

BWM.2/Circ.37
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**INTERNATIONAL CONVENTION FOR THE CONTROL AND MANAGEMENT
OF SHIPS' BALLAST WATER AND SEDIMENTS, 2004**

Information that should be made available in proposals for approval of ballast water management systems in accordance with the Procedure for approval of ballast water management systems that make use of Active Substances (G9)

1 The Marine Environment Protection Committee, at its sixty-third session (27 February to 2 March 2012), concurred with the conclusion of the Ballast Water Review Group regarding the minimum information that should be available in proposals for approval of ballast water management systems in accordance with paragraph 8 of the Procedure for approval of ballast water management systems that make use of Active Substances (G9), as set out in the annex.

2 Member Governments are invited to bring this circular to the attention of all parties concerned.

ANNEX

INFORMATION THAT SHOULD BE MADE AVAILABLE IN THE APPLICATIONS FOR APPROVAL IN ACCORDANCE WITH PARAGRAPH 8 OF THE PROCEDURE FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES (G9) (THE NON-CONFIDENTIAL INFORMATION TO BE SUBMITTED TO MEPC)

This document specifies the minimum information that should be contained in an application for Basic or Final Approval in accordance with paragraph 8 of Procedure (G9). It is structured based on the "Methodology for information gathering and the conduct of work of the GESAMP-BWWG" contained in document BWM.2/Circ.13/Rev.1.

The information should be presented in a clear and succinct manner. Tables should be used wherever possible. If it is not possible to submit the relevant information in the proposal for approval due to page limits agreed for MEPC submissions, a separate information document should be used that is submitted at the same time.

1 INTRODUCTION

The terms, definitions and abbreviations used in this document are defined in the "Methodology for information gathering and the conduct of work of the GESAMP-BWWG", contained in document BWM.2/Circ.13/Rev.1.

2 GENERAL

Whenever literature data is used, full reference information should be provided.

3 APPLICATION DATA SET

3.2 Identification of the Active Substance or Preparation (Procedure (G9))

- Chemical identification and description of the chemical components even if generated on board.
- A proposal for approval should include a list of the name and relative quantities (in volumetric percentages) of the components.

3.2.1 Preparations

- Name, CAS-number (if applicable), list of components, and concentrations of all hazardous components.

3.2.2 Active Substances

- Name, CAS number, concentration (if applicable: intended minimum and maximum application concentration), purity and identification of impurities (by chemical name and CAS number).

3.2.3 Relevant Chemicals (Procedure (G9), paragraph 2.1.4)

- Results of the chemical analysis of the treated ballast water.
- Name, CAS number, and concentration.
- Provide reasoning why substances were or were not selected for further investigation during risk assessment.

Information on all analysed substances, even if the analytical results were below the detection limits, is desired here. All substances in the treated ballast water that were detected above the detection limit are regarded as Relevant Chemicals and should be evaluated.

Chemical analysis results should be accompanied by a specification of the applied Active Substance concentration, test conditions, characteristics of the test water (temperature (T), pH, salinity, TOC, DOC, TSS), sampling time, handling and storage of samples before analysis, and analytical method.

If chemical analyses were performed during more than one test run, the number of test runs should be stated and results should be reported either in the form of mean values \pm standard deviation or minimum/maximum concentrations measured or individual measurements for each test run. Analytical results should be provided for both treated and control samples.

Reasoning should be provided, based on the documented state of knowledge, on which basis the selection of substances for inclusion in the chemical analysis was made, taking into account the chemical reactivity of the Active Substance and other components of the respective system. For instance, for chlorination systems, a minimal set of potentially relevant substances can be found in document MEPC 59/2/13. A more extensive list can be found in Annex II of the final report of the R&D-project "Proposal for a harmonized Emission Scenario Document on ballast water discharge" (MEPC 62/INF.19).

3.2.4 Other Chemicals

Information on all Other Chemicals (like cleaning agents, chemicals for neutralization, etc.) should be included here.

- Name, CAS number, concentration, and purpose.
- If required (e.g. in case of hazardous properties or qualification according to GHS) a human and an environmental risk assessment should be performed and a justification why such substances are not treated as Relevant Chemicals should be included.

3.3 Data on effects on aquatic plants, invertebrates and fish, and other biota, including sensitive and representative organisms (Procedure (G9), paragraph 4.2.1.1)

The tests for Active Substances, Preparations, Relevant Chemicals and Other Chemicals should be carried out in accordance with internationally recognized guidelines (preferably Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals, USA, and other EPA guidelines or other equivalent tests).

