BS ISO 13073-3:2016

BSI Standards Publication

Ships and marine technology — Risk assessment on anti-fouling systems on ships

Part 3: Human health risk assessment method of biocidally active substances used in anti-fouling paints on ships during the application and removal processes

Documents
Document Sharing Hub

Full document details: BS ISO 13073-3:2016

National foreword

This British Standard is the UK implementation of ISO 13073-3:2016.

The UK participation in its preparation was entrusted to Technical Committee SME/32, Ships and marine technology - Steering committee.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016.
Published by BSI Standards Limited 2016

ISBN 978 0 580 87306 5

ICS 13.020.99; 47.020.99

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2016.

Amendments issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS ISO 13073-3:2016

INTERNATIONAL STANDARD

ISO 13073-3

First edition
2016-06-01

Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 3: Human health risk assessment method of biocidally active substances used in anti-fouling paints on ships during the application and removal processes

Navires et technologie maritime — Évaluation des risques pour les systèmes antisalissure sur les navires —

Partie 3: Méthode d'évaluation du risque pour la santé humaine des substances bioacidement actives dans les peintures antisalissure sur les navires durant les processus d'application et d'élimination

Reference number
ISO 13073-3:2016(E)

Documents
Document Sharing Hub

© ISO 2016

Full document details: BS ISO 13073-3:2016

COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub

Full document details: BS ISO 13073-3:2016

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Terms and definitions ... **1**

3 General principles ... **5**
3.1 Application ... 5
3.2 Application consideration ... 5
3.3 Structure and procedure of human health risk assessment ... 5

4 Exposure assessment ... **6**
4.1 Selection of a representative product ... 6
4.2 Defining the exposure scenario ... 6
4.2.1 General ... 6
4.2.2 Types of exposure to consider ... 6
4.2.3 Determination of a representative exposure ... 7
4.3 Determination of dose ... 7

5 Hazard assessment ... **8**
5.1 Data and information ... 8
5.1.1 Collection and acquisition of data and information ... 8
5.1.2 Information acquisition through testing ... 8
5.1.3 Reliability assessment of the collected data ... 9
5.1.4 Consideration of animal welfare ... 9
5.2 Defining the NOAEL ... 9

6 Risk characterization ... **9**
6.1 General ... 9
6.2 Tiered system ... 10
6.3 Consideration of uncertainty factor ... 10
6.4 Characterization of risk ... 10

7 Assessment results ... **10**
7.1 Decision at each tier ... 10
7.1.1 Tier 1 decision: Preliminary acceptability ... 10
7.1.2 Tier 2 decision: Continuing acceptability ... 10
7.1.3 Tier 3 decision: Full acceptability ... 11
7.2 Expert judgement ... 11
7.3 Additional information obtained after last risk assessment ... 11

8 Risk assessment report ... **11**

Annex A (normative) **Risk characterization process for human health risk assessment of biocidally active substances used in anti-fouling paints on ships** ... **12**

Annex B (informative) **Examples of operator exposure models** ... **22**

Annex C (informative) **Predicting operator exposure values** ... **24**

Annex D (informative) **Examples of setting of uncertainty factor (UF)** ... **27**

Annex E (informative) **Examples of testing methods** ... **31**

Annex F (informative) **Examples of guidance for determining data quality** ... **33**

Annex G (normative) **Minimum required information for a risk assessment report** ... **34**

Bibliography ... **36**

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 8, *Ships and marine technology*, Subcommittee SC 2, *Marine environment protection*.

ISO 13073 consists of the following parts, under the general title *Ships and marine technology — Risk assessment on anti-fouling systems on ships*:

— *Part 1: Marine environmental risk assessment method of biocidally active substances used for anti-fouling systems on ships*

— *Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances*

— *Part 3: Human health risk assessment method of biocidally active substances used in anti-fouling paints on ships during the application and removal processes*

© ISO 2016 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

Introduction

The attachment of fouling organisms, such as barnacles and algae, on the submerged parts of a ship's hull increases the propulsive resistance of the hull against water, leading to increased fuel consumption. In addition, this may also result in accidental introduction of non-indigenous species to a foreign marine environment, which may possibly cause significant and harmful impact on the local environment. In order to prevent such circumstances, an anti-fouling system that employs biocidally active substances (e.g. anti-fouling paint) to prevent attachment of fouling organisms can be applied onto the hull of the ship. The harmful effects of organotin compounds used in the maritime industry as biocides against marine organisms have been of global concern on human health. To prevent the continued use of these compounds, the International Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention) was adopted at the International Maritime Organization (IMO) diplomatic conference held in London in October 2001 and entered into force in September 2008.

