

where ATE_{mix} is the acute toxicity estimate for the mixture and ATE_i is the ATE of the component of concentration C_i. (expressed in %). This additivity formula may be used for oral, dermal as well as inhalation toxicity. It should be noted that this algorithm does not take into account any potential for interaction of the components due to synergistic or antagonistic interaction. Such deviations have been observed in a limited proportion of cases and have been studied eg. by Corvaro et al (2016) and Van Cott et al. (2018).

Examples for using such additivity formula are shown for acute oral toxicity in Annex XIII, for acute dermal toxicity in Annex XIV, and for acute inhalation toxicity in Annex XV.

4.3.2 *Sub-column C1: Acute oral toxicity*

Standardized tests are preferred for evaluation (see Box 7). In evaluating a chemical whose toxic potential is unknown, it is often useful to conduct a range-finding study or a limit test. The ATE or LD_{50} would be reported as "greater than", if there are no deaths of experimental animals within 14 days. Such results are rated according to Table 10. The GESAMP ratings are consistent with Acute Toxicity (oral) Hazard Categories 1 to 4 of the GHS (for equivalents see Annex VIII).

Box 7

Guidance on acute oral, dermal and inhalation toxicity testing

Over the last several decades, test guidelines for assessing acute toxicity to mammals have been consolidated and published by the OECD. However, older published test data derived from testing procedures other than those listed (including the use of different mammalian species) should be evaluated before new testing is considered. Such existing data are equally valid for evaluating hazard ratings, provided the experimental procedures are sufficiently well documented and can be evaluated independently.

New testing should be based on OECD guidelines and performed in accordance with the OECD Principles of Good Laboratory Practice (GLP).

Acute oral toxicity

Wherever possible, testing for acute oral toxicity should be based on standardized 14-day post-dosing observation in rats. The recommended methods are:

- OECD No. 420, Acute oral toxicity – fixed dose procedure (OECD, 2002a)
- OECD No. 423, Acute oral toxicity – acute toxic class method (OECD, 2002b)
- OECD No. 425, Acute oral toxicity – up-and-down procedure (OECD, 2008b)

Following withdrawal of the OECD No. 401 guideline for acute oral toxicity, based on concerns for animal welfare, GESAMP no longer recommends its use for determining the LD_{50}.

Acute dermal toxicity

For measuring dermal toxicity, standardized LD_{50} tests with rats or rabbits are preferred, using 24-hour occlusion with two weeks of observation. The recommended guideline is OECD No. 402, acute dermal toxicity (OECD, 2017a).

Acute inhalation toxicity

Wherever possible, ratings for inhalation toxicity should be based on standardized 14-day post-dosing observation tests in rats. The recommended guidelines are OECD No. 403, Acute inhalation toxicity (OECD, 2009c), OECD No. 433, Acute inhalation toxicity - Fixed concentration procedure (OECD, 2017b), and OECD No. 436, Acute inhalation toxicity – Acute toxic class method (OECD, 2009d).

4.3.3 *Sub-column C2: Acute dermal toxicity (skin contact)*

Standardized tests are preferred for evaluation (see Box 7). In evaluating a chemical whose toxic potential is unknown, it is often useful to conduct a range-finding study or a limit test. The ATE or LD_{50} would be reported as "greater than", if no death of experimental animals is observed within 14 days. Such results are evaluated and rated according to Table 10.

Chemicals that are non-toxic by the oral route are generally also non-toxic by the dermal route, based on acquired experience. Similarly, orally toxic chemicals are also potentially toxic by dermal application. Default assumptions of this

nature enable experts to estimate the toxic potential in the case of route-specific missing data. Range-finding studies and limit tests are taken into account, as outlined for oral toxicity testing above. The GESAMP ratings are consistent with Acute Toxicity (dermal) Hazard Categories 1 to 4 of the GHS (for equivalents see Annex VIII).

4.3.4 *Sub-column C3: Acute inhalation toxicity*

4.3.4.1 Inhalation toxicity criteria

The criteria for inhalation toxicity are based on ATE or LC_{50} data for 4 hour exposures in rats; such information is therefore preferred where available. Where ATE or LC_{50} data for 1 hour exposure periods are available, for vapour/mist inhalation (sub-column C3a) these values can be divided by 4 for equivalency with the ATE/LC_{50} (4h). Conversions for exposure times for vapour-only inhalation (sub-column C3b) are based on the guidance in the UN GHS Chapter 3.1 for vapours (factor 2 for 1hr to 4hr).

The GESAMP ratings are generally based on cut-off values introduced by the GHS under Acute Toxicity (inhalation) Hazard Categories 1 to 4 for vapour exposure (for equivalents see Annex VIII).

Conversion from "ppm" to "mg/L" should be based on the formula:

$$\text{mg/L (20°C)} = \frac{\text{ppm x molecular weight}}{24000}$$

In some cases, ratings shown in brackets may overestimate the potential for poisoning by inhalation, particularly for substances with low saturated vapour pressure. Consequently, a decision may be taken through IMO bodies to utilize other methods as a basis for defining specific occupational health protection requirements on board ships (risk management).

4.3.4.2 Ratings

Column C3 dealing with acute inhalation toxicity contains two sets of related information:

- C3a: Acute inhalation toxicity by combined exposure to vapour and mist are rated according to the criteria shown in Table 11. High quality inhalation studies conducted with pure mists/aerosols without any exposure to vapour are to be assessed according to the cut-off values given in the UN GHS for dust/mist; and
- C3b: Acute inhalation toxicity by vapour-only exposure.

Whereas ratings in sub-column C3a are mostly relevant for accidental exposures and are the basis for ratings in sub-column E3 (interference with coastal amenities), ratings in sub-column C3b are more relevant for occupational exposure on board ships.

For the column C3 rating, the C3a rating is shown by default, but a C3b rating would overrule. The rating under column C3 is used by chapter 21 of the IBC Code for assigning certain carriage requirements, e.g. for tank venting requirements.

Table 11 – Rating scheme for acute inhalation toxicity

Rating*	**Relative Hazard**	**C3**		
		C3a		**C3b**
		Vapour+mist exposure ATE (mg/L/4h)	**Mist-only exposure** ATE (mg/L/4h)**	**Vapour-only exposure ATE (mg/L/4h)**
0	Negligible	>20	>5	>20
1	Slight	>10 and ≤20	>1 and ≤5	>10 and ≤20
2	Moderate	>2 and ≤10	>0.5 and ≤1	>2 and ≤10
3	Moderately high	>0.5 and ≤2	>0.05 and ≤0.5	>0.5 and ≤2
4	High	≤0.5	≤0.05	≤0.5

* Additional entry/rating could be "NI" (no information); ratings which are estimated are shown in brackets "( )".
** High quality inhalation studies conducted only with pure mists/aerosols (particles between 1 and 4 microns according to OECD guidelines) without any exposure to vapour.

Any read-across on structurally analogous substances to estimate the acute toxicity hazard will result in C3a and/or C3b ratings in brackets.

GESAMP inhalation toxicity extrapolation method

In practice, experimental data for evaluating acute inhalation toxicity is often not submitted to EHS since most acute studies are conducted by the oral route and may not be available for the following reasons:

.1 it is deemed unethical to carry out animal experiments on substances known to cause undue pain and suffering to animals; or

.2 the physical or chemical properties of the chemical are such that relevant tests cannot be conducted.

In such cases, the GESAMP EHS Working Group endeavours to provide a reliable estimate of acute inhalation hazard, in order to be able to complete the hazard profile.

The 'GESAMP inhalation toxicity extrapolation method' provides a consistent and acceptable estimate of acute inhalation hazard by mists or vapour/mist mixtures based on other data that is usually more readily available, namely:

.1 the oral and dermal acute toxicity;

.2 the irritant/corrosivity potential to the skin and eye; and

.3 any information regarding inhalation toxicity to aerosols, mists, etc. of the chemical itself or of analogous chemicals recognized to have similar bio-reactive properties.

The estimated rating for inhalation toxicity (presented in brackets) is based on the highest of the acute oral and/or the dermal ratings and the highest skin and/or eye irritation ratings as illustrated in Table 12.

Table 12 – The GESAMP acute inhalation toxicity extrapolation method

Highest acute oral and/ or dermal rating (columns C1/C2)	Highest skin and/or eye irritation rating (columns D1/D2)	Estimated acute inhalation toxicity rating (column C3a)
0	0	(0)
	1	(1)
	2	(2)
	3	(3)
1	0	(1)
	1	(2)
	2	
	3	(3)
2	0	(2)
	1	
	2	
	3	(3)
3	0	(3)
	1	(4)
	2	
	3	
4	0	(4)
	1	
	2	
	3	

If the GESAMP inhalation toxicity extrapolation method is used for the rating under column C3a for vapour+mist exposure, the ratings are shown in brackets "( )".

4.4 Column D: Irritation, Corrosion and Long-term Health Effects

This column considers the harmful effects of chemical substances on skin, eyes and mucous membranes resulting from irritant and/or corrosive substances, and also potential long-term health effects. The skin, eyes and mucous membranes of humans may become exposed to chemical substances, either by physical contact or inhalation in a wide variety of situations, e.g. in the work environment on board ship, on the dockside, when swimming in the ocean or during maritime rescue operations.

The effects of chemicals resulting from direct contact with skin or eyes are rated under sub-columns D1 and D2, respectively. A numerical rating is given based on test data or human experience. Potential effects of long-term exposure are indicated in sub-column D3

4.4.1 *Sub-column D1: Skin irritation/corrosion*

4.4.1.1 Introduction

Toxic insults to the skin can significantly affect the health and well-being of an individual. The classification of damage due to irritation or corrosion of the skin is based on morphology.

Skin irritation is measured as the production of reversible damage to skin following the application of a chemical substance for 4 hours. In the past, data on skin irritation has also been provided by dermal exposures over 24 hours. Exposures of 4-hour duration are preferred, but data from 24-hour exposures can also be accepted and this latter data is used directly, without extrapolation, whilst recognizing that this may err on the side of caution.

Skin corrosion is measured as the production of irreversible damage to skin, e.g. visible necrosis, following the application of a chemical substance for up to 4 hours. The rate of producing an adverse effect, within 3 minutes, 1 hour or 4 hours, can indicate the degree of corrosivity.

Data for the evaluation of skin irritation/corrosion can be obtained from human experience, animal experiments or from *in vitro* assays. The rating of skin irritation/corrosion is based only on test methods validated by OECD (see Box 8). However, all other tests and information are evaluated to derive a rating.

Box 8

Guidance on acute dermal and eye irritation and corrosion tests

Results from all previous testing and from human experience are evaluated, but new testing should be based on OECD guidelines and performed under Good Laboratory Practice (GLP).

Acute dermal irritation and corrosion

The recommended tests are the OECD No. 404, Acute dermal irritation/corrosion test (OECD, 2015a) and the *in vitro* alternative tests, OECD Nos. 430 (OECD, 2015b), 431 (OECD, 2016), 435 (OECD, 2006b) and 439 (OECD, 2015c).

Acute eye irritation

The recommended tests are the OECD No. 405, Acute eye irritation test (OECD, 2017c) and the *in vitro* alternative tests OECD Nos. 437 (OECD, 2017d), 438 (OECD, 2017e) and 460 (OECD, 2017f).

For the purpose of assigning a rating in sub-column D1, data are collected from current databases, the literature and test reports. These sources may reflect experiments of varying quality carried out during a wide time period. Sometimes the test may not have been conducted according to present day standards or evaluated under the current scoring systems. In such cases a cautionary approach is taken and a higher rating may be assigned.

4.4.1.2 Ratings

The ratings and descriptions for sub-column D1 are presented in Table 13 below. The GESAMP ratings are consistent with the Skin Corrosion/Irritation hazard categories 1 to 3 of chapter 3.2 of the GHS (for equivalents see Annex VIII). Ratings which are estimated by expert judgement are shown in brackets "( )".

Table 13 – Rating system for skin irritation and corrosion (D1)

Rating	Description	Signs	GHS Category
0	Not irritating	No clinical signs and/or inflammation	---
1	Mildly irritating	Mild erythema with or without oedema (rapidly reversible)	Mild Irritant Category 3
2	Irritating	Marked erythema, obvious and marked oedema	Irritant Category 2
3	Corrosive	Severe irritation indicating local tissue damage or full thickness skin necrosis (applied when exposure time is not reported)	Corrosive Category 1
3A		Full-thickness skin necrosis following exposure between 1 h and 4 h	Corrosive Category 1C
3B		Full-thickness skin necrosis following exposure between 3 min and 1 h	Corrosive Category 1B
3C		Full-thickness skin necrosis following exposure up to 3 min	Corrosive Category 1A

4.4.1.3 Application to mixtures

Ratings are based on guideline test data on the mixture itself, or where none are available, expert application of GHS "bridging" principles, (i.e. estimated based on similar mixtures with known toxicologically active ingredients). Taking into account expert judgement concerning the chemical nature of the ingredients and the mixture (i.e. impurities, additives or individual constituents), GHS concentration limits are applied to determine if the mixture is considered to be as similarly active (corrosive, irritant) as the ingredient (Table 14). The relevance of the applicability domain of some *in vitro* testing methods (as shown by Kolle et al 2017a) to mixtures is also carefully considered. Specific caution is exercised when estimating the effects of strongly corrosive ingredients (ratings 3C and 3B) in a mixture. Examples for using such concentration limits are shown in Annex XVI.

Table 14 – Concentration of ingredients of a mixture that would trigger ratings of the mixture

Sum of ingredients rated as	**Concentration triggering rating of the mixture**		
	3, 3A, 3B, or 3C	**2**	**1**
3, 3A, 3B, or 3C	$\geq$ 5%	$\geq$ 1% but $<$5%	
2		$\geq$ 10%	$\geq$ 1% but $<$10%
1			$\geq$ 10%

4.4.2 *Sub-column D2: Eye irritation*

4.4.2.1 Introduction

Eye irritation refers to changes that are fully reversible within 7 or 21 days following application of a chemical substance to the anterior surface of the eye. Serious eye damage is tissue damage in the eye, or serious physical decay of vision, following a similar application to the eye, which is not fully reversible within 21 days of application.

Testing the effects of chemicals on the eye is generally carried out by exposing the eye of experimental animals to a small amount of solid or dissolved chemical substance. The eye and the surrounding tissue are then inspected at various time intervals, e.g. after 1, 24, 48 and 72 hours. Effects on the cornea, iris and conjunctiva are noted and scoring systems have been developed in order to summarize the effects. Draize and co-workers introduced the best known of these in 1944 (Draize et al., 1944). Since then, changes have been introduced in study design and scoring, and some *in vitro* methods have been validated and are acceptable (see Box 8).

4.4.2.2 Ratings

The ratings and descriptions used in sub-column D2 are presented in Table 15 below. The GESAMP ratings are consistent with Serious Eye Damage/Eye Irritation hazard categories 1 to 2 of chapter 3.3 of the GHS (for equivalents see Annex VIII). Ratings which are estimated, e.g. based on skin corrosivity, extreme pH ($<$2 or $>$11.5), or evidence from analogous chemicals are shown in brackets "( )".

Table 15 – Ratings for eye irritation and corrosion (D2)

Rating	**Description**	**Clinical signs**	**GHS Category**
0	Not irritating	No clinical signs and/or inflammation	–
1	Mildly irritating	Mild conjunctival hyperaemia with or without chemosis, reversible within 7 days	Irritant Category 2B
2	Irritating	Marked conjunctival hyperaemia, chemosis, corneal injury – all reversible within 21 days	Irritant Category 2A
3	Severely irritating, with irreversible corneal injury	Severe conjunctoblepharitis, chemosis, corneal injury or similar effects not fully reversible within 21 days	Irritant Category 1

4.4.2.3 Application to mixtures

Ratings are based on test data on the mixture itself, where available or estimated through expert application of GHS bridging principles (based on similar mixtures with known toxicologically active ingredients). Taking into account expert judgement concerning the chemical nature of the ingredients and the mixture (i.e. impurities, additives or individual constituents), GHS concentration limits are applied to determine if the mixture is considered to be as similarly active (eye irritant) as the ingredient (Table 16). The applicability domain of *in vitro* testing methods, when applied to mixtures, have to be carefully considered (as shown e.g. by Kolle et al. 2017b). Particular caution is applied when estimating the effects of ingredients suspected to have an effect below these limits in mixtures and when estimating the effects of strongly corrosive ingredients (rating 3). The concentration limits in Table 16 are considered as very general guidance.

Their appropriate application based on knowledge of other components of the mixture requires expert evaluation. Examples for using such concentration limits are shown in Annex XVII.

Table 16 – Concentration of ingredients of a mixture that would trigger ratings of the mixture

Sum of ingredients rated as	Concentration triggering rating of the mixture		
	3	**2**	**1**
3	$\geq$ 3%	$\geq$ 1% but <3%	
2		$\geq$ 10%	$\geq$ 3% but <10%
1			$\geq$ 90%

Note: The concentration limits for rating 1 are not given by the GHS but are interpretations of GHS category 2B classification guidance.

4.4.3 *Sub-column D3: Long-term health effects*

4.4.3.1 Introduction

There is a wide variety of chemical hazards to human health besides those listed in sub-columns C1, C2, C3, D1 and D2. Long-term health effects, as a result of either single or repeated exposure, are identified in column D3. The evaluated hazards are listed in paragraph 4.4.3.3 below.

