GESAMP Reports & Studies No. 64

UNITED NATIONS
NEW YORK

UNITED NATIONS ENVIRONMENT PROGRAMME
NAIROBI

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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# The Revised GESAMP Hazard Evaluation Procedure for Chemical Substances Carried by Ships

**IMO/FAO/UNESCO–IOC/WMO/WHO/IAEA/UN/UNEP**
**Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP)**

## GESAMP Reports and Studies No. 64

Pub. no. 493/02

# The Revised GESAMP hazard evaluation procedure

**Columns A & B  Aquatic environment**

| Numerical Rating | A Bioaccumulation and Biodegradation | | | B Aquatic Toxicity | |
|---|---|---|---|---|---|
| | A 1 Bioaccumulation | | A 2 Biodegradation | B 1 Acute Toxicity | B 2 Chronic Toxicity |
| | log Pow | BCF | | LC/EC/$IC_{50}$ (mg/l) | NOEC (mg/l) |
| **0** | <1 or > ca. 7 | not measurable | **R**: readily biodegradable<br>**NR**: not readily biodegradable | >1000 | >1 |
| **1** | ≥1 - <2 | ≥1 - <10 | | >100 - ≤1000 | >0.1 - ≤1 |
| **2** | ≥2 - <3 | ≥10 - <100 | | >10 - ≤100 | >0.01 - ≤0.1 |
| **3** | ≥3 - <4 | ≥100 - <500 | | >1 - ≤10 | >0.001 - ≤0.01 |
| **4** | ≥4 -<5 | ≥500 - <4000 | | >0.1 - ≤1 | <0.001 |
| **5** | ≥5 | ≥4000 | | >0.01 - ≤0.1 | |
| **6** | | | | <0.01 | |

**Columns C & D  Human Health (Toxic Effects to Mammals)**

| Numerical Rating | C Acute Mammalian Toxicity | | | D Irritation, Corrosion & Long term health effects | | |
|---|---|---|---|---|---|---|
| | C 1 Oral Toxicity $LD_{50}$ (mg/kg) | C 2 Dermal Toxicity $LD_{50}$ (mg/kg) | C 3 Inhalation Toxicity $LC_{50}$ (mg/l) | D 1 Skin irritation & corrosion | D 2 Eye irritation & corrosion | D3 Long-term health effects |
| **0** | >2000 | >2000 | >20 | not irritating | not irritating | **C** – Carcinogen<br>**M** – Mutagenic<br>**R** – Reprotoxic<br>**S** – Sensitising<br>**A** – Aspiration haz.<br>**T** – Target organ systemic toxicity<br>**L** – Lung injury<br>**N** – Neurotoxic<br>**I** – Immunotoxic |
| **1** | >300 - ≤2000 | >1000 - ≤2000 | >10 - ≤20 | mildly irritating | mildly irritating | |
| **2** | >50 - ≤300 | >200 - ≤1000 | >2 - ≤10 | irritating | irritating | |
| **3** | >5 - ≤50 | >50 - ≤200 | >0.5 - ≤2 | severely irritating or corrosive<br>**3A** Corr. (≤4hr)<br>**3B** Corr. (≤1hr)<br>**3C** Corr. (≤3m) | severely irritating | |
| **4** | ≤5 | ≤50 | ≤0.5 | | | |

**Column E  Interference with other uses of the sea**

| E 1 Tainting | E 2 Physical effects on Wildlife & benthic habitats | Numerical rating | E 3 Interference with Coastal Amenities |
|---|---|---|---|
| **NT**: not tainting (tested)<br>**T**: tainting test positive | Fp: Persistent Floater<br>F: Floater<br>S: Sinking Substances | **0** | no interference<br>***no warning*** |
| | | **1** | slightly objectionable<br>***warning, no closure of amenity*** |
| | | **2** | moderately objectionable<br>***possible closure of amenity*** |
| | | **3** | highly objectionable<br>***closure of amenity*** |

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Marine Environmental Protection (GESAMP)

# The Revised GESAMP Hazard Evaluation Procedure for Chemical Substances Carried by Ships

INTERNATIONAL MARITIME ORGANIZATION
London, 2002

Printed by the International Maritime Organization
4 Albert Embankment, London SE1 7SR, United Kingdom

Pub. no. 491/01
ISSN 1020-4873
ISBN 92-801-5131-2



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**2.** This report is available in English only from any of the Sponsoring Agencies.

**3.** GESAMP wishes to draw attention to the fact that the hazard evaluation rationale was developed for the particular purpose of the development and implementation of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78). The guidance on hazard evaluation contained in this publication is therefore intended primarily to be used for that purpose. However, although it should not normally be used out of context, this guidance (or elements thereof) may be found to be 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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For bibliographic purposes this document should be cited as:

GESAMP (IMO/FAO/UNESCO-IOC/WMO/WHO/IAEA/UN/UNEP Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection), 2002. *Revised GESAMP Hazard Evaluation Procedure for Chemical Substances Carried by Ships.* Rep. Stud. GESAMP No. 64, 126 pp.

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Cover photo: Top shell, *Calliostoma zizyphinus*

## Executive summary

The revised GESAMP[1] Hazard Evaluation Procedure provides an updated set of criteria for evaluating the hazards of chemical substances that may enter the marine environment through operational discharge, accidental spillage, or loss overboard from ships. Hazards to both humans and the marine environment are considered and the information is collated in the form of a "hazard profile", an easily read fingerprint of the hazard characteristics of each substance. The hazard profiles of substances carried by ships that have been reviewed by the EHS[2] Working Group of GESAMP are published at regular intervals and a "composite list" is available from the International Maritime Organization (IMO).

In 1992, UNCED[3] [1], through its Agenda 21, Chapter 19, entitled "Environmentally Sound Management of Toxic Chemicals…", established a programme on the "harmonisation of classification and labelling of chemicals." This resulted in the United Nations "*Globally Harmonised System for Hazard Classification and Communication*" (GHS) [2], as developed by OECD[4]. The GHS is expected to enable the global harmonisation of chemical hazard classification and communication in the areas of transport, including sea, inland waterways, road and rail, as well as consumer, worker and environmental protection.

This coincided with an ongoing review of the operation of Annex II of the MARPOL 73/78[5] Convention [3], concerning the transport of bulk liquid substances by ships. After 25 years in operation IMO, together with GESAMP formed a review panel to examine the existing hazard evaluation procedure with a view to scientific modernisation. All of these initiatives provided GESAMP with the impetus to commence the revision of its hazard evaluation procedure. The revised GESAMP

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1 GESAMP; United Nations, Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection.

2 EHS; GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships.

3 UNCED; United Nations Conference on Environment and Development, 1992.

4 OECD; Organisation for Economic Co-operation and Development, Paris.

5 MARPOL 73/78; International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (IMO).

hazard evaluation procedure is concerned with chemicals transported by ships and with the protection of the marine environment, personnel at sea and people using coastal amenities. It was developed in close consultation with OECD, during its preparation of the GHS, and has therefore been carefully designed to be in harmony with the GHS. Where necessary, limited, additional hazard end-points, specific to maritime transport have been added.

The EHS Working Group of GESAMP evaluates the hazards of bulk liquid substances under Annex II and packaged dangerous goods under Annex III of the MARPOL 73/78 Convention [3]. Through its Marine Environment Protection Committee (MEPC), IMO is responsible for assigning bulk liquid substances to an appropriate pollution category on the basis of the GESAMP hazard profile. Hazard evaluation and categorisation or "classification" are thus the responsibility of separate bodies. The Pollution Categorisation System, together with appropriate ship design and operational requirements, forms the regulatory framework for the prevention of pollution from ships. Likewise, if relevant hazards are noted on the basis of the GESAMP hazard profile, the DSC[6] Sub-Committee of IMO classifies substances intended for maritime transport as a "Marine Pollutant" under the packaged dangerous goods regulations.

Much has changed since 1973 when, at the request of IMO, GESAMP first introduced principles for evaluating hazard, based on the intrinsic properties of the chemical substance, in support of the MARPOL 73/78 Convention [3]. 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 evaluation and risk assessment of chemical substances and mixtures[7], has evolved considerably over the last 30 years and GESAMP itself has done much 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, a large testing industry

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6 DSC; Dangerous Goods, Solid Cargoes and Containers Sub-Committee.

7 The definitions of "chemical substances" and "mixtures" have been taken from the GHS and are contained in the glossary. The word "product" is used as a general collective term.

provides data on a wide range of both human health and environmental end-points used in hazard evaluation and risk assessment.

Despite such advances, many substances, e.g. those that are poorly soluble, volatile, etc. are still difficult to test and evaluate. The most problematic are mixtures, particularly those, whose exact chemical composition may be poorly known and for which, little data may be available.

The volumes of chemical substances and mixtures transported by ship warrant special measures for the protection of the sea, just as they did when GESAMP first started its work 30 years ago. A single tank on board a bulk chemical tanker may hold up to as much as 3,000 tonnes and the ships themselves range from less than 1,000 to well over 40,000 tonnes. GESAMP felt that the ecological and human risk assessment of chemical substances and mixtures for marine transport would be complex under MARPOL 73/78, requiring considerably more environmental data. Early on in the process, it was therefore decided to base the revised GESAMP procedure on an expanded set of hazard endpoints[8].

With regard to bulk liquid substances and mixtures, there has been much recent debate on environmental grounds on the desirability of reducing the volume of operational discharges (tank washings) from ships. As a result of advances in ship design and construction, e.g. the application of "efficient tank stripping" devices, such reductions now seem possible.

GESAMP has revised its hazard evaluation procedure to focus on a broader range of human and environmental hazard end-points, in order to improve its usefulness. In addition to aquatic toxicity and bioaccumulation, "ready biodegradability" and physical behaviour in seawater have been included for the first time. The human health criteria have been expanded in support of occupational health and safety management on board ships. In both areas of human and environmental health, chronic effects are treated in more detail than previously.

The Revised GESAMP Hazard Evaluation Procedure replaces the original system published in 1982 as GESAMP Reports & Studies No. 17 [4] and later revised in 1989 as No. 35 [5]. The revised procedure was first published in draft form in the 1998 report of the

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[8] End-point; a discrete hazard to aquatic life or human health.

34th session of the GESAMP EHS Working Group [6]. Implementation commenced in 1999 with the re-evaluation of the approximately 660 bulk liquid substances contained in the IBC Code[9] [7], as part of a revision by IMO of Annex II of MARPOL 73/78 [3]. Valuable experience has already been gained in using the revised GESAMP hazard evaluation procedure and minor adjustments have been made accordingly.

Advice on preparing and submitting data to GESAMP, to support the evaluation of a substance, is also given. In this document, the function of each environmental or human health end-point is separately defined and their criteria described in a short introductory section; the scale on which it 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, brief guidance is given on approved, internationally available, experimental and estimation methods for generating the necessary data. Reference is made to the GHS throughout.

The "hazard profile" provides an alphanumerical fingerprint of each substance. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. In this way, information on substances evaluated by GESAMP, are made available to the widest possible audience in an instantly readable form.

Some aspects of the revised hazard evaluation procedure, e.g. relating to mixtures, poorly soluble substances, biodegradation rates in the marine environment, the use of chronic aquatic toxicity data, occupational exposure on board ships, and changes to test procedures designed to reduce the use of test animals, will all be the subject of future review. The implementation of the GHS is also a topic that will be monitored closely.

It is hoped that the revised GESAMP hazard evaluation procedure and the scientific work of GESAMP in evaluating chemical substances will continue to play an important role in protecting the marine environment and those who depend upon the sea.

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[9] IBC Code; International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.

## Acknowledgements

*Members of the EHS Working Group*

The revised GESAMP hazard evaluation procedure came to fruition through the efforts and dedication of the members of the GESAMP EHS Working Group and this report is the culmination of six years of their work: Tim Bowmer, (Netherlands; current Chairman), Peter Wells (Canada; past Chairman), Bryan Ballantyne (USA), Thomas Höfer (Germany), Derek James (United Kingdom), Peter Howgate (United Kingdom), Roger Kantin (France), Michel Marchand (France), Stefan Micallef (Malta), Mike Morrissette (USA), Finn Pedersen (Denmark), Tore Syversen (Norway), and Meiko Wakabayashi (Japan).

*Review panel*

Extensive technical and editorial comments were received from a panel of external referees, drawn from the global chemical industry, national administrations and the OECD Environment, Health and Safety Division. Their input contributed greatly to the improvement of the manuscript. Special thanks are due to: Keith Bradley (United Kingdom), Deborah Hooper (ACC), Herman Koëter (OECD), Heddy Lindeijer-Schoof (Netherlands), Hasso Marggraaf (CEFIC), Dick Schuddebeurs (CEFIC), Anthony Wagner (ACC), Heddy de Wijs (Netherlands) and Tomao Yoshida (JCIA).

*GESAMP members*

The following GESAMP members provided invaluable editorial and technical contributions to the production of this report and to the development of the revised hazard evaluation procedure: Mike Bewers (Canada), Rick Boelens (Ireland), Juan-Albert Sanchez-Cabeza (Spain), Donald Weston (USA) and Peter Wells (Canada).

The following persons were members or Technical Secretaries of GESAMP during the preparation of this report: Nik Abdullah (Malaysia), Lawrence Awosika (Nigeria), Robert Bowen (USA), Sabine Charmasson (France), Robert Duce (USA), Danny Elder (Switzerland), Robert Engler (USA), Ong Jin Eong (Malaysia), Scott Fowler (IAEA), John Gray (Norway), Richard Gowen (United Kingdom), Robert Gruszka (UN), Ramon Guardans (Spain), Paul Gurbutt (United Kingdom), John Hambrey (United Kingdom), Richard Helmer (WHO), Michael Huber (Australia), David Insull (United Kingdom), Ljubomir Jeftic (Croatia), Stjepan Keckes

(Croatia), Gwenda Matthews (UN), Piamsak Menasveta (Thailand), Heiner Naeve (FAO), Stephen Olsen (USA), Oladele Osibanjo (Nigeria), Velimir Pravdic (Croatia), Hillel Shuval (Israel), Kirsti-Liisa Sjoeblom (IAEA), Alexander Soudine (WMO), Ismat Steiner (UN), Umit Unluata (UNESCO/IOC), Omar Vidal (UNEP), Helen Yap (Philippines), Maged Younes (WHO) and Ivan Zrajevskij (UNEP).

*IMO*

The Working Group wishes to thank the following officers of IMO who supported this work over many years: René Coenen and Manfred Nauke (Technical Secretaries of GESAMP), Koji Sekimizu and Oleg Khalimonov (Administrative Secretaries of GESAMP), Norman Soutar (IMO Consultant). John Crayford (Secretary to the EHS Working Group) is especially acknowledged for many thought-provoking discussions on the nature of chemical hazards to man and the marine environment.

*General*

A special word of thanks is due to Marian Nieuwenhout (TNO) for the preparation of the final manuscript.

Finally, we wish to thank Manfred Nauke (IMO, retired) for his foresight and dedication in guiding the EHS Working Group through more than two decades of hazard evaluations on more than 2,000 chemicals, as well as for his encouragement in the writing of this report.

**Editor:** Tim Bowmer

**Technical Secretary:** René Coenen

# Abbreviations

| | |
|---|---|
| ACC: | American Chemistry Council |
| BLG: | Bulk Liquids & Gasses Sub-Committee of MEPC (IMO) |
| CG/HCCS: | Co-ordinating Group for the Harmonisation of Chemical Classification Systems (IPCS) |
| DSC: | Dangerous Goods, Solid Cargoes and Containers Sub-Committee (IMO) |
| ECETOC: | European Chemical Industry Ecology and Toxicology Centre |
| EHS: | GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships |
| ESPH: | Working Group of BLG on the Environmental Safety and Pollution Hazards of substances (IMO) |
| GESAMP: | Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (sponsored by Eight UN Agencies) |
| FAO: | Food and Agriculture Organization of the United Nations (Rome) |
| IAEA: | International Atomic Energy Agency (Vienna) |
| IBC Code: | International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IMO) |
| ILO: | International Labour Organization (Geneva) |
| IMO: | International Maritime Organization (London) |
| IOMC: | Inter-Organization Programme for the Sound Management of Chemicals (sponsored by six UN agencies and the OECD) |
| IMDG Code: | International Maritime Dangerous Goods Code (packaged dangerous goods, IMO) |
| IPCS: | International Program on Chemical Safety (Sponsored by three UN Agencies) |
| JCIA: | Japan Chemical Industry Association |
| MEPC: | Marine Environment Protection Committee (a senior Committee of IMO) |
| MARPOL 73/78: | International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 (IMO) |
| OECD: | Organisation for Economic Co-operation and Development (Paris) |
| UN: | United Nations (New York) |
| UNCED: | United Nations Conference on Environment and Development (1992) |
| UNCTDG: | United Nations Committee on the Transport of Dangerous Goods |
| UNEP: | United Nations Environment Programme (Nairobi) |

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|---|---|
| UNESCO-IOC: | United Nations Education, Scientific and Cultural Organization (Paris) |
| WHO: | World Health Organization (Geneva) |
| WMO: | World Meteorological Organization (Geneva) |

# Contents

# 1 Introduction

## 1.1 GESAMP

GESAMP was established in 1969 as an expert group to advise its sponsoring organisations (FAO, IAEA, IMO, UNESCO–IOC, WHO, WMO, UN and UNEP) on specific marine pollution problems and on issues of particular interest to its sponsors. It has met on thirty-one occasions.

The terms of reference of GESAMP were revised in 1994 (see Annex I) and broadened to create a multidisciplinary body of independent experts that provides advice at the request of its sponsoring organisations on the protection of the marine environment in general. Topics such as the global assessment of the health of the marine environment, coastal zone management, coastal aquaculture and the hazard evaluation of harmful substances carried by ships are reviewed and considered through Working Groups. These consist of GESAMP members and additional specialists chosen from around the world. Further information on the recent activities of GESAMP can be found in Wells et al. [8]. GESAMP publishes its findings through its sponsoring agencies as a series called “Reports and Studies”, 71 issues of which have appeared to date.

## 1.2 Marine pollution from ships: historical background

In the early 1970s, IMO prepared the text of provisions for an International Convention for the Prevention of Pollution from Ships (MARPOL 73). This was intended to cover all technical aspects of pollution from ships at sea. It included five Annexes covering regulations for the prevention and control of marine pollution by:

| | |
|---|---|
| Annex I | (mineral) oil, |
| Annex II | noxious liquid substances carried in bulk, |
| Annex III | harmful substances carried by sea in packaged form, |
| Annex IV | sewage from ships, |
| Annex V | garbage from ships. |

Prior to 1973, difficulties in categorising the hazards of chemical substances carried by ships, in a manner suitable for the development of control measures, were experienced by IMO. 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, GESAMP agreed in 1971 that an *ad hoc* Panel of IMO and GESAMP experts (see Annex II, Table II.1 of this document) 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 as part of MARPOL 73/78 [3].

Following the conclusion of the above Convention, GESAMP agreed 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 subsequently met on 37 occasions. The terms of reference of the EHS Working Group are shown in Annex I.2, while the list of experts who have been members is given in Annex II, Table II.2.

In 1982 GESAMP published both its hazard evaluation rationale and a list of hazard profiles of substances in GESAMP Reports and Studies No. 17 [4]. This was updated in 1989 in Reports and Studies No. 35 [5]. These reports provide detailed information on the development of the hazard evaluation of "harmful substances" carried by ships. Harmful substances are defined under MARPOL 73/78 [3], 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".*

Originally, GESAMP was requested to evaluate the properties of substances transported in bulk by sea. This was later extended to packaged dangerous goods but excluded:

- oil as defined in MARPOL 73/78 [3], Annex I; and
- radioactive substances transported as packaged dangerous goods.