The Convention envisages handling various harmful anti-fouling systems within its framework and lays out a process by which anti-fouling systems can be risk assessed. Annexes 2 and 3 of the Convention include the list of information needed to determine whether an anti-fouling system is harmful to the environment and should be restricted from use on ships; however, a marine environmental risk assessment method for making this decision is not provided. There is a global need for an international assessment method for scientific environmental risk assessment for biocidally active ingredients being substituted for organotin biocides in anti-fouling systems.

ISO 13073-1 and ISO 13073-2 specify the risk assessment methods for biocidally active substances and anti-fouling systems containing the biocidally active substances, respectively. In addition to these risk assessments to protect the delicate marine ecosystems, there is also a need for protecting human health. Anti-fouling paints, which are the most commonly used anti-fouling systems to ships, potentially result in risk to the workers applying or removing them.

This part of ISO 13073 describes a method which allows a pragmatic approach to introducing human health risk assessment particularly for the workers engaged in anti-fouling paint application and removal operations. This method provides comprehensive guidelines for a risk assessment that helps protect workers in countries without a self-regulation or approval system on anti-fouling paints or those with a less well-developed system.

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

Documents
Document Sharing Hub

INTERNATIONAL STANDARD ISO 13073-3:2016(E)

Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 3: Human health risk assessment method of biocidally active substances used in anti-fouling paints on ships during the application and removal processes

1 Scope

This part of ISO 13073 specifies a method of human health risk assessment that enables the evaluation of anti-fouling paint application and removal in order to determine if the product can be used safely where users are at risk of being exposed to biocidally active substances contained within anti-fouling paints. This can be used for a risk assessment to determine the impact(s), if any, on professional or non-professional operators.

This part of ISO 13073 does not specify a specific test method for evaluation of hazard and toxicity or recommend usage restrictions of certain substances.

NOTE 1 This part of ISO 13073 is a "minimum" method, i.e. additional regulations or assessments based on national needs can be warranted.

NOTE 2 While the approach prescribed is a tiered system, studies required in higher tiers can be undertaken in lieu of equivalent lower tier studies.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Some of the definitions for environmental risk assessment provided in ISO 13073-1 and ISO 13073-2 may be different from those of this part of ISO 13073.

2.1
adverse effect
change in morphology, physiology, growth, development or lifespan of an organism which results in impairment of its functional capacity or impairment of its capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences

Note 1 to entry: This definition is given in reference WHO/IPCS, 1994 [63].

2.2
anti-fouling paint
type of anti-fouling system supplied as a form of paint typically consisting of a matrix polymer, pigment(s) and solvent(s)

2.3
anti-fouling system
coating, paint, surface treatment, surface, or device that is used on a ship to control or prevent attachment of unwanted organisms

Note 1 to entry: Systems of control utilizing only physical means are not included within this International Standard.

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

2.4
biocidally active substance
substance having general or specific action such as mortality, growth inhibition, or repellence, on unwanted fouling organisms, used in anti-fouling systems, for the prevention of attachment of sessile organisms

2.5
by-stander
person who is not a direct user of the product or application/removal equipment but who nevertheless may be exposed to the product during its use

2.6
chemical substance
chemical element or its compound in the natural state or obtained by any manufacturing process

2.7
core data
information
study
basic data, information or study which should, in principle, be provided for all biocidally active substances

2.8
expert
person with great knowledge or skill in hazard assessment of chemicals certified by academic society, organization or authority

Note 1 to entry: Those experts include Diplomat of American Board of Toxicology (USA), Fellow of the American Toxicological Society (USA), Diplomat of Japanese Society of Toxicology (Japan), European Registered Toxicologist (EU), Diploma, Korean Board of Toxicology (Korea), Expert in Toxicology, DGPT: sponsored by the German Society of Experimental and Clinical Pharmacology and Toxicology (Germany), UK Register of Toxicologists: sponsored by the Society of Biology and the British Toxicology Society (UK) and Diplomat of the Chinese Society of Toxicology (China).

