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POSSIBLE APPROACH FOR DEVELOPING DATA TO ESTIMATE LEACHING RATES OF BIOCIDAL ACTIVE SUBSTANCES FROM ANTIFOULING COATING FILMS

Series on Biocides
No. 3

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FOREWORD

This document, describing a Possible Approach for Developing Data to Estimate Leaching Rates of Biocidal Active Substances from Antifouling Coating Films, was developed based on the need to address the leaching rate of biocides from antifouling products, which is one of the most important parameters to estimate the emission of antifoulants in an environmental risk assessment. Therefore, the purpose of this document is to outline various approaches used to estimate leaching rates of antifouling products. It is to be considered as a living document, likely to be revised when new data becomes available.

This document was approved by the Task Force on Biocides at its 9th meeting held on 1-2 December 2011.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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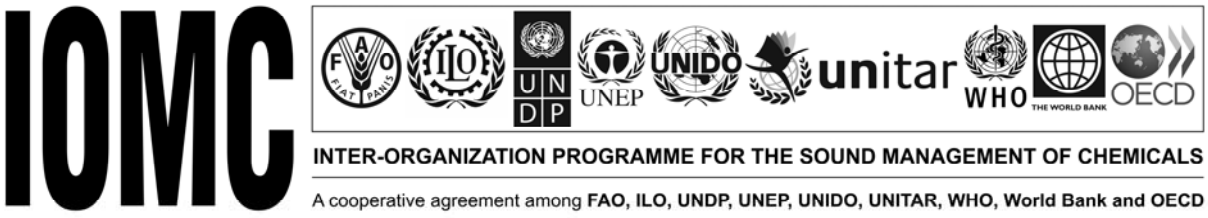

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This document only outlines available methods to estimate leaching rate and does not guarantee that any one method is acceptable internationally. Therefore, applicants must consult with individual regulatory authorities to discuss acceptability of specific methods / models in any country where registration / authorization is required.

1. USE OF LEACHING RATE DATA

1. One of the principal uses of biocide release rate data from antifouling coatings is in relation to environmental impact or risk assessments as part of the product regulatory and approval process. This process will often make use of a generic environmental chemical fate model such as MAMPEC (Marine Antifoulant Model to Predict Environmental Concentrations) which can take into account the many factors that will influence environmental concentration, for example emission factors (e.g. leaching rates, shipping intensities, residence times, ship hull underwater surface areas), compound related properties and processes (e.g. Kd, Kow, Koc, volatilisation, speciation, hydrolysis, photolysis, bacterial degradation), and properties and processes related to the specific environment (e.g. currents, tides, salinity, suspended matter load). Irrespective of the process that is followed, it is essential that the most reliable available estimate of the biocide release rate is used in order to allow a reliable assessment to be made of the environmental risk

2. REVIEW OF TEST METHODS

2. A number of alternative approaches have been used to estimate the release rates of biocides from antifouling coatings. There are three ways to estimate leach rates of antifouling agents: laboratory studies, calculation methods and field tests.

3. Laboratory tests used for the estimation of active substance release rates are based on standardized ASTM and ISO (rotating cylinder) methods. They are tests that can be carried out to recognized standards but are known to considerably overestimate product leaching rate (as much as 5-20 times) and the reproducibility of results has been shown to be poor. Testing needs only to last a minimum of 45 days which may only determine the initial surge for biocide release when the paint film first comes into contact with water and, as not all paints show a steady-state, may be too brief in some cases to reveal long-term changes in the release rate over the full in-service period, which may be >3 years.

