

## Version 1

### ***SKIM recommendation for assessment of biodegradation products of yellow substances with BOD28 < 60%***

SKIM has prepared a recommendation on how to comply with the new requirement of assessment of breakdown products from yellow substances with BOD28 < 60%, ref. §56a, Activities regulation: “For substances with moderate biodegradability (equivalent to BOD28 from 20 to 60%) also the properties of the degradation products shall be evaluated”.

An important presumption is that §56a1, last subsection, does not entail a requirement for **additional testing** other than what is already obligatory.

### ***Recommendation of prioritisation***

It is acknowledged that evaluation of the biodegradation products may require large resources due to the complex mechanisms involved in biodegradation. The legal requirement covers a large number of substances currently used. SKIM therefore recommends the following chemicals to be prioritised for assessment;

- New chemicals introduced to the market
- Chemicals with high discharges
- Chemicals with a high contribution to EIF

### ***Criteria for assessment of biodegradation products***

The assessment of the breakdown products implies an evaluation of these constituents being environmentally hazardous or not;

- Assessment of the toxicity and bioaccumulation potential of the degradation products is regarded to be difficult
- It is not necessary to assess the toxicity and bioaccumulation potential if the substance biodegrades completely, i.e. that the substance does not form persistent break-down products

### ***Documentation requirement for complete biodegradation***

Documentation, which demonstrates the probability of a complete biodegradation, may be;

- Other test data

- >60% (BOD) or > 70% (DOC) in freshwater tests. According to OECD, >60%/70% degradation is regarded as readily biodegradable and that the chemical will become completely degraded<sup>1</sup>.
  - both OECD 301 and OECD 302 series, together with C14-marked simulation tests are relevant in this context. See appendix for relevant tests.
  - Substances meeting the criteria given for P4 or P3 substances found in the document “Persistence of chemicals in the environmental, ECETOC Technical Report No. 90, 2003”, are regarded as completely biodegradable.
- Approved (valid) seawater test (ref. §56a1) within or extended beyond 28 days, which shows an increasing curve with a probable result above 60%
  - Theoretical assessments
    - can be done by supplier / primary manufacture / operator or consultants
    - must be viewed in context with the achieved results from sea or freshwater tests. This means that different conclusion from test and theoretical evaluations must be explained.
    - should include a relevancy assessment for the recipient.
    - should be based on literature data
    - should be based on knowledge of the molecular structure

### ***What should be included in the HOCNF, and where?***

- Biodegradation data for seawater tests extended beyond 28 days can be recorded in section 2.2.1 (aerobic ready)
- Available results from freshwater tests for readily biodegradation in 2.2.1
- Available results for inherent biodegradation in 2.2.2.
- The comment section: The conclusion and where relevant, the reference to the internal report detailing the theoretical assessment(s)

KPD should consider including a separate check box in CHEMS, identifying which chemicals have or have not an biodegradation assessment available for yellow substances, ref. next section.

### ***The supplier should state one of the following conclusions in the HOCNF***

- “The chemical is expected to biodegrade completely”.
- “The chemical is expected to biodegrade to products which are not environmentally hazardous”

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<sup>1</sup> <http://www.oecd.org/dataoecd/38/2/5598432.pdf>

- Likely endpoint with documented properties
- “The chemical is expected to biodegrade to products which may be environmentally hazardous”
  - In case of insufficient knowledge of the breakdown products, these will need to be categorised as potentially environmental hazardous based on the precaution principal.
  - Environmentally hazardous is defined by PBT, CMR, vPvB and the intentions in §56 b (black), but test results are not required!

## ***Operator***

- Can request the supplier’s documentation as basis for the conclusion, ref. Recommendation of prioritisation.

## ***References:***

- 1) Regulations relating to conduct of activities in the petroleum activities (The Activities Regulations)
- 2) Persistence of chemicals in the environment, ECETOC Technical Report No. 90, 2003. Can be ordered on <http://www.ecetoc.org/Content/Default.asp?>
- 3) EC Technical Guidance Documents (TGD) on risk assessment of chemicals, edition 2, 2003, Part II Environment (<http://ecb.jrc.it/> => Documents => Technical Guidance Document).

