

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (Text with EEA relevance)

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	Signature

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ANNEX I

Standards of accreditation, good laboratory practice and animal protection concerning the laboratories that are competent and authorised to provide the necessary service for checking compliance of detergents with the requirements of this Regulation and its Annexes

1. Standards applicable at the level of the laboratories:
2. Standards applicable at the level of the accreditation bodies and...

ANNEX II

PRIMARY BIODEGRADABILITY TEST  
METHODS FOR SURFACTANTS IN DETERGENTS

Primary biodegradability is measured by the determination in biodegraded liquors...

The pass criterion for primary biodegradability shall be a level...

The reference method for the laboratory testing of surfactants in...

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#### Test methods

- (1) The OECD method published in the OECD's technical report of...
- (2) The method in use in France, approved by the 'arrêté...
- (3) The method in use in Germany, established by the 'Verordnung...
- (4) The method in use in the United Kingdom called the...
- (5) The 'Confirmatory test procedure' in the OECD method, described in...
  - A. ANALYTICAL METHODS FOR ANIONIC SURFACTANTS
  - B. ANALYTICAL METHODS FOR NON-IONIC SURFACTANTS
  - C. ANALYTICAL METHODS FOR CATIONIC SURFACTANTS
  - D. ANALYTICAL METHODS FOR AMPHOTERIC SURFACTANTS

### ANNEX III

#### ULTIMATE BIODEGRADABILITY (MINERALISATION) TEST METHODS FOR SURFACTANTS IN DETERGENTS

- A. The reference method for laboratory testing of surfactant ultimate biodegradability...
- B. Depending on the physical characteristics of the surfactant, one of...

### ANNEX IV

#### COMPLEMENTARY RISK ASSESSMENT FOR SURFACTANTS IN DETERGENTS

For those surfactants for which an environmental risk assessment is...

The complementary risk assessment run in the scope of this...

The study shall cover the aquatic environmental compartment.

Additional information...

However, to minimise testing, and especially to avoid unnecessary animal...

As noted in Article 13, the guidelines included in this...

1. Identity of the surfactant (in accordance with the provisions laid...
  - 1.1. Name
    - 1.1.1. Names in the IUPAC nomenclature
    - 1.1.2. Other names
    - 1.1.3. CAS number and CAS name (if available)
    - 1.1.4. Einecs or Elincs numbers (if available)
  - 1.2. Molecular and structural formula
  - 1.3. Composition of the surfactant
2. Information on the surfactant
  - 2.1. Quantities of the surfactant used in detergents
  - 2.2. The information on use patterns given in this section shall...
3. Information on the potential recalcitrant metabolites
4. Additional studies
  - 4.1. Biodegradability tests
    - 4.1.1. Pre-adapted inoculum

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- 4.1.2. Inherent Biodegradability Tests
  - 4.1.3. Activated Sludge Simulation Biodegradability Tests
  - 4.2. Toxicity testing of biodegradation test liquors
    - 4.2.1. Chemical and physical information, such as:
    - 4.2.2. Effects on organisms. Tests to be conducted in compliance with...
    - 4.2.3. Degradation
- N.B.

## ANNEX V

### LIST OF SURFACTANTS THAT HAVE OBTAINED A DEROGATION

By way of derogation granted in accordance with Articles 4-6...  
Name in the IUPAC nomenclature EC Number CAS number  
Limitations...  
The ' EC number ' means the EINECS, ELINCS or...  
'EINECS' means the European Inventory of Existing Commercial  
Chemical Substances....  
'ELINCS' means the European List of Notified Chemical  
Substances. The...  
'NLP' means No-Longer Polymer. The term polymer is defined  
in...

## ANNEX VI

### LIST OF BANNED OR RESTRICTED DETERGENT SURFACTANTS

The following detergent surfactants have been identified as not  
complying...  
Name in the IUPAC nomenclature EC Number CAS number  
Limitations...  
The ' EC number ' means the EINECS, ELINCS or...

## ANNEX VIa

## ANNEX VII

### LABELLING AND INGREDIENT DATA SHEET

- A. Labelling of contents
- B. Labelling of dosage information
  - Consumer laundry detergents
  - Consumer automatic dishwasher detergents
- C. Ingredient data sheet
- D. Publication of the list of ingredients

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## ANNEX VIII

### TEST METHODS AND ANALYTICAL METHODS

The following test and analytical methods apply to control procedures...

A Storage vessel B Dosing device C Aeration chamber (three...

A Liquid level B Hard PVC C Glass or waterproof...

A Running-in period B Period used for calculation (twenty-one days)...