4. Calculation methods (such as the CEPE and ISO mass-balance models) compensate for the gross overestimation of rates derived by laboratory methods and the excessive cost of undertaking field tests. However, they are considered to be more representative than laboratory studies as they aim to consider typical leaching over the service life of a product. The original CEPE mass-balance method is a simplified, generic model that assumes an initial 14 day burst of biocide release followed by a constant rate of leaching over the lifetime of the antifouling paint. Its basic principle is that the amount of active substance released into the environment cannot exceed the amount that is added to the paint. The ISO mass-balance calculation method is a further development of the CEPE method. The ISO method can accommodate all possible changes in release rate over the paint lifetime (i.e. an initial 14 day burst followed by constant leaching are not assumed) and allows the maximum possible mean release rate of biocide over the lifetime of the paint to be calculated. This calculation method is applicable to all biocidal active substances in antifoulings and all antifouling paints, if the input values e.g. film thickness, paint life time etc. are accurate and representative for actual use (Marine Environment Protection Committee 60th session Annex MEPC 60/13, 13th December 2009).

5. Field tests (such as the US Navy Dome Method) are conducted whereby a ship's hull is painted with antifouling product and leaching rates measured over time by taking water samples from the "dome". This method is expected to give reliable and realistic leaching rate measurements. However, these data are very expensive to generate and so it is difficult in practice to routinely provide sufficient quantity and quality of data to demonstrate reproducibility and allow statistically valid comparisons of results.

6. In recognition of the fact that the ASTM/ISO laboratory methods and, to a lesser extent, the CEPE and ISO mass-balance calculation methods significantly overestimate the release rate of biocide to the environment, the application of suitable conservative default correction factors to the results of these methods has been proposed to allow the most accurate and reliable estimates of the release rate to the environment to be made in certain scenarios. This approach has been utilised by regulatory authorities in Europe in relation to biocide approvals under the Biocidal Products Directive.

7. A list of references has been provided with this document. Also provided below are various approaches used to determine leach rates of antifouling agents. It should be noted that these lists may not be exhaustive although every effort has been made to consider all currently available methods.

ASTM/ISO Rotating Cylinder Methods for Copper

8. These methods are currently chiefly required by regulatory organizations in the US for estimating copper leach rates.

ASTM Rotating Cylinder (method D6442-06): version 2006; and
ISO Rotating Cylinder (methods 15181-1 and 15181-2): published 01 June 2007.

9. These two methods are technically equivalent and differ only in standards society format. These methods are known to significantly overestimate biocide release rates and therefore do not accurately reflect the true release rate of a biocide.

ASTM/ISO Methods for Other Biocides

i. ISO Method for Zineb (method 15181-1 coupled with 15181-3): published 01 June 2007.

ii. ASTM Method for organotin (method D5108-07): re-approved 2007 (now only used to validate efficacy of sealer coats).

iii. ASTM Methods for organic biocides (zinc and copper pyrithione, DCOIT and CDMTD) (method D6903-07): published 2007.

iv. ISO Method for pyridine-triphenylborane (PTPB) (method 15181-1 coupled with 15181-4): published August 2008.

v. ISO Method for tolylfluanid and dichlofuanid (method 15181-1 coupled with 15181-5): published May 2008.

vi. ISO Method for tralopyril (method 15181-1 coupled with 15181-6): expected publication, 2011.

Harbour Exposed Panel Methods

10. This is a combined laboratory/field method developed by the US Navy (and used solely by the US Navy and associated agencies). These methods essentially involve exposing a coated panel to harbour conditions and then taking that panel to the lab for a release rate determination. A modified experimental set up to the static HEP method uses a rotating apparatus creating a dynamic rotation with a peripheral speed of 9,25 m sec^{-1}. There is limited data on accuracy and precision so the relationship to true environmental inputs directly from ship hulls is not reliably known.

Flume Method

11. Circulating Seawater Flume Method has been developed by the Japanese Maritime Research Institute which they have used to measure biocide release rates. This is still very much an experimental method at this stage and there are no reliable data yet on its reproducibility or the relationship between the results from this method and other methods.