## **Appendix:**

A pass result from any of the current standard ready tests indicates that the substance has a high potential for biodegradation. Aerobic ready biodegradability tests are used for aquatic hazard classification of chemicals, and a chemical attaining the pass level in these tests at a certain rate after ended lag phase may be classified as “readily biodegradable”. In these tests, a positive result can be considered as indicative of rapid ultimate<sup>2</sup> degradation in most environments. The pass level depends on the analytical parameter measured.

The tests which can be used to determine the ready biodegradability of organic chemicals include the six test methods described in the OECD Test Guidelines No. 301 A-F:

1. DOC Die-Away Test (TG 301 A),
2. CO<sub>2</sub> Evolution Test (TG 301 B),
3. Modified MITI Test (I) (TG 301 C),
4. Closed Bottle Test (TG 301 D),
5. Modified OECD Screening Test (TG 301 E) and
6. Manometric Respirometry Test (TG 301 F).

The following pass levels of biodegradation, obtained within 28 days, may be regarded as evidence of ready biodegradability:

1. 70% DOC;
2. 60% ThCO<sub>2</sub>;
3. 60% ThOD;
4. 60% ThOD;
5. 70% DOC;
6. 60% ThOD, respectively, for the tests listed above.

Reference: INTRODUCTION TO THE OECD GUIDELINES FOR TESTING OF CHEMICALS SECTION 3, PART1: PRINCIPLES AND STRATEGIES RELATED TO THE TESTING OF DEGRADATION OF ORGANIC CHEMICALS,  
<http://www.oecd.org/dataoecd/38/2/5598432.pdf>

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<sup>2</sup> Ultimate degradation is the degradation of the substance to CO<sub>2</sub>, biomass, H<sub>2</sub>O and other inorganic substances like NH<sub>3</sub>



**Notes:**

- (1) Assuming first-order decay kinetics over 28 days:

$$\text{Degradation half-life } (T_{1/2}; \text{ days}) = \ln 2/k$$

where

$$k = \text{degradation rate constant } (\text{day}^{-1}) = \{ \ln[(100 - \text{BOD}_{28})/100] \} / 28$$

(BOD<sub>28</sub> is the highest %BOD recorded during a 28-day test).

Estimations of T<sub>1/2</sub> obtained using calculation software such as the US EPA PBT Profiler can be used as additional support for the likely rapid degradation of the chemical in the environment.

- (2) ECETOC Technical Report No. 90, 2003: Persistence criteria

<b>P criterion</b>	<b>Estimated T<sub>1/2</sub></b>	<b>Probability of degradation in the environment</b>	<b>Classification</b>
<b>P4</b>	< 25 days	Very high	Non-persistent (easily degradable)
<b>P3</b>	5 – 50 days	High	Non-persistent
<b>P2</b>	10 – 150 days	Uncertain	Cause for concern
<b>P1</b>	> 150 days	Low	Persistent

- (2) Meeting specific criteria as described in Table 7, p 54 of TGD, part II (2003):

<b>Test result</b>	<b>Half-life (T<sub>1/2</sub>); days</b>
Readily degradable	15
Readily degradable, but failing 10-day window	60
Inherently biodegradable	150
Not degradable	∞

In the event that only data from inherent tests are available, the estimated T<sub>1/2</sub> should be ≤150 days for tests that meet the criteria stated in Note b of Table 6, p 52 of TGD, part II (2003).

- (3) OECD guideline 308 *Aerobic and Anaerobic Transformation in Aquatic Sediment Systems*.
- (4) An evaluation of degradation endproducts should not include transient (intermediate) products formed during the normal processes of metabolism by bacteria and used as substrates for subsequent metabolic steps in the same bacteria or by other bacteria (cometabolism).
- (5) Environmentally hazardous is defined by PBT, vPvB, CMR (1, 2) (§56b of Activities Regulations).
- (6) A useful source of documented bacterial metabolic pathways for over 160 chemicals can be found in the University of Minnesota Biocatalysis/Biodegradation database (<http://umbbd.msi.umn.edu/>).