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**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. (See end of Document for details) View outstanding changes

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## 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

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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 effects as soon as validated testing schemes to assess such adverse effects are available.

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### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/672 reg. 22](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(a\)](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(b\)](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(c\)](#)
- Annex 1 para. 2 words substituted by [S.I. 2019/672 reg. 23\(3\)\(a\)](#)
- Annex 1 para. 2 words substituted by [S.I. 2019/672 reg. 23\(3\)\(b\)](#)
- Annex 2 s. A words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. B words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. D words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. C words substituted by [S.I. 2019/672 reg. 24\(3\)](#)
- Art. 2(9) word omitted by [S.I. 2019/672 reg. 6\(2\)\(a\)](#)
- Art. 2(9) words substituted by [S.I. 2019/672 reg. 6\(2\)\(b\)](#)
- Art. 2(9) words substituted by [S.I. 2019/672, reg. 6\(2\)](#) (as substituted) by [S.I. 2020/1617 reg. 2\(4\)\(a\)](#)
- Art. 2(9a) words substituted by [S.I. 2019/672 reg. 6\(3\)](#)
- Art. 2(9A) words substituted in earlier amending provision [S.I. 2019/672, reg. 6\(3\)](#) by [S.I. 2020/1617 reg. 2\(4\)\(b\)](#)
- Art. 2(10) words inserted by [S.I. 2019/672 reg. 6\(4\)](#)
- Art. 2(10) words inserted by [S.I. 2019/672, reg. 6\(4\)](#) (as substituted) by [S.I. 2020/1617 reg. 2\(4\)\(c\)](#)
- Art. 2(13)-(15) inserted by [S.I. 2019/672 reg. 6\(5\)](#)
- Art. 2(16) inserted in earlier amending provision [S.I. 2019/672, reg. 6\(5\)](#) by [S.I. 2020/1617 reg. 2\(4\)\(d\)](#)
- Annex 3 Pt. B words omitted by [S.I. 2019/672 reg. 25\(3\)\(c\)](#)
- Annex 3 Pt. A para. 2 words substituted by [S.I. 2019/672 reg. 25\(2\)\(a\)](#)
- Annex 3 Pt. A para. 3 words substituted by [S.I. 2019/672 reg. 25\(2\)\(b\)](#)
- Annex 3 Pt. A para. 4 words substituted by [S.I. 2019/672 reg. 25\(2\)\(c\)](#)
- Annex 3 Pt. A para. 5 words substituted by [S.I. 2019/672 reg. 25\(2\)\(d\)](#)
- Annex 3 Pt. B para. 1 words substituted by [S.I. 2019/672 reg. 25\(3\)\(a\)](#)
- Annex 3 Pt. B para. 2 words substituted by [S.I. 2019/672 reg. 25\(3\)\(b\)](#)
- Art. 3(1)(a) substituted by [S.I. 2019/672 reg. 7\(2\)\(b\)](#)
- Art. 3(1)(a) words substituted in earlier amending provision [S.I. 2019/672, reg. 7\(2\)\(b\)](#) by [S.I. 2020/1617 reg. 2\(5\)](#)
- Art. 3(1)(b) words substituted by [S.I. 2019/672 reg. 7\(2\)\(c\)](#)
- Art. 3(1)(c) words substituted by [S.I. 2019/672 reg. 7\(2\)\(d\)](#)
- Art. 3A inserted by [S.I. 2019/672, reg. 7A](#) (as inserted) by [S.I. 2020/1617 reg. 2\(6\)](#)
- Annex 4 point 3 words inserted by [S.I. 2019/672 reg. 26\(8\)\(b\)](#)
- Annex 4 words omitted by [S.I. 2019/672 reg. 26\(6\)](#)
- Annex 4 point 1 heading words omitted by [S.I. 2019/672 reg. 26\(7\)](#)
- Annex 4 point 3 words omitted by [S.I. 2019/672 reg. 26\(8\)\(a\)](#)
- Annex 4 words omitted by [S.I. 2019/672 reg. 26\(13\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(2\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(3\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(4\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(5\)](#)
- Annex 4 point 4.1.2 words substituted by [S.I. 2019/672 reg. 26\(9\)\(a\)](#)
- Annex 4 point 4.1.2 words substituted by [S.I. 2019/672 reg. 26\(9\)\(b\)](#)
- Annex 4 point 4.1.3 words substituted by [S.I. 2019/672 reg. 26\(10\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(a\)](#)

- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(b\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(c\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(d\)](#)
- Annex 4 point 4.2.3 words substituted by [S.I. 2019/672 reg. 26\(12\)\(a\)](#)
- Annex 4 point 4.2.3 words substituted by [S.I. 2019/672 reg. 26\(12\)\(b\)](#)
- Annex 5 words omitted by [S.I. 2019/672 reg. 27](#)
- Annex 7 Pt. B words inserted by [S.I. 2019/672 reg. 28\(3\)\(b\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(a\)\(i\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(a\)\(ii\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(b\)\(i\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(b\)\(ii\)](#)
- Annex 7 Pt. B words substituted by [S.I. 2019/672 reg. 28\(3\)\(a\)](#)
- Annex 7 Pt. C words substituted by [S.I. 2019/672 reg. 28\(4\)](#)
- Annex 7 Pt. D words substituted by [S.I. 2019/672 reg. 28\(5\)](#)
- Annex 8 words substituted by [S.I. 2019/672 reg. 29](#)
- Art. 10(3)(4) inserted by [S.I. 2019/672 reg. 13\(4\)](#)
- Art. 15(3)-(8) inserted by [S.I. 2019/671 reg. 3\(4\)](#)
- Art. 15(3) words omitted in earlier amending provision [S.I. 2019/671, reg. 3\(4\)](#) by [S.I. 2020/1617 reg. 3\(2\)\(b\)\(i\)](#)
- Art. 15(6)(7) omitted in earlier amending provision [S.I. 2019/671, reg. 3\(4\)](#) by [S.I. 2020/1617 reg. 3\(2\)\(b\)\(ii\)](#)
- Art. 18A inserted by [S.I. 2019/672 reg. 21](#)
- Art. 18A(1) words omitted in earlier amending provision [S.I. 2019/672, reg. 21](#) by [S.I. 2020/1617 reg. 2\(9\)\(a\)](#)
- Art. 18A(3) substituted in earlier amending provision [S.I. 2019/672, reg. 21](#) by [S.I. 2020/1617 reg. 2\(9\)\(b\)](#)