Dome Method

12. Specifically designed to allow *in situ* measurements of biocide release rates directly from the hull of a ship under environmentally realistic conditions while in service. Originally developed to determine organotin release rates but historically more widely used for copper. At present, use of the Dome Method has largely been restricted to the US Navy and its associated agencies because of the expense, but it is considered to be the most reliable available method for directly measuring the release rate of biocide from antifouling paint in service on a ship or boat hull. Some work has recently been conducted by Japanese researchers using a modified dome or box attached to ship hulls. Unlike the US Navy dome, measurements are done in the dry-dock at the end of the coating lifetime and not in water and in service, and so direct measurement of the release rate of biocide to the environment are not possible with this device. Although the amount of data that has been generated using this method is limited, the researchers' results have further validated the mass-balance calculation method.

Calculation Methods

i. CEPE Mass-Balance Method – developed by the European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE). This method is a simplified generic empirical model of biocide release which is based on the underlying fact that the total amount of biocide released by coating cannot exceed the amount of biocide which is originally present in the coating when manufactured. CEPE calculation method significantly overestimates the environmental release rates but to a much lesser extent compared to the ASTM/ISO rotating cylinder methods. The CEPE mass-balance method is utilised by European regulatory authorities when evaluating biocidal active substances in antifouling products, who have also adopted the application of a correction factor to calculated release rates for harbour and marina scenarios to allow the most reliable estimates of release rate to be made.

ii. ISO mass-balance calculation method (ISO10890:2010, published October 2010) – the method addresses the perceived limitations of the CEPE method and is specifically designed to provide biocide release rate estimates that are more suitable for use than the ASTM/ISO laboratory methods. The method allows a worst-case estimate to be made of the total amount of biocide released to the environment over the lifetime of the coating, as well as calculation of the maximum possible mean release rate over the coating's lifetime. It is applicable to the release of any active ingredient from any antifouling paint. The results are numerically consistent with

those of the earlier CEPE calculation method and the use of similar default correction factors is recommended to allow the most reliable estimates of biocide release to the environment to be made.

iii. Polishing Rate Mass-Balance Method – relates the biocide release rate to the in service polishing rate for the antifouling paint. If the volume fraction of biocide in the paint film is known, then the release rate of active ingredient can be calculated if the polishing rate is known. The resulting calculated value can be considered to be the theoretical average release rate for the biocide over the entire lifetime of the coating. This does not take into account the short-term changes in release rate due to the vessel's sailing pattern, etc. The use of this method is restricted to selfpolishing, erodable/ablative and hybrid antifouling coatings.

Ion Exchange Method

13. An innovative method developed to quantify biocide release rates. In the published work, a commercially available antifouling coating underwent rotary immersion testing at 0, 0.51 and 2.05 m s^{-1}. Scanning electron microscopy (SEM) and energy dispersive x-ray (EDX) analysis were used to assess leach layer formation, percentage cuprous oxide by weight and particle size distribution (PSD). Biocide release rates and surface roughness were also measured. An increase in rotary speed caused a spike in Cu^{2+} release rate after which the release rate stabilized to previous levels. An increase in leach layer thickness was also observed after the rotary speed increase. A model is suggested to account for the observations.

Prolonged Copper Release Rate Method

14. This test method is based on ASTM 6442-05 ("Standard Test Method for Determination of Copper Release Rate from Antifouling Coatings in Substitute Ocean Water"), which is also similar to ISO 15181-1 & -2. The principle of the test is rotating test cylinders immersed in seawater. According to these standardised methods the testing time may be extended beyond the normal 45 days, which in a study on prolonged copper release rate (Forsberg, 2008) was extended to 122 days. The aim was to investigate how the steady-state leaching rate was affected by the test extension. The results from the study suggest that, for the paints studied, the leaching rate continues to fall beyond 45 days, and so a rotating cylinder test which is prolonged to around 120 days would give a more realistic steady state release value. Within the EU, it has been proposed to use a correction factor of 5.4 to release rate results obtained by the rotating cylinder method run over 45 days. With a prolonged test a smaller correction factor could be used, or such factor may not be needed at all. The purpose is to find a steady state and therefore it might be possible to decrease the number of samplings in the beginning of the test period. The results are broadly in line with other extended studies using this method but substantial further work would be required to identify the optimum standardized study length beyond 45 days and generate revised correction factors to reliably predict environmental inputs.