2.9
exposure assessment
estimation of the range of possible doses (of a biocidally active substance, its degradants and/or metabolites) to individuals (operators) exposed to the biocidally active substance, taking into account the magnitude, frequency, duration, route, and extent (number of people) of exposure

2.10
exposure scenario
set of conditions estimating or clarifying the exposure pathways of a chemical substance to the operator

Note 1 to entry: The exposure scenario should describe the conditions of use, including, but not limited to, routes of exposure, application method, protective equipment used, job duration, etc.

2.11
hazard assessment
process to identify and characterize the adverse effects of a biocidally active substance to which individuals could be exposed

Note 1 to entry: Effects should be assessed adverse only if they affect the viability and normal function of the organism under test.

2.12
lowest observed adverse effect level
LOAEL
lowest tested dose or exposure level at which there are statistically significant increases in frequency or severity of adverse effects between the exposed population and an appropriate control group

© ISO 2016 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

2.13
lowest observed effect level
LOEL
lowest concentration or amount of a substance, found by experiment or observation, that causes any alteration in morphology, functional capacity, growth, development, or life span of target organisms distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure

Note 1 to entry: This definition is given in reference IUPAC Compendium of Chemical Terminology Second Edition; 1997.

2.14
margin of exposure
MOE
ratio of the no observed adverse effect level (NOAEL) to the estimated exposure dose

Note 1 to entry: MOE is also defined as the following formula:

$$\text{MOE}=\frac{\text{NOAEL}}{\text{EXPOSURE}}$$

Note 2 to entry: MOE is used for toxic effects other than non-threshold oncogenic effects. For non-threshold oncogenic effects, then a lifetime exposure analysis with a unit risk should be developed.

Note 3 to entry: This definition is given in reference USEPA.

2.15
no observed adverse effect level
NOAEL
highest tested dose or exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control

Note 1 to entry: Some effects may be produced at this level, but they are not considered as adverse or as precursors to adverse effects.

2.16
no observed effect level
NOEL
greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable alteration of morphology, functional capacity, growth, development or life span of the target organism under defined conditions of exposure

Note 1 to entry: This definition is given in reference IUPAC Compendium of Chemical Terminology Second Edition; 1997.

2.17
non-professional operator
user of the anti-fouling paint, who is considered not to have received specific training relevant to the application or removal of anti-fouling paints and is also known as a consumer, Do It Yourself (DIY) or “amateur” user

2.18
operator
person applying and/or removing the anti-fouling paint

2.19
potential exposure rate
total amount of a defined substance found on the outer layers of clothing or overalls, plus the amount of substance found on subsequent layers inside the outer layer plus the amount of substance found on the skin

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

2.20
professional operator
user of the anti-fouling paint who has been formally trained in the use of both application or removal equipment and in the use of protective clothing necessary for the task

2.21
risk
combination of the probability and the severity of an adverse effect caused by exposure to a chemical substance under defined conditions

2.22
risk assessment
process intended to quantitatively or qualitatively estimate the risk posed by exposure to a substance

Note 1 to entry: A risk assessment may be qualitatively performed in case data on dose-response is insufficient to define a NOAEL (threshold dose).

2.23
risk characterization
estimation of the incidence and severity of the adverse effects likely to occur in a human population due to actual or predicted exposure to a substance

Note 1 to entry: Risk characterization may include "risk estimation", i.e. the quantification of that likelihood.

