



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien  
International Association for Soaps, Detergents and Maintenance Products

European Committee of  
Organic Surfactants and  
their Intermediates



A Sector Group of Cefic



The European Association of Chemical Distributors

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# **A joint A.I.S.E. / CESIO / ECOSOL / FECC Guideline on Implementation of the Detergent Regulation**

*with regard to the*

**Biodegradability of Surfactants**

*and*

**Transmission of information for  
Surfactants Biodegradability**

**Regulation (EC) No. 648/2004 of the European  
Parliament and of the Council of 31 March 2004  
on Detergents.**

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***Although all efforts have been made to try to ensure that the advice and interpretation given in these guidelines is correct, A.I.S.E., CESIO, ECOSOL and FECC emphasise that they can accept no liability for any errors or omissions or for any loss or damage of any kind arising from their use.***

# **1. Background**

The Detergent Regulation (EC) No 648/2004 was published on 8 April 2004 and entered into force on 8 October 2005. As a regulation, it is directly applicable law in all Member States. The Detergent Regulation has been amended in 2006 by (EC) No. 907/2006. This Regulation includes provisions relating to:

- Ultimate biodegradability requirements (both the level and methodologies used) for all surfactants (anionic, non-ionic, cationic and amphoteric) used in detergents.
- The provision of information provided to the consumer via the labelling of ingredients and via websites.
- Information to be held by manufacturers and to be supplied to Medical Professionals and competent authorities on request.
- A review of phosphate by April 2007 with a view to reduce usage.
- An evaluation of the anaerobic biodegradability of surfactants and of the biodegradability of non-surfactant organic detergent ingredients by April 2009.

After almost two years from its entry into force, one area that has emerged as apparently not being implemented in a fully satisfactory way is the transmission to the national authorities of the data supporting the biodegradability of a given surfactant following their request. Some Member States reported in June 2007 that the process was too slow and that in a minority of cases the data had not yet been provided.

This guideline concentrates on how we can improve that point and describes the process that surfactant manufacturers, surfactant distributors and detergents manufacturers should follow to ensure a swift submission of the biodegradability data to the authorities when requested. In addition it provides some background "reminders" on the scope of application of the Detergent Regulation and on some details regarding the "biodegradability" requirements for surfactants used in detergents.

Many of the points in this guideline are building on two documents that have been already shared with the EU Detergents Working Group (chaired by the European Commission – Enterprise and Industry Directorate-General – Chemicals, Metals, Forest-based & Textile Industries – Chemicals) and have been posted on the European Commission DG Enterprise website:

[http://ec.europa.eu/enterprise/chemicals/legislation/detergents/index\\_en.htm](http://ec.europa.eu/enterprise/chemicals/legislation/detergents/index_en.htm).

Specifically:

- the "A.I.S.E. Guideline on Implementation of the Detergent Regulation - Biodegradability of Surfactants and Annex VII (Labelling and Ingredient Datasheet)", dated 7<sup>th</sup> February 2005,
- the "CESIO guidance document on the Application of Article 9(2) about the Evidence of Biodegradability for Regulation (EC) No 648/2004 on Detergents & Updating of MSDS document" dated 6 February 2007.

## 2. Detergent 'Scope'

The term "detergents" can be summarised as applying to all products to clean textiles or to clean hard surfaces, in other words, any 'detergent / cleaning product' claiming a cleaning function.

Inter alia the following terms are defined in Article 2 of the Regulation:

**'Detergent'** means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.

**Other products to be considered as detergents are:**

- **'Auxiliary washing preparation'**, intended for soaking (pre-washing), rinsing or bleaching clothes, household linen, etc.;
- **'Laundry fabric-softener'**, intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
- **'Cleaning preparation'**, intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.: materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.);
- **'Other cleaning and washing preparations'**, intended for any other washing and cleaning processes.

**'Washing'** means the cleaning of laundry, fabrics, dishes and other hard surfaces.

**'Cleaning'** has the meaning defined by EN ISO 862.

**'Surfactant'** means any organic substance<sup>1</sup> and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.

The above definition of a surfactant includes (among others) the requirement of being "capable of reducing the surface tension of water", without a specific numeric value for deciding whether the surface tension has been reduced within the meaning of the Regulation. This was discussed at a later stage within the WG and the following clarification can be found in the Q&A document:

([http://ec.europa.eu/enterprise/chemicals/legislation/detergents/legislation/faq\\_detergent\\_regulation\\_july2007.pdf](http://ec.europa.eu/enterprise/chemicals/legislation/detergents/legislation/faq_detergent_regulation_july2007.pdf))

"For the purposes of the Regulation, the latter condition is fulfilled if the substance or preparation is capable of reducing the surface tension to below the internationally trade tariff value for surfactants of 45 mN/m."