3. MAIN METHODS CURRENTLY USED

15. There are several methods currently being used within Europe and the United States. The ASTM and ISO Rotating Cylinder Method(s) are the most popular regarding a standard laboratory method. However, the rotating cylinder method was not designed to provide 'real-life' data for use in environmental risk assessments, and the ASTM and ISO standards explicitly caution against such use. Even though the ASTM or ISO Rotating Cylinder Method(s) were not designed for developing risk assessments they have been validated for copper and, to a more limited extent, organic biocides if appropriate correction factors are used. It should be noted that since the repeatability of the methods have been found to be fairly good they are useful when comparing different products during research and development activities.

16. Additionally, two existing methods have been validated on a small number of coatings and only on one site. These methods are The Dome Method and the Harbor Exposed Panel Method developed by the US Navy. The CEPE mass-balance (calculation) method has also been developed and validated for copper release and this has recently been further developed as the ISO mass-balance calculation method for use with any biocide (or combination of biocides) in any paint.

17. An excellent source of information is a discussion document entitled "Improved Estimates of Environmental Copper Release Rates from Antifouling Products" written by Dr Alistair Finnie of International Paint Ltd on behalf of the Antifouling Working Group of CEPE and the North American Marine Antifouling Group of the US National Paint and Coatings Association. This should be available to members of either trade association and provides a comprehensive comparison of results from available leach rate methodologies (including results from the Dome Method) and establishes correction factors on that basis. This document has also been published in a peer-reviewed scientific journal (*Biofouling*) and is publically available. An updated overview of the generation of biocide release rate data and its use in environmental risk assessments was submitted by Dr Finnie to the International Maritime Organization on behalf of the International Paint and Printing Ink Council (IPPIC) in 2009.

4. MOST RELIABLE METHOD (OF THOSE CURRENTLY BEING USED)

18. Based on the survey of existing methods outlined in Dr Finnie's paper, "Improved Estimates of Environmental Copper Release Rates from Antifouling Products", the most reliable method to date for determining actual biocide release rates from a ship's hull in-service is generally considered to be the US Navy's Dome method. This method is not considered to be a practical method for the routine generation of release rate data because it requires access to underwater hulls of in-service vessels using divers which can significantly increase overall costs.

19. The ASTM/ISO rotating cylinder methods significantly overestimates the true environmental input of copper from an antifouling coating on a vessel under pier-side conditions. The CEPE mass balance calculation method also significantly overestimates the environmental release rates but to a lesser extent. The CEPE calculation method assumes that all of the biocide is released from the paint film over its specified lifetime (which can be supported by robust efficacy data). However, EU member states have indicated that they accept this to be an overestimate as paint is never entirely lost over the hull surface - it may be possible for applicants to justify reduction to a 90% loss of total biocide, with 10% remaining at the time that the hull will require coating with fresh antifouling product. 90% loss of total biocide over the lifetime of the paint is the default input for the ISO mass-balance calculation method.

20. In the absence of direct measurements of environmental copper release rates for individual vessels in specific waters, it is proposed that the most realistic and practical method to define a release rate for use in an environmental risk assessment is through an application of a correction factor to either release rates obtained using the ASTM/ISO method or the ISO & CEPE calculation method. Additionally, because direct measurements of environmental release rates show an apparent dependence on the coating type, in theory if suitable data were available, a separate correction factor could be derived for each coating type or even for individual coatings to provide the most accurate estimate of environmental release rates. In the absence of such detailed coating-specific data, the application of conservative default correction factors is preferred - this is discussed in detail within Dr Finnie's paper.