These are the subjects of different scientific expertise and regulatory control, outside of the remit of MARPOL 73/78 [3], Annexes II & III.

## 1.3 Review of MARPOL 73/78, Annex II

By the middle of the 1990s, IMO through its MEPC, had begun to review Annex II of MARPOL 73/78 [3], which regulates the control of pollution by "noxious liquid substances" carried in bulk by ships. The intention was to simplify the text and make it easier to understand, while at the same time taking new developments since its adoption into account.

At the same time, international, non-governmental organisations, as well as some governmental administrations requested that as part of the hazard evaluation procedure, developed by GESAMP more than twenty 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, themselves involved in the hazard evaluation of chemicals, were also of the opinion that the system was in need of review in order to take account of major advances in environmental sciences in the intervening years. In response, MEPC established a panel of experts in 1995, to review the GESAMP evaluation procedure. The experts (See Annex II, Table II.1) were selected from national administrations, members of GESAMP, chemical industry associations and environmental groups. 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.

The structure of the revised procedure itself was approved in principle by GESAMP in 1998. The full text, including many further refinements to ensure harmonisation with the GHS was finalised at the 37th session of the EHS Working Group and approved by GESAMP at its XXXI session in New York in August 2001.

## 1.4 Global harmonisation of chemical classification systems

In 1992, UNCED [1], through its Agenda 21, Chapter 19, entitled the "Environmentally Sound Management of Toxic Chemicals, Including Prevention of Illegal, International Traffic in Dangerous Products", established a programme on the "harmonisation of classifications and labelling of chemicals". Its objective was that

> *"a globally harmonised 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 IPCS as the nucleus for international co-operation on Chapter 19 activities. After the establishment of the Inter-Organization Programme on the Sound Management of Chemicals (IOMC) in 1995, the co-ordinating Group, CG/HCCS for this activity, which had already been established by ILO under the auspices of IPCS, was renamed IOMC CG/HCCS and was given the task to promote and oversee the work of developing the GHS. CG/HCCS had requested the 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 Harmonisation of Classification and Labelling in 1994, to oversee and manage this work. These activities resulted in the Harmonised Integrated Hazard Classification System for Chemical Substances and Mixtures [2] [10], which is currently being prepared for implementation as part of the "Globally Harmonised System" by a new (GHS) Sub-Committee of the UN Committee on the Transport of Dangerous Goods.

During the development of the GHS [2], concerns arose regarding the way in which a "harmonised" classification system might be used and whether it would meet the needs of its various end-users. In this regard attention is drawn to one of the principles outlined by the CG/HCCS Co-ordinating Group as follows:

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[10] In this report reference to the GHS is made through the original OECD document on classification of human health and environmental end-points, pending preparation of the full text of the GHS by the UNCTGD.

> *"harmonisation 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."*

It was also considered essential that uniform cut-off values[11] for each hazard end-point be identified as part of the evaluation criteria, so forming a fundamental basis for the GHS.

The activities of 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 Harmonisation 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 has been developed using these principles of harmonisation as its basis, while bearing the specific needs of evaluating chemical substances for transport by ships clearly in mind.

## 1.5 The modern shipping industry

The revised GESAMP hazard evaluation procedure is primarily concerned with the evaluation of the hazards of chemical substances and mixtures. The only substances not included are mineral oils and radioactive substances as pointed out above and the revised GESAMP hazard evaluation procedure is suitable for evaluating the hazard of substances transported by sea as bulk liquids, bulk solids or as packaged dangerous goods.

### 1.5.1 Bulk liquid cargoes

A modern chemical tanker may range in size from ca. 1000 to 50,000 tonnes dead weight, and for the purpose of carrying hazardous substances, most will be of double hulled construction to prevent

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[11] A cut-off value indicates the point on the scale of a given hazard criterion, e.g. acute aquatic toxicity, or skin irritation and corrosion, 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.

outflow of cargo in the event of collision or grounding. Tankers carrying less hazardous or non-hazardous chemical substances may be of far less sophisticated construction, and are often single hulled. A large chemical tanker may be equipped with as many as 35 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 within the harbour are removed 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 where compatibility from a safety standpoint is concerned and previous cargoes where contamination is concerned.

Chemical tankers need to discharge tank washings, and the IMO-designated pollution categories 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 clearly 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 100 litres or less. The double hull 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 pre-wash (e.g. with hot water and tank cleaning additives) after emptying to remove clinging material, in which case, the residues are discharged to shore. Some viscous substances are pumped on and off tankers at elevated temperatures and such a pre-wash is not always mandatory.

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 for dealing effectively with hazardous waste brought onshore is available in every country. In the absence of shore reception facilities, the tank washings from particularly hazardous cargoes may have to be transported on to a harbour where such facilities are available.

The residues of moderately hazardous substances are permitted to be discharged into the sea but only in limited quantities and in circumstances as follows:

- under the waterline,
- 12 miles offshore,
- with 25 meters or more of water under the keel, and
- at a speed of not less than 7 knots.

Currently, less hazardous substances must be diluted by a factor of 10:1 and can be discharged in unlimited volumes. So-called "non-hazardous" substances are unregulated and have no discharge criteria at present. However, it is increasingly recognised that even these substances should not be put into the sea in unlimited amounts and under uncontrolled conditions.

As indicated in section 1.3, for the present and new generations of chemical tankers, IMO is currently reviewing:

- "ship typing", i.e. the design of ships required for cargoes of various hazards (e.g. double hull),
- the Pollution Categorisation System (assigned on the basis of the GESAMP hazard profile),
- the carriage conditions, i.e. the minimum criteria required for safe handling and transport of each substance on board,
- the discharge criteria applied to the cargo, with a view to limiting discharges in line with advancing technologies.

It is anticipated that chemical tankers of the future will have tank stripping equipment that will reduce the volumes of cargo residue and, therefore, the volume of operational discharges at sea, or to harbour reception facilities to a very low level.

### 1.5.2 Packaged dangerous goods

Substances carried as packaged dangerous goods are defined under Annex III of Marpol 73/78 [3] as "those substances which are identified as Marine Pollutants in the IMDG Code" [9]. On the basis of the GESAMP hazard profile, the DSC Sub-Committee of IMO classifies substances intended for maritime transport. If the substance falls within the DSC criteria, then it is classified as a "Marine Pollutant".

Chemicals in the form of packaged dangerous goods are carried in approved packaging mostly within standardised containers. The packaging must be adequate to minimise the hazard to the marine environment, having regard to their specific contents. Furthermore, to ensure correct identification, the labelling on packages should be sufficient to withstand three months immersion in the sea.

Ships carrying such containers may be of very large size and the nature of the cargo is “mixed”. Each ship is obliged to carry a “special list or manifest setting forth all the harmful substances on board and the location thereof”. By contrast with bulk liquid cargoes, operational discharges are not involved.

# 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,
- to provide a set of human health and safety criteria to assist IMO in its work of assigning the "carriage conditions" for each substance, in particular those appropriate to the protection of the crew onboard chemical tankers,
- to help protect the marine environment from the effects of operational discharge, accidental spillage and loss overboard of substances from ships,
- to include hazard end-points which would enable IMO to regulate the transport of bulk chemical cargoes, considering that the load volume may exceed those of packaged dangerous goods (including portable tanks containing products regulated by the IMDG Code [9]) by several orders of magnitude and,
- to ensure harmonisation with the GHS [2].

## 2.2 The original hazard evaluation procedure

The five main columns (A to E) plus the "remarks" column of the original hazard profile took into account the list of effects of chemical substances which GESAMP had been requested to evaluate under MARPOL 73/78 [3]. These are listed in Table 1 below.

***Table 1*** *Explanation of the original GESAMP hazard evaluation procedure*

| Column | Title | Hazard | Comment |
|---|---|---|---|
| **A** | Bioaccumulation and tainting | ♦ bioaccumulation in fish and shellfish<br>♦ tainting of seafood | bioaccumulation to "significant extent", with attendant harm to the organism |
| **B** | Damage to living resources | aquatic toxicity to fish and crustaceans | measured in appropriate aquatic ecotoxicity tests |
| **C** | Hazard to human health: ingestion of water containing the chemical | acute oral toxicity to humans | measured in appropriate tests with laboratory animals |
| **D** | Risk to human health by skin and eye contact or inhalation | irritation or injury to the skin, mucous membranes, or eyes and inhalation hazard | measured in appropriate tests with laboratory animals, or from human experience |
| **E** | Reduction of amenities | ♦ objectionable slicks<br>♦ presence of poisonous, irritant or foul smelling substances<br>♦ impairment of scenic value<br>♦ drums or packages | amenities meant to mean all aspects of recreational use; this column was used to provide guidance to local authorities regarding the closure of beaches |
| **Remarks** | | ♦ "Unusual" hazards to fishing or navigation etc.<br>♦ Carcinogenicity<br>♦ Other adverse health effects | all other relevant hazards and explanatory remarks |

## 2.3 Structure of the revised GESAMP hazard profile

During the review process, the familiar five-column system has been retained; however, each column has been divided into several sub-columns, in order to separate the underlying hazard information as far as possible and make it clearer to the user. A summary of the end-points used can be found in Table 2, while the back cover contains a complete overview of end-points, cut-off values, rating and symbols.

***Table 2*** *Summary of the end-points used in the revised GESAMP hazard evaluation procedure*

| Title | Column | Hazard criterion | Comment |
|---|---|---|---|
| ***A Bioaccumulation and Biodegradation*** | | | |
| | **A1** | ♦ Octanol/Water partition coefficient (log Pow) and/or Bioconcentration factor (BCF) | ♦ measures of the tendency of a substance to bioaccumulate in aquatic organisms |
| | **A2** | ♦ Ready biodegradability | ♦ used to identify substances with favourable biodegradation characteristics (% degradation to CO2 and water in 28d) |
| ***B Aquatic toxicity*** | | | |
| | **B1** | ♦ Acute aquatic toxicity | ♦ toxicity to fish, crustaceans and micro-algae, generally measured in appropriate laboratory tests |
| | **B2** | ♦ Chronic aquatic toxicity | ♦ reliable data on chronic aquatic toxicity, primarily based on fish and crustaceans |
| ***C Acute mammalian toxicity*** | | | |
| | | Distinguishes 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 | |
| | **C2** | ♦ Dermal | |
| | **C3** | ♦ Inhalation | |

*(cont.)*

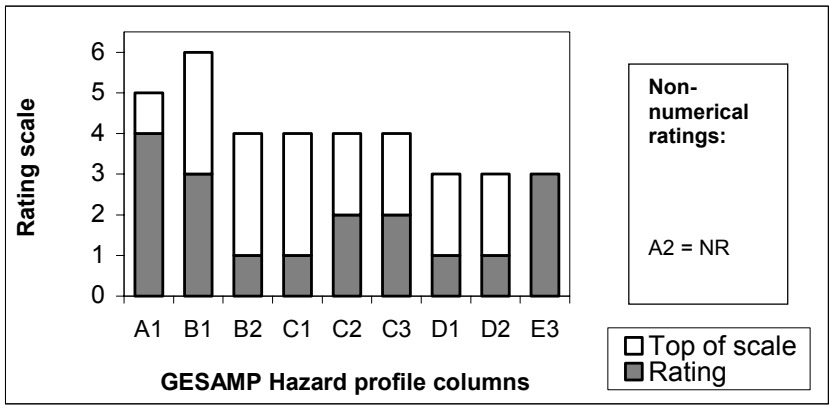
*Table 2 cont.*

| Title | Column | Hazard criterion | Comment |
|---|---|---|---|
| ***D Irritation, corrosion & 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 & corrosion | |
| | **D3** | ♦ Long-term health effects | Carcinogenic, Mutagenic, Reprotoxic, Sensitiser, Aspiration hazard Target Organ Systemic Toxicity: Lung injury, Neurotoxic, Immunotoxic |
| ***E Interference with other uses of the sea*** | | | |
| | **E1** | ♦ Tainting | ♦ Off flavours in seafood following spillage of cargo |
| | **E2** | ♦ Behaviour of chemicals in the marine environment and physical effects on wildlife and on benthic habitats | ♦ Behaviour in seawater, i.e. the tendency to form slicks or blanket the seabed; evaluated on the basis of solubility, vapour pressure, specific gravity & viscosity |
| | **E3** | ♦ Interference with coastal amenities | ♦ Necessity of closing beaches due to physical hazards and specific health concerns |

The revised GESAMP hazard profile consists of the end-points listed in Table 2 above. Each of the 13 new 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 Column B1 (acute aquatic toxicity). An abbreviated legend to the whole hazard profile and its ratings can be found on the back cover.

A hazard profile is illustrated below in Fig. 1, where it can be seen that the substance in question:

***Figure 1*** *Graphical and tabular (under) illustration of a revised GESAMP hazard profile for a given substance X (see text above for further explanation of columns and ratings)*




| A1 | A2 | B1 | B2 | C1 | C2 | C3 | D1 | D2 | D3 | E1 | E2 | E3 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4 | NR | 3 | 1 | 1 | 2 | 2 | 1 | 1 | C | 0 | Fp | 3 |

- 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 & B2);
- has a low oral, moderate dermal and a moderate inhalation toxicity to mammals (C1–C3);
- is mildly irritating to skin and eye (D1 & D2);
- is potentially carcinogenic (D3);
- is not liable to taint seafood (E1);
- is a floating substance liable to form persistent slicks on the water surface (E2);
- forms a significant physical hazard to onshore and offshore amenities (E3).

The explanation of the descriptive terms and the largely quantitative ratings is further developed in detail in Section 4. The rating scales

begin at 0 ("practically non-hazardous" or of "negligible hazard") and run to a maximum of 3 to 6, indicating steadily more severe hazard.

## 2.4 Relationship of the old and new hazard profile systems

Since early 1999, the EHS Working Group has evaluated over 500 of the ca. 660 bulk liquid substances contained in the IBC Code [7] according to the revised GESAMP hazard evaluation procedure, as presented in this report. The target date for completion of this task requested by IMO is the year 2002. In order to speed up this process, GESAMP has agreed that in future only hazard profiles according to the new evaluation procedure will be assigned, i.e. the revision will not update the old profiles.

## 2.5 Other uses of the profile

The original and revised GESAMP hazard evaluation procedures were designed for the particular purpose of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78).

The revised GESAMP hazard evaluation procedure provides a range of information on the properties of substances with respect to the protection of the aquatic environment and human health. In some cases the hazard profiles may be used outside their intended context, e.g. in assessing discharges of effluents into the aquatic environment from sea-based activities (e.g. offshore platforms), from land-based activities, as well as in emergency response situations. (See notes on page ii.)

# 3 Preparation of data: advice to manufacturers and administrations

## 3.1 Submitting data to GESAMP

Submissions on chemical substances 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

Copies of the form set out in Annex VII of this document may be obtained from IMO and should be used for this purpose. The following sections (3.2 to 3.11) provide information on data quality, confidentiality, how to deal with missing data, use of analogies, weight of evidence, as well as initial guidance on dealing with mixtures. In Section 4, guidance is provided on how to approach the testing of each end-point in the Hazard Profile.

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

The GESAMP EHS Working Group meets once, and occasionally twice, each year at IMO Headquarters in London to consider requests to evaluate new chemical substances, or to amend existing hazard profiles. Organisations planning to submit data on chemical substances for evaluation by GESAMP are advised to find out the dates of the relevant meeting by contacting the above address. Having submitted data, it is often helpful, if a representative of the company is available by telephone, fax or e-mail during EHS meetings, in case contact is required to clear up any issues relating to the evaluation of their chemical substances.

GESAMP, through its EHS Working Group, encourages industry involvement in the preparation of the hazard profiles. Of necessity, the sessions of the GESAMP EHS Working Group are closed meetings. However, representatives from chemical manufacturers, their branch 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 in cases where whole groups of substances are being reviewed or re-evaluated.

The results of the evaluation of chemical substances are published in the meeting reports of the GESAMP EHS Working Group and tabled at the next GESAMP session. Following approval by GESAMP, the hazard profiles are published periodically as circulars by IMO and distributed to IMO Member States and observer organisations. In addition, a composite list is published annually by IMO containing the hazard profiles of all chemical substances evaluated during the last thirty years.

## 3.2 Data recording by the EHS Working Group

In addition to retaining the supporting data on each substance, the EHS Working Group of GESAMP records the rationale behind its ratings for each hazard end-point (sub-column) of the hazard profile. The aim is to be able to reconstruct each profile in future years. With careful recording of all decisions on ratings, manufacturers and administrations should be able to query decisions that have been made by GESAMP and its EHS Working Group. The rationale as well as the supporting data will continue to be added to the confidential files on each substance maintained on behalf of the EHS Working Group by IMO.

## 3.3 Data confidentiality

Over 2,200 substances, including many mixtures, have been evaluated in the last 30 years. Original data submitted by manufacturers through administrations remain confidential. As noted above, such proprietary data are maintained by IMO and only made available to members of the GESAMP EHS Working Group.

In recent years, a large proportion of “proprietary” environmental data on industrial chemicals has entered the public domain e.g. through the IUCLID database [10], published by the European Chemicals Bureau.

## 3.4 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. In principle, GESAMP will continue to search for qualifying information, to complement and confirm the scientific data submitted by manufacturers. Where environmental data are concerned, the log Pow is generally calculated from the molecular structure (where known) of all organic chemicals and used as a quality control measure for both bioconcentration and aquatic toxicity data. For human health data, the accuracy of data contained in submissions is cross checked against information in the open literature.

## 3.5 Missing data

GESAMP strives to issue the hazard profiles in the most complete form possible. This, however, depends on the completeness, integrity and reliability of the data submitted by the manufacturer or shipper of the substance. 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 not be accepted for evaluation.

When reviewing older profiles, where data may often be lacking, the EHS Secretariat at IMO, may invite the chemical industry to co-operate in providing additional data. Such substances are reviewed again, once sufficient data has become available.

In the context of bulk liquid transport by ships, it should be noted that while several of the sub-columns are not used by IMO for assigning pollution categories or for “ship typing”, they may well be required to assign carriage requirements based on safety considerations.

## 3.6 Estimation techniques

GESAMP prefers the use of appropriate experimental data. However, in instances of accidental poisoning, human experience will also be taken into account. All available information is considered together by the experts and ratings are given on the basis of the total weight of evidence, in order to evaluate the hazard of substances.

However, where experimental data on bioaccumulation or acute aquatic toxicity are not available, then generally accepted estimation techniques may be applied on a case by case basis. Only *validated* or otherwise reliable Quantitative Structure Activity Relationships

(QSARs) for the chemical group in question are acceptable. Estimation techniques for biodegradation may be accepted to show that a substance is *not* readily biodegradable, in order to avoid further (and often pointless) testing.

Extrapolation techniques for deriving mammalian toxicity data and chronic aquatic toxicity are generally regarded as being inadequate. However, this is an aspect that will be reviewed in the future.

## 3.7 Rating by analogy

In cases where data on closely analogous substance(s) are available, these may be used as a basis to provide a rating for one or more hazard end-points (sub-columns), whether relating to the marine environment or to human health. It is always advisable to contact the EHS secretariat at IMO prior to making a submission on the basis of an analogy.

Manufacturers are encouraged to approach homologous groups of substances by first providing a complete data set for selected members. Following consultation, the EHS Working Group may then agree to rate the other substances in the group by analogy.

