

ISO 13073-3:2016-06 (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

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