3.3.2 Acute aquatic toxicity

- Data (LC₅₀/EC₅₀) for all Active Substances, Relevant Chemicals, Other Chemicals for three different trophic levels for the aquatic compartment (algae, fish, crustaceans), preferably including data on two additional marine taxonomic groups (e.g. echinoderms, molluscs).
- Data should be presented and discussed either on the basis of toxicological tests or existing toxicological knowledge for each end point listed.

3.3.3 Chronic aquatic toxicity

- Data (EC₁₀, NOEC) for all Active Substances, Relevant Chemicals, Other Chemicals for three different trophic levels for the aquatic compartment (algae, fish, crustaceans).
- Data should be presented and discussed either on the basis of toxicological tests or existing toxicological knowledge for each end point listed.

3.3.4 Endocrine disruption

It should be evaluated if any of the substances is an endocrine disrupting chemical using studies or, if none are available, literature data.

3.3.5 Sediment toxicity

To be able to evaluate risk to the sediment data on the partition, coefficient K_{oc} is needed. This is also important for the MAMPEC calculations. If the K_{oc} values are high (trigger: 500 L/kg), it would be desirable to assess sediment toxicity tests or, if these are not available, assess the toxicity using established national or international methods such as the equilibrium partitioning method (EPM) according to the "Technical Guidance Document on Risk Assessment" (TGD) to the European Biocides Directive (Directive 98/83/EC). An evaluation of the PNEC_{sediment} should be included if data indicate the risk of sediment toxicity.

3.3.6 Food web/population effects

The results of section 3.3.6 should be discussed referring to the effects of the substances on the food web here.

3.4 Data on mammalian toxicity (Procedure (G9), paragraph 4.2.1.2)

3.4.1 General

- For proprietary experimental data the applied test method should be specified.
- For each toxicological endpoint, the quality of the available data and the implications of the results should be briefly discussed.

3.4.2 Acute toxicity

- Lethal or limit dose information, exposure route, species.

3.4.3 Effects on skin and eye

- Application form/concentration tested, severity and reversibility of effect, species or in vitro model.
- If tests have not been carried out on account of extreme pH or known or suspected corrosive properties this should be clearly stated and supporting information provided.

3.4.4 Repeated-dose toxicity

- NOAEL or LOAEL, dose range tested, most sensitive effect observed (target organ), test duration, exposure route, species, and sex.

3.4.5 Chronic toxicity

- NOAEL or LOAEL, dose range tested, most sensitive effect observed (target organ), test duration, exposure route, species, and sex.

3.4.6 Developmental and reproductive toxicity

- NOAEL or LOAEL for systemic parental toxicity, effects on reproduction, and developmental effects, dose range tested, most sensitive effect observed, test duration, exposure route, and species.

3.4.7 Carcinogenicity

- NOAEL or LOAEL for tumour and non-tumour effects, dose range tested, most sensitive effect observed, test duration, exposure route, species, and sex.
- If available carcinogenicity classifications are cited, a full verbal description of the relevant classification should be provided as well as the year of the last assessment. It is not appropriate to cite carcinogenicity classifications that have been outdated by more recent relevant experimental data.

3.4.8 Mutagenicity/Genotoxicity

- Experimental model, dose range tested.

3.4.9 Toxicokinetics

3.5 Data on environmental fate and effect under aerobic and anaerobic conditions (Procedure (G9), paragraph 4.2.1.3)

3.5.2 Modes of degradation (biotic; abiotic)

Information on the specific degradation rates (biotic and abiotic) at different salinities and temperatures is desirable for the evaluation of the persistence of all substances and can be used for the MAMPEC calculations. Potential environmental, health and safety consequences of observed degradation rates should be discussed as appropriate.

3.5.3 Persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters)

The results from section 3.5.2 should be discussed here regarding the classification as persistent (PBT-approach) substances. Relevant metabolites should be identified and it should be discussed whether they possess hazardous properties according to the PBT assessment.

3.5.4 Bioaccumulation, partition coefficient, octanol/water partition Coefficient

To be able to evaluate the MAMPEC calculations the octanol-water partition coefficient K_{ow} is needed. The bioaccumulation already is discussed under 3.3.6 and 3.3.7.