1. Reference method (confirmatory test)
  - 1.1. Definition
  - 1.2. Equipment needed for measurement
  - 1.3. Synthetic sewage
  - 1.4. Preparation of samples
  - 1.5. Operation of equipment
  - 1.6. Checking measuring equipment
  - 1.7. Calculation of biodegradability
  
2. Determination of anionic surfactants in biodegradability tests
  - 2.1. Principle
  - 2.2. Reagents and equipment
    - 2.2.1. Buffer solution pH 10
    - 2.2.2. Neutral methylene blue solution
    - 2.2.3. Acidic methylene blue solution
    - 2.2.4. Chloroform (trichloromethane) AR freshly distilled
    - 2.2.5. Dodecyl benzene sulphonic acid methyl ester
    - 2.2.6. Ethanolic potassium hydroxide solution, KOH 0,1 M
    - 2.2.7. Ethanol pure, C<sub>2</sub>H<sub>5</sub>OH
    - 2.2.8. sulphuric acid, H<sub>2</sub>SO<sub>4</sub> 0,5 M
    - 2.2.9. Phenolphthalein solution
    - 2.2.10. Methanolic hydrochloric acid: 250 ml hydrochloric acid AR and 750...
    - 2.2.11. Separating funnel, 250 ml
    - 2.2.12. Graduated flask, 50 ml
    - 2.2.13. Graduated flask, 500 ml
    - 2.2.14. Graduated flask, 1 000 ml
    - 2.2.15. Round-bottomed flask with ground glass stopper and reflux condenser, 250...
    - 2.2.16. pH meter
    - 2.2.17. Photometer for measurements at 650 nm, with 1 to 5...
    - 2.2.18. Qualitative grade filter paper
  - 2.3. Procedure
  - 2.4. Calibration curve
  - 2.5. Calculation of results
  - 2.6. Expression of results
  
3. Determination of non-ionic surfactants in biodegradation test liquors

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- 3.1. Principle
  - 3.2. Reagents and Equipment
    - 3.2.1. Pure ethyl acetate, freshly distilled.
    - 3.2.2. Sodium bicarbonate, NaHCO<sub>3</sub> AR.
    - 3.2.3. Dilute hydrochloric acid [20 ml concentrated acid (HCl) diluted to...]
    - 3.2.4. Methanol AR, freshly distilled, stored in a glass bottle.
    - 3.2.5. Bromocresol purple, 0,1 g in 100 ml methanol.
    - 3.2.6. Precipitating agent: the precipitating agent is a mixture of two...
      - 3.2.6.1. Solution A
      - 3.2.6.2. Solution B
    - 3.2.7. Glacial acetic acid 99-100 % (lower concentrations are unsuitable).
    - 3.2.8. Ammonium tartrate solution: mix 12,4 g tartaric acid AR and...
    - 3.2.9. Dilute ammonia solution: 40 ml ammonia solution AR (d =...)
    - 3.2.10. Standard acetate buffer: dissolve 40 g solid sodium hydroxide AR,...
    - 3.2.11. Pyrrolidinedithiocarbamate solution (known as 'carbate solution'): dissolve 103 mg sodium...
    - 3.2.12. Copper sulphate solution (for standardisation of 3.2.11).  
STOCK SOLUTION  
STANDARDSOLUTION
    - 3.2.13. Sodium chloride AR.
    - 3.2.14. Gas-stripping apparatus (see Figure 5).
    - 3.2.15. Separating funnel, 250 ml.
    - 3.2.16. Magnetic stirrer with magnet 25-30 mm.
    - 3.2.17. Gooch crucible, diameter of the perforated base = 25 mm,...
    - 3.2.18. Circular glass-fibre filter papers, 27 mm diameter with fibre diameter...
    - 3.2.19. Two filter flasks with adapters and rubber collars, 500 and...
    - 3.2.20. Recording potentiometer fitted with a bright platinum indicator electrode and...
  - 3.3. Method
    - 3.3.1. Concentration and separation of the surfactant
    - 3.3.2. Precipitation and filtration
    - 3.3.3. Dissolution of the precipitate
    - 3.3.4. The titration
    - 3.3.5. Blank determinations
    - 3.3.6. Control of the factor of the 'carbate solution'
  - 3.4. Calculation of results
  - 3.5. Expression of results
4. Preliminary treatment of anionic surfactants to be tested
    - 4.1. Preliminary notes
      - 4.1.1. Treatment of samples
      - 4.1.2. Ion-exchange procedure
      - 4.1.3. Analytical control
    - 4.2. Principle
    - 4.3. Chemicals and equipment
      - 4.3.1. Deionised water
      - 4.3.2. Ethanol, 95 % (v/v) C<sub>2</sub>H<sub>5</sub>OH (permissible denaturant: methyl ethyl ketone...)
      - 4.3.3. Isopropanol/water mixture (50/50 v/v):
      - 4.3.4. Solution of carbon dioxide in ethanol (approximately 0,1 % CO<sub>2</sub>):...
      - 4.3.5. Ammonium bicarbonate solution (60/40 v/v): 0,3 mol NH<sub>4</sub>HCO<sub>3</sub> in 1...