Where manufacturers choose to submit data on a closely analogous substance, then the exact analogy and complete supporting information should be provided. Significant data gaps in the supporting analogy may lead to rejection. In such cases, estimated (non-experimental) data may be considered as a data gap.

## 3.8 Rating of mixtures

Extensive consideration has been given to the classification of mixtures as part of the GHS [2] in a separate chapter entitled the "*Harmonised Hazard Classification Criteria for Mixtures*". 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".*

"Mixtures" are defined as:

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

Using these definitions, the EHS Working Group of GESAMP encounters many mixtures, including "natural" mixtures such as hydrocarbon distillates, and deliberate mixtures such as solutions, preparations etc. The GHS "*Harmonised Hazard Classification Criteria for Mixtures*" has yet to be considered by the EHS Working Group of GESAMP, which is the body responsible for the hazard evaluation of substances. On the other hand, IMO is responsible for the pollution categorisation of bulk liquid substances and the classification of packaged dangerous goods as "Marine Pollutants".

Annex III of this report contains guidance on the naming of substances, particularly mixtures, for the purposes of submission to GESAMP and ultimately to IMO. The hazard profile provides an ideal format for a modular approach to mixtures, allowing components to be compared at a glance. Brief practical guidance on testing mixtures is given in Section 4 for some of the hazard end-points. This guidance will be further developed in the future.

At present the EHS Working Group of GESAMP rates the hazard of mixtures on a case by case basis, focussing on the most hazardous components present in significant quantities. The rationale behind each decision is recorded in the substance file at IMO. It is recognised that where the aquatic environment is concerned, 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.

## 3.9 Weight of evidence

Where only a single set of data is available, e.g. an acute fish, crustacean and algal toxicity test, then the lowest $LC_{50}$ value of the three is used to provide a rating. However, many substances have acquired large databases for many of the hazard end-points in recent years and a weight of evidence approach has become necessary to ensure that the rating reflects the body of data rather than simply the most conservative value.

The distribution of data often lies across more than one rating band. In such cases, the EHS Working Group of GESAMP examines the data at the upper and lower ends of the distribution to see whether they support the main body of evidence, or whether there is reason to disregard such data as "outliers". More severe, but less reliable data

may be rejected in favour of more reliable test results. Where the aquatic environment is concerned, taxonomic considerations, including whether the organism is of marine or freshwater origin may also be taken into account, and expert judgement is used by GESAMP to issue a rating in such cases.

In the future, GESAMP will examine the possibility of using statistical techniques to address this problem, e.g. the modelling of data distributions in combination with the use of appropriate "hazard" percentiles.

## 3.10 Rating notation and confidence in the supporting data

GESAMP issues a rating in one of the following ways:

- a full rating indicating that GESAMP reached consensus based on data specific for a product or on adequate supporting evidence;
- a rating "in brackets" may be used to indicate when an end-point has been rated by analogy, by an estimation method, etc. However, ratings in brackets may also be given for a limited period, indicating that the GESAMP experts have sufficient confidence to provide a provisional rating but that some clarification is still required. It should be pointed out that this would allow the product to be shipped.
- the symbol NI (no information) may be placed in any column to indicate that insufficient data were available to allow GESAMP to provide even a provisional rating for that end-point. In such circumstances, IMO may not be able categorise the product under Annex II or III of MARPOL 73/78 [3].

GESAMP makes every effort to list the hazards to human health including the long-term health effects covered in 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 is placed in 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.

## 3.11 Periodic review of substances by GESAMP

During its first decade of activities, GESAMP recognised that many substances could only be tentatively evaluated and that these initial assessments would need to be reviewed as more data became available. There have been cases where hazard profiles were challenged by manufacturers' representatives or trade associations. In the past, MEPC has regularly requested GESAMP to review major groups of chemical substances, e.g. polyether polyols, and vegetable/animal oils. Subject to the availability of new data, GESAMP accordingly reviews individual and groups of substances from time to time.

# 4 Hazard evaluation end-points

The hazards arising from a range of intrinsic properties of each chemical substance are evaluated. The selection of these hazard "end-points" was largely determined by the requirements of MARPOL 73/78 [3], as well as the current needs of IMO. Consideration was also given to the end-points included in the GHS [2]. These hazard end-points are set out below in the order of the GESAMP hazard profile columns.

The following sections are provided with an individual introduction to each hazard end-point; this is followed by a description of the ratings and the manner in which they are applied. Each section contains guidance on selecting the appropriate test methods (see boxes 1 to 10). Extensive guidance is contained in the relevant OECD document [11], included as part of the GHS [2].

## 4.1 Column A: Bioaccumulation and Biodegradation

The tendency of 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 in aquatic organisms is a general term describing the complex process by which chemical substances are taken up into the body through all exposure routes (water, food and sediment). Bioaccumulation results in the presence of a substance(s) in the tissues of an organism. 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 what happens in the marine environment. However, bioconcentration tests do provide an accurate measure of the *intrinsic* tendency of a given substance to accumulate in living tissues, and are therefore considered appropriate for use in the revised GESAMP hazard evaluation procedure.

**Box 1 Guidance on the required quality standards of test reports**

With regard to laboratory testing to generate data for the revised GESAMP hazard evaluation procedure, there is a strong preference for studies carried out under the OECD principles of Good Laboratory Practice (GLP) [12]. Studies should be carried out to Internationally standardised test guidelines, e.g. OECD, or International Standards Organisation (ISO) documents. In certain cases, National standards such as the US EPA Office of Pesticides, Prevention and Toxics (OPPTS) series which is largely derived from OECD test Guidelines may be appropriate.

Care should be taken to ensure:

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

With respect to the environmental end-points, a detailed technical guidance document has been prepared by the OECD as part of the GHS [2, 11] to aid in developing data for classifying substances as dangerous for the aquatic environment. The reader is referred to this document for a more detailed guidance on this issue than is possible here.

Expert judgement will be used by GESAMP to evaluate the quality and interpret the results of older studies.

A bioconcentration test proceeds until a constant concentration of the substance has been reached in the tissue of the test organism relative to the constant concentration in the water, through simultaneous uptake (e.g., by gill or epithelial tissue) and elimination. The exposure duration needed to reach such a steady state will often depend on how hydrophobic/lipophilic (see Log Pow below) the test substance is. In this way, the bioconcentration factor (BCF) can be established. The BCF is in fact the water–tissue partition coefficient.

However, a surrogate for the BCF, i.e. a partition coefficient, is available which can be measured or estimated in a much more simplistic manner for organic chemicals. The living organism is replaced by n-octanol, which can be seen as representing the fatty tissues of the fish, in particular the phospholipid bi-layers of the cell membranes. Usually, expressed as the logarithm to the base 10, it is referred to as the log Kow or log Pow. It is one of the most important of a group of partition coefficients used to predict the behaviour of chemicals in environmental compartments, e.g. Kd (soil/sediment

adsorption constant), Koc (organic matter adsorption constant), Ka (water-air partition constant), etc. Regrettably, the log Pow does not apply to inorganic chemicals.

The log Pow is used by the EHS Working Group in three ways:

- to predict the potential of an organic chemical to bioaccumulate in fish tissues;
- to estimate "baseline toxicity" to aquatic organisms for organic substances. Baseline toxicity data derived from the log Pow are routinely used by GESAMP for assessing the reliability of measured ecotoxicity test data (see Box 5 and section 4.2.1.3.3);
- In the absence of reliable water solubility data, the log Pow can be used to provide estimates of aqueous solubility.

There are several published methods for measuring the log Pow; two of the best known are internationally standardised [13, 14] and routinely used in the hazard assessment of chemicals. Additionally, there are two systems for calculating the log Pow [15, 16] from molecular fragment values.

For values below 4, log Pow data generally provide sufficient information in their own right. However, above values of 4, *measured* log Pow data may underestimate, whereas *calculated* log Pow data may overestimate bioaccumulation. Therefore, at log Pow 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. The measured BCF may ultimately result in a less severe hazard rating than the log Pow, as it allows for processes such as metabolism in the tissues of the organism, which may enhance the excretion of a substance.

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

- **A1a:** the log n-octanol/water partition coefficient (log Pow);
- **A1b:** the measured bioconcentration factor (BCF) using fish, crustaceans or molluscs as test organisms.

**Box 2 Guidance for experimentally measuring and calculating the log Pow**

Several methods are available. When commissioning log Pow 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. Readers are advised to use internationally accepted standards, e.g. OECD. Where very high log Pow values are expected, the slow stirring method is recommended as described below. Surface active and easily emulsified compounds are generally difficult to test experimentally.

*OECD Guideline 107; the shake flask method.* [13]
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 log Pow's of slightly below 0 (highly water soluble) to ca. 4 (moderately lipophilic). This method has the disadvantage that many chemicals are easily emulsified, in which case the equilibrium may be disturbed by non-dissolved substance in the water phase.

*OECD Guideline 117; reversed phase High Pressure Liquid Chromatography method [14]*
This is an indirect method, where the retention time on a C18 loaded HPLC column is used to estimate the log Pow. This method is suitable for measuring log Pow 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 Pow values in the range of 6 to 8 to the recommended calibration series.

*Slow-stirring method*
The slow-stirring method of de Bruijn et al. [17] 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 Pow of up to 8 can be measured depending on the limits of analytical detection available. It is not as well standardised as the two OECD methods.

*Generator column method [18]*
The generator column method is an indirect method in which the compound is dissolved in n-octanol and coated onto an appropriate material contained in a generator column (e.g. a HPLC column). The method is used to provide saturated solutions of the compound in water and is apparently suitable for highly hydrophobic substances up to log Pow values of 8.5. The disadvantage is that insufficient time may be available to reach equilibrium in all cases.

*Calculating the log Pow using fragmental constants*
It is extremely useful to be able to calculate the log Pow. The hydrophobic fragmental constant method of Rekker (1977) [19] and Rekker & Mannhold (1992) [15] and a comparable method provided by Hansch [16] are both suitable for estimating log Pow values. The two methods are roughly equivalent. Today there are several commercially available computer packages for calculating log Pow [20].

Data on fish are preferred, as frequently used and standardised test methods are available (see Box 2). 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, bioaccumulation data on microalgae are not used.

#### 4.1.1.2 Ratings

For bioaccumulation a rating scheme has been developed in sub-column A1 as shown in Table 3.

***Table 3*** *Revised GESAMP hazard profile rating scheme for bioaccumulation*

| Rating | Description | Criteria for log Pow | Criteria for BCF |
|---|---|---|---|
| **0** | No potential to bioaccumulate | ♦ *≤ 1, or*<br>♦ *>ca.7, or*<br>♦ *Mol. Wt. > 1000* | *no measurable BCF* |
| **1** | Very low potential to bioaccumulate | *≥ 1 – < 2* | *≥ 1-- < 10* |
| **2** | Low potential to bioaccumulate | *≥ 2 -- < 3* | *≥ 10 -- < 100* |
| **3** | Moderate potential to bioaccumulate | *≥ 3 -- < 4* | *≥ 100 -- < 500* |
| **4** | High potential to bioaccumulate | *≥ 4 -- < 5* | *≥ 500 -- < 4000* |
| **5** | Very high potential to bioaccumulate | *≥5 -- < ca. 7* | *≥ 4000* |

The substances most likely to pose a hazard to aquatic organisms through bioaccumulation typically have log Pow values ranging from 4 to 7.

From Table 3 above, it can be seen that a log Pow of > ca.7 would generally lead to a "0" rating. GESAMP felt that there was sufficient evidence to show that the majority of organic chemicals carried by ships with log Pow values of > ca. 7 would show little tendency to bioaccumulate. Van Leeuwen & Hermens [21] (see pages 257–260)

discuss this topic in some detail in relation to log Pow estimation methods. However, it is recognised that several groups of highly persistent substances, e.g. PCBs and PCDDs as well as other heavily chlorinated groups of substances, form well-known exceptions to this rule, and log Pow values of as high as 8.25 have been measured [21] where associated bioaccumulation does take place.

Measuring the bioconcentration and bioaccumulation of metals provides some problems due to the fact that grain size, solubility and therefore, bioavailability of the substance are often complicating factors. Most available data have been derived from testing of water-soluble metal salts. However such data may not be applicable for assessing the bioaccumulation potential of non-soluble metals and metal complexes. Suitable experimental methods "for assessing the transformation/dissolution of metals and metal compounds" have only recently been developed by OECD [2]. Moreover, some essential and even non-essential metals may be taken up by the organism through active transport rather than simple diffusion processes. The environmental hazard of metals posed through bioaccumulation remains difficult to estimate and interpret.

#### 4.1.1.3 Application

1. Where the log Pow exceeds a value of 4, the substance is considered to "bioaccumulate to significant extent" unless the measured 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. This cut-off value is being considered in the context of the revision of Annex II of MARPOL 73/78 [3], as part of the pollution categorisation and "ship typing" system and is also contained in the GHS [2].

2. In general, measured BCF data when available will be used to overrule log Pow data provided that the study is scientifically sound and well documented.

**Box 3 Guidance for measuring bioconcentration in fish**

The bioconcentration factor (BCF) is defined as the ratio (on a weight basis) between the concentration of the chemical in biota and the concentration in the surrounding water, at steady state. The BCF can thus be 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 in the past. However, most have been consolidated in the OECD 305 [22] test guideline, entitled "Bioconcentration: Flow-through fish test".

In measuring the BCF, the focus is generally on the parent compound and not the metabolites where pure substances are concerned. 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 metabolised carbon, which have been incorporated in the fish tissue in organic molecules. As a result, BCF values determined by the measurement of radioactivity tend to overestimate the presence of the parent compound in the fish tissues. When using radiolabelled substances, the labelling is most often placed in the stable part of the molecule, for which reason the measured BCF value includes the BCF of the metabolites. Occasionally, it is the metabolite which is the most toxic and which has the highest bioconcentration potential. In such cases, measurements of the parent substance as well as the metabolites may be important for the interpretation of the aquatic hazard (including the bioconcentration potential) of such substances.

3. Substances with very high log Pow values (> ca. 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 Pow will be used to derive a rating. This cut-off point was included to avoid classifying non-bioaccumulating substances with high log Pow values such as vegetable and animal oils (triglycerides).

4. Substances with molecular weights of >1,000 are also assumed not to be accumulated [23, 24] as the molecular size is generally too large to pass through cell membranes.

5. Log Pow values are only applicable to organic substances, including organo-metals. The bioaccumulation potential of inorganic substances must be derived from test results, although as indicated above, the testing of chemicals of low aqueous solubility is often difficult.

6. Experimentally derived bioconcentration factors may be more appropriate to assess the bioaccumulation potential of non-organic substances as well as some surfactants, and organo-metallic substances.

7. Where mixtures are concerned, data on a worst case (i.e. highest) value of a range of components may be used to provide a rating, depending on the proportion of that component in the mixture. In general, a log Pow or BCF value will be required for all major components. Expert judgement will be applied in such cases.

### 4.1.2 Sub-column A2: (Bio)degradation

#### 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 preventing biological effects. It is generally accepted that metabolism by microbes is one of the most important routes of degradation of organic substances. Other degradation routes, e.g. through hydrolysis and photolysis may also be of importance for some chemicals. With the exception of agricultural pesticides, there are little data available on the actual degradation rates of most chemicals in relevant environmental compartments, such as water and aquatic sediments, while data for the marine environment are particularly poor. As a result, an alternative "regulatory" approach is used. Tests designed to select rapidly biodegrading substances are used to group those that demonstrate the least environmental hazard. This is termed "ready biodegradability" and there is a wide range of tests, based on $O_2$ consumption, $CO_2$ evolution or dissolved organic carbon removal, with which it can be measured. Some of these tests are described in detail in Annex IV.

It is to be hoped that as biodegradation rate constants become more widely available, e.g. from a new generation of simulation tests currently under development [25], this rating system may be further developed. Photolysis, hydrolysis or other forms of rapid removal, e.g. by dissociation of inorganic substances in water, may also be taken into account as evidence of "ready" or rapid degradation. Inorganic compounds are not rated as part of this end-point, but are labelled as such (abbreviated to "inorg."), to indicate that (bio)degradability data is not required. The dissolution and transformation rates of non-soluble metal compounds in the aquatic environment may be further considered in the future, but this may be more appropriately related to bioaccumulation, aquatic toxicity and behaviour in water (e.g. sinking), rather than to degradation.

#### 4.1.2.2 Ratings

The rating notation for Sub-column A2 is shown in Table 4 and the pass and fail conditions are given in "Application" below.

***Table 4*** *Rating scheme for ready biodegradability*

| Rating | Description |
|---|---|
| **R** | readily biodegradable |
| **NR** | not readily biodegradable |
| **Inorg.** | Inorganic substance |

#### 4.1.2.3 Application

1. The (bio)degradation sub-column A2 refers to substances that are considered to be "readily biodegradable" if, in 28-day biodegradation studies, the following levels of degradation are achieved:

   - in tests based upon dissolved organic carbon (DOC) die-away: ≥ 70%;
     **or**
   - in tests based upon oxygen depletion or carbon dioxide generation: ≥ 60% of the theoretical maxima;
     **or**
   - where only COD and $BOD_5$ data are available, the ratio of $BOD_5/COD \geq 0.5$;
     **or**
   - 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.

2. The exact values of percentage biodegradation within 28 days should be reported, together with the methods that have been used.

**Box 4 Guidance for measuring ready biodegradability**

The area of biodegradation testing is complex and there are many test guidelines, some of which are more suitable than others. Annex IV contains an overview of "ready" biodegradation test methods, with some explanatory text. The terminology is further explained in the glossary.

Marine tests, e.g., OECD 306 [26] are preferred. There is evidence to show that biodegradation proceeds less rapidly in marine waters compared to freshwater environments [27], although this may vary widely from location to location, e.g. polluted harbours, coastal waters and pristine oceanic water. The above method uses non-adapted natural seawater as the only source of micro-organisms. However, as nutrients are added to sustain growth, it cannot be considered as a simulation of the natural environment. Further information is required on the relationship between freshwater biodegradability tests using non-adapted activated sewage sludge inocula (OECD 301 A-F) [28] and those using only seawater as the inoculum (e.g., OECD 306 [26]).

However, freshwater tests, e.g., the OECD 301 A-F series, ISO 9439 [29], ISO 10707 [30] or EPA-OPPTS equivalents, are acceptable at least for the foreseeable future. All of these tests are inoculated with activated sludge from sources such as "domestic" waste-water treatment plant (receiving domestic and not industrial effluent) and are thus expected to encourage biodegradation to a greater extent than the seawater design described above.

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

3. Biodegradation estimation methods based on structure–activity relationships are not generally accepted as evidence of ready biodegradability. However, evidence from recognised estimation methods which indicates that a compound *may not be readily biodegradable* may provide sufficient evidence to avoid testing, in which case an (NR) rating may be assigned. The brackets are used to signify that the substance has not been tested.

4. Given the diversity of test methods available for determining ready bioavailability and the generally conservative nature of this criterion, GESAMP did not feel that the application of the "10-day window", an even more stringent rate function recommended in the relevant OECD guidelines was justified.

5. It is strongly recommended that mixtures be approached on a modular basis, i.e. by testing their significant components separately. Biodegradation tests on mixtures only show

mineralisation of the most degradable components, while less degradable components remain behind.

## 4.2 Column B: Aquatic Toxicity

Column B has two sub-columns, one representing acute aquatic toxicity tests (B1), and the other containing information on chronic aquatic toxicity (B2).