4.4.3.2 Rating

A simple representation of the nature of the hazard is presented using a letter symbol as shown in Table 17. The GHS considers several of these hazards under its Specific Target Organ Toxicity (STOT) classification. Others, such as sensitization, carcinogenicity, mutagenicity and reproductive toxicity, are defined separately here and in the GHS. No sub-divisions of classification for these long-term health effects are distinguished in the ratings.

The GESAMP EHS Working Group makes every effort to list the hazards to human health including the long-term health effects covered in sub-column D3. This is based on the evidence available at the time the substance is reviewed. Accordingly, one or more of the set of notations defined in section 4.4.3 are presented in sub-column D3. However, this process is not exhaustive and the absence of any or all notations should not be taken to mean that such hazards do not exist. A notation “NI” is therefore not used under this column.

Table 17 – Long-term health effects covered under sub-column D3 and the corresponding GHS categories

Notation	Hazard	Description	GHS Category
C	Carcinogenicity	Chemicals which have been shown to induce or increase the incidence of cancer	Category 1 for Carcinogens
M	Mutagenicity	Cause a direct or indirect permanent change in the amount or structure of genetic material in cells (mutations).	Categories 1 and 2 for Germ Cell Mutagens
R	Reprotoxicity	Cause adverse effects on reproductive ability or capacity, or on the development of offspring	Category 1 for Reproductive Toxicants
Ss	Skin Sensitization	Cause specific skin hypersensitivity or allergy following skin contact	Category 1 for Skin Sensitizers
Sr	Respiratory Sensitization	Cause specific hypersensitivity of the airways, or asthma, following inhalation	Category 1 for Respiratory Sensitizers
A	Aspiration	Lung injury or chemical pneumonia following aspiration of a chemical through the oral or nasal cavity into the trachea or lower respiratory system	Category 1 for Aspiration Toxicity

Notation	Hazard	Description	GHS Category
T	Specific Target Organ Toxicity following single or repeated exposure	Significant changes which affect the morphology or biochemistry of tissues or organs; organ dysfunction up to death	Categories 1 and 2 for Specific Target Organ Toxicity Single (STOT-SE) or Repeated Exposure (STOT-RE)
N	Neurotoxicity	Like T, but specific for effects on the central nervous system or senses	
I	Immunotoxicity	Like T, but specific effects on the function of the immune system	

4.4.3.3 Application

The evaluation and rating aspects outlined in this paragraph are the key principles for assignment of ratings under the D3 column. For further and more detailed information and background for the evaluation criteria for these long-term health effects, see chapters 3.4 to 3.10 of the GHS.

Carcinogenicity (C)

The term carcinogenicity denotes substances or mixtures that are presumed to induce cancer or to increase its incidence in humans. Evidence to substantiate the notation 'carcinogenicity' in sub-column D3 should be available from epidemiological studies and/or from well-conducted studies in experimental animals. Chemicals are rated as 'C', based on the GHS criteria (Category 1A or 1B) for known or presumed human carcinogenicity. In principle, the EHS Working Group bases its ratings on the evaluation of reliable evidence and on expert judgement. "Suspected" human carcinogens are not covered by the GESAMP 'C' rating.

Mutagenicity (M)

A mutation is a permanent change in the structure of the genetic material in the cell. The term Genotoxicity applies to mutations, non-permanent changes of genetic material and cell death based on damage to genetic material. The term mutation applies to genetic changes both for somatic cells and for germ cells that may give rise to subsequent adverse changes at the phenotypic level. The term mutagenic denotes substances or mixtures that can give rise to an increased occurrence of mutations in vivo, in populations of cells and/or organisms. Evidence to substantiate a rating 'M' is normally provided from studies conducted on mammalian somatic cells or germ cells of exposed animals. Mutagenic effects determined by *in vitro* tests may also be considered. As such, the scoring is consistent with GHS categories 1, 1A, 1B and 2 for germ cell mutagenicity.

Reprotoxicity (R)

Reprotoxicity (or reproductive toxicity) includes adverse effects on sexual function or fertility in adult males and females or on the development of the offspring. The rating 'R' in sub-column D3 includes substances for which there is reliable evidence from human experience or from experimental animals of an adverse effect on reproductive ability or capacity, or on development of the offspring in the absence of other toxic effects. As such, the scoring is consistent with GHS categories 1, 1A and 1B for reproductive toxicity. Substances identified as "suspected" human reproductive toxicants, as defined by GHS Category 2, are not covered by the notation 'R'.

Skin Sensitizer (Ss)

The term skin sensitizer denotes substances or mixtures which can induce a condition of hypersensitivity following skin contact. Skin sensitization is thus the first step in the development of allergic contact dermatitis. Evidence to substantiate a rating 'Ss' in sub-column D3 should be available from human experience (Basketter et al., 2014) or appropriate studies. Although the standard tests have traditionally been conducted in experimental animals, the mechanistic understanding of skin sensitization is sufficient to support prediction by defined approaches incorporating *in vitro* and in silico inputs. (http://www.oecd.org/chemicalsafety/guidance-document-on-the-reporting-of-defined-approaches-and-individual-information-sources-to-be-used-within-integrated-9789264279285-en.htm). The criteria used for the evaluation of test results are consistent with those listed in the GHS for Hazard Categories 1, 1A and 1B for skin sensitizers.

Respiratory Sensitizer (Sr)

The term respiratory sensitizer denotes substances or mixtures which can induce a condition of hypersensitivity of the airways, or asthma, in individuals following inhalation. It should be noted that respiratory sensitization may be induced not only be inhalation but also by skin contact (Dotson et al., 2015). Evidence to substantiate a rating of 'Sr' in sub-column D3 is normally based on human experience, most often seen as asthma, but other reactions such as rhinitis/conjunctivitis or alveolitis, having the clinical character of an allergic response, are also considered. To date, recognized animal models are not available. However, some animal test data may be indicative for respiratory sensitization and could be part of a weight of evidence approach. The criteria used for the evaluation of test results are consistent with those listed in the GHS for Hazard Categories 1, 1A and 1B for respiratory sensitizers.

Aspiration hazard (A)

Severe acute effects or chemical pneumonia may be caused by aliphatic, alicyclic and aromatic hydrocarbons of low viscosity, as well as other substances that, based on clinical experience, may cause damage to the airways or lungs after direct aspiration or after being swallowed. The criteria used for the evaluation of test results are consistent with those listed in the GHS for Hazard Category 1 for aspiration hazards.

Specific Target Organ Toxicity (T)

Classification depends upon the availability of reliable evidence that single or repeated exposure to the substance has consistently produced a long-term toxic effect in humans or in experimental animals, including significant changes affecting the function or morphology of a tissue or organ, or has produced serious changes to the biochemistry or haematology of the organism, and these changes are relevant to human health. The criteria used for the evaluation of test results are consistent with those listed in the GHS for Hazard Categories 1 and 2 for Specific Target Organ Toxicity.

It should be noted that neurotoxicity (N) and immunotoxicity (I) fall within STOT under the GHS. However, in terms of the GESAMP hazard rating, N and I are considered separately since these terms are utilized in regulatory criteria.

Neurotoxic (N)

The term neurotoxic denotes substances or mixtures which are capable of causing injury to the central nervous system (brain and spinal cord) and/or peripheral nervous system (nerves arising from the brain and spinal cord). Neurotoxicity may appear as the result of single or repeated exposure. Evidence to substantiate a notation of "neurotoxic" in sub-column D3 should be available from epidemiological studies and/or from well-conducted and appropriate studies in experimental animals. The severity of the effects should be equivalent to those listed in the GHS for Hazard Categories 1 and 2 for Specific Target Organ Toxicity.

Immunotoxic (I)

The term immunotoxic denotes substances or mixtures which are capable of causing injury to the immune system and interfere with the body's defence mechanisms. Evidence to substantiate a rating of "immunotoxic" in sub-column D3 should be available from epidemiological studies and/or from well-conducted and appropriate studies in experimental animals. The severity of the effects should be equivalent to those listed in the GHS for Hazard Categories 1 and 2 for Specific Target Organ Toxicity.

4.4.3.4 Application to mixtures

Guideline testing on long-term health effects of mixtures is rarely conducted. According to the GHS, mixtures should be classified for long-term health effects when at least one ingredient has been classified and is present above the concentration limit specified for each of the classifications and hazard levels. It must be recognized, however, that these concentrations represent harmonized values developed in consensus discussions between regional or national risk managers, rather than strictly health-based concentration limits. Methodology to assess mixtures is an area of continuing focus and development to address the limitations of current approaches (Boobis et al.,2011; Sarigiannis and Hansen, 2012; Kienzler et al., 2016; and Meek, 2013). Together with expert judgement of the chemical nature of the ingredients and the mixture, concentration limits as shown in Table 18 are applied by GESAMP/EHS. Examples for using such concentration limits are shown in Annex XVIII.

Table 18 – Concentration of ingredients of a mixture that would trigger ratings of the mixture (D3)

Column D3	Hazard evaluation	Concentration limit
C	Carcinogenicity	$\geq$ 0.1%
M	Mutagenicity	$\geq$ 0.1%
	Mutagenicity equivalent to GHS cat. 2	$\geq$ 1%
R	Reproductive toxicity	$\geq$ 0.3%*
Ss	Skin sensitization equivalent to GHS sub-cat. 1A	$\geq$ 0.1%
	Skin sens. equivalent to GHS sub-cat. 1B	$\geq$ 1%
Sr	Respiratory sensitization equivalent to GHS sub-cat. 1A	$\geq$ 0.1%
	Resp. sens. equivalent to GHS sub-cat. 1B	$\geq$ 1%
A	Aspiration hazard	$\geq$ 10%**
T (N, I)	Specific target organ toxicity (STOT)	$\geq$ 1%
	STOT equivalent to GHS cat. 2	$\geq$ 10%

* GESAMP/EHS normally adopts a 0.3% limit value, which is accepted by most authorities; GHS specifies values of both 0.1% and 0.3%.

** The mixture must have a kinematic viscosity $\leq$ 20.5 mm^2/s, measured at 40°C.

4.5 Column E: Interference with other uses of the sea

Column E covers the hazards to other uses and users of the sea from operational discharges and accidental releases of substances. The results are presented in three sub-columns as shown in Table 19 below.

Table 19 – Column E: Interference with other uses of the sea

Sub-column	Potential interference with:	Criterion
E1	Shipping and emergency response	Flammability
E2	Wildlife and bottom habitats and emergency response	Physical behaviour of substances in seawater: • Effects of viscous, slick-forming substances on marine wildlife • Effects of sinking substances on benthic habitats, e.g. smothering of the seabed
E3	Use of coastal amenities	Hazards to humans using beaches, coastlines, onshore and offshore installations and harbours.

This aspect is specific to the objective of GESAMP ratings, differing markedly from other hazard classification systems such as the GHS. Given the large volumes of substances transported by tank ships, it is considered necessary to provide a separate criterion that enables IMO to regulate operational discharges of bulk liquid substances, which might not be identified by classical hazard parameters such as toxicity or bioaccumulation.

These hazard end-points may also provide information that can be of use during a maritime emergency when substances are spilled, or are likely to be spilled, into the marine environment.

4.5.1 *Sub-column E1: Flammability*

4.5.1.1 Introduction

For the carriage of bulk liquids in chemical tankers according to the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code) flashpoint information with 23°C and 60°C cut-off values is relevant for assigning carriage requirements. According to paragraph 21.7.11 of this Code, products with a flashpoint $<$23°C are classified as “highly flammable”, while those with a flashpoint $\geq$23°C and $\leq$60°C are classified as “flammable”.

First responders confirmed that the addition of flammability to the GESAMP hazard profile would provide valuable information when responding to incidents involving hazardous materials.

It is acknowledged that for some classifications (e.g. under the GHS) as well as for some types of accidents, the combination of flashpoint with the boiling point (providing an indication for vapour generation at a specific temperature) may under some circumstances result in a more sophisticated evaluation of the spill hazards and possible need for evacuation. A similar case could be made for the addition into the rating system of other flammability properties such as autoignition temperature and flammable limits. However, for spill responders, the most critical piece of information is the flashpoint – indicating whether and how easily the vapours of a substance will ignite.

4.5.1.2 Ratings

The ratings used in sub-column E1 are given in Table 20 below.

Table 20 – Ratings for flammability (E1)

Rating*	Description	Flashpoint temperature range (°C)
0	Not Flammable (does not burn)	-
1	Low Flammability Potential	$>$93
2	Combustible	$>$60 and $\leq$93
3	Flammable	$\geq$23 and $\leq$60
4	Highly Flammable	$<$23

* NI indicates that insufficient flashpoint data are available to allow a rating

Similarly, the GHS refers to the three cut-off values at 23°C, 60°C, and 93°C in chapter 2.6 for the hazard classification of flammable liquids.

However, for classification and labelling, a combination including the boiling point is used to differentiate between extremely flammable or highly flammable. The GESAMP rating in sub-column E1 is for meant for information and for use by emergency responders. As a result, flash point is the only criterion addressed here.

As for other GESAMP hazard ratings, ratings by extrapolation or by expert judgement are shown in brackets "( )".

4.5.1.3 Application

Required data on the flashpoint can be determined by testing, being identified in the literature or by calculation. Suitable methods for testing are given in paragraph 32.4 of the latest version of the United Nations' Manual of Tests and Criteria supplement to the United Nations' Recommendations on the Transport of Dangerous Goods and in paragraph 2.6.4.2 of the latest version of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

The flash point used by GESAMP is defined as the lowest temperature (corrected to a standard pressure of 101.3 kPa) in degrees Celsius at which the application of an ignition source causes the vapour to ignite under specific test conditions (determined by an approved flash point apparatus: closed-cup test).

When test data are conflicting, less reliable test data may be rejected in favour of more reliable test results, in particular those tested according to internationally validated test procedures. In such cases, expert judgement is essential.

4.5.2 *Sub-column E2: Behaviour of chemicals in the marine environment*

4.5.2.1 Introduction

The tendency of a spilled chemical to form a slick, to dissolve, to evaporate or to sink and blanket the seabed determines, to a large extent, its potential to exert physical effects on marine wildlife and benthic habitats.

The Bonn Agreement Behaviour Classification System (Bonn Agreement, 2005) evaluating the short-term behaviour of chemicals spilled at sea has been used as the basis for assessing such physical effects. This system is also utilized within the regional pollution prevention agreements for the North, Baltic and Mediterranean Seas, and is designed to facilitate cooperation in dealing with marine pollution emergencies, as well as by IMO (HELCOM, 1991) (IMO/UNEP, 2000; IMO, 1999). The system was slightly modified by GESAMP to meet the requirements of MARPOL Annex II and the IBC Code, to include viscosity as an additional end-point when evaluating "persistent floating" substances and this is further described below.

4.5.2.2 Bonn Agreement Behaviour Classification System for chemicals spilled into the sea

Chemicals that are spilled into the sea behave in different ways, depending on their properties and the prevailing environmental conditions. In principle, spilled chemicals can float, evaporate, dissolve or sink but in reality, they often show complex behaviour patterns when released in the marine environment. Information on the physical and chemical properties of substances (physical state, density, vapour pressure and solubility), enables at least some characterization of the behaviour pattern following release into the water to be obtained.

The Behaviour Classification System contained in the Bonn Agreement Counter Pollution Manual classifies chemicals according to their physical behaviour when spilled into the sea. The classification system covers gaseous, liquid and solid chemicals. The main principle of the system is to characterize spilled chemicals as: evaporators, floaters, dissolvers and sinkers.

From this basic categorization and from other details regarding their physical properties, the chemicals are classified in 12 property groups (Table 21).

Table 21 – Groups classified by physical state and properties (E2)

G	Gas	**GD**	Gas that dissolves
E	Evaporator	**ED**	Evaporator that dissolves
F	Floater	**FE**	Floater that evaporates
		FD	Floater that dissolves
		FED	Floater that evaporates and dissolves
D	Dissolver	**DE**	Dissolver that evaporates
S	Sinker	**SD**	Sinker that dissolves

Grouping of chemicals by their physical properties

The property groups of the Bonn Agreement Behaviour Classification System are defined according to the physical state of the substance (gas, liquid, solid) and by certain cut-off values of vapour pressure (v.p.), density (d), and solubility (s). The method of classifying chemicals by physical property cut-off values is shown in Figure 2.

Physical state of the substance

In this context, gases are chemicals that boil below ambient temperature at normal atmospheric pressure of 100 kPa. This means that gases are those chemicals with vapour pressures above 100 kPa at ambient temperature. The meaning of liquids and solids refers to the state of aggregation at ambient temperature and atmospheric pressure (100 kPa). Liquids are chemicals that boil above ambient temperature at 100 kPa, but melt below ambient temperature (melting point $<$ ambient temperature). Solids are chemicals that melt above ambient temperature at 100 kPa (melting point $>$ ambient temperature).

Density

The relative density of a chemical related to seawater makes it possible to predict whether it floats or not. The density of seawater is approximately 1025 kg/m^3.

Vapour pressure

Vapour pressure is only used for evaluating liquid substances. Below 0.3 kPa, a floating substance is not considered to evaporate and above 3 kPa evaporation is rapid. A dissolved substance will evaporate if the vapour pressure is higher than 10 kPa.

Solubility

The criteria adopted for solubility differ according to the physical state of the substance. Substances are considered insoluble when the solubility is $\leq$0.1 % for liquids and $\leq$10% for solids. Dissolution predominates when solubility is $\geq$5% for liquids and $\geq$100% ("totally miscible") for solids. For gases, dissolution is considered relevant when solubility is $>$10%.