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<sup>1</sup> The biodegradability requirements set by Regulation (EC) No. 648/2004 apply only to surfactants. A study on non-surfactant organic ingredients, thus not covered by this regulation, was prepared by Risk and Policy Analysts Limited, RPA and is available from DG Enterprise's Detergents website. Non-surfactant organics typically include, among others, substances such as phosphonates, polycarboxylates, EDTA and EDTA tetrasodium salt, silicones, polyethyleneglycol (PEG), carboxymethylcellulose (CMC), etc.

### **3. Biodegradability of Surfactants** ***(used in detergents)***

The Detergent Regulation introduced two fundamental changes regarding the biodegradability of surfactants used in detergent products:

- Proof of **ultimate aerobic biodegradation** is required for all surfactants used in detergents.
- The biodegradability criteria apply **also to cationic and amphoteric** surfactants.

(Previously requirements relating only to the primary biodegradability of anionic and non-ionic surfactants were specified).

**Preferably** the test methods listed in **Annex III A** of (EC) No. 907/2006 are to be used. The criterion for ultimate biodegradability is 60% mineralisation ("ultimate biodegradation" into carbon dioxide, water and mineral salts) within 28 days. "*If appropriately justified*" a method listed in **Annex III B** may be used **on application**.

In accordance with Article 4 (2), derogation may be requested for surfactants in detergents used in **special industrial or institutional sectors** that do not fulfil the criterion of ultimate biodegradation within the stipulated period.

- For this purpose it must be proven "*inter alia*" that the level of primary biodegradability of surfactants within the given period is at least 80%. Methods for the testing of primary biodegradability of surfactants in detergents are listed in **Annex II**. As regards the biodegradability of anionic and non-ionic surfactants this corresponds to the standard applicable prior to the Detergents Regulation.
- For this derogation tests according to **Annex IV** are to be conducted, following a "*tiered approach*". Technical guidance in respect of the tiered approach has been developed at the latest in time for the entry into force of the Regulation.

In accordance with Article 3 (1), surfactants that are used as biocidal actives are exempted from the provision of this Regulation. This applies if these surfactants are also active substances within the meaning of Directive 98/8/EC (Biocidal Products Directive). However, such surfactants must also be:

- Listed as Biocidal active under Annex I & IA of the Biocidal Product Directive,
- Constituents of a Biocidal product authorised under the Biocidal Product Directive or of a Biocidal Product allowed under the 10-year transitional measure of the Biocidal Product Directive.

If the biocidal product is also a detergent within the meaning of the Detergents Regulation, for the other surfactants contained in the preparation, and also for labelling, the provisions of the Detergents Regulation apply.

## **4. Guidance for manufacturers placing detergent products on the market**

With regard to the **information to be provided by manufacturers**, this is laid down in **Article 9**. In particular Article 9.2 reads:

*"Whenever substances and/or preparations covered by this Regulation are placed on the market, the manufacturer shall be responsible for the correct performance of the relevant tests mentioned above. He shall also have available documentation on the testing carried out to demonstrate compliance with this Regulation, and to show that he is allowed to benefit from the property rights concerning the test results, other than for those test results already in the public domain."*

The above text indicates that the legal responsibility for providing information is not shared. Whoever is asked by the Member State's competent authorities (CAs) to provide the data, must do so. Hence, both the surfactant manufacturers and the detergent manufacturers can be individually responsible for providing data to the CAs depending on who has been requested to do so.

Therefore in case of an inspection at a detergent manufacturer, the latter has the ultimate responsibility to provide to the CAs the data proving the biodegradability of the surfactants used in its products. However, those data are typically generated and hence owned by the surfactant manufacturer who has supplied the raw material. There is therefore the need for a close and prompt cooperation between the detergent manufacturer and its supplier(s) to ensure that the CAs receive the requested documentation within a total of five weeks from the date of inspection.

This issue of providing documentary evidence to the CAs had already been discussed in the past. CESIO had prepared and submitted to the Detergents Working Group a document<sup>1</sup> with a guideline on how to handle this process. Those guidelines were designed to accommodate the concern of surfactant manufacturers to protect their intellectual property, and it was therefore agreed that they should provide the data directly to the CAs when requested, as an alternative to providing the detergent formulator with it.

On that basis, DG Enterprise confirmed that detergent formulators should cooperate proactively with the CAs to pass on a request from them to their supplier of surfactants in line with the relevant CESIO guidelines, and surfactant suppliers should respond without delay.

In practice, this system did not prove to be sufficiently robust so far and needs therefore some improvement. The rest of this document addresses this point.