Aquatic toxicity is generally expressed as the $LC_{50}$, $EC_{50}$ or $IC_{50}$[12]. In acute tests, the $LC_{50}$ is usually determined for fish and crustaceans, the $EC_{50}$ (immobility) for the commonly used freshwater crustacean *Daphnia magna*, while the $IC_{50}$ or $EC_{50}$ (reproduction and/or growth) generally applies to microalgae. 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 a water solubility of <1 $mg.l^{-1}$ and two approaches are available for testing this type of substance.

With poorly soluble pure substances, the water solubility is first determined accurately. Then the substance is tested using a concentration series at and below the saturation level in water. Where no acute toxicity can be measured within 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",*

where *x* is the near-saturated 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 $LC/EC/IC_{50}$. Confirmation of the exposure concentrations using chemical analysis is essential.

Where mixtures are concerned, differential solubility of the components may make conventional testing and analysis very difficult and a different approach may need to be taken. 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 h to allow a partial equilibrium to be achieved. The phases are allowed to separate for ca. 4 h and the

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[12] $LC_{50}$, lethal concentration; $EC_{50}$, effect concentration (must be defined); $IC_{50}$, population inhibition concentration – all to 50% of a given test population.

test water (less test substance) is tapped directly into the test vessels and the test organisms introduced. In such cases, the test results are expressed as the "loading rate" ($LL_{50}$/$EL_{50}$ and $IL_{50}$*13*), rather than the exposure concentration.

### 4.2.1 Sub-column B1: Acute aquatic toxicity

#### 4.2.1.1 Introduction

In order to rate the hazard posed by chemical substances to aquatic organisms, the most practical solution available is still considered to be the use of acute toxicity test data. Data relating to organisms representing the middle to upper levels of an aquatic food chain, e.g. crustaceans and fish are used, in addition to microalgae which represent primary producers at the base of the food-chain.

It is recognised that the standardised tests carried out according to international guidelines do not represent what will necessarily happen when substances of low solubility, low density and high volatility are spilled or discharged at sea. However it is important that all substances be considered on the same basis, namely that of their toxicity under standardised and controlled conditions.

#### 4.2.1.2 Ratings

The acute aquatic toxicity ratings cover the range from > 1000 mg/l down to < 0.01 mg/l as shown in Table 5. The bands of toxicity separate groups of substances on a log scale in order to reflect the hazards associated with:

- very high volumes of substances with relatively low toxicities (e.g., LC/$EC_{50}$ 100–1,000 mg/L);
- the toxicity bands of the GHS (i.e. 10–100, 1–10 and < 1 mg/L*14*);

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*13* $LL_{50}$, Lethal Loading rate; $EL_{50}$; Effect Loading rate; $IL_{50}$, Inhibition Loading rate – all for 50% of a given test population.

*14* Acute class I of the GHS contains all substances with an LC/EC/$IC_{50}$ of < 1 mg/L. The revised GESAMP hazard evaluation procedure simply divides this group into three. Apart from the reasons given above, this is intended to enable IMO to consider in detail the categorisation of mixtures at a later date.

- substances which by their very high (0.1–0.01 mg/L) or extreme (> 0.01 mg/L ) toxicity may be hazardous in small quantities.

The majority of these bands of toxicity are used at present in regulating substances under MARPOL 73/78 [3], Annexes II and III (bulk liquids and packaged dangerous goods).

***Table 5*** *Revised GESAMP rating scheme for acute aquatic toxicity*

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

**Box 5 Guidance for measuring acute aquatic toxicity**

Acute aquatic toxicity tests are carried out commercially by many contract research laboratories. It is advisable to select reputable laboratories with experience in testing difficult substances, as many substances transported in bulk by sea fall into this category, by reason of their poor solubility (see Annex V), volatility, tendency to solidify at ambient temperatures, etc.

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 organo-metallic 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. In general, data from freshwater aquatic toxicity tests are acceptable for evaluation by GESAMP.

***Fish***
The appropriate test for measuring the acute aquatic toxicity to marine fish, is OECD 203 [31]. 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.

***Crustaceans***
Tests with marine crustaceans can be carried out according to the ISO 14669 [32] guideline. The recommended species in recent years are the copepod *Acartia tonsa* and the mysid shrimp *Mysidopsis bahia*. Other well-established guidelines covering additional marine crustaceans may also be acceptable. Where freshwater data is already available, a test with the water flea *Daphnia magna* according to OECD 202 Part A [33] is acceptable.

***Microalgae***
Microalgal toxicity tests can best be carried out under ISO 10253 (marine) [34], ISO 8692 (freshwater) [35] or OECD 201 (freshwater) [36] 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 materials is given in ISO 10634 [37]. Bowmer et al. [38] reported that small molecular weight reactive compounds such as formaldehyde, glutaraldehyde and chloroacetic acid are less toxic to diatomaceous algae (taken to be representative of the marine environment), such as *Skeletonema* or *Phaeodactylum* than they are to typical freshwater green algae such as *Scenedesmus* or *Selenastrum*.

**(cont.)**

**Box 5 (cont.)**

***Testing poorly soluble pure substances and mixtures***
Annex V to this document contains guidance on methods for exposing organisms to poorly soluble mixtures, whose components may exhibit a variety of different behaviours in water. For further advice on this topic, the reader is referred to the guidance provided by organisations such as ISO [37], ECETOC [39] and OECD [40].

***Analytical determination of exposure concentrations.***
In general, 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. Where mixtures are concerned, this may be problematic. A useful approach to testing may be to use Total Organic Carbon analysis of the test media rather than specific chemical analysis. The reader is referred to the specific guidance contained in the relevant OECD guidelines and to the above guidance documents [37, 39, 40].

#### 4.2.1.3 Application

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

   - 96 h $LC/LL_{50}$ fish tests,
   - 48-96 h $LC/LL_{50}/EC/EL_{50}$ crustacean tests, and
   - 72-96 h $EC/EL_{50}/IC/IL_{50}$ micro-algal growth inhibition tests.

2. Where only one value for each of 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 weight of evidence approach for larger data sets is considered in section 3.9.

3. Data from either standard freshwater or marine aquatic toxicity tests will be used for assigning ratings. The processes governing the expression of toxicity in freshwater and marine organisms are generally similar. Baseline toxicity upon exposure to non-polar organic substances, i.e., the accumulation of substances in the phospho-lipid bi-layer of the cell membrane until saturation is reached and the cell dies, is common to both freshwater and marine organisms. This also probably holds true for polar organic substances. However, reactive substances generally show much lower toxicity in seawater. In such cases, marine data are preferred and may provide a more realistic assessment of the toxicity of substances to marine organisms.

4. Toxicity data from groups of organisms other than fish, crustaceans and microalgae may be considered as additional evidence.

### 4.2.2 Sub-column B2: Chronic aquatic toxicity

#### 4.2.2.1 Introduction

Chronic toxicity addresses the impacts of longer-term exposure of aquatic organisms. Chronic toxicity 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;
- accidental spills from ships, where the time-scales involved may be longer than expected, bearing in mind the large volumes potentially involved, in particular where substances bioaccumulate or are slow to degrade.

Hazards due to chronic aquatic toxicity are also recognised by the GHS. However, for reasons such as the lack of data, expense, and its primary concern with packaged dangerous goods, the OECD elected instead to use "surrogate chronic" data in the form of acute aquatic toxicity, biodegradation and bioaccumulation, for the GHS noting that:

> *"... it has been recognised that where chronic toxicity data are available, it should be possible to use these in defining the appropriate hazard band. The development of specific criteria using such data is thus a high priority in the future development of the scheme" [2].*

GESAMP is of the opinion that there are strong scientific reasons for using real chronic data in its peer reviewed system and, bearing the above in mind, have included it on a discretionary basis in the revised hazard evaluation procedure. It is the remit of IMO to decide on the role, if any, of chronic aquatic toxicity or surrogate data systems e.g. in the pollution categorisation of bulk liquid substances.

A mechanism to link the acute and chronic rating scales was not felt to be appropriate, as it was not the intention that chronic toxicity should be used to overrule acute toxicity data but that it would be considered in its own right. As a result, the acute and chronic scales have been given an independent rating system. Many common industrial substances, particularly those with a (non) polar (baseline) mechanism of toxicity have acute to chronic ratios of less than 10. Many reactive

**Box 6 Guidance for measuring chronic aquatic toxicity**

Consultation with the GESAMP EHS secretariat at IMO is advisable prior to commissioning chronic aquatic toxicity tests.

***Fish***
Suitable tests for measuring chronic toxicity to fish include the fish early life stage test (OECD 210) [41] and the 28d fish juvenile growth test (OECD 215) [42]. Equivalent national or regional test guidelines may also be acceptable. Chemical analysis to measure the exact exposure concentrations is essential. For investigating such specific endpoints as endocrine disruption or reproductive disturbance in fish, suitably adapted versions of the above test guidelines are recommended.

***Crustaceans***
A suitable standardised test for determining chronic toxicity to marine crustaceans is described in the US-EPA 850.1350 guideline [43] for *Mysidopsis bahia*. A useful equivalent that is not yet internationally standardised is a chronic test with *Acartia tonsa* reported by Minshan & Møhlenberg [44]. Data from freshwater species, e.g. the *21d Daphnia magna* reproduction test (OECD Test Guideline 211, replacing 202 Part 2) [45] may also be 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 endpoints include time to first brood, number of offspring produced per female, growth, and survival.

substances and those with specific mechanisms of toxicity, such as biocides and pesticides may have much higher acute to chronic ratios (1000 or more). Substances with high acute to chronic ratios as well as specific long-term effects will be distinguished in this way.

#### 4.2.2.2 Ratings

The ratings for chronic aquatic toxicity are placed in a separate sub-column, using a log scale, based primarily on the No Observed Effect Concentration (NOEC) as shown in Table 6 below. The NOEC is defined as the highest concentration tested at which no significantly different effects from the control population are observed (e.g. survival, reproduction or growth). Where a NOEC is not available, an EC10 calculated from the experimental effect data may be substituted. Box 6 lists suitable test methods, including their exposure times and endpoints such as growth inhibition and reproduction. As with the GHS, substances with a chronic NOEC of > 1mg/L are not considered to be chronically toxic.

***Table 6*** *Ratings for chronic aquatic toxicity*

| Rating | Description | No Observed Effect Concentration *(mg/l)* |
|---|---|---|
| **0** | negligible | *> 1* |
| **1** | low | *> 0.1 -- ≤ 1* |
| **2** | moderate | *> 0.01-- ≤ 0.1* |
| **3** | high | *> 0.001-- ≤ 0.01* |
| **4** | very high | *≤ 0.001* |

#### 4.2.2.3 Application

1. Chronic aquatic toxicity data will not be routinely requested from industry. However, at the discretion of GESAMP, such data may be requested in the following cases:

   - ♦ for poorly soluble substances where the acute toxicity is difficult to estimate accurately and where there is a suspicion of effects, or where it is claimed that the substance is "non-toxic" within the limits of solubility,
   - ♦ where definite chronic effects are suspected, e.g., growth, development or reproduction,
   - ♦ where a specific mechanism of toxicity is expected, e.g. with pesticides, and
   - ♦ substances that are known to degrade slowly and/or bioaccumulate.

   The cost effectiveness of such tests may be taken into account prior to making such a request.

2. The choice of test organism will generally be the most sensitive group among the available acute tests.

## 4.3 Column C: Acute mammalian toxicity by swallowing, skin penetration and inhalation

### 4.3.1 General remarks

Column C addresses the toxic potential of chemicals to humans after single or short-term exposures. The hazards related to the oral, dermal, skin contact and inhalation exposure routes are considered under three sub-columns (C1, C2 and C3). The rating system is based on numerical dose or concentration values from animal tests, expressed as $LD_{50}$ [15], values for oral and dermal hazards, and $LC_{50}$ for inhalation hazards.

$LD_{50}$ or $LC_{50}$ values have been used for many decades to indicate the dose leading to severe, life threatening or acutely toxic effects and such data usually form the basis upon which chemicals are compared with each other regarding hazards for human health. Historically, such numerical data are used by many regulatory systems as the first and sometimes the most important hazard classification criterion for the protection of human health.

GESAMP is aware of the limitations when using data from acute toxicity tests with mortality as the single endpoint, in particular when no other detailed information can be examined. These issues have been extensively discussed in a variety of forums and publications. It is generally accepted that in principle, there should be considerably more aspects evaluated for defining an acute hazard than the median lethal dose alone. While most toxicological knowledge on this topic derives from animal experiments, human experience in instances of accidental poisoning has to be taken into account. All available information is considered together by the experts and ratings are given on the basis of the total weight of evidence.

Nevertheless, in combination with the above mentioned evidence, $LD_{50}$ and $LC_{50}$ values form an essential basis in evaluating hazard to human health and Column C has consequently been defined according to the GHS [2].

There has been growing public concern about the use of laboratory animals for lethal dose testing. Based on animal welfare principles, such tests are the subject of much criticism. The OECD has already published alternative guidelines to the classic $LD_{50}$ tests aimed at a

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[15] $LD_{50}$, lethal dose to 50% of the exposed population.

reduction in both the numbers used and the stress on test animals. Alternative testing approaches based on structure-activity relationships (SAR) or the use of *in vitro* test systems have been presented in the scientific literature but as yet have not been sufficiently validated. Developments of such alternative methods will be closely monitored by GESAMP and the content of this chapter may be amended as appropriate in the future.

#### 4.3.1.1 Ratings

The ratings, and the data on which these should be based, are shown in Table 7 below.

***Table 7*** *Rating system for acute mammalian toxicity by swallowing, skin penetration and inhalation (sub-columns C1, C2 and C3 respectively).*

| Rating | Relative Hazard | C1<br>Oral $LD_{50}$ (mg/kg) | C2<br>Dermal $LD_{50}$ (mg/kg) | C3<br>Inhalation $LC_{50}$ Vapours (mg/l/4hrs) |
|---|---|---|---|---|
| **0** | Negligible | > 2000 | > 2000 | > 20 |
| **1** | Slight | > 300 – ≤2000 | > 1000 – ≤2000 | >-10 – ≤20 |
| **2** | Moderate | > 50 – ≤300 | > 200 – ≤1000 | >-2 – ≤10 |
| **3** | Moderately high | > 5 – ≤50 | > 50 – ≤200 | > 0.5 – ≤2 |
| **4** | High | ≤5 | ≤50 | ≤0.5 |

#### 4.3.1.2 Application

1. The quality and consistency of the data are of great importance. Generally, reliable human data will be given precedence over animal data.

2. Values from the most susceptible mammalian species or sex are used, except where there is convincing evidence that toxicity in humans might be different. Occasionally, questionable data from animal studies may be disregarded even though it is reported in various databases.

3. In general, for interspecies extrapolation, detailed models e.g. based on metabolism or body surface are not taken into account and dose values in "mg/kg" are used directly.

4. The revised GESAMP Hazard Evaluation Procedure does not include a separate toxicity class from 2000 to 5000 mg/kg as contained in the GHS, because this is not currently required under MARPOL 73/78 [3] for categorising substances.

5. As the principle mode of exposure on board ships and after spillage is expected to be through vapours, the above ratings are orientated towards animal experiments using vapours. It is recognised that the test atmosphere in most experiments will not just be a vapour but will consist of a mixture of liquid and vapour phases. GESAMP will evaluate data on substances known to form mists, dusts and gasses on a case by case basis, bearing the cut-off values contained in the GHS [2] in mind.

### 4.3.2 Sub-column C1: acute oral toxicity

Standardised tests are preferred for evaluation (see Box 6). In evaluating a chemical whose toxic potential is unknown, it is often useful to conduct a range-finding study or a limit-test. The $LD_{50}$ ($LC_{50}$) would be reported as "greater than" if no death of experimental animals is observed within 14 days. Such results can be fitted into the rating scale and will be evaluated accordingly.

### 4.3.3 Sub-column C2: acute dermal toxicity (skin contact)

Experience has shown that chemicals that are non-toxic by the oral route are generally also non-toxic by the dermal route. Experience has also shown that orally toxic chemicals are also toxic by dermal application. Such facts may enable experts to estimate the toxic potential, thus allowing a rating in brackets. Range-finding studies and limit-tests are taken into account as outlined for oral toxicity testing above.

### 4.3.4 Sub-column C3: acute inhalation toxicity

The criteria for inhalation toxicity are based on $LC_{50}$ data relating to 4 hr exposures; where such information is available it should be used. Where $LC_{50}$ data relating to 1 hr exposures are available, such values can be divided by 4 to be considered equivalent to $LC_{50}$ (4 hr). From a scientific viewpoint and from practical experience in inhalation toxicity testing, the test atmosphere will not just consist of vapour but will consist of a mixture of liquid (mist) and vapour phases in most

cases. As long as there is no validated extrapolation method, GESAMP will err on the safe side when evaluating data close to the classification limits and especially in the case of experimental designs using nearly saturated vapour concentrations. Submissions to GESAMP should only state the original data and not extrapolated data in such cases.

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

$$mg / l\ (20°C) = \frac{ppm \times molecular\ weight}{24 \times 1000}$$

Because of the complexity of acute inhalation studies and the need to minimise animal testing, there is considerable interest in estimating inhalation toxicity based on other data, *inter alia,* the acute oral lethal toxicity. Although there have been proposals for extrapolation techniques, there is as yet no scientifically accepted nor validated method. For regulatory purposes, it may be possible to take such "indicators" into account for determining the need for testing or estimating the inhalation hazard. After thorough investigation GESAMP has decided to refrain from using numerical extrapolation in this respect and will note missing values accordingly. However, an evaluation of a number of toxicological and physical data of one chemical or inhalation test results from chemicals with similar structures may enable GESAMP experts to estimate the toxic potential, thus allowing a rating in sub-column C3 given in brackets.

Data for acute inhalation toxicity may not be available for several reasons, e.g.:

- it is deemed unethical to carry out animal experiments on substances known to cause undue pain and stress to the animal;
- the physical or chemical properties of the chemical is such that relevant tests cannot be carried out.

In such cases GESAMP will attempt to make a provisional rating in order to advise relevant bodies as to the hazards believed to be presented by inhaling the chemical. This will be identified in column C3 by a rating in brackets. In making such an advisory rating GESAMP will consider the following:

- the oral and dermal toxicity;
- the irritating/corrosion potential to the skin and eye;

**Box 7 Guidance on acute oral, dermal and inhalation toxicity testing**

Over the last twenty years, appropriate test guidelines for assessing acute toxicity to mammals have been consolidated and published by the OECD, to the extent that other guidelines are now seldom used. 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 if the experimental procedures are considered acceptable. It should be noted that small differences between protocols can cause large differences in the resultant median lethal dose values. It is recommended to evaluate old data by using original test reports as far as possible.

New testing should be based on OECD Guidelines and should be performed under *Good Laboratory Practice* (GLP) [12].

***Acute oral toxicity***
Wherever possible, testing for acute oral toxicity should be based on standardised 14 day post-dosing observation tests with rats. The recommended methods are:

- OECD 420, Acute Oral Toxicity – Fixed Dose Method [46]
- OECD 423, Acute Oral Toxicity – Acute Toxic Class Method [47]
- OECD 425, Acute Oral Toxicity: Up-and-Down Procedure [48]

Following withdrawal of the OECD 401 guideline for "Acute Oral Toxicity" based on concerns for animal welfare, GESAMP no longer recommend its use for determining the LD50.

***Acute dermal toxicity***
For measuring dermal toxicity, standardised LD50 tests with rats or rabbits are preferred, using 24 hour occlusion with two weeks of observation. The recommended guideline is OECD 402, Acute Dermal Toxicity (1987) [49]. Alternatives similar to the above 420, 423 and 425 methods are being drafted and discussed as part of the OECD test guideline development process.

