

Harmonised Offshore Chemical Notification Format OSPAR Recommendation 2010/13

SKIM Supplementary guideline for the Norwegian sector

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Introduction

This guideline describes the differences between the "OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format (HOCNF) (OSPAR Agreement: 2012/05. Update 2015)", OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) and the "Norwegian regulations relating to conducting petroleum activities (the Activities Regulations, 2016)", and to clarify the actual requirements under the Norwegian regulatory regime. The Norwegian regulation of offshore chemicals differs from other OSPAR countries. The Norwegian Activities Regulation requires that the operator is responsible for categorisation of offshore chemicals, for their environmental evaluation/ranking, for the preparation of substitution plans and for choosing the chemicals that give the lowest risk of environmental harm. Most operators handle this through the operator owned database NEMS chemicals, which is run by the consultant Add Energy. The authorities have full access to the database. The use of the NEMS database is not mandatory, but is the preferred solution for many operators/suppliers.

In Norway, the authorities do not authorise individual offshore chemicals, and are not responsible for registration. However, the operator shall obtain a permit from The Norwegian Environment Agency covering use and discharge of chemicals. The Environment Agency regulate use and discharge of chemicals through this permitting, and follow up through compliance monitoring and spot checks in the NEMS database.

When necessary, and in order to indicate the differences, quotations from both the "OSPAR guidelines" and "the Activities Regulations" have been stated. This text is written in *italics* in the document.

Abbreviations / explanations

The Norwegian Environment Agency

OSPAR: Oslo-Paris Commission for the protection of the Marine Environment of the North-East Atlantic.

OECD: Organisation for Economic Co-operation and Development.

PLONOR list: OSPAR List of substances/preparations used and discharged offshore which are considered to pose little or no risk to the environment.

Substance: The OSPAR definition of a substance is: "a chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

Pow: is equivalent to Kow and means the partition coefficient of a substance between octanol and water, measured or calculated according to the HOCNF.

EC50/LC50: Toxicity values from crustacean, fish and algae tests. The toxicity data are typically reported as the concentrations at which x % (e.g. 50%) mortality or inhibition of a function (e.g. growth) is observed and are expressed as the lethal concentration (LCx) or the effect concentration (ECx), e.g. LC50 or EC50. L/EC50-values are usually obtained from short term tests (duration in the range of hours to a few days).

BOD28: The value quoted on the biodegradation test. Refers to the percentage biodegradation of a chemical substance after 28 days.

BCF: Bioconcentration factor.

SDS: Safety Data Sheet.

SKIM: Samarbeidsforum offshorekjemikalier, industry og myndigheter (The Norwegian abbreviation for SKIM, it can be translated into "Industry and Authorities Working group for offshore chemicals")

Surfactant: means any substance, which has surface-active properties according to test method A.5 in Regulation EC 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) of 30 May 2008, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.

Guidance to sections of the HOCNF

Part 1: General Information

1.1 Trade name

When changing a product's composition, it is required that a new trade name is given. In this way it will be easier for both the operating oil companies and the Norwegian Environment Agency to assess a product's environmental properties.

1.2 Supplier and background information

Mandatory

1.3 SDS

An SDS must be attached to this HOCNF Format.

The substances' individual hazard labeling, and the hazard and precautionary statements must be stated either in the HOCNF or in an attached SDS sheet.

The SDS must meet the requirements in REACH article 31, annex II.

1.4 Use and discharge

State the product's group, function and dose rate. Dose rate only if relevant.

The operating oil company is responsible for permits pursuant to the Pollution Control Act.

1.5 Fate

OSPAR § 1.5 Fate, 26.

26. A description of the likely fate of the substance/preparation must be explained in general terms. This must include whether the substance/preparation is likely to change its form on use and/or will end up in the sediment, the water column, the air or biota.

For Norway: This section is not mandatory. Some products and substances change their chemical structure and/or performance during usage (e.g. due to high temperature, pressure or

reaction with other chemicals). If this change results in environmentally hazardous compounds it may be explained in the comments section.