Figure 2 shows the principles of the Bonn Agreement Behaviour Classification System for chemicals likely to be spilled into the sea. By this classification system, whole groups of chemicals (see Table 21) can be addressed by the same response strategies, thus simplifying preparedness measures for the response to an accidental release of chemicals.

<table>
<tr><td colspan="5">A – GASES (Vapour Pressure $>$ 101.3 kPa at 20°C)</td></tr>
<tr><td>Behaviour groups</td><td colspan="2">G</td><td colspan="2">GD</td></tr>
<tr><td>Solubility</td><td colspan="4">0% 10%</td></tr>
<tr><td colspan="5">B – FLOATING LIQUIDS (Density $<$ Seawater)</td></tr>
<tr><td>Vapour Pressure</td><td colspan="4">Standard European Behavior Classification (SEBC) groups</td></tr>
<tr><td rowspan="3">10 kPa
3 kPa
0.3 kPa</td><td colspan="2" rowspan="2">E</td><td rowspan="2">ED</td><td>DE</td></tr>
<tr><td rowspan="2">D</td></tr>
<tr><td>FE</td><td colspan="2">FED</td></tr>
<tr><td></td><td>F</td><td colspan="2">FD</td></tr>
<tr><td>Solubility</td><td colspan="4">0.1% 1% 5%</td></tr>
<tr><td colspan="5">C – SINKING LIQUIDS (Density $>$ Seawater)</td></tr>
<tr><td>Behaviour groups</td><td>S</td><td>SD</td><td colspan="2">D or DE
(if VP $>$10kPa)</td></tr>
<tr><td>Solubility</td><td colspan="4">0.1% 5%</td></tr>
<tr><td colspan="5">D – FLOATING SOLIDS (Density $\leq$ Seawater)</td></tr>
<tr><td>Behaviour groups</td><td>F</td><td>FD</td><td colspan="2">D</td></tr>
<tr><td>Solubility</td><td colspan="4">10% 100%</td></tr>
<tr><td colspan="5">E – SINKING SOLIDS (Density $>$ Seawater)</td></tr>
<tr><td>Groups</td><td>S</td><td>SD</td><td colspan="2">D</td></tr>
<tr><td>Solubility</td><td colspan="4">10% 100%</td></tr>
</table>

Figure 2 – *Bonn Agreement Behaviour Classification System of accidentally spilled chemicals according to their physical state and properties*

4.5.2.3 Ratings

Ratings and the associated criteria for determining potential physical effects on wildlife and on benthic habitats are given below in Table 22. As noted above, in addition to the Bonn Agreement Behaviour Classification System GESAMP has added an additional behaviour class by combining floating properties with high viscosity in order to predict longer lasting or persistent slicks. The first letter refers to the primary behaviour of a substance while subsequent letters describe subsidiary behaviour(s). The derived rating of 'Fp' defines a sub-group of the floaters shown in Figure 2. Under this column, estimated ratings are not shown in brackets as "( )".

Table 22 – GESAMP hazard profile ratings for determining potential effects on wildlife and benthic habitats (E2)

Rating	Description and criteria	Physical effects	Examples
F	Floating substance, not likely to evaporate or to dissolve quickly • Density: ≤ sea water (1025 kg/m³ at 20°C) • Vapour pressure: ≤0.3 kPa • Solubility: ≤0.1% (for liquids) ≤10% (for solids)	Effects on marine wildlife (e.g. smothering, immobilization)	iso-octanol octanoic acid undecane
Fp	Persistent slick forming substance • All of the criteria for a floating substance, as well as: • Viscosity: >10 cSt at 20°C	Effects on marine wildlife (e.g. smothering, immobilization)	pine oil soyabean oil dodecyl alcohol tallow
S	Sinking substance that would deposit on the seabed, not likely to dissolve quickly • Density: > seawater (1025 kg/m³ at 20°C) • Solubility: ≤0.1% (for liquids) ≤10% (for solids)	Effects on benthic habitats (e.g. blanketing and anoxia of the sediments, poisoning, immobilization)	perchloroethylene phenol dichlorobenzene
G	Gas • Vapour Pressure > 101.3 kPa at 20°C • Solubility < 10%		propane butane vinyl chloride
GD	Gas/Dissolver • Vapour Pressure > 101.3 kPa at 20°C • Solubility > 10%		ethylamine ethylene oxide
E	Evaporator • Vapour Pressure 3-10 kPa at 20°C • Solubility < 1%		benzene toluene hexane
ED	Evaporator/Dissolver • Vapour Pressure 3-10 kPa at 20°C • Solubility 1-5%		methyl-tert-butyl ether vinyl acetate ethyl acrylate
FE	Floater/Evaporator • Vapour Pressure 0.3-3 kPa at 20°C • Solubility < 0.1%		octane xylene
FED	Floater/Evaporator/Dissolver • Vapour Pressure 0.3-3 kPa at 20°C • Solubility 0.1-5%		butyl acetate butyl acrylate
FD	Floater/Dissolver • Vapour Pressure <0.3 kPa at 20°C • Solubility 0.1-5%		aniline di butyl ether
D	Dissolver • Vapour Pressure <5 kPa at 20°C • Solubility >5%		sulphuric acid butyl alcohol
DE	Dissolver/Evaporator • Vapour Pressure >5 kPa at 20°C • Solubility >5%		acetone acrylonitrile propylene oxide
SD	Sinker/Dissolver • Density: > seawater (1025 kg/m³ at 20°C) • Solubility • 0.1-5% (for liquids) • 10-100% (for solids)		dichloromethane benzyl acetate

The guidelines for categorization of Noxious Liquid Substances in MARPOL Annex II use only the F (floater), Fp (persistent floater) and S (sinker) ratings. However, for the benefit of other users of the GESAMP hazard profiles, the other physical behaviour categories are included in sub-column E2.

4.5.2.4 Application

The behaviour groups are defined according to the physical state of the substance (e.g. gas, liquid, solid) and its density, vapour pressure and solubility, which should be given at a temperature of 20°C.

Using the above method, which is based on the exponential relationship between dynamic viscosity (cP) and temperature, the viscosity of most chemicals at any temperature can be estimated if the viscosity is known at one temperature.

Example: Polybutene (density = 0.83) has a reported kinematic viscosity of 125 cSt at 37°C, equivalent to 104 cP (125 × 0.83 = 104 cP or mPa.s) at 37°C.

Its dynamic viscosity is estimated to be 280 cP at 20°C giving a kinematic viscosity of 337 cSt (280 ÷ 0.83 = 337 cSt) at 20°C.

For solutions (substances dissolved in water), e.g. ammonium sulphide solution (45% or less), the following selected properties of seawater are used to determine a behaviour category for the substance:

- Melting point −1.91°C
- Solubility 100%
- Vapour pressure 2000 Pa (nominal value based on seawater)

The solubility of a substance in water is often indicated in handbooks of physical properties by a range of vague expressions, e.g. soluble, slightly soluble, poorly soluble, etc. Table 23 is based on a review of the interpretation of solubility phrases from data sources where the descriptive term is qualified by a measured value or range. This interpretation is only used as a guide in estimating the solubility range for purposes of assigning a rating under sub-column E2 as the interpretations differ markedly from, for example, those used in ecotoxicology (see section 4.2) or analytical chemistry.

Table 23 – Terminology for describing solubility

Solubility for the purpose of sub-column E2	**Descriptive terminology commonly used in chemical handbooks**
≥5% for liquids ≥100% for solids	Infinite; completely soluble; soluble in all proportions; miscible; very soluble; soluble
0.1 – 5% for liquids 10 – 100% for solids	Partially soluble; moderately soluble; slightly soluble
≤0.1% for liquids <10% for solids	Insoluble; barely soluble; immiscible; almost insoluble; poorly soluble

It is recognized that the presence of dissolved salts or minerals in water leads to moderate decreases (and in a few cases an increase) in solubility.

However, since, for most substances, data for solubility in saline water are not available, the solubility quoted for pure water at 20°C is used.

4.5.2.5 Application to mixtures

In most cases, mixtures exhibit one predominant behaviour and can be rated under one of the existing groups in the present system (e.g. Fp, F, FE, DE and S). However, some mixtures contain components that possess distinctly different behaviours and, overall, do not fit within one of the established ratings within the system. For these mixtures, an E2 rating is assigned that reflects the most severe impact from an environmental standpoint (effects on marine wildlife and benthic habitats). The most severe impacts, in priority order, are considered to be Fp, F and S.

An example of such a mixture is Naphthalenes, crude (molten). This product contains 35% to 60% naphthalene, which is a sinker (S), with the remaining major components being related substances that are insoluble, less dense than water and viscous, leading to a rating, as a group, of Fp. Of the two behaviours S and Fp, the more severe is Fp and therefore this rating is assigned for E2.

To distinguish mixtures of this nature from those that exhibit more predictable behaviour when spilled, the group agreed to add an exclamation mark (!) notation to these substances in the Composite List with the following text:

"This mixture contains components with substantially different physical properties and therefore different physical behaviours when released in the marine environment. The E2 rating assigned reflects the most severe impact from an environmental standpoint. For example, a mixture assigned a rating of Fp may also have a major component(s) with sinker characteristics (S) or dissolver characteristics (D)."

This additional information may prove useful to spill responders and others to alert them that multiple behaviours are to be expected in the event of a marine spill. It should be emphasized, however, that the exact behaviour of these mixtures in spill situations cannot be accurately predicted due to possible physical interactions among the components, as well as sea conditions and other factors.

For mixtures, where a range is given for the viscosity at the carriage temperature, an estimate is made to establish the maximum of that range at 20°C. Conversion methods, such as that given by Gambill (Gambill, 1959), may be used in such cases.

Box 9

Guidance for measuring solubility in water, relative density, vapour pressure and viscosity

Solubility in water

Lyman et al. (Lyman et al., 1990) defined the solubility of a substance as the maximum amount that will dissolve in water at a specified temperature (usually 20°C). Aqueous concentrations are usually expressed in terms of weight per weight (g/kg) or weight per volume (g/L). The OECD No. 105 (OECD, 1995b) recommends one of two methods, i.e. the shake flask method or the column elution method. The former is suitable for solubilities above 10 mg/L, while the latter is suitable for solubilities below this value.

Relative density

The density of a substance is the quotient of its mass and its volume and is expressed in kg/m^3. The OECD No. 109 (OECD, 2012c) indicates that a wide variety of methods can be used and provides guidance on their applicability.

Vapour pressure

Vapour pressure is defined (Rumble, 2018) as the pressure exerted when a solid or a liquid is in equilibrium with its own vapour. At thermodynamic equilibrium, the vapour pressure is a function of temperature only. Vapour pressure can be measured in several ways depending on the expected range. The OECD No. 104 (OECD, 2006c) lists eight different methods. The static, effusion and gas saturation methods are suitable for low melting point solids and liquids over a wide range of possible vapour pressures. Vapour pressure is measured in Pascal (Pa).

Viscosity

Viscosity is a measure of a fluid's resistance to flow and the OECD No. 114 (OECD, 2012d) provides a working definition of viscosity (see Glossary). Viscosity is measured in milliPascals per second (mPa/s). Three principles are used for measuring the dynamic viscosity of Newtonian liquids, and most of the available methods, with the exception of the "flow cup", appear to be suitable for measuring a wide range of viscosities:

- flow under gravity through a capillary (capillary viscometer or flow cup);
- shearing of the fluid between concentric cylinders, cone-plate and parallel plate (rotational viscometer); and
- dynamic viscosity can be measured by movement of a ball in a vertical or inclined liquid-filled cylindrical tube (e.g. a rolling ball viscometer, or a drawing ball viscometer).

Only the rotational viscometer method is suitable for non-Newtonian liquids.

Viscosity units and conversion

- Dynamic viscosity: 0.01 poise (P) = 0.01 g/cm/s = 1 mPa/s
- Kinematic viscosity: 1 Centistoke (cSt) = 1 mm^2/s

Kinematic viscosity (cSt) is the ratio of viscosity (cP) to density (d) at a given temperature, i.e. cSt = cP/d.

4.5.3 *Sub-column E3: Interference with the use of coastal amenities*

4.5.3.1 Introduction

Interference with coastal amenities refers to the potential of a substance to interfere with activities in coastal waters, including ports or estuaries, fishing, usage of beaches, appearance of an area, the health of human coastal populations, marine mammals and the preservation of living resources.

Sub-column E3 is supported by data on human health hazards and physical properties from all of columns C and D as well as sub-columns E1 and E2.

4.5.3.2 Ratings

The ratings in sub-column E3 are presented in Table 24 below. It should be borne in mind that these ratings and their associated hazard warnings are based on the intrinsic properties of the chemical and are intended as guidance only. They are not intended as a risk assessment. They are designed to aid in decision-making with respect to closure of beaches in the event of chemical contamination.

Additional factors related to a spill situation, such as weather and hydrodynamic conditions, quantity spilled, local conditions, etc., must be evaluated by competent spill response authorities before a decision is taken to, for example, implement the closure of a beach.

Table 24 – GESAMP Hazard Rating scheme for evaluating "interference with coastal amenities" (E3)

Rating	Relative interference	Description	Interpretation	Hazard warning
0	None	is not a floater; **and** does not pose any known health hazards	E2 is not F or Fp; **and** C1, C2 and C3 = 0; **and** D1 and D2 = 0; **and** D3 is blank	None
1	Slightly objectionable	is a floater; **and/or** is slightly acutely toxic; **and/or** is mildly irritant to skin and/or eyes	E2 = F; **and/or** C1 and/or C2 and/or C3 = 1; **and/or** D1 and/or D2 = 1	Warning issued but no closure of amenities
2	Moderately objectionable	is a persistent floater; **and/or** is moderately acutely toxic; **and/or** is irritating to skin and/or eyes; **and/or** has long-term health effects other than carcinogenicity, mutagenicity or reprotoxicity; **and/or** is highly flammable; **and/or** is flammable and is a floater with evaporative properties	E2 = Fp; **and/or** C1 and/or C2 and/or C3 = 2–3; **and/or** D1 and/or D2 = 2; **and/or** D3 contains Ss, Sr, T, A, N, or I; **and/or** E1=4; **and/or** E1=3 and E2 = FE or FED	Warning issued and possible closure of amenities
3	Highly objectionable	is highly acutely toxic; **and/or** is severely irritant or corrosive to skin or eyes; **and/or** is carcinogenic, mutagenic or reprotoxic; **and/or** is a floater or persistent floater with associated health effects	C1 and/or C2 and/or C3 = 4; **and/or** D1 or D2 = 3, 3A, 3B, or 3C; **and/or** D3 contains C, M or R; **and/or** E2 = F or Fp and D3 contains Ss, Sr, T, A, N, or I	Warning issued leading to the closure of amenities

5 GLOSSARY

Activated sludge	Biomass produced in the aerobic treatment of wastewater by the growth of bacteria and other microorganisms in the presence of dissolved oxygen. It usually consists of small flocs (the sludge) made up of pieces of organic matter surrounded or activated by colonies of microorganisms.
Acute aquatic toxicity	Adverse effects on aquatic organisms that occur rapidly as a result of short-term exposure to a chemical or physical agent. A chemical is considered acutely toxic if by its direct action it kills 50% or more of the exposed population of test organisms such as fish or crustaceans in a relatively short period of time, such as 24-96 hours.
Acute toxicity	Adverse effects in humans or mammalian test animals produced by single exposure to a substance.
Acute Toxicity Estimate (ATE)	Refers to a dose range or extrapolated dose leading to lethal effects in mammals, equivalent to an LD_{50} or LC_{50}.
Allergen	Any substance which induces a state of, or brings on, manifestations of allergy; a hypersensitive reaction involving an immune-mediated response.
Aspiration hazard	Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. Aspiration hazard refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.
Baseline aquatic toxicity	Baseline toxicity is the (theoretical) aquatic toxicity exerted by a substance due to the simplest mode of toxic action, i.e. non-polar narcosis, a process whereby the phospholipid bi-layers of cell membranes become saturated with the substance, causing the cell to die.
Bioaccumulation	General term describing a process by which chemicals are taken up by aquatic organisms directly from water as well as from exposure through other routes, such as consumption of food and sediment containing the chemicals.
Biochemical oxygen demand (BOD)	A measure of the rate at which molecular oxygen is consumed by microorganisms during oxidation of organic matter. The standard test is the 5-day BOD test (BOD_5), in which the amount of dissolved oxygen required for oxidation over a 5-day period is measured. The results are measured in mg of oxygen/l (mg/L).
Bioconcentration	A process by which there is a net accumulation of a chemical directly from water into aquatic organisms resulting from simultaneous uptake (e.g. by gill or epithelial tissue) and elimination.
Bioconcentration factor (BCF)	A term describing the degree to which a substance can be concentrated in the tissues of an organism in the aquatic environment as a result of exposure through the water phase. At steady state during the uptake phase of a bioconcentration test, the BCF is a value equal to the concentration of a substance in one or more tissues of the exposed aquatic organisms divided by the average exposure water concentration of the chemical in the test.
Biodegradation	The transformation of a substance resulting from the complex enzymatic action of microorganisms (e.g. bacteria, fungi). It usually leads to disappearance of the parent structure and to the formation of smaller chemical species, some of which are used for cell anabolism.
Carcinogen	Denotes a chemical substance or mixture which induces cancer. Substances which are known to induce benign or malignant tumours in well-performed experimental studies on animals are also considered to be presumed or suspected human carcinogens, unless there is strong evidence that the mechanism of tumour formation is not relevant for humans.
Chemical	Chemical elements and their components including substances and mixtures.
Chemical oxygen demand (COD)	A measure of the oxygen equivalent of the organic matter in wastewater susceptible to oxidation by a strong chemical oxidizing agent (e.g. potassium permanganate; see also BOD).
Chemosis	A swelling of the conjunctiva due to accumulation of tissue fluid.
Chronic aquatic toxicity	Adverse effects on aquatic organisms that occur largely from continuous long-term exposure to chemicals, but where the exposure time covers only a portion of the life cycle (lifespan) of the aquatic species tested. The effects are more often the consequence of repeated or continuous long-term exposures.
Chronic toxicity	Effects resulting from repeated exposure to a substance for the lifespan of the species, or the greater part thereof.
Coastal amenity	Beach, mudflat, wharf, boardwalk or any other feature of the coastal zone considered to be of public value.