***Acute inhalation toxicity***
Wherever possible, ratings for inhalation toxicity should be based on standardised 14 day post-dosing observation tests with rats. The recommended guideline is OECD 403, "Acute Inhalation Toxicity", draft, updated guideline based on that first published in 1981 [50].

In the absence of LC50 data, substances may be rated based on simple threshold toxicity tests, e.g. as outlined in the UN Model Regulations on the Transport of Dangerous Goods [51].

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

There will undoubtedly be occasional cases where an advisory rating cannot be made and where GESAMP also recognises that inhalation studies cannot be carried out. In such cases, an "NI" rating will be applied in sub-column C3 and a remark added to the Remarks column indicating that inhalation studies will not be requested by GESAMP.

## 4.4 Column D: Irritation, corrosion and long term health effects

This column considers the hazards of chemical posed by irritation and corrosion of the skin and eyes, as well long term health effects.

The skin and eyes of humans may become contaminated by chemical substances in a wide variety of situations, e.g. in the work environment on board ship, or on the dockside, when swimming in the ocean and during maritime rescue operations. The effects of chemicals on direct contact with the skin and eyes are rated under sub-columns D1 and D2 respectively. A numerical rating is given based on data from human experience or animal tests. Long term human health concerns are given in 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 skin is one of the largest organs of the body (about 10% of the normal body weight) and is readily exposed to the surrounding environment. A number of environmental factors may play an important role in the development of chemically induced skin damage; e.g. temperature, humidity, friction and wind speed. Chemicals cause irritation and corrosion of skin through several mechanisms. In most cases several pathological pathways may occur at the same time. However, the classification of damage due to irritation or corrosion of the skin is based on morphology rather than on measures of specific mechanisms.

The most prominent effects of chemicals on the skin can be grouped as follows (the clinical terms used below are further explained in the glossary):

- Irritant dermatitis which includes sensory irritation (burning, stinging or itching sensations which are not due to infections), irritation and chemical burns (a continuum of varying tissue destruction) and cumulative dermatitis (effects occur after repeated exposure to mild irritants);

- Allergic contact dermatitis where the chemical is an allergen that induces an allergic reaction in the skin;
- Photosensitisation including phototoxicity (a non-immunological light induced dermatitis caused by a photoreactive chemical) and photoallergy (similar to allergic contact dermatitis except that the chemical must react with light before becoming allergenic);
- Skin carcinogenesis;
- Acne and specifically chloracne (induced by some chloro-hydrocarbons).

Sub column D1 only addresses the first of these groups (irritant dermatitis), some of the others being covered in Column D3.

Data for skin irritation/corrosion can be obtained from human experience, animal experiments and to a limited extent from *in vitro* assays. Testing in animals includes studies on sensitisation and irritation. Standard procedures as well as standard rating systems for evaluation have been developed.

For the purpose of assigning a rating in the sub-column D1, data are collected from current databases, the literature and test reports. These sources may reflect experiments carried out during a wide time period and performed under variable quality surveillance. Sometimes the test may not have been carried out 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. The tiered testing system designed by OECD to reduce the use of test animals, as recommended by the GHS should be followed when commissioning new tests.

Exposures of 4 hour duration are preferred but data from 24 hour exposures will also be accepted and this latter data will be used directly, without extrapolation, whilst recognising that this may err on the side of caution.

#### 4.4.1.2 Ratings

The ratings and descriptions used for sub-column D1 are shown in Table 8 below.

***Table 8*** *Rating system for skin irritation and corrosion*

| Rating | Description | Signs |
|---|---|---|
| **0** | Not irritating | No clinical signs and/or inflammation |
| **1** | Mildly irritating | Mild erythema with or without oedema (rapidly reversible) |
| **2** | Irritating | ♦ Marked erythema<br>♦ Obvious and marked oedema<br>♦ Other signs of local injury |
| **3** | Severely irritating or corrosive | ♦ Severe irritation indicating local tissue damage<br>♦ Full-thickness skin necrosis, applied when exposure time is not reported |
| **3A** | Corrosive | Full-thickness skin necrosis by 4 hr |
| **3B** | | Full-thickness skin necrosis by 1 hr |
| **3C** | | Full-thickness skin necrosis by < 3 min |

#### 4.4.1.3 Comparison with the GHS

The following table illustrates the relationship between the GESAMP rating and the GHS [2].

***Table 9*** *A comparison between the GESAMP skin irritation and corrosion ratings and those of the GHS [2], allowing conversion of ratings from both systems*

| **GESAMP** | | **GHS** | |
|---|---|---|---|
| **Rating** | **Description** | **Rating** | **Description** |
| **0** | Not irritating | | |
| **1** | Mildly irritating | **Class 3** | Mild Irritant |
| **2** | Irritating | **Class 2** | Irritant |
| **3** | Severely irritating or corrosive without exposure time being indicated | | |
| **3A** | Corrosive 4 hr | **Corrosive sub-class 1C** | Corrosive 4 hr |
| **3B** | Corrosive 1 hr | **Corrosive sub-class 1B** | Corrosive 1 hr |
| **3C** | Corrosive < 3 min | **Corrosive sub-class 1A** | Corrosive < 3 min |

The following may help to explain some of the apparent differences between the two rating systems shown in Table 9 above:

- All GESAMP sub-columns representing hazard end-points, with the exception of D3 and E2 use a rating of "0" indicating that the available data indicate that no effects have been found for the end-point/criterion in question;
- All GESAMP hazard ratings are numbered from low to high numerical values representing increasing degrees of hazard, or in this case irritation and/or corrosion;

- Accepting these differences in presentation, it is possible for substances to be rated in either system using the same set of data.

### 4.4.2 Sub-column D2: eye irritation

#### 4.4.2.1 Introduction

Injuries to the eye are quite common both in the workplace and in the home. Correct hazard classification of chemical substances that may cause eye injury is therefore of prime importance in preventing injury.

The eye can be a target itself or a route for toxicity as follows:

- direct contact with the eye can cause irritant, corrosive, allergic or deep tissue damage to the eye itself or the surrounding tissue;
- chemicals can be absorbed through surrounding blood vessels and cause systemic toxicity;
- chemicals can be absorbed through other routes and reach the eye through systemic circulation.

The D2 sub-column addresses only the first of these issues.

Testing possible effects of chemicals on the eye is generally carried out in a rather simple manner by exposing the eye 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 conjunctivae are noted and scoring systems have been developed in order to summarise the effects. Draize and co-workers introduced the best known of these in 1944 [52]. Alternative testing methods have been developed where fewer animals are used, and in some cases *in vitro* methods are being introduced. The GHS recommends a tiered testing system, including *in vitro* tests, to reduce the numbers of test animals used.

The hazard rating used by GESAMP accommodates data from existing studies as well as the type of data recommended by the GHS [2]. However, GESAMP does not at this time, readily accept data from *in vitro* studies, as such methods have yet to be fully validated. This is an issue that will be kept under review.

#### 4.4.2.2 Ratings

The ratings and descriptions used in sub-column D2 are given in Table 10 below.

***Table 10*** *Ratings for eye irritation and corrosion*

| Rating | Description | Clinical signs |
|---|---|---|
| **0** | Not irritating | No clinical signs and/or inflammation |
| **1** | Mildly irritating | Reversible mild conjunctival hyperaemia with or without chemosis |
| **2** | Irritating | Marked conjunctival hyperaemia, chemosis, corneal injury – all reversible within three weeks |
| **3** | Severely irritating with irreversible corneal injury | Severe conjunctoblepharitis, chemosis, irreversible corneal injury (may be accompanied by deformity, ulceration and neovascularisation) |

#### 4.4.2.3 Comparison with the GHS

Table 11 illustrates the relationship between the GESAMP ratings and the UN-GHS [2] system as developed by OECD.

***Table 11*** *A comparison between the GESAMP eye irritation and corrosion ratings and those of the GHS [2], allowing for conversion of ratings from both systems*

| GESAMP | | GHS | |
|---|---|---|---|
| **Rating** | **Description** | **Rating** | **Description** |
| **0** | Not irritating | | |
| **1** | Mildly irritating | **Class 2A** | Mild Irritant |
| **2** | Irritating | **Class 2** | Irritant |
| **3** | Severely irritating with irreversible corneal injury | **Class 1** | Corrosive |

The following may help to explain some of the apparent differences between the two systems shown in Table 11 above:

- All GESAMP hazard end-points (with the exception of D3 and E2) use a rating of "0" indicating that no effects have been found;
- All GESAMP hazard ratings are numbered from low to high numerical values representing increasing degrees of hazard or in this case irritation and/or corrosion;
- Accepting these differences in presentation, it is possible for most chemicals to be rated in either system using the same set of data.

**Box 8 Guidance on acute dermal and eye irritation and corrosion tests**

Both of the current OECD test guidelines are under review and, while these revisions have not yet been officially published, the reader is none the less advised to take the draft, updated guidelines into account when commissioning testing.

***Acute dermal irritation & corrosion***
The recommended test is:

OECD 404: Acute Dermal Irritation/Corrosion [53], and the revised draft, updated guideline.

***Acute eye irritation & corrosion***
The recommended test is:

OECD 405: Acute Eye Irritation/Corrosion [54], and the revised draft, updated guideline.

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

#### 4.4.3.1 Introduction

There are a wide variety of chemical hazards to human health besides those listed in Columns C1, C2, C3, D1 and D2. Long term health hazards as a result of either single or repeated exposures are listed in Table 12 below.

***Table 12*** *Sub-column D3, long term human health effects not given in other columns, showing the hazard end-points and their descriptions, as well as abbreviations for use in the GESAMP hazard profile sub-column.*

| Notation in Column D3 | Hazard end-points | Description |
|---|---|---|
| *The end-points Carcinogenic, Mutagenic, Reprotoxic and Sensitising are also considered separately under the GHS, whereas Photosensitising is not.* | | |
| **C** | Carcinogenic | Chemicals which have been shown to induce or increase the incidence of cancer. |
| **M** | Mutagenic | Chemicals that have been shown to cause increased incidence of permanent changes in the amount or structure of the genetic materials. |
| **R** | Reprotoxic | Chemicals causing adverse effects on reproductive ability or capacity, or on the development of offspring. |
| **S** | Sensitising | Chemicals causing skin or airway hypersensitisation. Photosensitising chemicals are those which require light to become activated, and will be indicated by an **Sp** symbol. |
| **A** | Aspiration hazard | Lung injury directly or after swallowing. |
| **T** | "Target organ oriented systemic toxicity" (TOST) following single or repeated exposure | Significant changes to the function or morphology of an organ, or the biochemistry or haematology of an organism and which are relevant to the health of the organism (See the GHS) |

*cont.*

*Table 12 (cont.)*

| Notation in Column D3 | Hazard end-points | Description |
|---|---|---|
| *The following long-term health effects would be classed as: single or repeated exposure target organ oriented systemic toxicity by the GHS, but because of their relevance to the working environment on board ships and previously adopted practice within GESAMP, have been separately listed here below.* | | |
| **L** | Lung injury | Chemicals causing injury to the lung after single or repeated inhalation exposure. |
| **N** | Neurotoxic | Chemicals causing damage to the central or peripheral nervous system. |
| **I** | Immunotoxic | Chemicals causing adverse effects to the immune system and interfering with body defence mechanisms. |

#### 4.4.3.2 Rating

The GHS considers several of these hazards under its Target Organ Oriented Systemic Toxicity (TOST) classification. Others such as Carcinogenicity, Mutagenicity and Reprotoxicity are defined separately here and in the GHS.

#### 4.4.3.3 Application

*Carcinogenic*

The term carcinogenic denotes substances or mixtures that are presumed to induce cancer or to increase its incidence in humans. Evidence to substantiate the notation “carcinogenic” in Column D3 should be available from epidemiological studies and/or from well conducted studies in experimental animals. On a case by case basis, scientific judgement may warrant a decision of presumed human carcinogenicity (C) derived from studies showing limited evidence in humans with limited evidence in experimental animals. In principle, GESAMP will base its decision on the evaluation of reliable evidence and on expert judgement.

*Mutagenic*

A mutation is a permanent change in the amount or structure of the genetic material in a cell. 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 notation of "mutagenicity" (M) is normally provided from studies conducted *in vivo* on mammalian somatic cells or germ cells. It is recognised that genetic events are central in the overall process of cancer development. Therefore, evidence of mutagenicity indicates that a substance has a potential to induce carcinogenic effects.

*Reprotoxic*

Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females or on the development of the offspring. The notation "reprotoxic" (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, capacity, or on development of the offspring in the absence of other toxic effects.

*Sensitiser*

The term sensitising denotes substances or mixtures, which can induce a condition of hypersensitivity in individuals following inhalation (respiratory sensitiser) or skin contact (contact sensitiser). Evidence to substantiate a notation of "sensitising" (S) in sub-column D3 should be available from human experience and/or from appropriate studies using experimental animals. The term photosensitising (Sp) denotes substances or mixtures that require light to become active and may subsequently induce a condition of contact sensitivity. Evidence to substantiate the notation of "photosensitising" in sub-column D3 should be available from human experience and/or from appropriate studies using experimental animals.

*Aspiration hazard*

Such hazards may be caused by aliphatic, alicyclic and aromatic hydrocarbons of low viscosity as well as other substances that, based on clinical experience, may cause lung damage when reaching the lung directly or after being swallowed (A). Injury is caused by the substances severe irritancy or corrosivity and may cause a

granulomatous reaction because of its insolubility and persistence in the respiratory tract.

*Target Organ Oriented Systemic Toxicity (following single or repeated exposure) (TOST)*

Under Target Organ Oriented Systemic Toxicity, according to the GHS:

> *"classification depends upon the availability or reliable evidence that* [single or repeated] *exposure to the substance has produced a consistent and reliable toxic effects in humans or, in experimental animals, toxicologically significant changes which have affected 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 purpose of this criterion is to capture adverse health effects after single or repeated exposure that are not considered under the separate headings elsewhere in the GHS. GESAMP may use this criterion in a similar manner. Some hazards that might typically fall under this criterion have previously been used by GESAMP and will therefore continue to be separately listed in Sub-column D3, e.g. neurotoxicity and immunotoxicity.

*Lung injury*

Chemicals causing injury to the lung after single or repeated inhalation exposure as evidenced by epidemiological studies or well documented animal experiments.

*Neurotoxic*

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 some time after a single exposure or may be the result of repeated exposure, even to very low doses/concentrations. 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.

*Immunotoxic*

The term immunotoxic denotes substances or mixtures, which are capable of causing injury to the immune system and interfere with body defence mechanisms. Evidence to substantiate a notation of "immunotoxic" in sub-column D3 should be available from epidemiological studies and/or from well conducted and appropriate studies in experimental animals.

## 4.5 Column E: Interference with other uses of the sea

Column E covers the hazards of operational discharges and accidental releases of substances to other uses and users of the sea and is set out in three sub-columns as shown in Table 13 below.

***Table 13*** *Column E: Interference with other uses of the sea*

| Sub-column | Potential interference with: | Criterion |
|---|---|---|
| **E1** | Fisheries | Tainting of seafood |
| **E2** | Wildlife and bottom habitats | Physical behaviour of substances in seawater<br>♦ Effects of viscous, slick-forming substances on marine wildlife<br>♦ Effects of sinking substances on benthic habitats e.g. smothering of the seabed |
| **E3** | The use of coastal amenities | Hazards to humans using beaches, coastlines, onshore and offshore installations and harbours. |

This aspect differs markedly from other hazard classification systems, e.g. the various EU new and existing chemicals directives or the GHS [2]. Given the large volumes of substances transported by ships, it was considered necessary to provide a separate criterion that would allow IMO to regulate operational discharges of less hazardous 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 marine emergency when substances are spilled, or are likely to be spilled, in the marine environment.

### 4.5.1 Sub-column E1: Tainting of seafood

#### 4.5.1.1 Introduction

*Chemical taint*

Tainting, in this context, is the process whereby seafood acquires an off-flavour following exposure of the food organism to chemical substances. Despite depuration and excretion of the substance, once the exposure has ceased, e.g. after a spill has dispersed, the flesh of the organism continues to give an off-flavour or smell. In 1982, GESAMP [4] defined taint as:

> *"a foreign flavour or odour in the organisms induced by conditions in the water to which the organisms are exposed".*

Although best known as a result of oil contamination, tainting has been induced by inadequate aquaculture practices and effluent disposal, although scientific studies have also shown that tainting is regularly produced naturally in seas without any relevant marine pollution. Höfer [55] has recently reviewed much of the available data on tainting of seafood.

*Laboratory tests for tainting by chemical substances*

In the late 1980s, GESAMP [5] and ECETOC [56] developed separate test guidelines for measuring taint. Poels et al. [57] reported that the ECETOC method was tested in a collaborative study, which demonstrated its imprecision at the desired threshold levels. Published data on tainting substances are scarce in the scientific literature and, regrettably, little testing has been done on pure chemicals with which to build up a database since GESAMP first introduced this criterion. Experimental studies are available on approximately 40 chemical substances and as a result there has been little opportunity for laboratories to gain experience or for the method to be standardised. A further disadvantage is that understandably, the testing of industrial chemicals using human tasting panels is strictly regulated in many countries, especially where the long-term toxicity of such chemical substances is unclear.

*Tainting by oil spills*

Many cases of tainting have been observed as a result of heavy pollution following accidental spillage from oil tankers or, as a result of continuous sources of pollution from harbour or river areas [58]. However, mineral oils, as covered under Annex I of MARPOL 73/78 [3], are outside the scope of the present report.

**Box 9 Guidance on laboratory tests for estimating tainting**

**Note:** For the purposes of detecting chemical taint, tainting tests have been shown to be insufficiently precise at the required exposure level of 1 mg/l. While they are not required any longer to finalise GESAMP Hazard Profiles, such tests may well be of use to detect taint in seafood organisms exposed following oil spills.

Tainting is generally measured in a triangular tasting test in which a panel of 15 to 20 human tasters assess groups of three samples of cooked seafood, one of which has been exposed to the chemical at an appropriate concentration, the other two being blank controls. The fish is first exposed to the chemical in water for 24h, then killed, filleted and steamed in tightly wrapped foil.

The available methods are

- GESAMP [5]
- ECETOC [56]
- ISO 4120 [61] is generally followed for setting up the triangular tasting tests with panels of human volunteers.

The ECETOC recommendation is similar to that issued by GESAMP but it allows the fish to be kept after exposure in non-contaminated water for excretion or metabolism. The testing of industrial chemicals of unknown long-term toxicity by a human tasting panel, according to the guidelines, is strictly regulated in many countries.

Generally, the qualitative detection of taint is not the method of choice following oil spills. Chemical analysis is used instead as a more accurate alternative giving quantitative results. Residue limits for many chemical groups are defined by FAO and adopted in developed countries as quality standards for seafood. However, tainting measurement is still recommended by the newly published FAO/IMO "Guidance on Managing Seafood Safety During and After Oil Spills" [59]. Additionally, Whittle [60] reported that in the aftermath of the *Braer* oil tanker accident and subsequent spillage off the Shetland Islands in 1993, the assessment of taint proved to be a high-capacity, rapid and sensitive screening method for the dominant Alkyl (C1-C4) naphthalene contamination of seafood.