21. One of the main obstacles to widespread acceptance of the original CEPE method is the shortage of validation data for biocides other than copper, especially organic co-biocides. Most antifouling products on the market, including self-polishing copolymer coatings, contain a main biocide and 1 or more co-biocides which, by design, should have synchronous leaching rates. Although a study (Finnie, 2008) has shown that leaching of the main and co-biocide is highly synchronous for the series of paints that were

tested and that the leaching of both biocides from the paint is consistent with the CEPE model, it is conceivable in principle that the leaching of the main and co-biocide(s) could be less synchronised for some other paints. In such cases, the underlying assumptions of the CEPE calculation – the 14-day initial burst followed by a constant steady state release rate for each biocide present – would not necessarily hold true.

22. In developing the ISO 10890:2010 calculation method, the valid criticisms of the CEPE calculation have been addressed. This resulted in a revised calculation that is scientifically robust and universally applicable to all paint types and all biocides.

23. In March 2010, IPPIC presented an overview of the generation and use of biocide release rate data to the International Maritime Organization's Marine Environmental Protection Committee (IMO-MEPC). This concluded that the mass-balance calculation method, when used in conjunction with suitable conservative default correction factors, is the most appropriate route to generate representative biocide release rate estimates for anti-fouling products. This approach enables more accurate environmental risk and exposure evaluations to be made, allowing any decisions on the restriction of anti-fouling products to be made with greater confidence, without subjecting the aquatic environment to greater risk. These conclusions were accepted by the Committee and were formally noted.

5. METHODS USED IN THE US AND EU

24. For regulatory purposes in the US, the ASTM rotating cylinder methods are in use. There are 3 methods: 1 for organotin, 1 for copper and 1 for a total of four organic biocides (zinc and copper pyrithione, DCOIT and CDMTD).

25. The US EPA accepts data from the ASTM/ISO rotating cylinder methods and also uses the MAMPEC model to determine concentrations of antifouling agents in water. At this time, the US EPA believes the proposed CEPE method may be an appropriate release rate method which could potentially be used in future.

26. The US Navy developed data using the Dome and Harbour Exposed Panel methods. Dr Finnie has used those data (among other data sets) to develop his correction factor approach. However, the US EPA does not actively require Dome data and/or Harbour Exposed Panel data for regulatory purposes.

27. Although a decision on future leaching rate data requirements in support of product authorisations under the EU Biocidal Products Directive (BPD) has still to be fixed, the EU, like the US, accepts the ASTM/ISO rotating cylinder methods to determine the release rates of biocides from antifouling coatings and may therefore require these methods to support product authorizations. However, the CEPE mass-balance is also considered acceptable and has been submitted to support antifouling active substance reviews under BPD and contribute towards support of product authorizations. This method is used to estimate the steady state leaching rate after equilibrium is reached (taken to be 14 days after immersion of newly coated hull). A correction factor may be applied to compensate for overestimation of leaching rate as refinement to risk assessment (harbour and marina scenario) if the PEC/PNEC value exceeds 1.0 to make predicted environmental concentrations more realistic. The approach applied under the BPD is described in the workshop report "Harmonisation of leaching rate determination for antifouling products under the Biocidal Products Directive" of 2006, and the extension of the correction factor approach to both harbour and marina scenarios was subsequently agreed at the Biocides Technical Meeting in June 2010.

28. Although the ISO mass-balance calculation method can be considered to be an improved version of the CEPE method, it has only recently been published in its final form and so the US and EU regulatory authorities have yet to formally decide on its acceptability.

6. DEVELOPMENT OF NEW METHODS

29. Besides the methods for the determination of the leaching rate of antifouling paints as mentioned in the references to this paper, there are currently no further active developments of methods known to the authors of this document. However, it should be kept in mind that ongoing development of new tests and refinement of existing ones may be taking place so discussion with relevant trade associations and regulatory authorities should be undertaken before commissioning leaching rate studies.

30. Based on the available models that can be used for evaluating leaching rates of antifoulants, the OECD Task Force on Biocides wishes to progress work in this arena by adopting a tiered approach. For tier 1 (i.e. laboratory and calculation methods), more data need to be reviewed before possibly agreeing on (a) recommended method(s). Once tier 1 is completed, the TFB can work on tier 2 (i.e. field and semi-field methods) for determining antifouling leach rates.

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