Conjunctiva	Mucous membrane which lines the anterior chamber of the eye.
Cornea	The clear, transparent portion of the eye covering the iris and lens.
Corrosive	Capable of causing erosive destruction of tissues.
Cut-off value	Indicates the point on the scale of a given hazard criterion, e.g. acute aquatic toxicity, chosen to represent a perceived degree of hazard. The cut-off values are generally chosen to represent quantitative degrees of hazard and spaced at order of magnitude intervals, or are qualitative in nature, reflecting a descriptive degree of injury or potential damage.
Dermal toxicity	Systemic toxic effects produced as a result of a substance being absorbed across the skin.
Dermatitis	Inflammation of the skin evidenced by itching redness and various skin lesions.
Dissolved Organic Carbon (DOC)	That part of the organic carbon in the water which cannot be removed by specified phase separation, for example by centrifugation at 40000 m s-2 for 15 min or by membrane filtration using membranes with pores of 0.2–0.45 µm diameter.
EC_{10}	Term used for aquatic toxicity: The concentration of a substance which produces a 10% response in the defined end-point.
EC_{50}	Term used for aquatic toxicity: Median effective concentration. The concentration of a substance which produces a 50% response in the defined end-point. The EC50 should be cited for a specific exposure period.
EL_{50}	Term used for aquatic toxicity: Effective loading rate 50%. The loading rate in excess of the aqueous solubility of a substance or mixture at which a 50% effect is caused in tests with aquatic organisms following exposure to water accommodated fractions of the substance (see annex V).
(Hazard) End-point	A discrete hazard to aquatic life or human health, related to one or more intrinsic properties of a substance, which can be experimentally measured, or evaluated.
Erythema	Excess of reddening of a tissue due to increased flow of blood.
Immunotoxic	Capable of causing injury to the immune system and interference with body defence mechanisms.
Inherent biodegradability	Biodegradation of the test compound under enhanced conditions, either with a preadapted innoculum or a high level of activated sludge. The tests may be either static or flow-through, e.g. simulating a wastewater treatment process.
IC_{50}	Inhibition concentration 50%. A point estimate of the chemical concentration that would cause a given percent reduction (e.g. IC50) in a non-lethal biological measurement of the test organisms, such as reproduction or growth. The IC should be cited for the specific exposure period.
IL_{50}	Inihibition load 50%. The loading rate in excess of the aqueous solubility of a substance or mixture at which a 50% inhibition of population growth is measured in tests with microalgae following exposure to water accommodated fractions of the substance (see annex V).
Irritant	Capable of causing a local inflammatory response.
LC_{50}	Lethal Concentration 50%. The concentration, in air (e.g. for mammals) or in a solution (e.g. for aquatic organisms), which causes 50% mortality of the test species. It is calculated from the incidence of mortality at various concentrations to which different groups of the test species are exposed. Since mortality will depend on the time of exposure, the LC50 should be cited for the specific exposure period.
LD_{50}	Lethal Dose 50%. The amount (dose) of test substance that causes 50% mortality of the test species. It is calculated from the incidences of mortality at various doses given to different groups of the test species. It is usually expressed as mg (or g) of test substance per g or kg of body weight of the test species. Also referred to as the median lethal dose.
LL_{50}	Lethal load 50%. The loading rate in excess of the aqueous solubility of a substance or mixture at which a 50% mortality is caused in tests with aquatic organisms following exposure to water accommodated fractions of the substance (see annex V).
Log P_{ow}	See n-octanol-water partition coefficient.
Mixture	Mixtures composed of two or more substances which are not chemically combined and which cannot be separated by physical methods.
Mutagen	A substance causing permanent, heritable changes in the structure of the genetic material in cells (see also definition of Mutagenicity in paragraph 4.4.3.3).
Necrosis	Death of areas of tissue or bone surrounded by healthy parts.

Neurotoxic	Capable of causing injury to the central nervous system (brain and spinal cord) and/or peripheral nervous system (nerves arising from the brain and spinal cord). Delayed neurotoxicity refers to injury to the nervous system following a single exposure, but for which there is a significant latent period between exposure and the appearance of signs of a neurotoxic effect.
Newtonian fluids	Fluids are distinguished as Newtonian if the viscosity is constant for different rates of shear that does not change with time, e.g. water or gasoline. The viscosity of non-Newtonian fluids either varies with the rate of shear or varies with time, even though the rate of shear is constant, e.g. some mineral slurries (behaving like quicksand).
No Observed Effect Concentration (NOEC)	The highest concentration of a substance in a toxicity test that has no statistically significant adverse effect on the exposed population of test organisms compared with the controls. When derived from a life cycle or partial life cycle test, it is numerically the same as the lower limit of the Maximum Acceptable Threshold Concentration (MATC), also called No Observed Adverse Effect Level (NOAEL).
n-Octanol-water partition coefficient (K_{ow} or P_{ow})	The ratio of a chemical's solubility in n-octanol and water at steady state; also expressed as P. The logarithm of P_{ow} or K_{ow} (i.e. log P_{ow} or K_{ow}) is used as an indication of a chemical's propensity for bioconcentration by aquatic organisms.
Oedema	Swelling of a tissue due to excess accumulation of tissue fluid.
Primary biodegradation	The structural change (transformation) of an organic chemical compound by microorganisms resulting in the loss of a specific property.
Ready biodegradability	70% removal of dissolved organic content (DOC) and 60% removal of theoretical oxygen demand (ThOD) or theoretical carbon dioxide ($ThCO_2$) production (for respirometric methods), reached within a 10 d window in 28 d using non-adapted bacterial innocula.
Risk	The likelihood of harm occurring, e.g. when exposure of an organism to a substance is considered in conjunction with hazard data (Hazard x Exposure = Risk). If either hazard or exposure can be minimized, the risk or likelihood of harm will be reduced.
Reproductive toxicity	Injury to the male or female reproductive system, interfering with the propagation of the species.
Reprotoxic	Causing adverse effects on reproductive ability or capacity, or on the development of offspring.
Sensitization	Exposure to the substance results in stimulation of the immune system, resulting in a state of hypersensitivity to the substance. Sensitization by skin contact results in local allergic responses. Sensitization by inhalation (respiratory sensitization) can cause asthma or similar symptoms of respiratory distress.
Specific Target Organ Toxicity (STOT)	As defined in the GHS, refers to specific, non-lethal toxic effects on target organs occurring after a single or repeated exposure. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed as irritation, sensitizing, carcinogenic, mutagenic, reprotoxic or aspiration hazard.
Sub-chronic toxicity	Effects resulting from repeated exposure to a substance for 10% to 15% of the lifespan of the species. For rodents this is about one to three months.
Substance	For the purposes of this guidance, 'substance' refers to pure and technically pure substances as well as mixtures to facilitate maritime regulatory requirements, noting that this deviates from the GHS definition for substances.
Systemic toxicity	Adverse effects produced by a substance (or conversion products) after absorption into, and circulation by, the bloodstream. Systemic effects occur in tissues remote from the site where the substance comes into contact with the body, and from where it is absorbed.
Teratogen	A substance capable of causing injury to the conceptus and resulting in permanent structural and/or functional malformations.
Theoretical Oxygen Demand (ThOD)	The theoretical maximum amount of oxygen required to oxidize a chemical compound completely, calculated from the molecular formula, expressed in this case as mg oxygen required per mg or g test compound.
Toxic	Capable of causing adverse effects, detrimental to the survival or normal functioning of the organism.

Viscosity	Defined by OECD No. 114 as “the measure of the property of a fluid substance of absorbing a stress”, in which reference, definitions of dynamic and kinematic viscosity can also be found. More simply put: the resistance of a fluid (liquid or gas) to a change in shape, or movement of neighbouring portions (e.g. layers) relative to one another, i.e. viscosity denotes opposition to flow.
Water Accommodated Fractions	The fractions of a mixture dissolved in water following a fixed period of high-energy stirring, at a loading rate of test substance well in excess of saturation, followed by phase separation.

6 BIBLIOGRAPHY

Basketter D.A., Alepee N., Ashikaga T., Barrosos J., Gilmour N., Goebel C., Hibatallah J., Hoffmann S., Kern P., Martinozzi-Teissier S., Maxwell G., ResingerK., Sakaguchi H., Schepky A., Tailhardat M., and M. Templier (2014): *Categorization of chemicals according to their relative human skin-sensitization potency.* Dermatitis 25(1): 11-21 (2014).

Bonn Agreement (2005): *Bonn Agreement Counter Pollution Manual.* London: Bonn Agreement, 2005. https://www.bonnagreement.org/publications.

Boobis A., Budinsky R., Collie S., Crofton K., Embry M., Felter S., Hertzberg R., Kopp D., Mihlan G., Mumtaz M., Price P., Solomon K., Teuschler L., Yang R. and R. Zaleski (2011): *Critical analysis of literature on low-dose synergy for use in screening chemical mixtures for risk assessment.* Critical reviews in Toxicology 41(5) 369-383 (2011).

Corvaro M., Gehen S., Andrews K., Chatfield R., Arasti C., and J. Mehta (2016): *GHS additivity formula: a true replacement method for acute systemic toxicity testing of agrochemical formulations.* Regulatory Toxicology and Pharmacology 82: 99-110 (2016).

De Bruijn, J., F. Busser, W. Seinen, and J. Hermens (1989): *Determination of octanol/water partition coefficeints for hydrophobic organic chemicals with the "slow-stirring" method.* s.l.: Environmental Toxicology and Chemistry, 1989, Vols. 8: 499-512 (1989).p.

Dotson G.S., Maier A., Siegel P.D., Anderson S.E., Green B.J., Stefaniak A.B., Codispoti C.D. and I. Kimber (2015): *Setting occupational exposure limits for chemical allergens – understanding the challenges.* Journal of Occupational and Environmental Hygiene 12: S82-S98 (2015).

Draize, J.H., Woodward G., and H.O. Calvery (1944): *Method for the study of irritancy and toxicity of substances applied topically to the skin and mucus membrane.* J. Pharmacol. Exp. Ther., 1944, Vols. 82: 377-389 (1944).

ECETOC (1996): *Aquatic toxicity testing sparingly soluble, volatile and unstable substances.* Brussels: European Centre for Ecotoxicity and Toxicology of Chemicals, 1996. Monograph No. 26.

ECETOC (2009): *Collation of existing marine biodegradation data and its use in environmental risk assessment.* Brussels: European Centre for Ecotoxicology and Toxicology of Chemicals, Technical Report No.108, 2009.

ECHA (2017): *Guidance on the application of the CLP criteria. Guidance to Regulation EC NO 1271/2008 on classification, labelling and packaging (CLP) of substances and mixtures.* Helsinki: s.n., 2017, Vol. Version 5.0. Helsinki, 2017.

ECHA (online): European Chemicals Agency (ECHA). Information on Chemicals. *European Chemicals Agency (ECHA).* [Online]. www.echa.europa.eu.

EU (2006): REACH. REACH Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and … *EUR OJ 3396 (2006).*

EU (2008): CLP. Regulation (EC) No.1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and … EUR OJ L353 (2008).

Gambill, W.R. (1959): *Viscosity extrapolation with temperature.* Gambill, W.R. s.l.: Chem. Engineering, 1959, Vols. 127: 123-126. (1959).

GESAMP (1972): *Report of the fourth session, GESAMP IV/19.* London: GESAMP, 1972. http://www.gesamp.org/publications/report-of-the-4th-session-1972

GESAMP (1982): *The evaluation of the hazards of harmful substances carried by ships.* Reports and Studies No. 17. London: GESAMP, 1982.

GESAMP (1989): *The Evaluation of the Hazards of Harmful Substances Carried by Ships.* Revision of Reports and Studies No. 17. Reports and Studies No. 35. London: GESAMP, 1989.

GESAMP (2002): *The Revised GESAMP Hazard Evaluation Procedure*. London: GESAMP, 2002.

GESAMP (2005): *Report of the 41st session. Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, Working Group on the evaluation of the hazards of harmful substances carried by ships.* 2005.

GESAMP (2013): *Report of the 40th session of GESAMP, GESAMP Reports & Studies No. 88.* London: GESAMP, 2013.

GESAMP (2019): *Report of the 45th session of GESAMP, GESAMP Reports & Studies in print.* London: GESAMP, 2019.

Hansch, C. and A. Leo (1979): *Substituent Constants for Corellation Analysis in Chemistry and Biology.* New York: Wiley Interscience, New York, 1979.

HELCOM (1991): *Manual on Co-operation in Combating Marine Pollution within the Framework of the Convention on the Protection of the Marine Environment of the Baltic Sea Area 1974 (Helsinki Convention), vol. III: Response to Incidents Involving Chemicals.* Helsinki: Baltic Marine Environment Protection Commission, 1991.

Höfer, T., D. James, D., T. Syversen, T., and T. Bowmer (2011): *Estimation of the acute inhalation hazards of chemicals based on route-to-route and local end-point extrapolation: experience from bulk maritime transport.* Altern. Lab. Anim. 39(6): 541-556 (2011).

IMO (1999): Section 1, Problem Assessment and Response Arrangements. *Manual on Chemical Pollution.* London: International Maritime Organization, 1999.

IMO (2007): *Revised tank cleaning additives guidance note and reporting form.* MEPC.1/Circ.590. London: International Maritime Organization, 2007.

IMO (2016a): *IBC Code. International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code).* London: International Maritime Organization, 2016.

IMO (2016b): *IMDG Code. International Maritime Dangerous Goods Code.* London: International Maritime Organization, 2016.

IMO (2016c): *International Code for the construction and equipment of ships carrying liquefied gasses in bulk (IGC Code).* London: International Maritime Organization, 2016.

IMO (2017a): *MARPOL. Consolidated edition. Unified interpretations of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto.* London: International Maritime Organization, 2017.

IMO (2017b): *IMSBC Code. International Maritime Solid Bulk Cargoes Code.* London: International Maritime Organization, 2017.

IMO (2019): *Guidelines for the Provisional Assessment of Liquid Substances Transported in Bulk.* MEPC.1/Circ.512/Rev.1. London: International Maritime Organization, 2019.

IMO/UNEP (2000): *Regional Information System, Part D, Operational Guides and Technical Manuals.* UNEP/IMO. Practical Guide to Chemical Spills. REMPEC, 1999, updated Jan 2000.

ISO (1994): *Water quality – Evaluation in an aqueous medium of the "ultimate" aerobic biodegradibility of organic compounds – Method by analysis of biochemical oxygen demand (closed bottle test).* ISO 10707. Geneva: International Organization for Standardization, 1994.

ISO (1995): *Water quality – guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium.* ISO 10634. Geneva: International Organization for Standardization, 1995.

ISO (1999a): *Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium – Carbon dioxide evolution test.* ISO 9439. Geneva: International Organization for Standardization, 1999.

ISO (1999b): *Water quality – Determination of acute lethal toxicity to marine copepods (Copepoda, Crustacea).* ISO 14669. Geneva: International Organization for Standardization, 1999.

ISO (2012): *Water quality – Fresh water algal growth inhibition test with unicellular green algae.* ISO 8692. Geneva: International Organization for Standardization, 2012.

ISO (2015): *Water quality – Calanoid copepod early-life stage test with Acartia tonsa.* ISO 16778. Geneva: International Organization for Standardization, 2015.

ISO (2016): *Water quality – Marine algal growth inhibition test with Skeletonema costatum and Phaedactylum tricornutum.* ISO 10253. Geneva: International Organization for Standardization, 2016.

Kienzler A., Bopp S.K., van der Linden S., Berggren E. and A. Worth (2016): *Regulatory assessment of chemical mixtures: Requirements, current approaches and future perspectives.* Regulatory Toxicology and Pharmacology 80: 321-334 (2016).

Kolle S.N., Van Cott A., van Ravenzwaay B., and R. Landsiedel (2017b): Lacking applicability of *in vitro* eye irritation methods to identify seriously eye irritating agrochemical formulations: results of bovine cornea opacity and permeability assay, isolated chicken eye test and EpiOcular™ ET-50 method to classify according to UN GHS. Regulatory Toxicology and Pharmacology 85: 33-47 (2017).

Kolle S.N., van Ravenzwaay B., and R. Landsiedel (2017a): Regulatory accepted but out of domain: *in vitro* skin irritation tests for agrochemical formulations. Regulatory Toxicology and Pharmacology 89: 125-130 (2017).

Lyman, W.J., W.F. Reehl and D.H. Rosenblatt (1990): *Handbook of chemical property estimation methods: Environmental behaviour of organic compounds.* Washington: American Chemical Society, 1990.

Meek M.E. (2013): International experience in addressing combined exposures: increasing the efficiency of assessment. Toxicology 313(2-3): 185-189 (2013).

Newsome, L.D., J.V. Nabholz, and A. Kim (1996): Designing Aquatically Safer Chemicals. [book auth.] eds. S.C. DeVito and R.L. Garrett. *Designing Safer Chemicals – Green Chemistry for Pollution Prevention.* s.l.: ACS Symposium Series 640. Washington: American Chemical Society, 1996.