1.6 Composition

OSPAR § 1.6a, 27: *All applications must include the names of all deliberately added substances within a preparation. Sufficient information must also be available to operators to allow them to properly assess the chemicals they intend to use.*

OSPAR § 1.6a, 29: *The full chemical composition must be provided when submitting the form to government bodies. The complete and precise composition of the substance or preparation must be reported, including each "active" substance, "inert" substance, solvent and additive substance and their proportions, using CAS numbers and recognised chemical formulae or recognised chemical names for all substances. EINECS, or ELINCS or REACH numbers must also be provided if they are available. Please note that trade names will not be accepted by the government bodies. Trade names are; however, useful additional information and should be provided where possible.*

OSPAR § 1.6a, 31: *All substances known to be deliberately added, including those present at less than 1% by weight of an entire preparation, should be declared. Impurities are not considered to be deliberately added. However, residue substances from the manufacturing process and other impurities present at greater than 1% should be declared as part of the formulation. Substances (except those stated in paragraph §1.6.b of the OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF), that are not deliberately added and are present at less than 1% by weight should not be declared.*

OSPAR § 1.6a, 34. *Substances which are on the latest REACH Annex IV list or satisfy the criteria detailed in REACH Annex V or which are on the latest OSPAR List of Substances / Preparations Used and Discharged Offshore Which are Considered to Pose Little or no Risk to the Environment (PLONOR) must also be declared. The REACH Annex IV and Annex V lists can be found on the ECHA website at:*

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF> and the OSPAR PLONOR list can be found on the OSPAR website at www.ospar.org

For Norway: In all applications concerning chemicals used offshore, the names of all deliberately added substances must be declared in section 1.6 the HOCNF. All residue substances from manufacturing process and impurities within a preparation shall be described in the comments field in the HOCNF.

A Substance which is on the PLONOR list or REACH Annex IV must be stated with a CAS number, EINECS number or other identifiers that match the CAS or EINECS number given in the PLONOR list or REACH Annex IV.. CAS number should also be provided for all classified substances, ref "REACH article 31, annex II".

Substances that are not labeled hazardous should preferably be identified with Cas or EINECS number if available, but may be listed only with its chemical functional groups. These functional groups must describe the substance in such a way that the operating oil company is able to perform an environmental evaluation. In case the supplier chooses to omit the exact chemical name, these must be documented internally, and be provided to the Norwegian Environment Agency.

Substances covered by Annex V of REACH are exempt from the obligation to register in REACH. Entry 7, 8 and 9 of Annex V covers substances which occur in nature or are obtained from natural sources and which are not chemically modified. Substances in entry 8 and 9 which do not meet the criteria for classification as dangerous according to CLP regulation, or which do not meet PBT, vPvB criteria of Annex XIII, or are not identified as substances of equivalent level of concern according to article 57 (f) in REACH can be equated with substances on the PLONOR list. Substances in Entry 7 can be treated likewise. If questions whether a substance is covered by REACH Annex V is in green category, the Norwegian Environment Agency shall be contacted. Companies benefiting from an exemption must provide the authorities on request with appropriate information to show that their substance qualifies for the exemption.

Molecular weight should be stated as exactly as possible, but may be listed as an interval or as greater than or less than (< / >). Exemption for PLONOR substances, REACH Annex IV and V substances and inorganic substances.

Concentration intervals (in percentage) may be used instead of exact concentration. They following seven intervals shall be used:

0 - 0,1	0,1 - 1	1 - 5	5 - 10	10 - 30	30 - 60	60 - 100
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Discharge factor shall be given for process chemicals and well intervention chemicals. CHARM default values for surfactants are not valid on the Norwegian sector. Log Pow-values can be used for non-surface active substances.

1.7 General physical properties

Section 1.7 "General physical properties" must be entered.