2.24
ships
vessels of any type whatsoever operating in the marine environment including hydrofoil boats, air-cushion vehicles, submersibles, floating craft, fixed or floating platforms, floating storage units (FSUs) and floating production storage and off-loading units (FPSOs)

2.25
systemic dose
amount of biocidally active substance absorbed by the exposed individual (operator)

2.26
uncertainty factor(s)
UF(s)
factor(s) used to derive a safe dose for humans with (most often) an experimental NOAEL as a starting point

Note 1 to entry: For animal data, a 100-fold uncertainty factor is usually applied to the NOAEL, which includes a 10-fold factor to allow for differences between animals and an average human, and 10-fold to allow for differences between average humans and sensitive sub-groups (WHO/IPCS, 1987 [61]). Where data exists on the level of effects shown in humans versus animals, for example, in physiologically based kinetic effects, then a lower factor may be employed on a case-by-case basis.

2.27
worst case scenario
realistic scenario in which operators are expected to be most exposed to the biocidally active substance

2.28
50 % lethal concentration
LC50
concentration at which 50 % of the test organisms would die in an experiment

© ISO 2016 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

3 General principles

3.1 Application

This part of ISO 13073 can be used for the risk assessment of users exposed to anti-fouling paints (i.e. painters) and other individuals exposed during the application of paint (such as co-workers or painting assistants) for the purpose of protecting persons from unacceptable exposure to biocidally active substances used in anti-fouling paints. Both professional and non-professional operators can be assessed; special attention should be paid to ensuring that the exposure scenarios which most accurately reflect the activities involved are chosen.

This part of ISO 13073 provides minimum guidelines for the following uses:

— regulation of anti-fouling paints by government organizations;

— self-regulation or approval systems carried out for industries or industrial organizations or other third parties;

— evaluations conducted for product development by industries.

Risk assessment shall be conducted for biocidally active substances including their impurities if they meet the requirements for classification as health hazards according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

This part of ISO 13073 will enable quantification of the risk posed to operators handling an anti-fouling paint containing a biocidally active substance.

3.2 Application consideration

This part of ISO 13073 shall be used with considerations described below.

— This part of ISO 13073 provides a method for evaluating the risk of a biocidally active substance (and its relevant metabolites) when applying or removing anti-fouling paints. It does not directly regulate or approve the use or commercialization of the substance.

— This part of ISO 13073 does not include a method for general risk assessment of industrial chemical substances based on the assumption that it can be carried out adequately by other methods.

— When using this part of ISO 13073 in systems of regulation, approval or use of a biocidally active substance which is demonstrated as not having an acceptable risk assessment at Tier 1 and Tier 2 shall be restricted and the substance shall be evaluated according to the process of Tier 3. These restrictions shall be established by considering the potential severity of the substance on the persons potentially exposed.

All data submitted by an applicant are considered the property of the applicant under this part of ISO 13073. These data shall not be made available to other applicants without prior written approval from the owner of the data.

3.3 Structure and procedure of human health risk assessment

Human health risk assessment consists of three procedures: exposure assessment, hazard assessment and risk characterization (see Figure 1). Exposure assessment is a procedure to estimate the dose that the persons receive, while the hazard assessment aims at defining the dose at which a potential health effect would be expected. If a threshold dose (i.e. a safe dose) cannot be found, qualitative hazard assessment should be applied.

Risk characterization is the final phase of the human health risk assessment process. It integrates hazard assessment and exposure assessment. This phase determines the probability of an adverse effect to human health at the estimated exposure levels. The quantitative risk characterization is shown

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

as a "margin of exposure (MOE)" using the data derived from the exposure and hazard assessments. The MOE is a quantitative index for the risk assessment.

Detailed procedures of the risk assessment are given in Annex A.