NITE (online): Japan National Institute of Technology and Evaluation. Chemical Risk Information Platform. [Online] http://www.safe.nite.go.jp/english/sougou/view/Disclaimer_en.faces.

OECD (1992a): *Test Guideline Series No. 306: Biodegradability in seawater.* Paris: Organisation for Economic Co-operation and Development, 1992.

OECD (1992b): *Test Guideline Series No. 301: Ready Biodegradability.* Paris: Organisation for Economic Co-operation and Development, 1992.

OECD (1992c): *Test Guideline Series No. 203: Fish, acute toxicity test.* Paris: Organisation for Economic Co-operation and Development, 1992.

OECD (1995a): *Test Guideline Series No.107: Partition coefficient (n-octanol/ water): shake flask method.* Paris: Organization for Economic Co-operation and Development, 1995.

OECD (1995b): *Test Guideline Series No. 105: Water Solubility.* Paris: Organisation for Economic Co-operation and Development, 1995.

OECD (1997): *Principles of Good Laboratory Practice.* ENV/MC/ CHEM(98). Paris: Organisation for Economic Co-operation and Development, 1997.

OECD (1998): *Test Guideline Series No. 212: Fish, short term toxicity test on embryo and sac-fry stages.* Paris: Organisation for Economic Co-operation and Development, 1998.

OECD (2000a): *Series on testing and Assessment No.23, Guidance document on aquatic toxicity testing of difficult substances and mixtures.* s.l.: Organisation for Economic Co-operation and Development, Paris, 2000.

OECD (2000b): *Test Guideline Series No. 215: Fish, juvenile growth test.* Paris: Organisation for Economic and Co-operation and Development, 2000.

OECD (2002a): *Test Guideline Series No. 420: Acute oral toxicity – fixed dose procedure.* Paris: Organisation for Economic Co-operation and Development, 2002.

OECD (2002b): *Test Guideline Series No. 423: Acute oral toxicity – acute toxic class method.* Paris: Organisation for Economic Co-operation and Development, 2002.

OECD (2004a): *OECD principles for the validation, for regulatory purposes, of (Quantitative) Structure-Activity Relationship Models.* OECD. [Online] http://www.oecd.org/env/ehs/risk-assessment/37849783.pdf.

OECD (2004b): *Test Guideline Series No. 117: Partition Coefficient (n-octanol/ water): HPLC method.* Paris: Organisation for Economic Co-operation and Development, 2004.

OECD (2004c): *Test Guideline Series No. 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test.* Paris: Organisation for Economic Co-operation and Development, 2004.

OECD (2004d): *Test Guideline Series No. 202: Daphnia sp. Acute immobilisation Test.* Paris: Organisation for Economic Co-operation and Development, 2004.

OECD (2006a): *Test Guideline Series No. 123: Partition Coefficient (n-octanol/water): Slow-Stirring Method.* Paris: Organisation for Economic Co-operation and Development, 2006.

OECD (2006b): *Test Guideline 435: In Vitro Membrane Barrier Test Method for Skin Corrosion.* Paris: Organisation for Economic Co-operation and Development, 2006.

OECD (2006c): *Test Guideline Series No. 104: Vapour pressure.* Paris: Organisation for Economic Co-operation and Development, 2006.

OECD (2007): *Series on Testing and Assessment No.79: Validation report of the full life cycle test with the Harpacticoid Copepods Nitrocra spinipes and Amphiascus tenuiremis and the Calanoid Copepod Acartia tonsa – Phase 1.* Paris: Organisation for Economic Co-operation and Development, 2007.

OECD (2008a): *Test Guideline Series No. 211: Daphnia magna reproduction test.* Paris: Organisation for Economic Co-operation and Development, 2008.

OECD (2008b): *Test Guideline Series No. 425: Acute oral toxicity: up-and-down procedure.* Paris: Organisation for Economic Co-operation and Development, 2008.

OECD (2009a): *Test Guideline Series No. 229: Fish, short term reproduction assay.* Paris: Organisation for Economic Co-operation and Development, 2009.

OECD (2009b): *Test Guideline Series No. 230: 21-day fish assay, a short-term screening for oestrogenic and androgenic activity, and aromatase inhibition.* Paris: Organisation for Economic Co-operation and Development, 2009.

OECD (2009c): *Test Guideline Series, No. 403: Acute inhalation toxicity.* Paris: Organisation for Economic Co-operation and Development, 2009.

OECD (2009d): *Test Guideline Series, No. 436: Acute inhalation toxicity, acute toxic class method.* Paris: Organisation for Economic Co-operation and Development, 2009.

OECD (2011a): *Test Guideline Series No. 201: Freshwater algal and cyanobacteria, growth inhibition test.* Paris: Organisation for Economic Cooperation and Development, 2011.

OECD (2011b): *Test Guideline Series No. 234: Fish, sexual development test.* Paris: Organisation for Economic Co-operation and Development, 2011.

OECD (2012a): *Test Guideline Series No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure [Replaces: Bioconcentration: Flow-through Fish Test, 1996].* Paris: Organisation for Economic Co-operation and Development, 2012.

OECD (2012b): *The Adverse Outcome Pathway for skin sensitization initiated by covalent binding to proteins. Part 1: Scientific evidence.* Series of Testing and Assessment No. 168. Organisation for Economic Co-operation and Development, 2012.

OECD (2012c): *Test Guideline Series, No. 109: Density of liquids and solids.* Paris: Organisation for Economic Co-operation and Development, 2012.

OECD (2012d): *Test Guideline Series No. 114: Viscosity of liquids.* s.l.: Organisation for Economic Co-operation and Development, 2012.

OECD (2013): *Test Guideline Series No. 210: Fish, early-life stage toxicity test.* Paris: Organisation for Economic Co-operation and Development, 2013.

OECD (2015a): *Test Guideline Series No. 404: Acute dermal irritation/corrosion.* Paris: Organisation for Economic Co-operation and Development, 2015.

OECD (2015b): *Test Guideline 430: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER).* Paris: Organisation for Economic Co-operation and Development, 2015.

OECD (2015c): *Test Guideline 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method.* Paris: Organisation for Economic Co-operation and Development, 2015.

OECD (2016): *Test Guideline 431: In Vitro Skin Corrosion: Human Skin Model Test.* Paris: Organisation for Economic Co-operation and Development, 2016.

OECD (2017a): *Test Guideline Series No. 402: Acute dermal toxicity.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (2017b): *Test Guideline Series No.433: Acute inhalation toxicity: Fixed concentration procedure.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (2017c): *Test Guideline Series No. 405: Acute eye irritation/corrosion.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (2017d): *Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (2017e): *Test Guideline 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (2017f): *Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants.* Paris: Organisation for Economic Co-operation and Development, 2017.

OECD (online): *Assessment of Chemicals – Published Assessments.* OECD. [Online] OECD. http://www.oecd.org/chemicalsafety/risk-assessment/publishedassessments.htm.

Rekker, R.F.F and R. Mannhold (1992): *Calculation of drug lipophilicity: the dydrophobic fragmental constant approach.* VCH Verlagsgesellschaft mbH, Weinheim, 1992.

Rhomberg L.R., Goodman J.E., Bailey L.A., Prueitt R.L., Beck N.B., Bevan C., Honeycutt M., Kaminski N.E., Paoli G., Pottenger L.H., Scherer R.W., Wise K.C., and Becker R.A. (2013): *A survey of frameworks for best practices in weight-of-evidence analyses.* Crit. Rev. Toxicology 43(9): 753-784 (2013).

Rumble, J.R. (2018): *Handbook of Physics and Chemistry, 99th edition.* s.l.: CRC Press, 2018.

Sarigiannis D.A. and U. Hansen (2012): *Considering the cumulative risk of mixtures of chemicals – a challenge for*

policy makers. Environmental Health 11(Suppl 1): S18 (12 pages) (2012).

Steinhäuser, K.G. and T. Höfer (2000): *Use of Health Hazard Criteria for Estimating the Hazard Potential of Chemicals to Water in Case of a Spill.* Regulatory Toxicology and Pharmacology 31: 1-12 (2000).

United Nations (1992): *UNCED. Declaration on Environment and Development. Agenda 21: Programme of Action for Sustainable Development; The final text of agreements negotiated by Governments at the United Nations Conference on Environment and Development.* s.l.: United Nations, 1992. UN Publications No.E.93.1.11., 1992.

United Nations (2017): *Globally harmonized system of classification and labeling of chemicals (GHS), 7th edition.* New York and Geneva: United Nations, 2017.

US EPA (1996a): *Mysid acute toxicity test, Ecological effects test guidelines.* s.l.: US Environmental Protection Agency, Office of Prevention, Pesticides and Toxics, 1996.

US EPA (1996b): *Pesticides and Toxic Substances, Ecological Effects Test Guidelines OPPTS 850 1350-Mysid Chronic Toxicity Test.* s.l.: United States Environmental Protection Agency, Office of Prevention, 1996. EPA 712-C-120.

US EPA (online, a): US EPA Chemical Safety Research – Methods, Models, Tools and Databases. *US Environmental Protection Agency.* [Online] www.epa.gov/research/methods-models-tools-and-databases.

US EPA (online, b): US EPA Estimation Program Interface (EPI) Suite for Microsoft Windows, v.4.11. *Exposure Assessment Tools and Models.* [Online] http://www.epa.gov/opptintr/exposure/pubs/episuite.htm.

Van Cott A., Hastings C.E., Landsiedel R., Kolle S., and S. Stinchcombe (2018): *GHS additivity formula: can it predict the acute systemic toxicity of agrochemical formulations that contain acutely toxic ingredients?* Regulatory Toxicology and Pharmacology 92: 407-419 (2018)

Van Leeuwen, C. J., and T.J. Vermeire (2007): *Risk assessment of chemicals: An introduction.* 2nd edition. Dordrecht: Springer, 2007.

Vandebriel R.J. and H. van Loveren (2010): *Non-animal sensitization testing: state-of-the-art.* Critical Reviews in Toxicology 40: 389 – 404 (2010).

Verhaar, H.M.J., C.J. van Leeuwen, and J.L.M. Hermens (1992): *Classifying environmental pollutants.* Verhaar, H.M.J., C.J. van Leeuwen and J.L.M. Hermens. Chemosphere 25: 471-491 (1992).

ANNEX I – TERMS OF REFERENCE FOR THE GESAMP EHS WORKING GROUP

GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships (GESAMP EHS Working Group)

The terms of reference of the GESAMP EHS Working Group, as revised by GESAMP at its 45th session in Rome in 2018 (GESAMP, 2019) are:

> *"The GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships is an expert group to provide best available scientific assessment of the environmental, occupational and safety hazards of chemicals, in particular to:*
>
> *.1 provide scientific advice on the hazards of chemicals transported by ships as may be requested, particularly by IMO;*
>
> *.2 evaluate safety data and test reports on specific chemicals submitted by industry in accordance with the rationale approved by GESAMP for this purpose and create a GESAMP Hazard Profile for such chemicals accordingly;*
>
> *.3 maintain a list of hazard evaluations ("Composite List" of GESAMP Hazard Profiles) for the use by IMO and keep it up to date based on available scientific data; and*
>
> *.4 observe the developments concerning the international harmonization of hazard classification by the United Nations and scientific guidance on hazard assessment published by international organizations to improve the GESAMP Hazard Evaluation Procedure and GESAMP Hazard Ratings."*

ANNEX II – MEMBERS AND MEETINGS OF THE GESAMP EHS WORKING GROUP

This list represents past and present members of the GESAMP EHS Working Group. Those marked with an asterisk have served as Chair of the Group.

Ms D.M.M. Adema	Netherlands	1975 – 1994
Dr O. Awodele	Nigeria	2012 – 2013
Dr B. Ballantyne	United States	1977 – 2000
Dr F. Bathie	United Kingdom	1990 – 1991
Dr B-E. Bengtson	Sweden	1974 – 1989
Dr R. Blackman	United Kingdom	1989 – 1992
Dr C.T. Bowmer*	Netherlands	1995 – 2013
Mr D. Enreth	United States	1980 – 1981
Prof W. Ernst*	Germany	1984 - 1990
Mr L. Foyn	Norway	1974 – 1984
Dr T. Höfer*	Germany	1993 to present
Mr P. Howgate	United Kingdom	1984 - 1995
Dr D. James	United Kingdom	2000 – 2017
Dr P. Jeffery*	United Kingdom	1974 – 1992
Dr W. Jiang	China	2010 to present
Dr R. Kantin	France	1992 – 1996
Dr M. Kitano	Japan	1989 – 1993
Dr S. le Floch	France	2008 to present
Dr P. Lefcourt	United States	1978
M R. Luit	Netherlands	2014 to present
Dr M. Marchand	France	1997 – 2006
Dr. M.E. Meek	Canada	2016 to present
Dr S. Micallef	Malta	1995 – 2001
Mr M. Morrissette	United States	1985 to present
Prof S.D. Murphy	United States	1978 – 1985
Dr F. Pedersen	Denmark	2000 – 2006
Dr J.K. Portmann*	United Kindom	1974 – 1982
Dr P.H. Rodriguez	Chile	2014 to present
Dr H. Saito	Japan	2007 to present
Prof T. Syversen	Norway	1985 to 2008
Dr G.H. Thompson	United States	1974 – 1978
Prof E. Vigliani	Italy	1974 – 1976
Dr M. Wakabayashi	Japan	1995 – 2006
Mr T.A. Wastler	United States	1977
Dr P. Wells*	Canada	1988 – 1999
Dr K.W. Wilson	United States	1977
Prof. T. Yoshida	Japan	1982 – 1988
Dr V. Zitko	Canada	1975

Secretariat to the EHS Working Group – Past and present

Ms P. Charlebois	Secretary	2013-2017
Mr J.V.C.Crayford	Secretary	2001-2004
Dr P. Jeffery	Technical Advisor	1989-1992
Mr L. Kontogiannis	Secretary	2017 to 2019
Dr K. McDonald	Secretary/Technical Advisor	2008 to present
Dr S. Micallef	Secretary	2005-2007
Dr M. Nauke	Secretary	1978-2000
Mr B. Okamura	Secretary	1977, 1993
Mr N. Soutar	Technical Advisor	1993-2013
Mr S.L.D. Young	Secretary	1974-1976
Mr L.C. Espenes	Secretary	2019 to present

Meetings of the EHS Working Group

1	14–15 October	1974	London
2	4–6 June	1975	London
3	15–17 October	1975	London
4	12–14 July	1976	London
5	22–24 October	1976	London
6	9–13 May	1977	Delft
7	4–6 July	1977	London
8	22–26 May	1978	Bergen
9	5–9 November	1979	Burnham
10	2–6 June	1980	London
11	15–19 December	1980	Houston
12	21–25 September	1981	London
13	25–29 October	1982	Delft
14	6–10 June	1983	London
15	9–13 January	1984	Aberdeen
16	21–25 May	1984	London
17	11–15 February	1985	Plymouth
18	7–11 October	1985	London
19	26–30 May	1986	Delft
20	3–7 November	1986	London
21	18-22 May	1987	Trondheim
22	18–22 January	1988	London
23	29 August–2 Sept	1988	London
24	13–17 February	1989	London
25	26–30 March	1990	London
26	8–12 April	1991	London
27	17–21 February	1992	London
28	15–19 February	1993	London
29	14–18 February	1994	London
30	27 February–3 March	1995	London
31	28 August–1 Sept	1995	London
32	20–24 May	1996	London
33	10–14 February	1997	London
34	23–27 February	1998	London
35	1–5 February	1999	London
36	3–7 April	2000	London
37	31 April–4 May	2001	London
37a	6–10 August (toxicologists)	2001	London
37b	5–9 November (ecotoxicologists)	2001	Tokyo
37c	18-19 April (phys-chem experts)	2002	Brest
38	22–26 April	2002	London
39	5–9 May	2003	London
40	19–23 April	2004	London
41	9–13 May	2005	London
42	20–24 February	2006	London
43	6–8 June	2006	London
44	30 April–4 May	2007	London
45	22–25 April	2008	London
46	20–24 April	2009	London
47	26–30 July	2010	London
48	11–15 April	2011	London
49	25–28 June	2012	London
50	15–19 April	2013	London
51	12-16 May	2014	Brest
52	13-17 April	2015	London
53	23-27 May	2016	Berlin
54	22-26 May	2017	London
55	30 April – 4 May	2018	London

ANNEX III – SYSTEM FOR ASSIGNING CHEMICAL NAMES

Both GESAMP and the IMO bodies responsible for the pollution categorization of substances are required to consider the name of each substance, in order to ensure that it is:

- unique;
- properly defines the composition of the substance or mixture;
- properly reflects the associated hazards; and
- preferably self-explanatory.

The EHS Working Group of GESAMP examines the nomenclature of each substance submitted and assigns a chemical name. Accepted rules of chemical nomenclature are generally applied, while avoiding excessively complicated or long names. Bearing in mind that many chemicals are in fact proprietary mixtures or preparations and provided the four points above can be met, the EHS Working Group is generally amenable to using names which make clear to which chemical group the substance belongs, without divulging its exact chemical structure in the interests of confidentiality. To ensure a proper hazard evaluation by the EHS Working Group, knowledge of the full chemical structure is essential. Trade names are not accepted.

The EHS Working Group provides the manufacturer with a hazard profile and proposes a working name for the substance. When the manufacturer submits the name and hazard profile plus additional (largely safety related) data to the appropriate IMO bodies, in order to allow categorization, a “product” name is then formally assigned by IMO.