Part 2: Ecotoxicological Information

OSPAR Part 2, 40: *Ecotoxicological information can be mandatory or conditional. If the offshore chemical is on the PLONOR List or all the relevant ecotoxicological information has already been submitted to the authority, Part 2 of Annex 1 to OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) need not be completed. Reference should be provided to the document in which this information is given.*

For Norway: Chemicals in the green category include PLONOR substances, substances listed on REACH annex IV or REACH annex V, meeting criteria in entry 7,8,9,(ref OSPAR Recommendation 2013/3 on a Harmonized Offshore Chemical Notification Format, Part 2)

The current operating oil company, who is responsible for the HOCNF information towards The Norwegian Environment Agency, needs to have access to the complete HOCNF, as explained in this guideline. It is not sufficient to submit the ecotoxicological information to the Norwegian authorities.

All ecotoxicological tests must be performed on all deliberately added substances. Test report number, methodology and test results must be registered. Complete address for the GLP approved laboratory must be provided.

2.1.1 Partitioning and bioaccumulation potential (logPow)

OSPAR §2.1

47. *N-octanol water partitioning data must be provided for all organic substances with the exception of surfactants. For preparations, information for all the deliberately added substances is required. The data can be derived by measuring, estimating or calculating the partitioning of the substances between water and n-octanol (Pow).*

48: *log Pow is used for two purposes. In the pre-screening (OSPAR Recommendation 2010/4) it is used to advise on bioaccumulation potential, and in the CHARM model it is used to estimate how a substance partitions between oil and water with the aim of predicting the environmental concentration (PEC). As a consequence of this dual use of log Pow data, whenever a range of log Pow values is quoted in the report, the maximum and minimum value should be stated in the HOCNF. The maximum values will be used for estimating bioaccumulation potential and the minimum as an indication of the potential of the substance to partition into the water phase.*

Norwegian Activities Regulations:

Section 62: Chemicals shall be tested for the individual organic substances' potential for bioaccumulation, in accordance with OECD's guidelines for testing of chemicals, test number 117 or test number 107. This applies to substances with molecular weight lower than 700 g/mol only. For substances that cannot be tested according to standardised methods, the bioaccumulation potential shall be calculated based on modelling or professional evaluations, which shall be documented and described in HOCNF, cf. fifth subsection.

For Norway: Substances with molecular weight > 700 do not need to be tested for bioaccumulation potential and this is an indicator of limited bioaccumulation. For substances which do not need log Pow information, one of the following conclusions must be stated in the comments section:

- "The substance is inorganic and bioaccumulation data are not relevant".
- "The substance is PLONOR listed and bioaccumulation data are not required".
- "The substance has a MW > 700 as this is an indicator of limited bioaccumulation.
- "The substance already has a BCF-test, and log Pow data are not required".

If the bioaccumulation potential is known to be very high, based on chemical structure or solubility properties, a value of log Pow $\geq 4,5$ may be stated without further documentation. When using the HPLC- method (OECD 117), if the span of peaks is greater than 2 Log Pow units, then an alternative method such as OECD 107 should be considered. When using OECD 117, all peaks with an area > 5% should be stated with the corresponding log Pow value and %-area under the peak. The log Pow for the substance is taken to be the highest log Pow peak with area > 5%. An example is given below. In this case the log Pow for the substance is 5,2.

Peak nr.	log Pow	Area
1	1,5	75,0
2	2,9	15,0
3	5,2	5,1
4	5,9	4,9

Weighted average log Pow should be calculated by adding all peaks multiplied with corresponding areas. In the example above, weighted average is: log Pow = 2,1

To perform oil/water distribution analysis using the HPLC- method (OECD 117), all peaks with an area above 5% should be stated, and with the corresponding log Pow value and %-area under the peak. The area percentage is normalized to 100 %⁽¹⁾. Weighted average log Pow is calculated as a weighted average of the Pow-values SUM of (Pow x areal/100)⁽²⁾. log Pow is calculated as log⁽³⁾. An example is given below:

Peak nr.	Log Pow	Area	%-area	Normalised area ⁽¹⁾	Pow = 10logPow ⁽²⁾	Average Pow ⁽³⁾ : (1)* (2)/100
1	0,8	145000	34,0	35,03	6,31	2,21
2	1,3	268888	63,1	64,97	19,95	12,96
3	3,2	12450	2,9		N/A	
Sum		426338	100,0	100,00		15,17

Note: If applicable, the values typed in **bold** must be entered into the log Pow table in the HOCNF.

$$\text{Weighted average log Pow} = \text{log } 15.17 = 1.2$$

All components present in products with relevant applications (products for which amounts of discharges depend on the partitioning between oil and water phase) should be issued with discharge factors. The discharge factor is a number between 0-100% giving the partition following the water phase and by so describe the solubility route for the component if blended into a 50:50 oil:water environment. The CHARM default values are example only and should not be used unless these can be documented as valid for the specific substance. Offshore products are a wide group of chemicals and there is no single method to measure oil/water partition.

The discharge factor can be given in the comment field in section 1.6a) or in section 1.6b).

Bioconcentration factor (BCF)

When a BCF test has been used, the report should conclude whether the substance has a potential for bioaccumulation or not.

OSPAR § 2.1

52. ...BCF data are relevant for all deliberately added substances with a log Pow > 3. The BCF is determined on the basis of the ratio of animal tissue concentration to water concentration of the test substance at equilibrium, or on the basis of the ratio of the uptake and depuration rate constants. The competent national authority should be consulted beforehand to ensure that the proposed test method is suitable. In general, for fully water

miscible substances, either a fish or a bivalve mollusk accumulation test would normally be appropriate, whereas for substances that give rises to suspended particles a filter feeding organism such as a bivalve mollusk would be appropriate.

2.2 Biodegradability

OSPAR § 2.2:

55. *If the substance is found not to be readily biodegradable, or if a ready aerobic biodegradation test has not been performed, it will be assumed that the substance is persistent in aerobic conditions unless a simulation test (e.g. OECD 308, OECD 309) is performed which indicates the opposite.*

56. *... In the absence of valid results for such tests, authorities may accept data from freshwater tests according to OECD Guidelines for Testing of Chemicals, 1992, 301 A-F and freshwater BODIS tests, if these data are already available.*

57. *In a screening test, the highest value for the percentage biodegradation during the period of testing shall be used as a measure of the biodegradation potential provided that the value is not an outlier. The substance will be considered persistent if:*

i) Biodegradation is <20% in OECD 306, Marine BODIS or any other accepted marine protocols or <20 % in 28 days freshwater (ready test).

ii) Half-life values derived from aquatic simulation tests (e.g. OECD 308, 309) indicate persistence to REACH (EC 1907/2006) Annex XIII criteria

58. *Tests on substances known to be toxic to microbes (e.g. biocides) should follow the recommendations in Annex II of OECD 1992 301.*

59. *Biodegradability tests on poorly soluble materials should follow the recommendations set out in ECETOC Technical Report No. 20 (1986), Annex III of OECD 1992 301 and ISO Guidance Document ISO 10634.*

Norwegian Activities Regulations, section 62:

Chemicals shall be tested for the individual organic substances' biodegradability in accordance with OECD's guidelines for testing of chemicals, test number 306. If this test cannot be used because the substance is insoluble in water, the marine BODIS test shall be carried out in accordance with ISO 10708:1997, with modifications as described in "Biodegradability of chemical substances in seawater – Results of the four OSPARCOM ring tests." On application, the Norwegian Environment Agency may accept the use of alternative test methods for substances that are known to be toxic to microorganisms, if the methods are standardised

