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For those non-ionic surfactants not reacting to the abovementioned BiAS method, or if it seems more appropriate for reasons of efficiency or precision, appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.

#### C. ANALYTICAL METHODS FOR CATIONIC SURFACTANTS

The determination of cationic surfactants in the tests shall be done by the Disulfine Blue Active Substance (DBAS) analysis according to the following DBAS procedures:

The method in use in the Federal Republic of Germany, (1989) DIN 38 409 — Ausgabe: 1989-07.

For those cationic surfactants not reacting to the abovementioned test method, or if it seems more appropriate for reasons of efficiency or precision (this must be justified), appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.

# D. ANALYTICAL METHODS FOR AMPHOTERIC SURFACTANTS

The determination of amphoteric surfactants in the tests shall be done by analysis following the procedures listed below:

1. If cationics absent:

The method in use in the Federal Republic of Germany, (1989) DIN 38 409-Teil 20.

2. Otherwise:

Orange II method (Boiteux, 1984).

For those amphoteric surfactants not reacting to the above-mentioned tests, or if it seems more appropriate for reasons of efficiency or precision (this must be justified), appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.

### ANNEX III

Ultimate biodegradability (mineralisation) test methods for surfactants in detergents

- A. The reference method for laboratory testing of surfactant ultimate biodegradability in this regulation is based on the en iso standard 14593: 1999 (CO<sub>2</sub> headspace test). Surfactants in detergents shall be considered as biodegradable if the level of biodegradability (mineralisation) measured according to one of the five following tests (¹) is at least 60 % within twenty-eight days:
  - 1. EN ISO Standard 14593: 1999. Water quality. Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium. Method by analysis of inorganic carbon in sealed vessels (CO<sub>2</sub> headspace test). Pre-adaptation is not to be used. The ten days window principle is not applied. (Reference method).
  - 2. Method of the Directive 67/548/EEC Annex V.C.4-C [Carbon dioxide (CO<sub>2</sub>) Evolution Modified Sturm Test]: Pre-adaptation is not to be used. The ten days window principle is not applied.
  - 3. Method of the Directive 67/548/EEC Annex V.C.4-E (Closed Bottle): Pre-adaptation is not to be used. The ten days window principle is not applied.

<sup>(1)</sup> These five tests are identified as the most suitable for surfactants.

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- 4. Method of the Directive 67/548/EEC Annex V.C.4-D (Manometric Respirometry): Pre-adaptation is not to be used. The ten days window principle is not applied.
- 5. Method of the Directive 67/548/EEC Annex V.C.4-F (Miti: Ministry of International Trade and Industry-Japan): Pre-adaptation is not to be used. The ten days window principle is not applied.
- B. Depending on the physical characteristics of the surfactant, one of the methods listed below might be used if appropriately justified (¹). It should be noted that the pass criterion of at least 70 % of these methods is to be considered as equivalent to the pass criterion of at least 60 % referred to in methods listed in point A. The adequacy of the choice of the methods listed below shall be decided on a case by case confirmation, in accordance with Article 5 of this Regulation.
  - 1. Method of the Directive 67/548/EEC Annex V.C.4-A (Dissolved Organic Carbon DOC Die-Away): Pre-adaptation is not to be used. The ten days window principle is not applied. The pass criteria for biodegradability measured according to the test shall be at least 70 % within twenty-eight days.
  - 2. Method of the Directive 67/548/EEC Annex V.C.4-B (Modified OECD Screening-DOC Die-Away): Pre-adaptation is not to be used. The ten days window principle is not applied. The pass criteria for biodegradability measured according to the test shall be at least 70 % within twenty-eight days.
- N.B. All the abovementioned methods, taken from Council Directive 67/548/EEC, can also be found in the publication 'Classification, Packaging and Labelling of Dangerous Substances in the European Union', Part 2: 'Testing Methods'. European Commission 1997. ISBN 92-828-0076-8.
- (¹) The DOC methods could give results on the removal and not on the ultimate biodegradation. The Manometric Respirometry and the MITI would not be appropriate in some cases because the high initial test concentration could be inhibitory.

## ANNEX IV

Complementary risk assessment for surfactants in detergents

For those surfactants for which an environmental risk assessment is available in the context of Directive 93/67/EEC, or Regulation (EEC) No 793/93 and Regulation (EC) No 1488/94, and Technical Guidance Documents, this risk assessment shall be considered together with the complementary risk assessment run in the scope of this Regulation.

The complementary risk assessment run in the scope of this Regulation, in case it is likely that recalcitrant metabolites are produced, shall be considered in the context of assessments made on the basis of Directive 93/67/EEC or Regulation (EEC) No 793/93. This is to be assessed case by case and in particular on the basis of the results of the tests referred to in part 3.

The study shall cover the aquatic environmental compartment. Additional information relating to specific risk assessment concerns might be required by the Committee referred to in Article 12(2) on a case by case basis. Additional information might include other environmental compartments such as sewage sludge and soil. A tiered approach shall be adopted concerning the information required for the technical file referred to in Articles 5 and 9. The file shall contain at least the information described under points 1, 2 and 3 below. However, to minimise testing, and especially to avoid unnecessary animal testing, the additional studies listed under point 4.2.2 should be requested only where such information is necessary and propor-