The evaluation of a substance as listed in the Composite List is in general based on the product carried by ship as a bulk liquid according to data presented. Products carried in tankers are either pure chemical substances or crude or semi-refined industrial products containing a number of chemical substances. In the latter case the descriptive name used in the Composite List reflects the key components.

Mixtures (complex)

The length of hydrocarbon chains is of importance in assessing the hazard of complex mixtures, e.g. the number of carbon atoms and the molecular weight greatly influence aquatic toxicity. With the alkanes, aquatic toxicity increases from C5 (pentane, the first liquid homologue) to C9, the most toxic. Thereafter, acute aquatic toxicity decreases and disappears, as solubility in water decreases below concentrations sufficient to cause an effect in short- term tests. Many bulk liquids are fractions from refining processes and contain substances predominately in a specific chain length range.

Mixtures (isomeric)

Isomeric mixtures are generally indicated with the word (all isomers) in brackets after the name. Where one isomer is more hazardous than the rest, then the worst case rating(s) in the hazard profile is assigned. Less hazardous isomers may be named separately, reflecting their appropriate hazards.

Mixtures (containing a particular component)

Natural mixtures are generally named so as to identify their composition and to prevent any other substances (with different hazards) being carried under the same name. Where a given component can affect the hazard profile by its presence, it is usually specified, e.g. “resin acids $<$10%”.

Mixtures (preparations)

Deliberate mixtures of pure substances, e.g. formulations or preparations, are generally named so as to reflect all the most important components, particularly where the quantity of one component may influence the hazard of the whole mixture, e.g. Alkyl acrylate/vinyl pyridine copolymer in toluene. In this case, if the mixture has not been tested with the toluene component present, then toluene will be evaluated also and mixture calculation rules will be applied.

Mixtures (solutions)

Solutions always refer to aqueous solutions unless otherwise specified. Usually, the strength of the solution is specified after the name if the concentration indicates a relevant hazard limit. Where the word “solution” is given after the name of a substance without specifying the strength of that solution, then the hazard profile applies to all strengths, i.e. the ratings for human health and environmental properties are the same for all strengths. Alternatively, the strength of solution may be given by the manufacturer to indicate the maximum practicable or safe concentration that may be carried in water.

Mixtures (molecular weight)

Sometimes the molecular weight (range) is cited in brackets after the name. This is done for several reasons:

- where the molecular weight of all the components is >1000, the substance is unlikely to bioaccumulate or exert aquatic toxicity (since the molecules are too big to pass through cell membranes); and
- substances may be produced in several molecular weight ranges with varying hazard profiles and the molecular weight may be conveniently used to separate them.

Mixtures (polymeric chains)

The length of polymeric chains is indicated by the prefix “poly” followed by the number of units in brackets, then by the name of the monomeric unit.

Physical state

Where a substance is normally a solid, it may be transported in bulk by heating, in which case, the word “molten” appears in brackets after the name.

ANNEX IV – BIODEGRADATION TESTS SUITABLE FOR TESTING UNDER MARINE CONDITIONS

Table IV.1 - OECD biodegradation tests specifically developed for testing under marine conditions

Guideline	Name	Principle of the method	Scope and recommended usage
OECD No. 306 (1992)	Marine biodegradation test: .1 Shake flask method; .2 Closed bottle method (seawater variant of the closed bottle test OECD 301).	Method using natural seawater as the aqueous phase and the sole source of microorganisms (i.e. an innoculum is not added as in freshwater tests) to evaluate the biodegradability. Suitable for lower test substance concentrations. In a more conservative test, DOC removal or ThOD are measured in a 28 day closed bottle test (can also be extended to 56 days).	The test can be used for organic substances which: • are soluble at the test concentration (Shake flask method, 5 to 40 mg DOC/l; Closed bottle, 2 to 10 mg/L l-1 DOC); and • are volatile providing suitable precautions are taken. Relatively simple test method suitable for measuring the ultimate biodegradation of organic chemicals in seawater. Despite the use of natural seawater bacteria, this is not a simulation test owing to the addition of nutrients.
OECD No. 301 E (1992)	Shake flask method (seawater variant of the modified screening test).	Suitable for higher test substance concentrations. DOC removal or ThOD are measured in a shake flask test lasting for up to 60 days.	Idem ditto.
OECD No. 309 (2004) Based on ISO/ DIS 14592-1 (see below) and elements from OECD 307[10] and 308[11]	Aerobic mineralization in surface water – Simulation biodegradation test.	Simulation test to measure the time course of biodegradation and kinetic rate of a test substance at low concentration in aerobic natural water (fresh, brackish or marine): a) shake flask batch test; b) semi-continuous operation for long test times, in order to prevent deterioration of the test microcosm.	Suitable for testing substances at very low concentrations (<1 µg/L to 100 µg/L) to ensure that the biodegradation kinetics reflect those expected in the environment, that the test substance will serve only as a secondary substrate, that the biodegradation kinetics are expected to be first order (“non-growth” kinetics) and that the test substance may be degraded by “co-metabolism”. The use of 14C labelled test substances and the determination of the phase distribution of 14C at the end of the test, enable ultimate biodegradability to be determined.

[10] OECD 307, Aerobic and anaerobic transformation in soils.
[11] OECD 308, Aerobic and anaerobic transformation in aquatic sediment systems.

Table IV.2 - ISO biodegradation simulation design, specifically developed for testing natural (fresh) water

Guideline	Name	Principle of the method	Scope and recommended usage
ISO 14592.1 ASTM E-1279 EPA-OPPT S 835-3170; refers to test type 1 only	Shake flask batch test Water quality evaluation of the aerobic biodegradability of organic substances at low concentrations in water Method follows the die-away of the parent compound.	Method for evaluating the biodegradability of organic substances at low concentrations by aerobic microorganisms in water: • Part 1 is designed to simulate surface water or sediment-water suspensions, while Part 2 is a continuous-flow simulation of a river, including biomass attached to surfaces; • evaluation of the test result is carried out by specific chemical analysis of the parent compound; and • Part 1 uses stoppered flasks with an air headspace, while Part 2 uses an open cascade type system.	The test can be used for organic substances which are water soluble at the test concentration (preferably $<$100µg/L); this includes many poorly soluble substances. The test method is suitable for measuring the primary biodegradation of substances at environmentally realistic concentrations.

ANNEX V – AQUATIC TOXICITY TESTS WITH POORLY SOLUBLE COMPLEX MIXTURES

1 Introduction

Aquatic toxicity tests should be based on dissolved exposure concentrations; most modern test guidelines provide instructions to this effect. However, with poorly soluble mixtures, this is often difficult if not impossible to determine with any degree of certainty due to the differential solubility of the various components. Typical examples of such chemicals are hydrocarbon distillates in general, and more specifically "lubricating oil additives". This standard operating procedure was developed in the 1980s to replace traditional dispersion tests for measuring aquatic toxicity, where the undissolved test material was often found to cause physical effects on the test organisms.

Several documents have been published which provide guidance on testing difficult chemicals in general. The most informative of these is that published by ECETOC, which provides a step-by-step practical key to selecting the appropriate dosing and exposure techniques to match the expected behaviour of the test substance in water. Of probably more regulatory importance, is an OECD guidance document on "aquatic toxicity testing of difficult substances and mixtures" (OECD, 2000), which describes a wide variety of differing test conditions. It focuses on the definition of "exposure concentrations" and the provision of supporting analytical evidence and provides some guidance on when it is appropriate to use water accommodated fraction techniques such as the one described below.

The method described here was originally designed for use in the preparation of test media for aquatic toxicity testing of hydrocarbon mixtures. However, it is suitable for the preparation of other poorly soluble complex mixtures in seawater. Generally, the method follows the recommendations for testing difficult chemicals provided by Whitehouse and Mallet (1993) and uses "water accommodated fractions" (WAF). It is based on methods developed by Girling (1989) and Girling et al. (1994) and adopted by CONCAWE (1993).

2 Terminology and definitions

- The term *test substance* is used here to describe mixtures, whether simple or complex, and includes both natural mixtures, such as oils and isomeric mixtures from a chemical process, as well as artificial or deliberate mixtures such as preparations.
- The term *water accommodated fraction* (WAF) refers exclusively to mixtures and is not applicable to pure substances (equivalent term: aqueous extracts).
- Although it contains a dissolved substance, a WAF can best be referred to in reporting as the *test medium* and not as the "test solution".
- The initial concentrations mixed in seawater should be consistently referred to as the *loading rate* when presenting results and not as the "test concentration", as the initial amount was never present in the media actually tested.

3 Principles

3.1 The test substance is first homogenized thoroughly, bearing in mind that mixtures with a tendency to emulsify in water may have to be rolled or shaken for several hours and then weighed out immediately.

3.2 As a WAF should ideally comprise a differential equilibrium of the components of the mixture, between the non-dissolved and the dissolved phases, each test concentration/loading rate of a series must be prepared separately. Dilution of a single stock is not acceptable.

3.3 If it is uncertain how long the major components of the substance will take to reach equilibrium with the water phase, then a preliminary study should be run, samples should be taken after, e.g. 4, 16 and 20 hours stirring and analysed with an appropriate analytical method.

3.4 Accurately weighed amounts of homogeneous test substance are thoroughly mixed with a given volume of (sea) water using a magnetic stirrer, i.e. for a period that is long enough to obtain an equilibrium between the (sea) water and the test substance. The mixture is then left to stand for a further short period, to allow for phase separation. It is desirable to confirm that equilibrium has been reached by chemical analysis of relevant components or other suitable means, e.g. total organic carbon (TOC).

3.5 Following phase separation, the required volume of test medium is tapped off from the middle of the mixing vessel. Substances may float, settle to the bottom or remain in suspension, depending on their specific gravity. This "clear" fraction is called the "water accommodated fraction" (WAF). The WAF may contain very small (invisible) droplets or particles.

3.6 The WAF is used directly for testing except in cases where it is judged to be sufficiently turbid as to cause physical hampering of the test organisms (particularly crustaceans). In such cases, it may be filtered through a glass wool plug. In order to prevent losses of sparingly soluble substances by evaporation (filtration under low pressure) or adsorption (in filter material), the WAF may not be filtered through a fine membrane or other filter. Centrifugation may be considered, if no other alternatives are available.

3.7 Substances containing volatile components may have to be mixed and tested in sealed vessels. Substances that degrade rapidly may need shorter equilibrium and shorter phase separation times.

4 Apparatus

Ordinary laboratory apparatus is used, in particular:

- magnetic stirring apparatus;
- glass stoppered Erlenmeyer flasks with a glass tap assembly approximately 3 cm above the base;
- laboratory balance;
- glass microscope cover slips; and
- time clock(s) for electrical power (if possible).

5 Preparation of the test media

5.1 Start the preparation of the media one day (20 h + 4 h) in advance of the test exposure.

5.2 Homogenize the test substance thoroughly, e.g. by rolling overnight on a roller bank in a cool environment (15°C to 20°C).

5.3 Accurately weigh the necessary amounts of test substance. Small amounts may be weighed on a glass microscope cover slip (one amount for each test solution to be prepared); avoid the use of non-inert materials to transfer the test substance.

5.4 Fill Erlenmeyer flasks (with a glass stopper) almost completely with a known amount of seawater (the seawater type and temperature of choice for the test). Introduce a suitable teflon/glass magnetic stirring rod and place each of these flasks on a magnetic stirrer at about the test temperature, making sure that the vortex reaches a depth of ⅓ of the water column. The depth of the vortex is important in ensuring that the individual loading rates are stirred with approximately equal energy.

5.5 Introduce the weighed amounts of test substance, one for each flask, when the seawater is already stirring; this may improve the mixing procedure.

5.6 The preparation of the WAFs is generally carried out in the dark as some substances, e.g. hydrocarbons, may be sensitive to photo-oxidation.

5.7 Stir for 16–20 h, followed by 4 h standing for phase separation. If possible, carry out the stirring a few degrees below the test temperature, as stirring may slightly warm the seawater.

5.8 Following the period allowed for phase separation, tap the WAFs from the middle of the water column directly into the test vessels (not more than 70% of the volume).

5.9 This procedure is followed on each occasion the test media are replaced, i.e. for a 96 h (fish) test with daily renewal, the test media are prepared 4 times.

6 Reporting

Refer accurately to the procedure in the report:

- state that water accommodated fractions were used;
- give the stirring and standing times; and
- quote the results as lethal loading rates and effect loading rates (LL_{50}, EL_{50}, NOEL) etc., not as LC/EC_{50}s or NOECs.

7 Bibliography

CONCAWE (1993): *Report no. 92/56 – Ecotoxicity testing of petroleum products; test methodology.* Report no. 92/56. Brussels: Conservation of Clean Air and Water in Europe, 1993.

Girling A.E. (1989): *Preparation of aqueous media for aquatic toxicity testing oils and oil-based products: a review of the published literature.* s.l.: Chemosphere, 1989, Vols. 19 (10/11): 1635-1641 (1989).

Girling, A.E., G.F. Whale and D.M.M. Adema (1994): *A guideline supplement for determining the aquatic toxicity of poorly water-soluble complex mixtures using water-accommodated fractions.* s.l.: Chemosphere, 1994, Vols. 29(12): 2645-2649.

OECD (2000): *Series on testing and Assessment No.23, Guidance document on aquatic toxicity testing of difficult substances and mixtures.* Paris: Organisation for Economic Co-operation and Development, 2000.

Whitehouse, P. and M. Mallett (1993): *Report No. C – Aquatic toxicity testing for notification of new substances: an advisory document dealing with difficult substances. Report to the chemical notification unit, Department of the Environment (UK).* Medmenham: Water Research Council, 1993.

ANNEX VI – GESAMP/EHS PRODUCT DATA REPORTING FORM

Please note that this form may be amended from time to time. The most up to date form may always be accessed at the following URL under the heading 'related documents' on the right hand side of the page:

http://www.imo.org/en/ourwork/environment/pollutionprevention/chemicalpollution/pages/chemicalsreportingforms.aspx

GESAMP
Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection

GESAMP/EHS Product Data Reporting Form Characteristics of Liquid Chemicals Proposed for Marine Transport	
Date of submission [dd/mm/yy]	

Section 1 – Product Identity

Proper Shipping Name*	
Main Chemical Name	
Main Trade Name	
Synonyms	

* This is the first name that should appear on the shipping documentation and will be reflected in the IBC Code

Section 2 – Product Identification Numbers

CAS Number	
EHS Number	
UN Number	

Section 3 – Product Chemical Details

Chemical Formula:	
Physical State During Transport: (liquid, solution (with %) or molten)	
Chemical Structure:	

Section 4 – Composition

Component name	%	Range	Type

Section 5 – Physical Properties

Property		Qual	Value or Range	References and Comments
Molecular Weight				
Density @ 20°C	**(kg/m^3)**			
Flash Point (cc)	**(°C)**			
Boiling Point	**(°C)**			
Melting Point/Pour Point	**(°C)**			
Water solubility @ 20°C	**(mg/L)**			
Viscosity @ 20°C	**(mPa.s)**			
Vapour Pressure @ 20°C	**(Pa)**			
SVC @ 20°C	**(mg/L)**			

Notes:

1 If values are not available at 20°C temperature, please provide the value and reference temperature.

2 SVC refers to saturated vapour concentration. This value is used to assess the inhalation hazard for products that may be toxic by inhalation, but may not produce vapours in sufficient concentrations to constitute an inhalation hazard.