3.5.5 Bioavailability/biomagnification/bioconcentration

For the evaluation of the potential for bioaccumulation, the $\log K_{ow}$ and/or the bioconcentration factors (BCF) data is needed. Calculation of the K_{ow} according to acknowledged standards, e.g. ACD is acceptable. A substance is regarded as (potentially) bioaccumulative if the $\log K_{ow}$ is >3 and $BCF > 2000$. If the $\log K_{ow}$ is above 3, testing of the bioaccumulation potential should be considered. The BCF, for example, could be calculated with the *formulae* 74 and 75 of the TGD (see 3.3.5) using the $\log K_{ow}$. Other established methods for deriving the BCF may be used. Where tests are not applicable, or if $\log K_{ow} < 3$, BCF values may be estimated using (Quantitative) Structure-Activity Relationship ((Q)SAR) models.

3.5.6 Reaction with organic matter

If there are reactions with organic matter these should be discussed. It should be described to what extent this issue was investigated, experimentally or by analysis of available literature data.

3.5.7 Potential physical effects on wildlife and benthic habitats

If there are effects on wildlife and benthic habitats, these should be discussed.

3.5.8 Potential residues in seafood

If there are potential residues in seafood, these should be discussed taking into account the PBT and mammalian toxicity properties of the substances.

3.5.9 Any known interactive effects

It should be described to what extent this issue was investigated, experimentally or by analysis of available literature data. If there are identified or suspected interactive effects, these should be discussed.

3.6 Physical and chemical properties for the Active Substances and Preparations and treated ballast water, if applicable (Procedure (G9), paragraph 4.2.1.4)

3.6.1 To be able to evaluate the fate and behaviour in the environment, a basic data set on the physico-chemical properties of all substances is needed.

3.6.2 Melting point.

- 3.6.3 Boiling point.
- 3.6.4 Flammability (flash point).
- 3.6.5 Density (relative density).
- 3.6.6 Vapour pressure, vapour density – The Henry's constant in [$\text{Pa}\cdot\text{m}^3/\text{mol}$] at 20°C and the vapour pressure in [Pa] at 20°C is needed to be able to evaluate the MAMPEC calculations.
- 3.6.7 Water solubility/dissociation constant – The solubility in [g/m^3] at 20°C is needed to be able to evaluate the MAMPEC calculations.
- 3.6.8 Oxidation/reduction potential.
- 3.6.9 Corrosivity to the materials or equipment of normal ship construction.
- 3.6.10 Auto-ignition temperature.
- 3.6.11 Explosive properties.
- 3.6.12 Oxidizing properties.
- 3.6.13 Surface tension.
- 3.6.14 Viscosity.
- 3.6.15 Thermal stability and identity of relevant breakdown products.
- 3.6.16 Reactivity towards container material.
- 3.6.17 pH – Since the pH of test waters can influence the formation of disinfection by-products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of the pH of untreated and treated ballast water.
- 3.6.18 Salinity – Since the salinity of test waters can influence the formation of disinfection by-products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of the salinity of untreated and treated ballast water. If water of different sources was mixed or any additives were added to natural test water to achieve the given salinity, this should be specified.
- 3.6.19 TOC, DOC, % particulate matter – Since the organic carbon and particulate matter content of test waters can influence the formation of disinfection by-products, all chemical analysis results relating to the investigation of by-product formation should be accompanied by a specification of TOC, DOC, and total suspended solids (TSS) of untreated and treated ballast water. If any additives were added to natural test water to achieve the given concentrations, these should be specified.
- 3.6.20 Other known relevant physical or chemical hazards.

3.7 Analytical methods at environmentally relevant concentrations (Procedure (G9), paragraph 4.2.1.5)

3.7.1 All chemical analysis results should be accompanied by a specification of the applied analytical method, its detection and quantification limits and known potential interferences.

4 USE OF ACTIVE SUBSTANCE OR PREPARATION

4.1 The manner of application

All of the following information is deemed to be relevant for environmental and/or human health protection and should be included in the non-confidential dossier:

- manner of application of the Active Substance or the Preparation, including required dosage and retention time;
- recommended methods and precautions concerning safe handling, use, storage, and transport;
- procedure to be followed in case of fire, and the nature of reaction products, combustion gases, etc.;
- emergency measures in case of an accident;
- an indication of the possibility of destruction or decontamination following release in the marine environment;
- procedures of waste management of the Active Substance;
- the possibility of reuse or recycling;
- the possibility of neutralization;
- conditions for controlled discharge;
- the amount of substance on board ship;
- appropriate risk management measures; and
- an evaluation of proposed risk management measures in respect to the hazards to ship, personnel and the environment.

5 MATERIAL SAFETY DATA SHEETS (Procedure (G9), paragraph 4.2.7)

The classification under GHS should be given for all Active Substances, components of a Preparation, Relevant Chemicals and other by-products. Where a substance is not classified as hazardous under GHS, this should be indicated.