*Regulatory standards for tainting*

Chemical tainting of seafood is considered by MARPOL 73/78 [3] in order to prevent "harm to amenities or other legitimate uses of the sea". Tainting is considered as a criterion for classifying the pollution category of bulk liquid substances under Annex II of MARPOL 73/78 [3]. However, the BLG Sub-Committee of MEPC noted that its ESPH Working Group had discontinued the use of tainting as a criterion for up-grading bulk liquid substances to a higher Pollution Category. Likewise, based on a decision of MEPC, regulations under

MARPOL 73/78 [3] Annex III and the IMDG Code [9] have been amended and tainting has been deleted as a criterion for the definition of Marine Pollutants. Tainting has not been adopted as a hazard criterion under the GHS [2].

*Conclusion*

**Given the foregoing, it therefore seems inevitable that tainting will disappear as a regulatory criterion for classifying chemical substances for transport purposes.** The GESAMP composite list has been checked in 2000 to ensure that all ratings are supported by sufficient evidence. Substances that have been rated on this basis will continue to be listed in Column E1 but it is not expected that ratings on new substances will become available in the future.

#### 4.5.1.2 Ratings

Two ratings are used in Sub-column E1 relating to the potential of a substance to taint seafood (see Table 14 below). These are based on the availability of data up to the year 2000.

***Table 14*** *Revised GESAMP hazard profile rating scheme for tainting of seafood*

| Rating | Description & criteria |
|---|---|
| **T** | Substances are considered to cause tainting if a statistically significant off-flavour or smell can be detected following exposure of the fish for 24h to 1mg/l or less |
| **NT** | The substance has been tested for tainting and found not to taint following exposure of the fish for 24h to 1mg/l. |

### 4.5.2 Sub-column E2: Behaviour of chemicals in the marine environment and physical effects on wildlife and on benthic habitats

#### 4.5.2.1 Introduction

The tendency of a spilled chemical to form a slick 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 European Behaviour Classification System [62], for evaluating the short-term

behaviour of chemicals spilled at sea, has been used as a basis for assessing such physical effect. This system is also utilised within the regional pollution prevention agreements for the North, Baltic and Mediterranean Seas, and is designed for co-operation in dealing with marine pollution emergencies, as well as by IMO [62, 63, 64, 65]. The system was slightly modified to include the additional end-point viscosity when evaluating "persistent floating" substances. It is described further in Annex VI.

#### 4.5.2.2 Ratings

Ratings and the associated criteria for determining potential physical effects on wildlife and on benthic habitats are given below in Table 15.

***Table 15*** *Revised GESAMP hazard profile ratings for determining potential effects on wildlife and benthic habitats*

| Rating | Description & criteria | Physical effects | Examples |
|---|---|---|---|
| **F** | Floating substance, not likely to evaporate or to dissolve quickly<br>♦ Density: ≤ sea water (1025 kg/m$^3$ @ 20°C)<br>♦ Vapour pressure: ≤ 0.3 kPa<br>♦ Solubility: ≤ 0.1% (for liquids) ≤ 10% (for solids) | Effects on marine wildlife (e.g. smothering, immobilisation) | ♦ Tallow<br>♦ Ethyl-benzene<br>♦ Olefins (C12+) |
| **Fp** | Persistent slick forming substance.<br>♦ All of the criteria for a floating substance as well as:<br>♦ Viscosity: > ca. 10 cSt (at 10-20°C) | *Idem.* | ♦ Pine oil<br>♦ Octanol<br>♦ Dodecyl alcohol |
| **S** | Sinking substance that would deposit on the seabed, not likely to dissolve quickly<br>♦ Density: > seawater (1025 kg/m$^3$ @ 20°C)<br>♦ Solubility: ≤ 0.1% (for liquids) ≤ 10% (for solids) | Effects on benthic habitats (e.g. blanketing and anoxia of the sediments, poisoning, immobilisation) | ♦ Trichloro-ethylene<br>♦ Perchloro-ethylene<br>♦ Phenol |

The revised GESAMP hazard evaluation procedure uses only the rating F (floater), Fp (persistent floater) and S (sinker). However, for the benefit of other users of the GESAMP hazard profiles, the other physical behaviour categories are also included in column E2 (see Table 16 and Annex VI).

For mixtures, which will have a range of values for each of the relevant properties, a value giving the most conservative rating will be used.

***Table 16*** *Designations of the European Behaviour Classification groups, not used by GESAMP, including some examples. The first letter code refers to the primary behaviour of a substance whereas subsequent letters describe subsidiary behaviour(s). These ratings are given for the benefit of other users of the hazard profiles.*

| Rating | Behaviour of the substance | Examples |
|---|---|---|
| **G** | Gas | – propane<br>– butane<br>– vinyl chloride |
| **GD** | Gas/Dissolves | – ammonia |
| **E** | Evaporates | – benzene<br>– hexane<br>– cyclohexane<br>– heptane |
| **ED** | Evaporates/Dissolves | – methyl-tert-butyl ether<br>– vinyl acetate<br>– ethyl acrylate |
| **FE** | Floats/Evaporates | – toluene<br>– xylene |
| **FED** | Floats/Evaporates/Dissolves | – butyl acetate<br>– butyl acrylate |
| **FD** | Floats/Dissolves | – aniline<br>– cyclohexanol |
| **D** | Dissolves | – hydrochloric acid<br>– n-butanol<br>– isobutanol |
| **DE** | Dissolves/Evaporates | – acetone<br>– acrylonitrile<br>– mono-ethyl amine (sol.)<br>– propylene oxide<br>– methyl ethyl ketone |
| **SD** | Sinks/Dissolves | – dichloromethane<br>– carbon disulphide |

### 4.5.2.3 Application

1. 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 temperatures of 10°C to 20°C.

2. For mixtures, where a range is given for the viscosity at the carriage temperature, a "best estimate" will be made to establish the maximum of that range at 20°C. Conversion methods such as that given by Gambill (1959) [66] may be used in such cases.

   ***Example****: 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. Polybutene (density = 0.83) has a reported kinematic viscosity of 125 cSt at 37°C, equivalent to 104 cP at 37°C. Its dynamic viscosity is estimated to be 280 cP at 20°C giving a kinematic viscosity of 340 cSt at 20°C.*

3. For solutions, e.g., ammonium sulphide solution (45% or less), the following selected properties of seawater will be used to determine a behaviour category for the substance:

   - Freezing point -1.91°C
   - Solubility 100%
   - Vapour pressure 2000 Pa (nominal value based for seawater)

4. 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 17 below 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 will only be used as a guide in estimating the solubility range for purposes of assigning a rating to column E2 as the interpretations differ markedly from, for example, those used in ecotoxicology (see Section 4.2).

***Table 17*** *Descriptive terms of solubility*

| Solubility for the purpose of Column E2 | Descriptive term commonly used in chemical handbooks |
|---|---|
| ≥ 5% for liquids<br>≥ 100% for solids | Infinite; completely soluble; soluble in all proportions; miscible; very soluble; soluble |
| 0.1-5% for liquids<br>10-100% for solids | Partially soluble; moderately soluble; slightly soluble |
| ≤ 0.1% for liquids<br><10% for solids | Insoluble; barely soluble; immiscible; almost insoluble |

5. It is recognised that the presence of dissolved salts or minerals in water leads to moderate decreases in solubility. However, since for most substances data for solubility in saline water are not available, the solubility quoted for pure water at 10°C to 20°C will be used.

### 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 coastal populations and the preservation of living resources. Sub-column E3 is supported by data on environmental and human health hazards from columns A to D.

*Physical hazards*

A physical hazard is one in which harm could be caused to humans or wildlife as a consequence of the physical properties of the chemical, e.g., stickiness, flammability, etc.

*Objectionable odours*

Frequently, an objectionable odour is taken to indicate a potential health hazard by local authorities. Strong odours at the beach may induce symptoms of ill health (for example, nausea or headache) in humans that have a relatively high sensitivity to chemical odours. As a

**Box 10 Guidance for measuring solubility in water, relative density, vapour pressure and viscosity**

*Solubility in water*
Lyman et al. [67] defined the solubility of a substance in water 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 105 guideline [68] 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/m3. OECD 109 guideline [69] indicates that a wide variety of methods can be used and refers to the specific guidelines for their applicability.

*Vapour pressure*
The CRC Handbook of Chemistry and Physics [70] defines vapour pressure 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 104 guideline [71] lists seven 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 Pascals (Pa).

*cont.*

result, warnings may be issued and beaches may be closed. Data on the characteristic odours of various chemicals and knowledge of the concentrations at which they can be detected by humans is limited. It is therefore difficult to classify an odour as "objectionable" and this property could not be further evaluated by GESAMP.

#### 4.5.3.2 Ratings

The ratings in sub-column E3 are presented in Table 18 below. It should be borne in mind that these ratings and their associated hazard warnings are intended as guidance only and are not based on a thorough risk assessment. They are intended as an aid in decision making with respect to closure of beaches in the event of chemical contamination. **Additional factors related to the 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 on closure of the beach.**

**Box 10 cont.**

*Viscosity*
Lyman et al [67] define viscosity of a liquid as a measure of the forces that work against or flow when a shearing stress is applied. The OECD 114 guideline [72] defines viscosity as the property of a fluid substance of absorbing stress during deformation which depends on the rate of the deformation. Viscosity is measured in milliPascal second (mPa.s). Three measurement principles are used for measuring the dynamic viscosity of Newtonian liquids, and most of the available methods, with the exception of the 'flow cup', seem 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, consplate and parallel plate (rotational viscometer);
- 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, drawing ball viscometer, etc).

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-1 s-1= 1 mPa.s.
- Kinematic viscosity: 1 Centistoke (cSt) = 1 mm2/s
- Kinematic viscosity (cSt) is the ratio of viscosity (cP) to density (d) at a given temperature, i.e. 1 cSt = 1 cP/d

One of the physical hazards considered is the flammability of the substance and for the purposes of determining ratings in sub-column E3, the following substances are considered to be flammable:

- liquids with a flash-point below 23°C;
- liquids with a flash-point between 23°C and 61°C that are floaters and also possess evaporative (FE) or evaporative and dissolving (FED) behaviour.

***Table 18*** *Revised GESAMP hazard rating scheme for evaluating "interference with coastal amenities"*

| Rating | Relative Interference | Description | Interpretation | Hazard warning |
|---|---|---|---|---|
| **0** | None | 1 is not a floater; **and**<br>2 does not have any health hazards. | 1 E2 is not F or Fp; **and**<br>2.1 C1, C2 and C3 = 0; **and**<br>2.2 D1 and D2 = 0; **and**<br>2.3 D3 is blank. | ***None*** |
| **1** | Slightly objectionable | 1 is a floater; **and/or**<br>2 is slightly acutely toxic; **and/or**<br>3 is mildly irritant to skin and/or eyes. | 1 E2 = F; **and/or**<br>2 C1 and/or C2 and/or C3 = 1; **and/or**<br>3 D1 and/or D2 = 1. | ***Warning issued but no closure of amenities*** |
| **2** | Moderately objectionable | 1 is a persistent floater; **and/or**<br>2 is moderately acutely toxic; **and/or**<br>3 is irritating to skin and/or eyes; **and/or**<br>4 has long term health effects other than carcinogenicity, mutagenicity or reprotoxicity; **and/or**<br>5 is highly flammable; **and/or**<br>6 is moderately flammable and is a floater with evaporative properties. | 1 E2 = Fp; **and/or**<br>2 C1 and/or C2 and/or C3 = 2–3; **and/or**<br>3 D1 and/or D2 = 2; **and/or**<br>4 D3 contains S, Sp, N, T, A, L or I; **and/or**<br>5 Flashpoint <23°C; **and/or**<br>6 Flashpoint >23–61°C and E2 = FE or FED. | ***Warning issued and possible closure of amenities*** |
| **3** | Highly objectionable | 1 is highly acutely toxic; **and/or**<br>2 is severely irritant or corrosive to skin or eyes; **and/or**<br>3 is carcinogenic, mutagenic or reprotoxic; **and/or**<br>4 is a floater or persistent floater with health effects ascribed to rating 2. | 1 C1 and/or C2 and/or C3=4; **and/or**<br>2 D1 or D2 = 3, 3A, 3B, or 3C; **and/or**<br>3 D3 contains C, M or R; **and/or**<br>4 E2 = F or Fp and D3 contains S, Sp, N, T, A, L or I. | ***Warning issued leading to the closure of amenities*** |

## 4.6 Remarks

Remarks related to the substance itself as opposed to its hazards may be added to the end of a hazard profile. A formal "remarks column" is no longer used to identify specific human health hazards (see section 4.4.3). Remarks may include:

- Specific behaviour, e.g. tendency to polymerise in seawater, rapid hydrolysis, reactivity with seawater, spontaneous release of poisonous gas, etc;
- Chemicals for review (reasons for review to be noted), flagged due to missing data, etc;
- Rating by analogy with another chemical substance;
- Use of stabilisers or other additives, presence of impurities, comments on composition, etc.

# 5 Glossary

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| Acne and chloracne | Acne is a general term for a variety of chronic inflammatory conditions in the sebaceous glands and hair follicles of the skin. It can be induced by a number of factors including substances like oils and other hydrocarbons. The term chloracne is used to denote halogenated aromatic hydrocarbons as the causative agent. |
| Activated sludge | Biomass produced in the aerobic treatment of wastewater by the growth of bacteria and other micro-organisms in the presence of dissolved oxygen. |
| Acute toxicity | Adverse effects produced by single exposure to substance. |
| Acute (aquatic) toxicity | Adverse effects that occur rapidly as a result of short-term exposure to a chemical or physical agent. In fish and other aquatic organisms, effects that occur within a few hours, days or weeks are considered acute. A chemical is considered acutely toxic if by its direct action it kills 50% or more of the exposed population of test organisms in a relatively short period of time, such as 24-96h. |
| Allergen | Any substance which induces a state of, or brings on manifestations of allergy. |
| Allergy | A hypersensitive reaction involving an immune-mediated response. |
| Allergic contact dermatitis | Dermatitis caused by a second exposure to a minute amount of a given substance. |

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| Aspiration hazard | Any substance which, if inhaled into the respiratory tract during swallowing or vomiting of the substance, will cause respiratory tract (usually lung) injury because of its severe irritancy or corrosivity, or cause a granulomatous reaction because of its insolubility and persistence in the respiratory tract. |
| Baseline aquatic toxicity | Baseline toxicity is the (theoretical) aquatic toxicity exerted by a substance due to the most simple 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. |
| Biological oxygen demand (BOD) | A measure of the rate at which molecular oxygen is consumed by micro-organisms during oxidation of organic matter. The standard test is the 5-day BOD test, 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. |

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| 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 micro-organisms (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 | The term carcinogen denotes a chemical substance or mixture which induces cancer or increase its incidence. 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 oxygen demand (COD) | A measure of the oxygen equivalent of the organic matter in wastewater susceptible to oxidation by a strong chemical oxidising agent (e.g., potassium permanganate; see also BOD). |
| Chemosis | A swelling of the conjunctiva due to accumulation of tissue fluid. |
| Chronic toxicity | Effects resulting from repeated exposure to a substance for the lifespan of the species, or the greater part thereof. |

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| Chronic (aquatic) toxicity | Adverse effects on aquatic organisms that occur largely from continuous long-term exposure to a chemical or other potentially toxic substance or agent, alone or in combination, but where the exposure time covers only a portion of the life cycle (lifespan) of the aquatic species tested or exposed naturally. The effects may be the result of a single exposure (e.g., to a strong acid) but more often they are the consequence of repeated or continuous long-term exposures. Subchronic toxic effects may be lethal or sublethal. |
| Coastal amenity | Beach, mudflat, wharf, boardwalk or any other feature of the coastline considered of public value. |
| Conjunctiva | Mucous membrane which lines the eyelid. |
| Conjunctoblepharitis | An inflammation of the conjunctiva and eyelids. |
| Convulsant | A substance which causes seizures. |
| Cornea | The clear, transparent portion of the eye covering the iris and lens. |
| Corrosive | Capable of causing erosive destruction of tissues. |
| Delayed lung injury | A condition in which there is a delay (usually hours or a few days) between acute exposure to a chemical and the subsequent development of lung injury. |
| 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. |

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| 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 ms'2 for 15 min or by membrane filtration using membranes with pores of 0.2–0.45 μm diameter. |
| $EC_{50}$ | Effective concentration 50%: The concentration of a substance which produces a 50% response in the defined end-point. The $EC_{50}$ should be cited for a specific exposure period. |
| $EL_{50}$ | 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). |
| Endocrine disrupter | An exogenous substance or physical agent that causes adverse health effects in the intact organism or its progeny through changes in endocrine function. |
| (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 in the latter case, on the basis of human experience. |
| Erythema | Excess of reddening of a tissue due to increased flow of blood. |
| Granulomatous reaction | A granular tumour or growth, usually of lymphoid and epitheloid cells. |
| Hazard | A substance is considered to be hazardous when it possesses one or more intrinsic properties which may cause significant harm to human health or the aquatic environment. |
| Hazard evaluation | A process whereby hazard is assessed on the basis of a series of end-points relating to its intrinsic properties, e.g. toxicity. |

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| Immunotoxic | Capable of causing injury to the immune system and interference with body defence mechanisms. |
| Inflammation | Tissue reaction to injury caused by chemical, bacterial or mechanical irritation. |
| Inherent biodegradability | Biodegradation of the test compound under enhanced conditions, either with a pre-adapted innoculum or a high level of activated sludge. The tests may be either static or flow-through, e.g. simulating a waste-water treatment process. |
| $IC_{50}$ | Inhibition concentration 50%: a point estimate of the chemical concentration that would cause a given percent reduction (e.g., $IC_{50}$) 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. |
| $IL_{50}$ | 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 or in a solution, 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 $LC_{50}$ should be cited for the specific exposure period. |

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| $LD_{50}$ | 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. |
| $LL_{50}$ | 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 Pow | See n-octanol-water partition coefficient. |
| Mechanism of toxicity | The way in which a chemical alters basic biological functions and structures in order to exert its toxic effect(s). |
| Mutagen | A substance capable of causing molecular injury to the genetic substance (DNA: deoxyribonucleic acid). |
| Necrosis | Death of areas of tissue or bone surrounded by healthy parts. |
| Neovascularisation | New blood vessels in damaged tissue. |
| 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 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. |

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| 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 (Kow) | The ratio of a chemical's solubility in n-octanol and water at steady state; also expressed as P. The logarithm of P or Kow (i.e., log P or Kow) 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. |
| Photoallergy | Similar to allergic contact dermatitis except that the chemical must react with light before becoming allergenic. |
| Photosensitiser | A substance which is converted in the skin circulation by light into a derivative capable of causing skin sensitisation. |
| Phototoxic | A substance which is converted in the skin circulation by light to a derivative capable of causing local irritation; non-immunological light induced dermatitis caused by a photo-reactive chemical. |
| Physical hazard | A physical hazard is when harm could be caused to humans or wildlife as a consequence of the physical properties of the chemical, e.g., stickiness or viscosity. |
| Pre-exposure/ adaptation | The pre-incubation of a microbial inoculum in the presence of the test compound, with the aim of enhancing the ability of an inoculum to biodegrade the test compound by adaptation and selection of the micro-organisms. |

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| Primary biodegradation | The structural change (transformation) of an organic chemical compound by micro-organisms resulting in the loss of a specific property. |
| Ready biodegradability | 70% removal of DOC and 60% removal of ThOD or $ThCO_2$ production (for respirometric methods), reached within a 10d window in 28d 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 × Exposure = Risk)*. If either hazard or exposure can be minimised, 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 | Similar to the above: a substance causing adverse effects on reproductive ability or capacity, or on the development of offspring. |
| Sensitisation | Exposure to the substance results in stimulation of the immune system, resulting in a state of hypersensitivity to the substance. Sensitisation by skin contact results in local allergic responses. Sensitisation by inhalation (respiratory sensitisation) causes asthma. |
| Subchronic toxicity | Effects resulting from repeated exposure to a substance for 10 to 15% of the lifespan of the species; for rodents this is about three months. |
| Systemic toxicity | Adverse effects produced by a substance (or conversion products) after absorption into, and circulation by, the blood stream. Systemic effects occur in tissues remote from the site where the substance comes into contact with the body, and from where it is absorbed. |

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| Tainting | Taint is defined as a foreign flavour or odour in marine organisms, induced by conditions in the water to which the organisms are exposed. |
| Testicular toxicity | Causing injury to the testis; a specific subdivision of reproductive toxicity. |
| 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 oxidise a chemical compound completely, calculated from the molecular formula, expressed in this case as mg oxygen required per mg or g test compound. |
| TOST | Target Organ Oriented Systemic Toxicity – see [2]. |
| Toxic | Capable of causing adverse effects, detrimental to the survival or normal functioning of the individual. |
| 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. |

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# Annex I Terms of reference

## I.1 IMO/FAO/UNESCO-IOC/WMO/WHO/IAEA/ UN/UNEP: Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP)

### UPDATED MEMORANDUM OF 1994

### Introduction

1 In the late 1960s marine pollution problems were of particular concern to several organizations and their subsidiary bodies within the United Nations family. Following consideration by the Administrative Committee on Coordination, a number of Agencies agreed in 1967 to establish a joint group of experts to advise them and, as appropriate, through them their Member States, on scientific aspects of marine pollution. In 1993 the sponsoring organizations agreed to extend the role of GESAMP to cover all scientific aspects on the prevention, reduction and control of the degradation of the marine environment to sustain its life support systems, resources and amenities. The Joint Group is open to sponsorship by any organization of the United Nations system concerned wishing to participate in the arrangements described in this memorandum and specifically by, *inter alia*, supporting the operational costs of the Joint Group. The establishment of this Joint Group was intended, *inter alia*, to encourage the various organizations concerned at their discretion to disband or to refrain from establishing other interdisciplinary groups on the subject and so to avoid duplication of efforts.