Section 6 – Relevant Chemical Properties

Water Reactivity (0 – 2)		0	Any chemical which, in contact with water, would not undergo a reaction to justify a value of 1 or 2.
		1	Any chemical which, in contact with water, may generate heat or produce a non-toxic, non-flammable or non-corrosive gas.
		2	Any chemical which, in contact with water, may produce a toxic, flammable or corrosive gas or aerosol.
Details/References			
Does the product react with air to cause a potentially hazardous situation? (Y/N)			
If so, provide details			
Reference			
Is an Inhibitor or Stabilizer needed to prevent a hazardous reaction? (Y/N)			
If so, provide details			
Reference			
Is refrigeration needed to prevent a hazardous reaction? (Y/N)			
If so, provide details			
Reference			

Section 7 – Mammalian Toxicity

7.1 Acute Toxicity

		Qual	Value or Range	Species	Reference/Comments
Oral ATE/LD_{50}	**(mg/kg)**				
Dermal ATE/LD_{50}	**(mg/kg)**				
Inhalation ATE/LC_{50}	**(mg/L/4h)**				

7.2 *Corrosivity and Irritation*

	Observation	Species	Reference/Comments
Skin Irritation/Corrosion*			
Eye Irritation			

* If corrosive, exposure time (hrs)

Options: not irritating, mildly irritating, irritating, severely irritating or corrosive

7.3 *Sensitization*

	Y/N	Reference/Comments
Respiratory Sensitizer (in humans)		
Skin Sensitizer		

7.4 *Other Specific Long-term Effects*

	Y/N	Reference/Comments
Carcinogenic		
Mutagenic		
Toxic to reproduction		
Other long-term effects		

7.5 *Relevant Mammalian Toxicity*

Acute Mammalian Oral Toxicity Data Taken Into Account

Effect	Qual	Value or Range	Units	Species	Reference

Acute Mammalian Dermal Toxicity Data Taken Into Account

Effect	Qual	Value or Range	Units	Species	Reference

Acute Mammalian Inhalation Toxicity Data Taken Into Account

Effect	Qual	Value or Range	Units	Species	Reference

Skin Irritation/Corrosion Data

Qty (mg)	Cover	Exp. Time (hrs)	Species	Observation	Reference

Eye Irritation Data

Qty (mg)	Cover	Exp. Time (hrs)	Species	Observation	Reference

Additional Notes on Mammalian Toxicity

Section 8 – Aquatic Toxicity, Bioaccumulation and Biodegradation

8.1 Acute Toxicity

	Units	Qual	Value or Range	Species	Reference
Fish LC_{50}	**mg/L/96h**				
Crustacea EC_{50}	**mg/L/48h**				
Algae IC_{50}	**mg/L/72h**				

8.2 *Chronic Toxicity*

	Units	Qual	Value or Range	Species	Reference
Fish LC_{50}	**mg/L/96h**				
Crustacea EC_{50}	**mg/L/48h**				
Algae IC_{50}	**mg/L/72h**				

8.3 *Biodegradation and Bioaccumulation*

Test	Units (%)	Qual	Value	Method
28d Biodegradation				
BOD_5				
COD				
BCF				
Log Pow				
Reference				

8.4 *Acute Fish Toxicity Taken Into Account*

Effect	Qual	Value or Range	Units	Species	Reference

8.5 ***Acute Crustacea Toxicity Taken Into Account***

Effect	Qual	Value or Range	Units	Species	Reference

8.6 ***Acute Algal Toxicity Taken Into Account***

Effect	Qual	Value or Range	Units	Species	Reference

8.7 ***Bioaccumulation – BCF values***

Qual	Value or Range	Duration (days)	Species	Reference

8.8 ***Bioaccumulation – Log P_{ow} Values***

Qual	Value or Range	Method	Reference

8.9 ***Biodegradation Values***

Qual	Value or Range	Duration	Method	Reference

8.10 ***Additional Aquatic Toxicity Notes***

8.11 ***Additional Bioaccumulation Notes***

8.12 ***Additional Biodegradation Notes***

Section 9 – Submission Information

ANNEX VII – RELATIONSHIP BETWEEN GESAMP HAZARD RATINGS AND GHS CATEGORIES FOR SUBSTANCES HAZARDOUS TO THE AQUATIC ENVIRONMENT

Acute Toxicity Rating (col. B1)	GESAMP Description	EC/LC_{50} (mg/L)	GHS Acute Categories
0	Non-toxic	>1000	No Classification
1	Practically non-toxic	>100 – ≤1000	No Classification
2	Slightly toxic	>10 – ≤100	Acute 3
3	Moderately toxic	>1 – ≤10	Acute 2
4	Highly toxic	>0.1 – ≤1	Acute 1
5	Very highly toxic	>0.01 – ≤0.1	Acute 1
6	Extremely toxic	≤0.01	Acute 1

Chronic Toxicity Rating (col. B2)	GESAMP Description	EC_{10} and/or NOEC (mg/l)	GHS Chronic Categories	
			with A=R*	with A2=NR**
0	Negligible	>1	No Classification	No Classification
1	Low	>0.1 – ≤1	Chronic 3	Chronic 2
2	Moderate	>0.01 – ≤0.1	Chronic 2	Chronic 1
3	High	>0.001 – ≤0.01	Chronic 1	Chronic 1
4	Very high	≤0.001	Chronic 1	Chronic 1

* Rapidly degradable substances for which there are adequate chronic toxicity data available
** Non-Rapidly degradable substances for which there are adequate chronic toxicity data available

ANNEX VIII – RELATIONSHIP BETWEEN GESAMP HAZARD RATINGS AND GHS CATEGORIES FOR HEALTH HAZARDS

GHS Classification	Hazard Statement (Code)	GHP rating	Remark
Acute Tox. 1 (oral)	300	C1 = 4	
Acute Tox. 2 (oral)		C1 = 3	
Acute Tox. 3 (oral)	301	C1 = 2	
Acute Tox. 4 (oral)	302	C1 = 1	
Asp. 1	304	D3 = A	
Acute Tox. 1 (dermal)	310	C2 = 4	
Acute Tox. 2 (dermal)		C2 = 3	
Acute Tox. 3 (dermal)	311	C2 = 2	
Acute Tox. 4 (dermal)	312	C2 = 1	
Skin Corr. 1	314	D1 = 3	Rating 3 is assigned as long as long as no specific test data are existing and classification could either be 3A, 3B or 3C.
Skin Corr. 1C		D1 = 3A	
Skin Corr. 1B		D1 = 3B	
Skin Corr. 1A		D1 = 3C	
Skin Irr. 2	315	D1 = 2	
Skin Irr. 3		D1 = 1	
Skin Sens. 1	317	D3 = Ss	
Eye Irr. 1	318	D2 = 3	
Eye Irr. 2 / 2A	319	D2 = 2	
Eye Irr. 2B		D2 = 1	
Acute Tox. 1 (inhalation)	330	C3a/b = 4	Not fully harmonized (see footnote*)
Acute Tox. 2 (inhalation)		C3a/b = 3	
Acute Tox. 3 (inhalation)	331	C3a/b = 2	
Acute Tox. 4 (inhalation)	332	C3a/b = 1	
Resp. Sens. 1	334	D3 = Sr	
Muta. 1A / Muta. 1B	340	D3 = M	
Muta. 2	341		
Carc. 1A / Carc. 1B	350	D3 = C	
Repr. 1A / Repr. 1B	360	D3 = R	
STOT SE 1	370	D3 = T	
STOT SE 2	371		
STOT RE 1	372		
STOT RE 2	373		

* The classification boundaries of the GHS for acute toxicity are not equidistant across classification classes and are inconsistent between gases, vapours, and aerosols (dusts and mists). GESAMP ratings are differentiating between vapour and mist or mist-vapour exposure (in line with the GHS cut-off system), whilst the GHS has non-specific classification/labelling rules for final classification (H-code) and labelling of the acute inhalation toxicity hazard.

ANNEX IX – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN A1)

Bioaccumulation

Where mixtures are concerned, and consistent with the summation method of the GHS (GHS, 7th revision, 2017), the resulting rating of a mixture is the sum of the concentrations of the individual components weighted by the concentration and rating, where the cut-off limit is set at 25% as w/w%. The procedure is indicated in Table 3 under paragraph 4.1.1.4 Application to mixtures.

Table 3 - Classification of mixtures for Bioaccumulation

Classification of mixtures for Bioaccumulation, using log P_{ow} (or log K_{ow}) (A1a) and/or Bioconcentration factors (A1b) data, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the ingredients i=1 to n and where R for columns A1a and/or A1b goes from 0 to 5.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\,(R=5)}$	$\geq$ 25%	5
$\left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=4)}$	$\geq$ 25%	4
$\left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=3)}$	$\geq$ 25%	3
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=2)}$	$\geq$ 25%	2
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$\geq$ 25%	1
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$<$ 25%	0

Example

The example given here is a typical chemical intermediate product carried in chemical tankers for further manufacturing of plastics. The mixture is of 5 components including stabilizers and a solvent.

Table IX.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	**Concentration as %**	**Rating**
A	0.1	4
B	0.01	5
C	24	2
D	60	1
E	15.89	0

For assessing the rating of the mixture under column A1 the formulae from Table 3 have to be used according to Table IX.2.

Table IX.2 - Assessment of the mixture rating using the equations in Table 3

Component	**Rating 5**	**Rating 4**	**Rating 3**	**Rating 2**
A	–	0.1%	0.1% x 10	0.1% x 100
B	0.01%	0.01% x 10	0.01% x 100	0.01% x 1000
C	–	–	–	24%
D	–	–	–	–
E	–	–	–	–
Sum	**0.01%**	**0.20%**	**2%**	**44%**
Criteria	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**
Mixture rating	**-**	**-**	**-**	**2**

As shown in the assessment table, the mixture met the criteria for a rating of “2” in column A1. Please note that components of lower rating (e.g. D and E) are not considered, since they have a lower rating and do not contribute to a higher hazard rating in this case.

ANNEX X – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN A2)

Biodegradation

To assess the biodegradation rating of a mixture, where not readily biodegradable (NR) and readily biodegradable (R) ingredients are present, the rating is calculated as the sum of the concentrations of the individual components, weighted by their concentration and rating, where the cut-off limit is set at 25% as w/w%, as indicated in Table 5 under Paragraph 4.1.2.4 Application to mixtures.

Table 5 - Classification of mixtures for biodegradation

Classification of mixtures for biodegradation, column A2, based on the summation of components rated by GESAMP as not readily biodegradable (NR) or readily biodegradable (R). Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for rating in column A2 is NR or R.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{R=NR}$	$\geq$ 25%	NR
$\sum_{i=1}^{n} \%C_{R=NR}$	$<$ 25%	R

Example

The chemical mixture shown here is a typical crude chemical product carried in chemical tankers. It consists of 3 components. The corresponding concentrations in the mixture and the GESAMP Hazard Ratings for column A2 are shown in the following table:

Table X.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	**Concentration as %**	**Rating**
A	1	NR
B	18	NR
C	81	R

For assessing the rating of the mixture under column A2 the formulae from Table 5 have to be used according to Table X.2.

Table X.2 - Assessment of the mixture rating using the equations in Table 5:

Component	**Rating NR**
A	1%
B	18%
C	–
Sum	**19%**
Criteria	**$\geq$ 25%**
Mixture rating	**R**

As shown in the assessment table, the mixture does not meet the criteria for a NR rating but met the criteria for a rating of “R” in column A2. Please note that components with an R rating are not considered, since they do not contribute to the NR hazard rating.

ANNEX XI – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN B1)

Acute aquatic toxicity

Short term toxicity of mixtures (acute toxicity) with known components rated by GESAMP is calculated as the sum of the concentrations of the individual components weighted by their concentration and rating, where ingredients with high toxicity rating contribute to the rating of the lower mixture toxicity rating. Consistent with the GHS (GHS 7th revision, 2017) the cut-off limit is set at 25% as w/w%, as indicated in Table 7 under paragraph 4.2.1.4.

Table 7 - Classification of mixtures for short-term (acute) aquatic hazard

Classification of mixtures for short-term (acute) aquatic hazard, column B1, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for ratings in column B1 ranges from 0 to 6.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\,(R=6)}$	$\geq$ 25%	6
$\left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=5)}$	$\geq$ 25%	5
$\left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=4)}$	$\geq$ 25%	4
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[10x \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=3)}$	$\geq$ 25%	3
$\left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=2)}$	$\geq$ 25%	2
$\left[100000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$\geq$ 25%	1
$\left[100000 \times \sum_{i=1}^{n} \%C_{i\,(R=6)}\right] + \left[10000 \times \sum_{i=1}^{n} \%C_{i\,(R=5)}\right] + \left[1000 \times \sum_{i=1}^{n} \%C_{i\,(R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\,(R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\,(R=2)}\right] + \sum_{i=1}^{n} \%C_{i\,(R=1)}$	$<$ 25%	0

Example

The example given here is a typical chemical intermediate product carried in chemical tankers for further manufacturing of plastics. The mixture is of 7 components including stabilizers and a non-toxic solvent.

Table XI.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	Concentration as %	Rating
A	0.1	4
B	0.01	5
C	2	2
D	1	2
E	10	1
F	30	1
G	56.89	0

For assessing the rating of the mixture under column B1 the formulae from Table 7 have to be used according to Table XI.2.

Table XI.2 - Assessment of the mixture rating using the equations (from Table 7)

Component	Rating 6	Rating 5	Rating 4	Rating 3	Rating 2	Rating 1
A	–	–	0.10%	0.1% x 10	0.1% x 100	0.1% x 1000
B	–	0.01%	0.01% x 10	0.01% x 100	0.01% x 1000	0.01% x 10000
C	–	–	–	–	2%	2% x 10
D	–	–	–	–	1%	1% x 10
E	–	–	–	–	–	10%
F	–	–	–	–	–	30%
G	–	–	–	–	–	–
Sum	**0%**	**0.01%**	**0.20%**	**2%**	**23%**	**270%**
Criteria	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**
Mixture rating	**–**	**–**	**–**	**–**	**–**	**1**

As shown in the assessment table, the mixture meets the criteria for a rating of “1” in column B1. Please note that components of lower ratings (e.g. G) are not considered, since they have a lower rating and do not contribute to a higher hazard rating.

ANNEX XII – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN B2)

Chronic aquatic toxicity

Long term toxicity of mixtures (chronic toxicity) with known components rated by GESAMP, is calculated as the sum of the concentrations of the individual components weighted by the concentration and rating, where ingredients with high toxicity rating contribute to the rating of the lower mixture toxicity rating. Consistent with the GHS (GHS 7th revision, 2017) the cut-off limit is set at 25% as w/w%, as indicated in Table 9 under paragraph 4.2.2.4.

Table 9 - Classification of mixtures for long-term (chronic) aquatic hazard

Classification of mixtures for long-term (chronic) aquatic hazard, column B2, based on the summation of components rated by GESAMP. Where C indicates the sum of concentrations (as %) of the individual ingredients i=1 to n, and R for ratings in column B2 ranges from 0 to 4.

Sum of concentrations (in %) of ingredient in the mixture rated as:	**If**	**Mixture is rated as:**
$\sum_{i=1}^{n} \%C_{i\ (R=4)}$	$\geq$ 25%	4
$\left[10 \times \sum_{i=1}^{n} \%C_{i\ (R=4)}\right] + \sum_{i=1}^{n} \%C_{i\ (R=3)}$	$\geq$ 25%	3
$\left[100 \times \sum_{i=1}^{n} \%C_{i\ (R=4)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\ (R=3)}\right] + \sum_{i=1}^{n} \%C_{i\ (R=2)}$	$\geq$ 25%	2
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\ (R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\ (R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\ (R=2)}\right] + \sum_{i=1}^{n} \%C_{i\ (R=1)}$	$\geq$ 25%	1
$\left[1000 \times \sum_{i=1}^{n} \%C_{i\ (R=4)}\right] + \left[100 \times \sum_{i=1}^{n} \%C_{i\ (R=3)}\right] + \left[10 \times \sum_{i=1}^{n} \%C_{i\ (R=2)}\right] + \sum_{i=1}^{n} \%C_{i\ (R=1)}$	$<$ 25%	0

Example

The example given here is a typical cleaning additive used in warm washing water inside the tanks of chemical tankers to clean off the residues of bulk liquids after unloading. The mixture is composed of 7 components.

Table XII.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	**Concentration as %**	**Rating**
A	0.1	4
B	0.1	4
C	5	2
D	1	2
E	10	1
F	30	1
G	53.8	0

For assessing the rating of the mixture under column B2 the formulae from Table 9 have to be used according to Table XII.2.

Table XII.2 - Assessment of the mixture rating using the equations (from Table 9)

Component	Rating 4	Rating 3	Rating 2
A	0.1%	0.1% x 10	0.1% x 100
B	0.1%	0.1% x 10	0.1% x 100
C	–	–	5%
D	–	–	1%
E	–	–	–
F	–	–	–
G	–	–	–
Sum	**0.2%**	**2%**	**26%**
Criteria	**$\geq$ 25%**	**$\geq$ 25%**	**$\geq$ 25%**
Mixture rating	**–**	**–**	**2**

As shown in the assessment table, the mixture meets the criteria for a rating of “2” in column B2. Please note that components of lower rating (e.g. for components E to G) are not considered, since they have a lower rating and do not contribute to a higher hazard rating in this case.

ANNEX XIII – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN C1)

Acute oral toxicity

Short term toxicity of mixtures (acute oral toxicity) with known components rated by GESAMP is calculated based on bridging principles or based on concentration addition of the components as long as test data from the mixture itself are not existing. The “additivity formula” is shown in paragraph 4.3.1.4. Application to mixtures:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{\mathrm{ATE}_i}$$

where ATE_{mix} is the acute toxicity estimate for the mixture and ATE_i is the ATE of the component of concentration C_i.

Example

The chemical mixture shown here is a typical crude chemical product carried in chemical tankers. It consists of 3 components. The corresponding concentrations in the mixture and the GESAMP Hazard Ratings for column C1 are shown in the following table:

Table XIII.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	Concentration as %	Rating
A	1	2
B	18	2
C	81	1

The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). There is a need for conversation from the GESAMP Hazard Rating in column C1 into acute toxicity point estimates for use in the “additivity formula” for the rating of mixtures. For this approach, table 3.1.2 from the GHS (Chapter 3.1, paragraph 3.1.3.3) is used for a harmonized approach. The following table shows the application for the GESAMP evaluation of mixtures. Most of the recent acute toxicity tests using less animals than in the past are not resulting in a single LD_{50} or ATE value but obtain acute toxicity ranges which cannot been used directly by the calculation using the “additivity formula”. Any specific LD_{50} or ATE value used for deriving a GESAMP Hazard Rating will be used in the formula directly with conversion of rating ranges to point estimates.

Table XIII.2 - Conversion of acute toxicity range values to acute toxicity point estimates

Rating	Acute toxicity range (mg/kg)	Converted acute toxicity point estimate (mg/kg)
0	$>$ 2000	-
1	$>$ 300 - $\leq$ 2000	500
2	$>$ 50 - $\leq$ 300	100
3	$>$ 5 - $\leq$ 50	5
4	$\leq$ 5	0.5

Please note that components with zero ratings are not considered, since they do not contribute to a hazard rating.

Table XIII.3 - Derived ATE values with components and concentrations

Component	Concentration as %	ATE (mg/kg)
A	1	100
B	18	100
C	81	500

The “additivity formula” is used with these ATE values of the components.

$$\frac{100}{ATE_{mix}} = \frac{1}{100} + \frac{18}{100} + \frac{81}{500}$$

When using the “additivity formula” based on these concentrations and ATE values, the resulting ATE will be 284 mg/kg corresponding to a GESAMP Hazard Rating in column C1 of “2”.