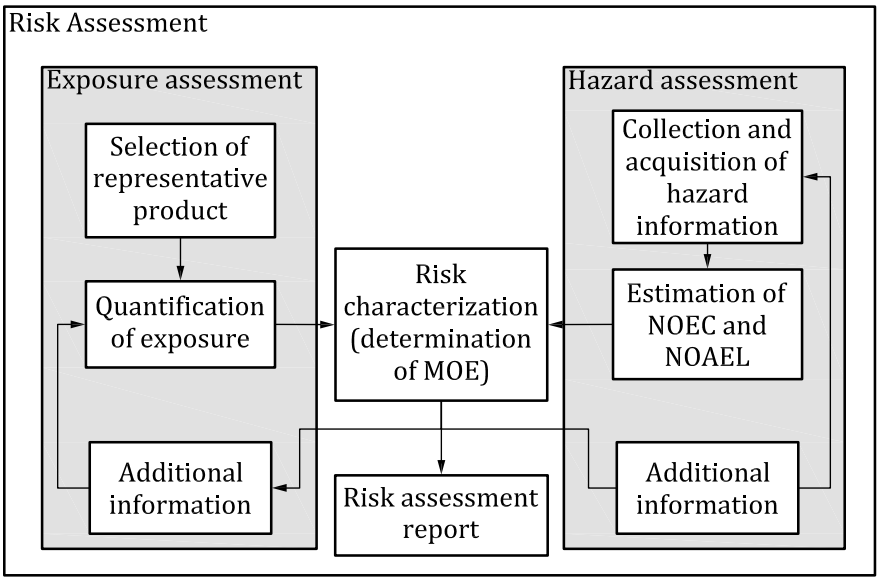

Figure 1 — Composition and schematic procedure of human health risk assessment

4 Exposure assessment

4.1 Selection of a representative product

A representative product for exposure assessment shall be selected to ensure that the anti-fouling paint contains the biocidally active substance to be assessed. In order to assume the worst case, the product chosen shall contain the highest concentration of the biocidally active substance as proposed for use in the marketplace. If no product exists in the marketplace, an experimental product can be used where the level of biocidally active substance has been found to return acceptable anti-fouling performance.

4.2 Defining the exposure scenario

4.2.1 General

An exposure scenario defines the route of exposure and potential level of exposure for the exposed individuals carrying out the activity under consideration. The scenario defined shall consider all elements of the task involved in order to model the exposure as accurately as possible for determining the dose received by the person using the product.

Examples of existing human exposure scenarios can be found in Annex B.

4.2.2 Types of exposure to consider

The risk assessment shall take into account all people who are likely to be exposed to the paint during application or removal. This will depend upon the intended use scenario and could include the use by either professional or non-professional operators [Consumers or Do It Yourself, (DIY)].

It is important to define activities of persons that will be exposed to the product during use. For example, in a dockyard, the following personnel may be exposed:

— sprayers;

© ISO 2016 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016

— other persons in close contact with the sprayer such as boom operators;

— pot-men (operators using spray pumps to supply the sprayers);

— by-standers, etc.

Similar considerations should be given to all other use scenarios such as boatyards.

4.2.3 Determination of a representative exposure

Once the persons who will be exposed have been identified, the task should be defined, i.e. the parameters governing the amount of exposure that the person will receive. The following considerations shall be taken into account:

a) the application/removal method(s):

   1) airless spray;

   2) brush and roller;

   3) blast cleaning;

   4) all other application and removing processes (e.g. sand papering, ultra high pressure water jetting);

b) the actual exposure period for each activity of the person in a given day;

   NOTE For example, a person spraying paints may only do so for 3 h during a normal working day because time will be required for preparing equipment for use/meal breaks/waiting, etc.

c) frequency and duration of exposure (days per month or year);

d) level of personal protective equipment (PPE).

NOTE It is important to determine how much protection is offered by the equipment.

Defining the parameters mentioned above for the exposure will provide the baseline data to establish how much paint the worker is exposed to, that is how much paint comes into contact with skin (dermal exposure) or is inhaled.

NOTE Inhalation exposure should take account of the respirable fraction of any particles.

4.3 Determination of dose

Once the exposure scenario parameters have been determined, the potential dose can be calculated. In order to determine the total potential exposure to the paint, define the rate of exposure when applied using the application/removal method of interest. In simple terms, the amount of paint that is deposited on the worker's overalls and the concentration of paint in the working atmosphere shall be determined. There are two principal ways to define the potential exposure rate:

— measured data from worker's exposure studies;

— extrapolation of existing exposure data for comparable methods.

Once the potential exposure rate is known, the actual exposure to the paint shall be determined by taking into account the protection afforded to the operator by the PPE and the length of time taken to complete that task.

To determine the actual dose from the exposure to the paint, the following data are needed:

— the content of the biocidally active substance in the paint which is typically expressed in % weight/weight wet paint (%w/w wet paint) terms;

© ISO 2016 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 13073-3:2016