### Functions of GESAMP

2 The functions of the Joint Group are:

.1 to provide advice relating to the scientific aspects of marine environmental protection to:

.1.1 the sponsoring organizations on specific questions referred to it;

.1.2 the other organizations of the United Nations system and to Member States of the United Nations organizations on particular problems

referred to it through a sponsoring organization; and

.2 to prepare periodic reviews and assessments of the state of the marine environment and to identify problems and areas requiring special attention.

3 Such advice is given on the scientific aspects of marine environmental protection, especially those of an interdisciplinary nature, including pollution of the sea as a result of the operation of ships and other equipment in the marine environment; of sea-bed exploration and exploitation; of waste disposal at sea; of discharges of wastes through rivers, land run-off and pipelines; and the pollution of the sea through the atmosphere. The main subject areas on which advice is given include, *inter alia*:

.1 assessment of the potential effects of marine pollutants;

.2 scientific bases for research and monitoring programmes;

.3 international exchange of scientific information relevant to the assessment and control of marine pollution;

.4 scientific principles for the control and management of marine pollution sources;

.5 scientific bases and criteria relating to legal instruments and other measures for the prevention, control or abatement of marine environmental degradation.

**Reports and recommendations**

4 The Joint Group reports to the Executive Heads of the sponsoring organizations, which make such reports available to Governments and, as appropriate, to other international organizations, institutions and individuals concerned with marine pollution problems. Each sponsoring organization arranges for distribution of these reports according to its own needs.

5 Any recommendation by the Joint Group which pertains to or requires for its implementation concerted action by several of the sponsoring organizations may be referred to relevant ACC subsidiary bodies.

6 Proposals and recommendations relevant to the work of other organizations which are not among the sponsors of the Joint Group are, as appropriate, communicated to such organizations.

## Membership

7 Each sponsoring organization nominates from one to four experts according to their needs. The Joint Group is composed of such nominees, the experts being appointed to act in their individual capacities. The multidisciplinary composition of the Joint Group is agreed among the sponsoring organizations. Some experts are nominated to serve for a period of up to four years to provide a continuing nucleus, while others can be appointed as occasion demands, having in mind the particular subjects to be considered at each session of the Joint Group.

## Participation in sessions

8 Sessions are normally held annually and in rotation at the headquarters of the sponsoring organizations. In certain circumstances however the Joint Group may be convened elsewhere.

9 Organizations of the United Nations systems which are not among the sponsors of the Joint Group may be represented at its sessions. Other organizations which are not members of the United Nations systems may also be invited to send observers to sessions of the Group by agreement among the sponsoring organizations.

## Financial arrangements for sessions

10 The sponsoring organizations share appropriately the costs of conference services and documentation pertaining to sessions of the Joint Group. Each sponsoring organization accepts responsibility for the expenses for participation in sessions by the experts it nominates and for maintaining contact with such experts.

## Secretariat

11 IMO acts as the Administrative Secretariat for the Joint Group and assigns the Administrative Secretary, each sponsoring organization assigns a Technical Secretary. The Administrative and Technical Secretaries form a joint secretariat. The Administrative Secretary maintains continuity and keeps the central archives relative to the work of the Joint Group. The Technical Secretary from the organization hosting a session acts in each case as the secretary for the session and takes responsibility for the preparation of the report of that session. The provisional agenda for each session is drawn up jointly by the sponsoring organizations under the initiative of the Administrative Secretary and after consultation with the Chairman, taking into account any suggestions received from any organizations

in the United Nations system which may be interested in taking part in the session.

**Procedure of work**

12 Detailed arrangements for the conduct of the business of the Joint Group and for its support (including inter-secretariat preparations, intersessional activities, sharing of responsibilities for documentation, costs of sessions, election of officers, conduct of sessions, routeing of correspondence, etc.) are covered by guidelines based on this memorandum and drawn up jointly by the Secretaries.

*[This Memorandum was signed by the Executive Heads of the Sponsoring Agencies]*

## I.2 GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships (EHS)EHS Working Group

The terms of reference of the GESAMP EHS Working Group, as given by GESAMP at its 6th session in Geneva (1974) [73] and amended at its 8th session in Rome (1976) [74] are:

> *"To examine and evaluate data and to provide such other advice as may be requested, particularly by IMO, for evaluating the environmental hazards of harmful substances carried by ships, in accordance with the rationale approved by GESAMP for this purpose".*

At that time, the "rationale" for hazard evaluation specified for the Working Group was laid down in GESAMP IV/19/ Supp. 1; this was replaced in 1982 by GESAMP Reports & Studies No. 17 [4], which was in turn superseded by Reports & Studies No. 35 [5] in 1989. As approved by GESAMP at its XXVIII session in 1998, the present procedure (R&S 64, 2001) replaces all previous versions. The terms of reference remain the same.

# Annex II Membership of GESAMP *ad hoc* panel (1972/73), GESAMP expert panel (1995), EHS Working Group (1974 to 2001)

***Table II.1*** *List of the original 1972/73 GESAMP ad hoc panel and the 1995 GESAMP expert panel*

| **The 1972/73 IMO/GESAMP *ad hoc* panel on environmental hazards of noxious substances other than oil transported by ships** | **The 1995 expert panel on procedures for the evaluation of the hazards of harmful substances carried by ships** |
|---|---|
| Dr A.H. Cole (Chairman), United Kingdom | Dr P.G. Wells (Chairman), Canada |
| Dr G.J van Esch, Netherlands | Dr B Ballantyne, United States |
| Dr R. W. Haan Jr., United States | Dr C.T. Bowmer, Netherlands |
| Dr P.G. Jeffery, United Kingdom | Mr K. de Bruin, CEFIC |
| Mr R.J. Lakey, United States | Ms I. de Wilde, CEFIC |
| Dr K.H. Palmork, Norway | Mr A.O. Hanstveit, Netherlands |
| Dr J.E. Portmann, United Kingdom | Dr T. Höfer, Germany |
| Dr M. Sharratt, United Kingdom | Mr P. Howgate, United Kingdom |
| Dr C. H. Thompson, United States | Dr P. Johnston, Greenpeace International |
| Dr M. Waldichuk, Canada | Dr M. Nauke, IMO |
| | Mr N.M. Soutar, IMO |

***Table II.2*** *Past & present members of the EHS Working Group: 1974-2001*

| | ■ = Chairman<br>✦ = Members<br>C = IMO Consultant | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dr P. Jeffery | United Kingdom | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | ✦ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ✦ | ✦ | C | C | C | C | | | | | | | | | | |
| Dr J.K. Portmann | United Kingdom | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | | | | | | | | | | | | | | | |
| Dr G.H. Thompson | United States | ✦ | | | | ✦ | ✦ | | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dr B-E. Bengtson | Sweden | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | | ✦ | ✦ | ✦ | | ✦ | ✦ | | | | | | | | | | | | | |
| Mr L. Foyn | Norway | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | | | | | | | | | | | | | | | | | | | | | | |
| Prof. E. Vigliani | Italy | ✦ | | ✦ | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ms D.M.M. Adema | Netherlands | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | | | | | |
| Dr V. Zitko | Canada | | | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dr B. Ballantyne | United States | | | | | | | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | |
| Mr T.A. Wastler | United States | | | | | | | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dr K.W. Wilson | United Kingdom | | | | | | | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prof. S.D. Murphy | United States | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | ✦ | ✦ | | | | | | | | | | | | | | | | | | |
| Dr P. Lefcourt | United States | | | | | | | | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mr D. Enreth | United States | | | | | | | | | | | ✦ | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prof. T. Yoshida | Japan | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | | | | | | | | | | |
| Prof. W. Ernst | Fed. Rep. Germany | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | | ✦ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | | | |
| Mr P. Howgate | United Kingdom | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | | |
| Prof. T. Syversen | Norway | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ |
| Mr M. Morissette | United States | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ |

| | ■ = Chairman<br>✦ = Members<br>C = IMO Consultant | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dr P. Wells | Canada | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ✦ | ✦ | | |
| Dr M. Kitano | Japan | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | | | | | |
| Dr R. Blackman | United Kingdom | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | | | | | | | | | | |
| Dr F. Bathie | United Kingdom | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | | | | | | | | | | | |
| Dr R. Kantin | France | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | |
| Dr T. Höfer | Fed. Rep. Germany | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ |
| Dr C.T. Bowmer | Netherlands | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ■ | ■ | ■ | ■ |
| Dr. S. Micallef | Malta | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ |
| Dr M. Wakabayashi | Japan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ |
| Dr M. Marchand | France | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ |
| Dr D. James | United Kingdom | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ |
| Dr F. Pedersen | Denmark | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | |
| *SECRETARIAT* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mr S.L.D. Young | IMO | ✦ | ✦ | ✦ | ✦ | ✦ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mr B. Okamura | IMO | | | | | | ✦ | ✦ | | | | | | | | | | | | | | | | | | | | | ✦ | | | | | | | | | |
| Dr M. Nauke | IMO | | | | | | | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | ✦ | |
| Mr N.M. Soutar | IMO | | | | | | | | | | | | | | | | | | | | | | | | | | | | C | C | | C | C | C | C | C | C | C |
| Mr J. V. Crayford | IMO | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ✦ | ✦ | ✦ |

***Table II.3*** *Meetings of the EHS Working Group*

| No | Location & Date | | Year |
|---|---|---|---|
| 1 | London | 14-15 October | 1974 |
| 2 | London | 4-6 June | 1975 |
| 3 | London | 15-17 October | |
| 4 | London | 12-14 July | 1976 |
| 5 | London | 22-24 October | |
| 6 | Delft | 9-13 May | 1977 |
| 7 | London | 4-6 July | |
| 8 | Bergen | 22-16 May | 1978 |
| 9 | Burnham | 5-9 November | 1979 |
| 10 | London | 2-6 June | 1980 |
| 11 | Houston | 15-19 December | |
| 12 | London | 21-25 September | 1981 |
| 13 | Delft | 25-19 October | 1982 |
| 14 | London | 6-10 June | 1983 |
| 15 | Aberdeen | 9-13 January | 1984 |
| 16 | London | 21-25 May | |
| 17 | Plymouth | 11-15 February | 1985 |
| | London | 7-11 October | |
| 18 | Delft | 26-30 May | 1986 |
| 19 | London | 3-7 November | |
| 20 | Trondheim | 18-22 May | 1987 |
| 22 | London | 18-22 January | 1988 |
| 23 | London | 29 August-2 September | |
| 24 | London | 13-17 February | 1989 |
| 25 | London | 26-30 March | 1990 |
| 26 | London | 8-12 April | 1991 |
| 27 | London | 17-21 February | 1992 |
| 28 | London | 15-19 February | 1993 |
| 29 | London | 14-18 February | 1994 |
| 30 | London | 27 February-3 March | 1995 |
| 31 | London | 28 August-1 September | |
| 32 | London | 20-24 May | 1996 |
| 33 | London | 10-14 February | 1997 |
| 34 | London | 23-27 February | 1998 |
| 35 | London | 1-5 February | 1999 |
| 36 | London | 3-7 April | 2000 |
| 37 | London | 31 April-4 May | 2001 |

# Annex III System for assigning chemical names

Both GESAMP and the IMO bodies responsible for the pollution categorisation 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 is
- 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 products are in fact proprietary mixtures or preparations, the EHS Working Group is generally amenable to using names which make clear to which chemical group the substance belongs (bearing the four points above in mind), without divulging its exact chemical structure. To ensure a proper hazard evaluation, knowledge of the full chemical structure is essential. Trade names are not accepted.

The EHS Working Group of GESAMP 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 categorisation, a “proper shipping” name is then assigned by IMO. While generally similar to names given by GESAMP, the proper shipping name may be simplified for everyday use and easy recognition, as well as to reflect relevant safety concerns on board ship.

The definitions of substances and mixtures used here are those given in the GHS [2].

***Table III.1*** *Typical names of substances and mixtures as assigned by GESAMP, illustrating the naming conventions.*

| Group | Example |
|---|---|
| Mixtures | |
| ♦ Isomeric | - Octene (all isomers) |
| ♦ Natural (complex) | - Tall oil fatty acid (resin acids less than 10%)<br>- Dodecylbenzene sulphonic acid (contains 1.5% sulphuric acid)<br>- Alkylbenzenes (C9-C17) (straight or branched)<br>- n-alkanes (C10-C20)<br>- Alcohols (C13+) (as individuals & mixtures) |
| ♦ Formulations | - Nitropropane (60%)/Nitroethane (40%) (mixture)<br>- Sodium salycilate, overbased, in mineral oil<br>- Alkyl acrylate/Vinyl pyridine copolymer in toluene |
| ♦ Solutions | - Calcium hypochlorite solutions containing less than 15% but more than 1.5% Ca(OCl)2<br>- Methylamine (42% or less) |
| ♦ Molecular weight | - Polyolefin aminoester (Molecular weight 2000+) |
| ♦ Polymeric chains | - Nonylphenol Poly(4-12)ethoxylate<br>- Alcohol (C13-C15) poly (7) ethoxylate |
| Physical state | - Naphthalene (molten) |
| Pesticides | - Alachlor (ISO) |

*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

disappears, as solubility in water decreases below concentrations sufficient to cause an effect in short-term tests.

*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 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, 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 itself will be evaluated and the most severe profile of the two 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. Solutions are defined as mixtures under the GHS.

*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 (the molecules are too big to pass through cell membranes);

- 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 bracket, then by the name of the monomeric unit, e.g. as in the ethoxylated (EO) examples given in the table above. Each EO functional group is hydrophilic. Thus, a molecule with a hydrophobic carbon chain can be balanced (in terms of log Pow/water or oil solubility) by a suitably long hydrophilic ethoxylate chain. The length of the carbon chain relative to the ethoxylate chain determines the aquatic toxicity.

*Pesticides*

Pesticides are always given an ISO name for the sake of clarity (and brevity) and this is indicated by including (ISO) in brackets after the name.

*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 (adapted mainly from ISO documents)

ISO, OECD, EPA-OPPTS and ASTM aquatic biodegradation tests (adapted from an ISO listing)

| Guideline equivalence | Name | Principle of the method | Scope & Recommended usage |
|---|---|---|---|
| **ISO 7827**<br>**OECD 301A**<br>**EPA-OPPTS 835-3110 para. L**<br>**EC C.4-A** | **DOC die-away method**<br>Evaluation of the primary and ultimate aerobic biodegradability in an aqueous medium by analysis of dissolved organic carbon (DOC) | Static, aquatic test system using organic test substances as the sole source of carbon and energy for an inoculum of aerobic mixed micro-organisms:<br>♦ removal of dissolved organic carbon (DOC) measured to determine ultimate biodegradability in 28 days<br>♦ specific analysis used to determine the primary biodegradability<br>♦ the inoculum may be obtained from activated sludge, sewage effluents, surface waters, soils or a mixture of these | The test can be used for organic substances which are:<br>♦ water-soluble at the test concentration (10-40 mg/l DOC);<br>♦ non-volatile, or having a negligible vapour pressure;<br>♦ not significantly adsorbed on glass and activated sludge;<br>♦ non-inhibitory to the test micro-organisms at the test concentration. |
| **ISO 9439**<br>**OECD 301B**<br>**EPA-OPPTS 835-3110 para. M**<br>**EC C.4-C** | **CO2 evolution/Modified Sturm method**<br>Evaluation of the “"ultimate" aerobic biodegradability of organic substances in an aqueous medium by analysis of carbon dioxide production. | Static, aquatic test system using organic test substances as the sole source of carbon and energy for an inoculum of aerobic mixed micro-organisms.<br>♦ measurement of biogenically produced $CO_2$ to determine ultimate biodegradability in 28 days<br>♦ test results are evaluated in relation to the theoretical amount<br>♦ for water soluble test substances, the DOC removal at the end of the test can be determined to obtain additional information on substance elimination | The test can be used for organic substances which are:<br>♦ water-soluble at the test prescribed concentration (10-40 mg/l DOC);<br>♦ water-insoluble under the test conditions<br>♦ non-volatile, or having a negligible vapour pressure<br>♦ non-inhibitory to the test micro-organisms |

| Guideline equivalence | Name | Principle of the method | Scope & Recommended usage |
|---|---|---|---|
| **OECD 301C**<br>**EPA-OPPTS 835-3110 para. N**<br>**EC C.4-F** | **MITI (I) method**<br>Evaluation of the “"primary and ultimate" aerobic biodegradability of organic substances in an aqueous medium – by analysis of $O_2$ consumption. | Stirred, aquatic test system using organic test substances as the sole source of carbon and energy for an inoculum of aerobic mixed micro-organisms.<br>♦ measurement of oxygen consumption to determine the ultimate biodegradability in 28 days<br>♦ uses an inoculum specially cultured in a sludge unit from at least 10 sites, where a variety of chemicals are discharged, the micro-organisms are considered as un-adapted following continuous incubation<br>♦ primary biodegradation may be calculated from chemical analysis of the parent compound and ultimate biodegradation can be confirmed by DOC analysis | The test can be used for organic substances which are:<br>♦ water soluble or to some extent poorly soluble<br>♦ adsorptive<br>♦ volatile<br>Test method uses a fixed high dosage of compound (100 mg/l). Some suitability claimed for poorly soluble substances. Relatively conservative test. |
| **ISO 10707**<br>**OECD 301 D**<br>**EPA-OPPTS 835-3110 para. O**<br>**EC C.4-E**<br>**(Related to OECD 306)** | **Closed bottle test**<br>Evaluates the “ultimate” aerobic biodegradability of organic substances, in an aqueous medium by analysis of biochemical oxygen demand. | Static aquatic test system using organic test substances as the sole source of carbon and energy for an inoculum of aerobic mixed micro-organisms.<br>♦ measurement of the biochemical oxygen demand (BOD) in completely filled closed bottles to determine the ultimate biodegradability within 28 days<br>♦ evaluation of the test results by comparing the BOD with the theoretical oxygen demand (ThOD) or the chemical oxygen demand (COD) | The test can be used for organic substances which:<br>♦ are water-soluble at the test concentration (2-10 mg/l)<br>♦ are water-insoluble, provided a suitable dosing technique is used<br>♦ are volatile, provided a suitable dosing technique is used<br>♦ are inhibitory to micro-organisms<br>Simple test method – used extensively – has the advantage of relatively low test concentrations, conservative, used for volatile and toxic test substances. |