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- 4.3.6. Cation exchanger (KAT), strongly acidic, resistant to alcohol (50-100 mesh)...
- 4.3.7. Anion exchanger (AAT), macro-porous, Merck Lewatit MP 7080 (70-150 mesh)...
- 4.3.8. Hydrochloric acid, 10 % HCl (w/w)
- 4.3.9. 2 000 ml round-bottomed flask with ground glass stopper and...
- 4.3.10. 90 mm diameter suction filter (heatable) for filter papers
- 4.3.11. 2 000 ml filter flask
- 4.3.12. Exchange columns with heating jacket and tap: inner tube 60...
- 4.3.13. Water-bath
- 4.3.14. Vacuum drying oven
- 4.3.15. Thermostat
- 4.3.16. Rotary evaporator
- 4.4. Preparation of extract and separation of anionic active agents
  - 4.4.1. Preparation of extract
  - 4.4.2. Isolation of alcohol-soluble constituents
  - 4.4.3. CATION-EXCHANGE COLUMN  
ANION-EXCHANGE COLUMN
  - 4.4.4. Connect the exchange columns so that the cation-exchange column is...
  - 4.4.5. The cation exchanger is rejected after use.
- 5. Preliminary notes
  - 5.1. Treatment of samples
    - 5.1.1. The treatment of non-ionic surface-active agents and formulated detergents prior...
    - 5.1.2. Isolation and separation of non-ionic surface active agents from soap,...
    - 5.1.3. After homogenising, the concentration of anionic and non-ionic surfactants in...
  - 5.2. From a homogeneous sample (powders, dried paste and dried liquids)...
  - 5.3. Deionised water
    - 5.3.1. Ethanol, C<sub>2</sub>H<sub>5</sub>OH 95 % (v/v) (permissible denaturant: methyl-ethyl ketone or...
    - 5.3.2. Isopropanol/water mixture (50/50 v/v):
    - 5.3.3. 50 parts by volume isopropanol, CH<sub>3</sub>CHOH.CH<sub>3</sub>, and
    - 5.3.4. 0,3 mol NH<sub>4</sub>HCO<sub>3</sub> in 1 000 ml of an isopropanol/water...
    - 5.3.5. Anion exchanger (AAT), macro-porous, Merck Lewatit MP 7080 (70-150 mesh)...
    - 5.3.6. Hydrochloric acid, 10 % HCl w/w
    - 5.3.7. 2 000 ml round-bottomed flask with ground glass stopper and...
    - 5.3.8. 90 mm diameter suction Filter (heatable) for filter papers
    - 5.3.9. 2 000 ml filter flask
    - 5.3.10. Exchange columns with heating jacket and tap: inner tube 60...
    - 5.3.11. Water-bath
    - 5.3.12. Vacuum drying oven
    - 5.3.13. Thermostat
    - 5.3.14. Rotary evaporator
    - 5.3.15. Preparation of extract and separation of non-ionic active agents
  - 5.4. Preparation of extract
    - 5.4.1. The quantity of surfactant necessary for the degradation test is...
    - 5.4.2. Add 250 g of the synthetic detergent to be analysed...
    - 5.4.3. Preparation of ion-exchange columns  
CATION-EXCHANGE COLUMN  
ANION-EXCHANGE COLUMN

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- 5.4.4. Ion-exchange procedure
- 5.4.5. Regeneration of ion exchange resins

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- (1) OJ C 95, 23.4.2003, p. 24.
- (2) Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council Common Position of 4 November 2003 (OJ C 305 E, 16.12.2003, p. 11) and Position of the European Parliament of 14 January 2004 (not yet published in the Official Journal). Decision of the Council of 11 March 2004.
- (3) OJ L 347, 17.12.1973, p. 51. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
- (4) OJ L 347, 17.12.1973, p. 53. Directive as amended by Directive 82/243/EEC (OJ L 109, 22.4.1982, p. 11).
- (5) OJ L 109, 22.4.1982, p. 1.
- (6) OJ L 109, 22.4.1982, p. 18.
- (7) OJ L 80, 25.3.1986, p. 51.
- (8) OJ L 291, 10.10.1989, p. 55.
- (9) OJ L 215, 1.8.1998, p. 73.
- (10) OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
- (11) OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.
- (12) Directives 73/404/EEC and 86/94/EEC.
- (13) Directives 73/405/EEC and 82/243/EEC.
- (14) Directive 82/242/EEC.
- (15) OJ L 184, 17.7.1999, p. 23.
- (16) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2004/21/EC (OJ L 57, 25.2.2004, p. 4).
- (17) OJ L 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003.
- (18) OJ L 227, 8.9.1993, p. 9.
- (19) OJ L 161, 29.6.1994, p. 3.
- (20) OJ L 123, 24.4.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.
- (21) OJ L 50, 20.2.2004, p. 44.
- (22) OJ L 50, 20.2.2004, p. 28.
- (23) OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

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