ANNEX IV

COMPLEMENTARY RISK ASSESSMENT FOR SURFACTANTS IN DETERGENTS

4. Additional studies

4.1. Biodegradability tests

4.1.1. Pre-adapted inoculum

Any of the tests described in Annex III, may be run with pre adapted inoculum in order to provide evidence of the relevance of pre-adaptation for the surfactant.

4.1.2. Inherent Biodegradability Tests

At least one of the tests referred to below shall be included:

— method of the Directive 67/548/EEC, Annex V.C.12 (Modified SCAS test),

— method of the Directive 67/548/EEC, Annex V.C.9 (Zahn-Wellens).

Failure to pass the inherent biodegradability test would indicate potential for persistency which may be considered, in general terms, as sufficient to prohibit the placing on the market of such a surfactant except in cases where the criteria set out in Article 6 indicate that there is no justification for refusing a derogation.

4.1.3. Activated Sludge Simulation Biodegradability Tests

The following tests referred below shall be included:

— method of the Directive 67/548/EEC, Annex V.C.10 (including possible changes in operating conditions as proposed in EN ISO 11733).

Failure to pass the activated sludge simulation biodegradability test would indicate potential for the release of the metabolites by sewage treatment, which may be considered, in general terms, as evidence of need for a more complete risk assessment.

4.2. Toxicity testing of biodegradation test liquors

Toxicity information on test liquors is to be provided on:

4.2.1. Chemical and physical information, such as:

— identity of the metabolite (and analytical means by which it was obtained);

— key physical chemical properties (water solubility, Octanol: Water partition coefficient (Log Po/w, etc.).

4.2.2. Effects on organisms. Tests to be conducted in compliance with the principles of good laboratory practice.

Fish: the test recommended is that in Annex V.C.1 of Directive 67/548/EEC

Daphnia: the test recommended is that in Annex V.C.2 of Directive 67/548/EEC

Algae: the test recommended is that in Annex V.C.3 of Directive 67/548/EEC

Bacteria: the test recommended is that in Annex V.C.11 of Directive 67/548/EEC

4.2.3. Degradation

Biotic: the test recommended is that in Annex V.C.5 of Directive 67/548/EEC

Abiotic: the test recommended is that in Annex V.C.7 of Directive 67/548/EEC. The information to be provided will consider as well the potential of metabolites for bio-concentration and their partitioning to the sediment phase.

Moreover, if some metabolites are suspected for endocrine disrupting activity, it is recommended to determine if these have potential to result in adverse affects as soon as validated testing schemes to assess such adverse effects are available.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.