| Guideline equivalence | Name | Principle of the method | Scope & Recommended usage |
|---|---|---|---|
| **OECD 301 E**<br>**EPA-OPPTS 835-3110 para. P**<br>**EC C.4-B** | **Modified OECD Screening Test** | Static, aquatic test system using organic test substances as the sole source of carbon and energy for an inoculum of aerobic mixed micro-organisms.<br>♦ DOC die-away is measured to follow biodegradation<br>♦ primary biodegradation may be calculated from chemical analysis of the parent compound.<br>♦ the inoculum is derived from the secondary effluent of a sewage treatment plant or laboratory scale unit receiving predominately domestic sewage. | The test can be used for organic substances which:<br>♦ have a water solubility of at least 100 mg/l<br>♦ are non-volatile, or having a negligible vapour pressure<br>Similar to DOC die-away method ISO 7827, OECD 301 A, but employs a relatively low concentration of micro-organisms. Limited by requirement for high water solubility. |
| **OECD 306** | **Marine biodegradation test**<br>1 **Shake flask method** (seawater variant of the Modified OECD 301 E screening test).<br>2 Closed **bottle method** (seawater variant of the closed bottle test OECD 301D). | Method using natural seawater as the aqueous phase and the sole source of micro-organisms to evaluate the biodegradability.<br>♦ for higher test substance concentrations, DOC removal or ThOD are measured in a shake-flask test lasting for up to 60d.<br>♦ for lower test substance concentrations, in a more conservative test, DOC removal or ThOD are measured in a 28d closed bottle test (can also be extended to 56d). | The test can be used for organic substances which:<br>♦ are soluble at the test concentration (Shake flask method, 5-40 mg/l DOC; Closed bottle, 2-10 mgl-1 DOC)<br>♦ are volatile providing suitable precautions are taken.<br>Relatively simple test method suitable for measuring the ultimate biodegradation of organic chemicals in seawater. They are not simulation tests owing to the use of added nutrients, despite the use of natural seawater bacteria. |

| Guideline equivalence | Name | Principle of the method | Scope & Recommended usage |
|---|---|---|---|
| **ISO 14592 Draft**<br>**ASTM E-1279**<br>**EPA-OPPT S 835-3170; refers to test type 1 only** | **Die-away tests**<br>1. Shake-flask batch test<br>2. Continuous flow river model with attached biomass (not in ASTM guideline).<br>Water quality evaluation of the aerobic biodegradability of organic substances at low concentrations in water.<br>Method follows the die-away of the parent compound. | Method for evaluating the biodegradability of organic substances at low concentrations by aerobic micro-organisms in water.<br>♦ 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.<br>♦ Evaluation of the test result is carried out by specific chemical analysis of the parent compound.<br>♦ 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:<br>♦ are water soluble at the test concentration (preferably < 100mg/l), this includes many poorly soluble substances.<br>Test method suitable for measuring the primary biodegradation of substances at environmentally realistic concentrations. |

# Annex V Aquatic toxicity tests with poorly soluble complex mixtures

## V.1 Introduction

It is generally accepted that aquatic toxicity tests should be based on dissolved "exposure" concentrations [41]. 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 the "lub 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 substances in general. The most informative of these is that published by the ECETOC [39], 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 [40] on "aquatic toxicity testing of difficult substances and mixtures", 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 substances provided by Whitehouse & Mallet [75] and uses "water accommodated fractions" (WAF). It is based on methods developed by Girling [76] and Girling et al. [77] and adopted by CONCAWE [78].

## V.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.

## V.3 Principles

V.3.1 The test substance is first homogenised 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.

V.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.

V.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.

V.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).

V.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.

V.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.

V.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.

## V.4 Apparatus

Ordinary laboratory apparatus is used, in particular:

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

## V.5 Preparation of the test media

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

V.5.1 Homogenise the test substance thoroughly, e.g., by rolling overnight on a roller bank in a cool environment (15–20°C).

V.5.2 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.

V.5.3 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 1/3 of the water column. The depth of the vortex is important in ensuring that the individual loading rates are stirred with approximately equal energy.

V.5.4 Introduce the weighed amounts of test substance, one for each flask, when the seawater is already stirring; this may improve the mixing procedure.

V.5.5 The preparation of the WAFs is generally carried out in the dark as some substances, e.g., hydrocarbons, may be sensitive to photo-oxidation.

V.5.6 Stir for 16-20 hr, followed by 4 hr standing for phase separation. If possible, carry out the stirring a few degrees below the test temperature, as stirring may slightly warm the seawater.

V.5.7 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).

V.5.8 This procedure is followed on each occasion the test media are replaced, i.e. for a 96 hr (fish) test with daily renewal, the test media are prepared 4 times.

## V.6 Reporting

Refer accurately to the procedure in the report:

- state that water accommodated fractions were used;
- give the stirring and standing times;
- 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.

# Annex VI Standard European Behaviour Classification System of chemicals spilled into the sea

Chemicals[16] that are spilled into the sea behave in different ways depending on their properties and environmental conditions. In principle, spilled chemicals can evaporate, float, dissolve or sink. In reality, they often show complex behaviour patterns on contact with seawater. A spill of *iso*-butanol will spread out on the water surface and float for a while, at the same time vaporising into air and dissolving in the water. Based on information on the physical properties of chemicals (physical state, density, vapour pressure, solubility), an indication of the behaviour pattern following release into the water can be obtained.

The European Behaviour Classification System [62] was initiated within the framework of the Bonn Agreement for the North Sea in order to classify chemicals according to their physical behaviours when spilled into the sea. The classification system covers gaseous, liquid and solid chemicals. The main principle of the system is to characterise spilled chemicals as: evaporators, floaters, dissolvers and sinkers. From this basic categorisation and from other details regarding their physical properties, the chemicals are classified in the following 12 Property Groups.

| **Main group** | | **Subgroup** | |
|---|---|---|---|
| **G** | Gas | **GD** | Gas that dissolves |
| **E** | Evaporator | **ED** | Evaporator that dissolves |
| **F** | Floater | **FE**<br>**FD**<br>**FED** | Floater that evaporates<br>Floater that dissolves<br>Floater that evaporates and dissolves |
| **D** | Dissolver | **DE** | Dissolver that evaporates |
| **S** | Sinker | **SD** | Sinker that dissolves |

[16] This text is taken largely from the Bonn Agreement and the term "chemical" is used as therein defined.

## VI.1 Grouping of chemicals by their physical properties

The Property Groups of the European 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), solubility (s). The method of classifying chemicals by physical property cut-off values is shown in the Figure below.

## VI.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 (m.p. > ambient temperature).

## VI.3 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 about 1025 kg $m^{-3}$.

## VI.4 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.

## VI.5 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 predomiates when solubility is $\geq$ 5% for liquids and $\geq$ 100% (“totally miscible”) for solids.

Figure 1 below shows the principles of the European Behaviour Classification System for chemicals that may be spilled into the sea. Starting with their physical state and their properties, chemicals can be classified into 12 groups (G, GD, E, ED, F, FE, FED, FD, D, DE, S and SD). By this classification system, whole groups of chemicals can

be related to the same response strategies, thus simplifying preparedness to take action against accidental release of chemicals.

**GASES** (Vapour Pressure > 101.3 kPa at 20°C)

| **SEBC Code** | ***G*** | ***GD*** |
|---|---|---|
| **Solubility** | 0% | 10% |

**FLOATING LIQUIDS** (Density ≤ Seawater)

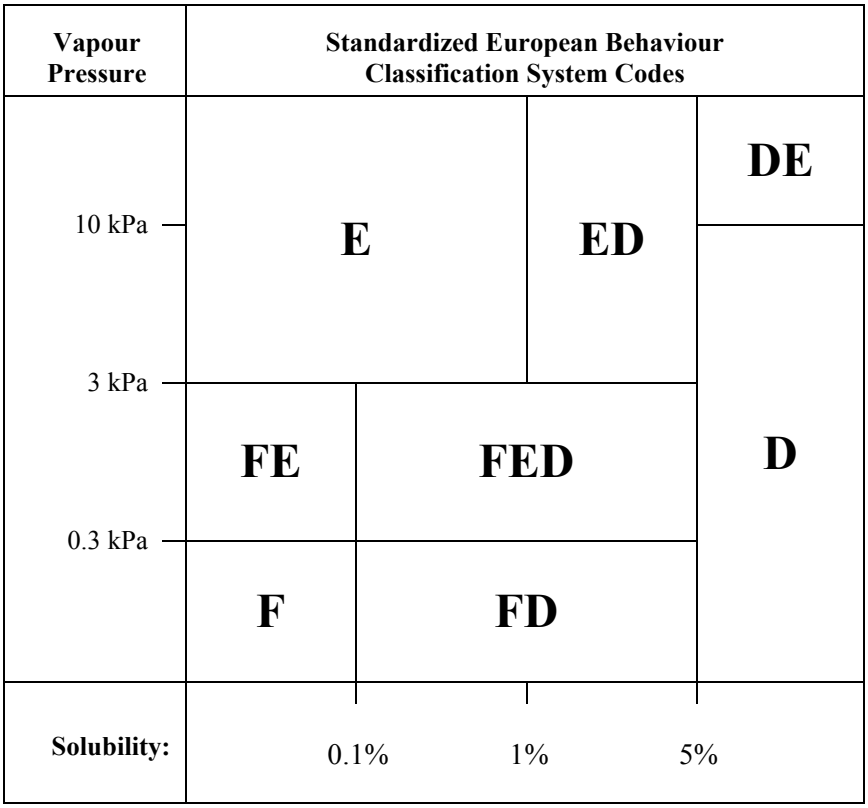


***Figure VI.1*** *European Behaviour Classification System of accidentally spilled chemical products according to their physical state and physical properties*

## **SINKING LIQUIDS** (Density > Seawater)

| **SEBC Code** | **S** | **SD** | **D or DE** (if v.p. >10kPa) |
|---|---|---|---|
| **Solubility** | 0.1% | 5% | |

## **FLOATING SOLIDS** (Density ≤ Seawater)

| **SEBC Code** | **F** | **FD** | **D** |
|---|---|---|---|
| **Solubility** | 10% | 100% | |

## **SINKING SOLIDS** (Density > Seawater)

| **SEBC Code** | **S** | **SD** | **D** |
|---|---|---|---|
| **Solubility** | 10% | 100% | |

***Figure VI.1*** *Continued*

# Annex VII Draft sample form for submitting data to GESAMP

**Please send any requests for this form to IMO (see section 3.1).**

# GESAMP/EHS Product Data Reporting Form

( Characteristics of Liquid Chemicals Proposed for Marine Transport )

**Section 1 : Product Names**

| Bulk (y/n) | | Packaged (y/n) | |
|---|---|---|---|

| | | |
|---|---|---|
| **Proper Shipping Name** : | | |
| This is the first name that should appear on the shipping documentation and will be reflected in the IBC or IMDG Code | | |
| **Main Chemical Name** : | | |
| **Main Trade Name** : | | |
| **Synonyms** : | **Synonym name** | **Synonym type** |
| | | |

**Section 2 : Product Identification Numbers**

| | |
|---|---|
| **C.A.S Number** : | |
| **EHS Number** : | |
| **BMR Number** : | |
| **RTECS Number** : | |
| **UN Number** : | |

**Section 3 : Product Chemical Details**

**Chemical Structure**

| | | |
|---|---|---|
| **Chemical Formula** : | | |
| **Chemical Class** : | | |
| **Physical State During Transport** : (Liquid, Solution (with %) or Molten) | | |

**Section 4 : Composition**

| Component name | % | Range | Type |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**Section 5: Physical Properties**

| Property | Units | Qual | Lower Val | Upper Val | References and Comments |
|---|---|---|---|---|---|
| Molecular weight | (Daltons) | | | | |
| Density @ 20 ° C | ($kg/m^3$) | | | | |
| Flash Point (cc) | (°C) | | | | |
| Boiling Point | (°C) | | | | |
| Melting Point/Pour | (°C) | | | | |
| Water solubility @ | (mg/l) | | | | |
| Viscosity @ 20 °C | (mPa.s) | | | | |
| Vap. Press. @ 20 | (Pa) | | | | |
| AutoIgnitionTemp | (°C) | | | | |
| *Explosion Limits | (% v/v) | | | | |
| Carriage temperature | (°C) | | | | |
| Unloading temperature | (°C) | | | | |
| **MESG (electrical apparatus) | (mm) | | | | |
| Sat. Vapour Conc. | (mg/l) | | | | |
| Where the Carriage/Unloading Temperature is not 'ambient' indicate the viscosity and vapour pressure at that temperature | | | | | |

Notes: * **Only needed if the flash point is less than or equal to 60°C.**
** **Only need if the flash point is less than or equal to 60°C OR the product is transported within 15°C of its flash point.**

## Section 6: Relevant Chemical Properties

| | | | | |
|---|---|---|---|---|
| **Water Reactivity Index**<br>1=Reactive<br>2=Highly<br>0=No Reactivity | **(0 - 2)** | | **Ref:** | |
| | **Details** | | | |

| | | |
|---|---|---|
| **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

### Acute Toxicity

| | Qual | Lower Val | Upper Val | Species | Reference/Comments |
|---|---|---|---|---|---|
| **Oral $LD_{50}$ (mg/kg)** | | | | | |
| **Dermal $LD_{50}$ (mg/kg)** | | | | | |
| **Inhalation $LC_{50}$ (mg/l/4h)** | | | | | |

### Corrosivity and Irritation

| | Observation | Species | Reference/Comments |
|---|---|---|---|
| **Skin Irritation/Corrosion** | | | |
| | (Not irritating, Mildly irritating, Irritating, Severely irritating or Corrosive) | | |
| **If Corrosive, exposure time (hrs)** | | | |
| **Eye Irritation** | | | |
| | (Not irritating, Mildly irritating, Irritating or Severely irritating) | | |

### Sensitization

| | Y/N | Reference/Comments |
|---|---|---|
| **Respiratory Sensitizer (y/n)** | | |
| **Skin Sensitizer (y/n)** | | |

### Other Specific Long-Term Effects

| | | Y/N | Reference/Comments |
|---|---|---|---|
| Carcinogen | (Yes/No) | | |
| Mutagen | (Yes/No) | | |
| Toxic to Reproduction | (Yes/No) | | |
| Other Long term effects | (Yes/No) | | |

### Other Relevant Mammalian Toxicity

Acute Mammalian Oral Toxicity Data Taken Into Account

| Effect | Qual | Lower Val | Upper Val | Units | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Acute Mammalian Dermal Toxicity Data Taken Into Account

| Effect | Qual | Lower Val | Upper Val | Units | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Acute Mammalian Inhalation Toxicity Data Taken Into Account

| Effect | Qual | Lower Val | Upper Val | Units | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Additional Skin Irritation Data

| Qty (mgs) | Cover | Exp. Time (hrs) | Species | Observation | Reference |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

Additional Eye Irritation Data

| Qty (mgs) | Exp. Time (hrs) | Species | Observation | Reference |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Additional Notes on Mammalian Toxicity

## Section 8: Marine Pollution

### Acute Toxicity

| | Units | Qual | Lower Val | Upper Val | Species | Reference |
|---|---|---|---|---|---|---|
| 96h Fish LC50 | mg/l/96h | | | | | |
| 48h Crust. EC50 | mg/l/96h | | | | | |
| 72h Algae IC50 | mg/l/96h | | | | | |

### Chronic Toxicity

| | Units | Qual | Lower Val | Upper Val | Species | Reference |
|---|---|---|---|---|---|---|
| 96h Fish LC50 | mg/l/96h | | | | | |
| 48h Crust. EC50 | mg/l/96h | | | | | |
| 72h Algae IC50 | mg/l/96h | | | | | |

**Biodegradation and Bioaccumulation**

| Test | Units | Qual | Value | Method |
|---|---|---|---|---|
| | Reference | | | |
| 28d Biodegradation | (%) | | | |
| | | | | |
| BOD5 | | | | |
| | | | | |
| COD | | | | |
| | | | | |
| BCF | | | | |
| | | | | |
| Log Pow | | | | |
| | | | | |

**Other Relevant Environmental Information**

**Acute Fish Toxicity Taken Into Account**

| Effect | Qual | Lower val mg/l | Upper val mg/l | Exp. Time (hrs) | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Acute Crustacea toxicity Taken Into Account**

| Effect | Qual | Lower val mg/l | Upper val mg/l | Exp. Time (hrs) | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Acute Algal toxicity Taken Into Account**

| Effect | Qual | Lower val mg/l | Upper val mg/l | Exp. Time (hrs) | Species | Reference |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Bioaccumulation – BCF Values**

| Qual | Lower val | Upper val | Duration (days) | Species | Reference |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Bioaccumulation – Log Pow Values**

| Qual | Lower val | Upper val | Reference |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**Biodegradation Values**

| Qual | Lower val | Upper val | Time (days) | Test | Reference |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Additional Ecotoxicity Notes**

**Additional Bioaccumulation Notes**

**Additional Biodegradation Notes**

## Section 9: GESAMP Hazard Profiles and Carriage Requirements

GESAMP Hazard Profiles

| | New Hazard Profile | | Old Hazard Profile | | |
|---|---|---|---|---|---|
| Column:Property | Existing | Proposed | Column | Existing | Proposed |
| | | | | | |
| A1: Bioaccumulation | | | A | | |
| A2: Biodegradation | | | B | | |
| B1: Acute Aquatic Toxicity | | | C | | |
| B2: Chronic Aquatic Toxicity | | | D | | |
| C1: Acute Oral Toxicity | | | E | | |
| C2:Acute Dermal Toxicity | | | | | |
| C3: Acute Inhalation Toxicity | | | | | |
| D1: Skin Irritation/Corrosivity | | | | | |
| D2: Eye Irritation/Corrosivity | | | | | |
| D3: Other long term health effects | | | | | |
| E1: Tainting and Odour | | | | | |
| E2: Wildlife and Seabed | | | | | |
| E3: Beaches and Amenities | | | | | |
| F: Remarks | | | | | |

Carriage Requirements

| Carriage Conditions | Existing | Calculated |
|---|---|---|
| C: Pollution Category | | |
| D: Safety/Pollution Properties | | |
| E: Ship Type | | |
| F: Tank Type | | |
| G: Tank Vents | | |
| H: Tank Environmental Control | | |
| I': Elec. equip - Class | | |
| I'': Elec. equip - Group | | |
| I''':Elec. equip - Fpt >60 C. | | |
| J: Gauging | | |
| K: Vapour detection | | |
| L:Fire Protection | | |
| M: Materials of Construction | No Longer Used | |
| N: Respiratory and Eye protection | | |
| O: Special requirements | | |