ANNEX XIV – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN C2)

Acute dermal toxicity

Short term toxicity of mixtures (acute dermal toxicity) with known components rated by GESAMP is calculated based on bridging principles or based on concentration addition of the components as long as test data from the mixture itself are not existing. The “additivity formula” is shown in paragraph 4.3.1.4. Application to mixtures:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{\mathrm{ATE}_i}$$

where ATE_{mix} is the acute toxicity estimate for the mixture and ATE_i is the ATE of the component of concentration C_i.

Example

The chemical mixture shown here is a typical crude chemical product carried in chemical tankers. It consists of 3 components. The corresponding concentrations in the mixture and the GESAMP Hazard Ratings for column C2 are shown in the following table:

Table XIV.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	Concentration as %	Rating
A	1	2
B	18	(2)
C	81	(1)

The ratings in brackets for components B and C show expert judgement without any specific ATE value derived from animal testing.

The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). There is a need for conversation from the GESAMP Hazard Rating in column C2 into acute toxicity point estimates for use in the “additivity formula” for the rating of mixtures. For this approach, table 3.1.2 from the GHS (Chapter 3.1, paragraph 3.1.3.3) is used for a harmonized approach. The following table shows the application for the GESAMP evaluation of mixtures. Most of the recent acute toxicity tests using less animals than in the past are not resulting in a single LD_{50} or ATE value but obtain acute toxicity ranges which cannot be used directly by the calculation using the “additivity formula”.

Any specific LD_{50} or ATE value used for deriving a GESAMP Hazard Rating will be used in the formula directly with conversion of rating ranges to point estimates.

Table XIV.2 - Conversion of acute toxicity range values to acute toxicity point estimates

Rating	Acute toxicity range (mg/kg)	Converted acute toxicity point estimate (mg/kg)
0	$>$ 2000	-
1	$>$ 1000 - $\leq$ 2000	1100
2	$>$ 200 - $\leq$ 1000	300
3	$>$ 50 - $\leq$ 200	50
4	$\leq$ 50	5

Please note that components with zero ratings are not considered, since they do not contribute to a hazard rating.

Table XIV.3 - Derived ATE values for components and concentrations

Component	Concentration as %	ATE (mg/kg)
A	1	300
B	18	300
C	81	1100

The “additivity formula” is used with these ATE values of the components

$$\frac{100}{ATE_{mix}} = \frac{1}{300} + \frac{18}{300} + \frac{81}{1100}$$

When using the “additivity formula” based on these concentrations and ATE values, the resulting ATE will be 730 mg/kg corresponding to a GESAMP Hazard Rating in column C2 of “(2)”. The bracketed rating results from the use of ratings in brackets for some components.

ANNEX XV – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN C3)

Acute inhalation toxicity

Short term toxicity of mixtures (acute inhalation toxicity) with known components rated by GESAMP is calculated based on bridging principles or based on concentration addition of the components as long as test data from the mixture itself are not existing. The “additivity formula” is shown in paragraph 4.3.1.4. Application to mixtures:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{\mathrm{ATE}_i}$$

where ATE_{mix} is the acute toxicity estimate for the mixture and ATE_i is the ATE of the component of concentration C_i.

Example

The example shown refers to an evaluation for column C3a hazard rating.

The chemical mixture shown here is a typical crude chemical product carried in chemical tankers. It consists of 3 components. The corresponding concentrations in the mixture and the GESAMP Hazard Ratings for column C3 are shown in the following table:

Table XV.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	Concentration as %	Rating
A	1	(3)
B	18	(2)
C	81	1

The ratings in brackets for components A and B show expert judgement based on the GESAMP inhalation toxicity extrapolation method without any specific ATE value derived from animal testing.

The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). There is a need for conversation from the GESAMP Hazard Rating in column C3 into acute toxicity point estimates for use in the “additivity formula” for the rating of mixtures. For this approach, table 3.1.2 from the GHS (Chapter 3.1, paragraph 3.1.3.3) is used for a harmonized approach. The following table shows the application for the GESAMP evaluation of mixtures.

Most of the recent acute toxicity tests using less animals than in the past are not resulting in a single LC_{50} or ATE value but obtain acute toxicity ranges which cannot been used directly by the calculation using the “additivity formula”. Any specific LC_{50} or ATE value used for deriving a GESAMP Hazard Rating will be used in the formula directly with conversion of rating ranges to point estimates.

Table XV.2 - Conversion of acute toxicity range values to acute toxicity point estimates

Rating	Acute toxicity range (mg/L)	Converted acute toxicity point estimate (mg/L)
0	$>$ 20	-
1	$>$ 10 - $\leq$ 20	11
2	$>$ 2 - $\leq$ 10	3
3	$>$ 0.5 - $\leq$ 2	0.5
4	$\leq$ 0.5	0.05

Please note that components with zero ratings are not considered, since they do not contribute to a hazard rating.

Table XV.3 - Derived ATE values for components and concentrations

Component	Concentration as %	ATE (mg/kg)
A	1	0.5
B	18	3
C	81	11

The “additivity formula” is used with these ATE values of the components

$$\frac{100}{ATE_{mix}} = \frac{1}{0.5} + \frac{18}{3} + \frac{81}{11}$$

When using the “additivity formula” based on these concentrations and ATE values, the resulting ATE will be 6.5 mg/L corresponding to a GESAMP Hazard Rating in column C3a of “(2)”. The bracketed rating results from the use of ratings in brackets for some components.

ANNEX XVI – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN D1)

Skin irritation / corrosion

As long as no testing or hazard classification data (e.g. pH) are available for the complete mixture, skin irritation and corrosion of mixtures with known components rated by GESAMP is calculated based on bridging principles or based on concentration limits triggering the mixture hazard rating. The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). The procedure is indicated in Table 14 under Paragraph 4.4.1.3 Application to mixtures:

Table 14 - Concentration of ingredients of a mixture that would trigger ratings of the mixture

Sum of ingredients rated as	**Concentration triggering rating of the mixture**		
	3, 3A, 3B, or 3C	**2**	**1**
3, 3A, 3B, or 3C	$\geq$ 5%	$\geq$ 1% but $<$5%	
2		$\geq$ 10%	$\geq$ 1% but $<$10%
1			$\geq$ 10%

Example

The example given here is a typical cleaning additive used in warm washing water inside the tanks of chemical tankers to clean off the residues of bulk liquids after unloading. The mixture is composed of 6 components.

Table XVI.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	**Concentration as %**	**Rating**
A	0.5	3
B	0.5	3
C	1	3
D	5	2
E	10	0
G	83	1

For assessing the rating of the mixture under column D1 the concentration limits from Table 14 have to be used according to Table XVI.2.

Table XVI.2 - Conversion of acute toxicity range values to acute toxicity point estimates

Component	**Concentration (%) triggering a rating of 3**	**Concentration (%) triggering a rating of 2**	**Concentration (%) triggering a rating of 2**
A	0.5	0.5	0.5*
B	0.5	0.5	0.5*
C	1	1	1*
D			5
E			
G			
Criteria	**$\geq$ 5**	**$\geq$ 1 but $<$5**	**$\geq$ 10**
Mixture rating		**2**	**2**

* A weighting factor is used for skin corrosive components (usually of 10) when using them together with lower ratings and their generic concentration limit. Particular care must be taken when rating mixtures containing corrosives, phenols and surfactants. Expert judgement is used by GESAMP in all cases.

When adding up the percentages of the relevant components and applying the concentration triggering a rating according to Table 14, the GESAMP Hazard Rating in column D1 is “2”.

ANNEX XVII – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN D2)

Eye irritation

As long as no testing or hazard classification data (e.g. pH) are available for the complete mixture, eye irritation of mixtures with known components rated by GESAMP is calculated based on bridging principles or based on concentration limits triggering the mixture hazard rating. The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). The procedure is indicated in Table 16 under Paragraph 4.4.2.3 Application to mixtures:

Table 16 - Concentration of ingredients of a mixture that would trigger ratings of the mixture

Sum of ingredients rated as	**Concentration triggering rating of the mixture**		
	3	**2**	**1**
3	$\geq$ 3%	$\geq$ 1% but $<$3%	
2		$\geq$ 10%	$\geq$ 3% but $<$10%
1			$\geq$ 90%

Note: The concentration limits for rating 1 are not given by the GHS but are interpretations of GHS category 2B classification guidance.

Example

The example given here is a typical cleaning additive used in warm washing water inside the tanks of chemical tankers to clean off the residues of bulk liquids after unloading. The mixture is composed of 6 components.

Table XVII.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	**Concentration as %**	**Rating**
A	0.5	3
B	0.5	3
C	1	(3)
D	5	(2)
E	10	0
F	83	1

For assessing the rating of the mixture under column D2 the concentration limits from Table 16 have to be used according to Table XVII.2.

Table XVII.2 - Components and concentrations triggering the mixture rating

Component	**Concentration (%) triggering a rating of 3**	**Concentration (%) triggering a rating of 2**	**Concentration (%) triggering a rating of 2**
A	0.5	0.5	0.5*
B	0.5	0.5	0.5*
C	1	1	1*
D			5
E			
F			
Criteria	**$\geq$ 5**	**$\geq$ 1 but $<$3**	**$\geq$ 10**
Mixture rating		**2**	**2**

* A weighting factor is used for corrosive components (usually of 10) when using them together with lower ratings and their generic concentration limit. Particular care must be taken when rating mixtures containing corrosives, phenols and surfactants. Expert judgement is used by GESAMP in all cases.

When adding up the percentages of the relevant components (25% after use of weighting factors) and applying the concentration triggering a rating according to Table 14, the GESAMP Hazard Rating in column D2 is “(2)”. The bracketed ratings results from the use of rating in brackets for some components.

ANNEX XVIII – EXAMPLE FOR A MIXTURE CALCULATION (COLUMN D3)

Long-term health hazards

The long-term health hazards of mixtures with known components rated by GESAMP is calculated based on bridging principles or based on concentration limits triggering the mixture hazard rating. The approach taken by GESAMP is consistent with the GHS (GHS 7th revision, 2017). The procedure is indicated in Table 18 under Paragraph 4.4.3.4 Application to mixtures:

Table 18 - Concentration of ingredients of a mixture that would trigger ratings of the mixture

Column D3	Hazard evaluation	Concentration limit
C	Carcinogenicity	$\geq$ 0.1%
M	Mutagenicity	$\geq$ 0.1%
	Mutagenicity equivalent to GHS cat. 2	$\geq$ 1%
R	Reproductive toxicity	$\geq$ 0.3%*
Ss	Skin sensitization equivalent to GHS sub-cat. 1A	$\geq$ 0.1%
	Skin sens. equivalent to GHS sub-cat. 1B	$\geq$ 1%
Sr	Respiratory sensitization equivalent to GHS sub-cat. 1A	$\geq$ 0.1%
	Resp. sens. equivalent to GHS sub-cat. 1B	$\geq$ 1%
A	Aspiration hazard	$\geq$ 10%**
T (N, I)	Specific target organ toxicity (STOT)	$\geq$ 1%
	STOT equivalent to GHS cat. 2	$\geq$ 10%

* GESAMP/EHS normally adopts a 0.3% limit value, which is accepted by most authorities; GHS specifies values of both 0.1% and 0.3%.

** The mixture must have a kinematic viscosity $\leq$ 20.5 mm²/s, measured at 40°C.

Example

The example given here is a cleaning additive used inside tanks of chemical tankers to clean off the residues of bulk liquids after unloading. The mixture is composed of 7 components including a mineral oil like solvent and a non-toxic solvent.

Table XVIII.1 - Components, concentrations and GESAMP Hazard Ratings of mixture components

Component	Concentration as %	Rating
A	0.1	M R
B	0.2	Ss R
C	0.5	M
D	9.5	T
E	15	–
F	30	A
G	43.1	–

For assessing the rating of the mixture under column D3 the concentration limits from Table 18 have to be used according to Table XVIII.2 and XVIII.3.

Table XVIII.2 - Components and concentrations triggering any C, M, or R mixture rating

Component	Concentration (%) triggering a C rating	Concentration (%) triggering an M rating	Concentration (%) triggering an R rating
A		0.1	0.1
B			0.2
C		0.5	
D			
E			
F			
G			
Criteria	**$\geq$ 0.1**	**$\geq$ 0.1**	**$\geq$ 0.3**
		$\geq$ 1 for GHS Cat.2 *	
Mixture rating		**M**	**R**

* According to test data in the GESAMP data files used to assign a rating, this would need to correspond to a GHS Cat. 2 classification.

Table XVIII.3 - Components and concentrations triggering a T, Ss, or A mixture rating

Component	Concentration (%) triggering a T rating	Concentration (%) triggering Ss rating	Concentration (%) triggering a A rating
A			
B		0.2*	
C			
D	9.5*		
E			
F			30
G			
Criteria	**$\geq$ 1 for GHS Cat.1**	**$\geq$ 1 for GHS Cat. 1B**	**$\geq$ 10****
	$\geq$ 10 for GHS Cat.2 STOT *	**$\geq$ 0.1 for GHS Cat.1A**	
Mixture rating			**A**

* According to test data in the GESAMP data files used to assign a rating, this would need to correspond to a GHS Cat. 2 or a sub-cat. 1B classification. For those who have no access to the confidential GESAMP information, a different rating of the mixture would result.

** The mixture must have a kinematic viscosity $\leq$ 20.5 mm^2/s, measured at 40°C.

When adding up the percentages of the relevant components and applying the concentration triggering a rating according to Table 18, the GESAMP Hazard Rating in column D3 would read "**A M R**".

However, for those not having access to the scientific evaluation and test data of the components B, C and D for assigning the GESAMP Hazard Rating a rating of the mixture under column D3 with "**A M R Ss T**" would result (see the footnotes under Tables XVII.2 and XVIII.3).

The GESAMP Hazard Evaluation Procedure

	A Bioaccumulation and Biodegradation			B Aquatic Toxicity	
Numerical Rating	A1 Bioaccumulation		A2 Biodegradation	B1 Acute Toxicity $LC/EC/IC_{50}$ (mg/L)	B2 Chronic Toxicity EC_{10} or NOEC (mg/L)
	A1a: log P_{ow}	A1b: BCF			
0	log <1, or log > ca.7, or MW > 1000	no measurable BCF	R: readily biodegradable	AT >1000	CT >1
1	1≤ log <2	1≤ BCF <10	NR: not readily biodegradable	100< AT ≤1000	0.1< CT ≤1
2	2≤ log <3	10≤ BCF <100		10< AT ≤100	0.01< CT ≤0.1
3	3≤ log <4	100≤ BCF <500		1< AT ≤10	0.001 < CT ≤0.01
4	4≤ log <5	500≤ BCF <4000		0.1< AT ≤1	CT ≤0.001
5	5≤ log ≤ ca.7	BCF ≥4000		0.01< AT ≤0.1	
6				AT ≤0.01	

	C Acute Mammalian Toxicity				
Numerical Rating	C1 Oral Toxicity	C2 Dermal Toxicity	C3 Inhalation Toxicity		
			C3a		C3b
			vapour/mist	mist only	vapour only
	LD_{50}/ATE (mg/kg)	LD_{50}/ATE (mg/kg)	LC_{50}/ATE (mg/L)	LC_{50}/ATE (mg/L)	LC50/ATE (mg/L)
0	ATE >2000	ATE >2000	ATE >20	ATE >5	ATE >20
1	300< ATE ≤2000	1000< ATE ≤2000	10< ATE ≤20	1< ATE ≤5	10< ATE ≤20
2	50< ATE ≤300	200< ATE ≤1000	2< ATE ≤10	0.5< ATE ≤1	2< ATE ≤10
3	5< ATE ≤50	50< ATE ≤200	0.5< ATE ≤2	0.05< ATE ≤0.5	0.5< ATE ≤2
4	ATE ≤5	ATE ≤50	ATE ≤0.5	ATE ≤0.05	ATE ≤0.5

	D Irritation, Corrosion and Long-term Health effects		
Numerical Rating	D1	D2	D3
	Skin irritation and corrosion	Eye irritation and corrosion	Long-term Health effects
0	not irritating	not irritating	**C** – Carcinogenic **M** – Mutagenic **R** – Reprotoxic **Ss** – Sensitizing to skin **Sr** – Sensitizing to respiratory system **A** – Aspiration hazard **T** – Target Organ Toxicity **N** – Neurotoxic **I** – Immunotoxic
1	mildly irritating	mildly irritating	
2	irritating	irritating	
3	severely irritating or corrosive	severely irritating	
	3A Corr. (≤4 h)		
	3B Corr. (≤1 h)		
	3C Corr. (≤3 min)		

	E Interference with other Uses of the Sea		
Numerical Rating	E1 Flammability Flashpoint (°C)	E 2 Physical effects on wildlife and benthic habitats	E 3 Interference with Coastal Amenities
0	– (not flammable, does not burn)	**Fp** - Persistent Floater **F** - Floater **S** - Sinker **G** - Gas **E** - Evaporator **D** - Dissolver and combinations thereof	no interference ***no warning***
1	Fp >93		slightly objectionable ***warning, no closure of amenity***
2	60< Fp ≤93		moderately objectionable ***possible closure of amenity***
3	23≤ Fp ≤60		highly objectionable ***closure of amenity***
4	Fp <23		

Science for Sustainable Oceans

ISSN 1020–4873