For Norway: The marine BODIS test is only accepted for insoluble substances. The acceptance of results from an alternative test method, like a freshwater OECD 301 test, has to be discussed with the Environment Agency. Such tests can be accepted in cases where the test substance is known to be toxic to microorganisms. If a freshwater test is accepted by the Environment Agency, a factor 0,7 is applied to the biodegradation result (%) to correct for higher biodegradation in freshwater compartment compared to marine water (REACH guidance R.11 PBT assessment)

Substances with Norwegian environmental category "yellow" and which have moderate biodegradability ($20\% \leq \text{BOD}_{28} < 60\%$) must be further evaluated. The hazardous properties of the degradation products of these substances must be assessed and one of the following three Y-phrases should be stated (text from Activities regulation, section 63)

- a) *subcategory 1 if the degradation products are expected to biodegrade completely,*
- b) *subcategory 2, if the degradation products are expected to biodegrade to substance(s) which are not hazardous,*
- c) *subcategory 3, if the degradation products are expected to biodegrade to substance(s) that may be hazardous.*

- In case of insufficient knowledge of the degradation products, these will need to be categorised as potentially environmental hazardous based on the precautionary principle.
- Environmental hazardous means substances that would have been categorized as substances in black and red category if they were covered by the categorization requirements, cf. criteria in section 63. If there is a lack of knowledge on degradation products, these should be considered as environmental hazardous in accordance with the precautionary principle.

Biodegradation data is not required for substances in one or more of the following categories:

- "The substance is inorganic and biodegradation data are not relevant".
- "The substance is PLONOR listed and biodegradation data are not required".

A note should be made in the comments section of 2.2.1 indicating which phrase applies.

If the substance is known to be non-biodegradable, a value of $\text{BOD}_{28} = 0\%$ may be stated, without further documentation.

2.4 Aquatic toxicity

OSPAR: § 2.3 60: *Toxicity data must be provided for all substances. Marine data should be provided where possible but competent national authorities can also accept freshwater toxicity data in lieu of marine data, provided the freshwater tests are carried out using test species mentioned in the OECD 201, 202 and 203 guidelines or any other suitable internationally-accepted protocol.*

OSPAR: § 2.3 62 *The relevance of toxicity test data other than that specified in the notification format should be agreed in consultation with the competent national authority. However, for freshwater data or non-OSPAR marine data, application of safety factors may be necessary, as required by the CHARM model. For certain substances, additional marine toxicity data may be required at any time, if evidence casts doubt on the relevance of the existing test data.*

Norwegian Activities Regulations, section 62:

Chemicals shall be tested for the individual organic or inorganic substances' acute toxicity with the following tests:

- a) *growth inhibition on Skeletonema costatum or Phaeodactylum tricornutum in compliance with ISO 10253:2006,*
- b) *acute lethal toxicity on Acartia tonsa or Tisbe battaglia in compliance with ISO 14669:1999,*
- c) *acute toxicity on juvenile of Scophtalmus maximus or juvenile of Cyprinodon variegatus in compliance with Part B in OSPAR's protocol for testing of chemicals used in the offshore petroleum industry. This does not apply if the substance is inorganic and has a EC50 or LC50 less than or equal to 10 mg/l on the other test organisms,*
- d) *toxicity test on Corophium sp. in compliance with OSPAR's protocol for testing of chemicals used in the offshore petroleum industry, if the substance is a sinker, has a Koc > 1000, has a log (Pow) >4, on in any other way are known to adsorb to particles or end up in the sediments, or contain surfactants.*

The Norwegian Environment Agency can approve other relevant toxicity tests if they are performed according to standardized methods.

For Norway: State whether the EC/LC50 value was based on nominal (n) or measured (m) exposure concentration or on the water accommodated fraction (WAF).

For substances diluted by water, toxicity tests shall be performed on the concentrate. If not, the toxicity values must be recalculated and stated as toxicity for the concentrated substance.

Part 3: Confirmation statement

The supplier must sign the last page of the HOCNF to confirm the data.

In Norway, an electronic signature in NEMS Chemicals is considered valid. The signature must be renewed every third year.