6 RISK CHARACTERIZATION

6.1 Screening for persistence, bioaccumulation and toxicity (Procedure (G9), paragraph 5.1)

This section should include a comparison between the PBT properties of the substances that were already discussed in the sections 3.3.2 (acute toxicity), 3.3.3 (chronic toxicity), 3.5.3 (bioaccumulation) and 3.5.4 (persistence) and the PBT criteria. Again an orientation could be the TGD (section 4.4.2, paragraph 3.5.5). The conclusions from the PBT assessment should be given.

6.2 Evaluation of the treated ballast water (Procedure (G9), paragraph 5.2)

The test conditions should be described in detail (organisms tested, salinities, duration of the test, temperature, organism density, sediment load, etc.). A presentation of the results in tables is desirable. The results should be discussed. In a first step, a conservative approach with no dilution should be discussed; in a second step realistic dilution scenarios (dilution factor according to the GESAMP-BWWG Methodology) should be used. The rationale for taking a conservative approach is that there could be multiple discharges into one location (even though this is not necessarily the case).

The test results to be provided should include all endpoints as appropriate based on the experimental design, e.g. acute 24-hour, 48-hour, 72-hour, and 96-hour Lethal Concentration at which x% of the test organisms die (LC_x), No Observed Adverse Effect Concentrations (NOAECs), chronic No Observed Effect Concentration (NOEC) and/or Effect Concentration at which x% of test organisms show effect (EC_x).

6.2.3 Determination of holding time

Based on the efficacy, the decay rates and the ecotoxicity tests with treated ballast water the holding time should be determined. It is important to note the range of water temperatures, salinity and other relevant variables at which this holding time is valid.

6.3 Risk characterization and analysis

6.3.1 Prediction of discharge and environmental concentrations

The Predicted Environmental Concentrations (PEC) should be predicted for all substances relevant for the risk assessment preferably using the latest MAMPEC model. The input parameters for the substance properties, the environment and the emission should be stated here. To be able to recalculate the MAMPEC results, screenshots of the input screens are helpful. If no information on the degradation rates is available, no degradation should be assumed in MAMPEC. It should be declared if that was the case. To be able to calculate the PEC/PNEC ratios, the environmental concentrations (maximum concentration) for all substances relevant for the risk assessment should be noted in this section.

6.3.2 Effects assessment

A short summary of the data for ecotoxicity should be provided.

6.3.3 Effects on aquatic organisms

Predicted No Effect Concentrations (PNEC) should be derived using the appropriate assessment factors (AF) according to TGD (section 3.3.1.1). The chosen AFs should be discussed. A tabular overview on the data is desirable.

6.3.4 Comparison of effect assessment with discharge toxicity

A short discussion is eligible whether the discharge toxicity shows any unexpected effects that cannot be explained by the toxicity data of the single substances.

7 RISK ASSESSMENT

7.1 Risk to safety of ship

For corrosion testing, an overview of the evaluation and results should be included and the test duration and the materials and concentrations tested should be clearly stated.

For all potential risks to ship/crew including:

- increased corrosion;
- fire and explosion;
- storage and handling of the substances;
- contact with, or inhalation of, process products; and
- noise.

Minimum relevant information should include the identification and discussion of risks or justification as to why there is no risk.

7.2 Risks to human health

The basic approach followed should be outlined. If specific guidelines were applied, these should be identified. Identified hazards (according to sections 3.2 and 3.4) should be specified.

7.2.2 Health effects in humans

Potential health effects arising from each identified hazard (according to sections 3.2 and 3.4) should be discussed and quantified. Particular attention should be given to the possibility of interactions and/or cumulative effects.

7.2.3 Human exposure scenario

It should be clearly stated which unit operations can be identified for the operation of the BWMS, regardless of their exposure potential. For each unit operation a brief appraisal of the potential of human exposure should be given. Where human exposure cannot be excluded, the exposure scenario should be described in detail and the quantitative exposure estimation should be given for each relevant substance, population group and exposure route, accompanied by information on the input parameters used.

The applied approach for risk characterization should be described and the calculated level of risk should be stated. Envisaged risk reduction measures should be listed together with an evaluation of their effectiveness.

7.3 Risks to the aquatic environment

The calculated PNEC values should be compared with the PECs derived from MAMPEC. A PEC/PNEC ratio greater than 1 indicates a risk for the environment. Appropriate risk mitigation measures should be proposed.

8 ASSESSMENT REPORT (Procedure (G9), paragraph 4.3)