***CESIO, ECOSOL, A.I.S.E. and FECC commit to make this guideline known by all their respective members and to make it available via public websites also to non-members, recognising though that these are more difficult to be reached. In this context, CESIO, ECOSOL, A.I.S.E. and FECC would like to encourage the EU Commission and the National Competent Authorities to make the guideline available via their relevant websites.***

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<sup>1</sup> CESIO guidance document on the Application of Article 9(2) about the Evidence of Biodegradability for Regulation (EC) No 648/2004 on Detergents & Updating of MSDS document (6 February 2007)

#### 4.1. What is recommended to surfactant suppliers

On the basis of the points mentioned in the previous chapter, CESIO had recommended its entire membership to employ Safety Data Sheet (SDS) to report compliance with biodegradability criteria required by the Detergent Regulation. CESIO, ECOSOL and FECC believe this to be the most efficient and transparent way to satisfy the Regulation.

All the CESIO, ECOSOL and FECC member companies (i.e. the major European surfactant suppliers) have committed to include an appropriate sentence in section 12 and/or section 15 of the SDS<sup>1</sup>.

Here below two options, (1) and (2), are given to surfactant suppliers so as to accommodate the diversity of surfactant products placed on the market.

<b>Option 1</b>	<b>Option 2</b>
<p><b>The surfactant(s) contained in this preparation complies (comply) with</b> the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.</p>	<p><b>This surfactant complies with</b> the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.</p>

The translations of these sentences in most EU languages are listed in Appendix 1.

In addition to the above sentence, the SDS must indicate the name, e-mail address and the tel. number of the person or a specific service which must be contacted at the surfactant supplier for requesting the data and which is responsible for ensuring that they are going to be provided to the CAs that requested them (in case of a distributor, they will ensure that the request is communicated to the next level up the supply chain and will be responsible to follow up the communication process). If the surfactant is being evaluated for derogation or is listed in Annex V (derogated surfactants), this must be indicated in section 12 or 15 of the SDS using one of the following statements:

<b>Option 1</b>	<b>Option 2</b>
<p><b>This surfactant is being evaluated for derogation</b> according to art. 6 of Regulation No 648/2004.</p>	<p><b>This surfactant has been granted derogation</b> according to art. 6 of Regulation No 648/2004.</p>

The translations of these sentences in most EU languages are listed in Appendix 2.

In fact, in practice, it is likely that it is the detergent manufacturer which will be inspected by the CAs and the request for surfactant biodegradability data will be expressed directly to the detergent manufacturer. They are therefore expected to forward the specific request to the surfactant supplier which will provide the necessary proof of biodegradation to the CAs (via the name indicated on the SDS).

<sup>1</sup> It is understood that no “automatic” request for this data will be made to surfactant suppliers by a detergent manufacturer and that such a request can only be made following a similar request from a Member State Competent Authority. In fact, the expression in the SDS, ‘be made available to them’, clearly states that the data are only for the CAs.

**The surfactant supplier is expected to provide the biodegradability data to the CAs within three weeks from the date of the request by the detergent manufacturer.**

#### **4.2. What is recommended to detergents manufacturers**

As indicated above, detergent manufacturers are the ones most likely to be inspected by CAs and hence to be asked to provide evidence of the biodegradability of the surfactants they use in their detergents. Normally they will not have on hand those data, which are typically generated by the surfactant manufacturers. Exceptions to this could exist when biodegradability data for a certain surfactant are in the public domain<sup>1</sup>. But even in those cases, the detergent manufacturer could be asked to prove the chemical and physical equivalence of the surfactant used with the material for which the data reported were generated.

A.I.S.E. therefore recommends that manufacturers placing detergent products on the market should always obtain from their surfactant suppliers, within the EU and from outside the EU, **written confirmation** (on the SDS or on a specific document) that the surfactants used may be placed on the market without further limitation due to their ultimate biodegradability, in accordance with Article 4(1) of the Detergent Regulation. If the detergent manufacturer has multiple suppliers for the same type of surfactant, such a written confirmation should be provided by each individual supplier. Surfactant- and detergent manufacturers shall ensure by appropriate means that chemical distributors and/or traders are involved in this process, and that information circulates without delay along the supply chain.

It is worth remembering that if the criteria for ultimate biodegradability are not fulfilled, derogations are possible only for certain surfactants in detergents used in **industrial or institutional** (I&I) sectors in applications more closely defined in Article 6 (1). Also in those instances, detergents manufacturers must make sure of the following:

- Either a written confirmation must be obtained that surfactants fulfil the pass criterion of 80% for primary biodegradability pursuant to Annex II;
- Or a document showing that a derogation has been granted by the Commission for the surfactant in question (copy of the letter of the Commission to the surfactant manufacturer, or minutes of meetings of the European Commission Working Group on Detergents, or Annex V of the Regulation once updated).

In case of an inspection, the CAs will likely ask the detergent manufacturer for the documentation proving the biodegradability of the surfactants used. The detergent manufacturer will have to ask immediately this information from the supplier(s), who in turn will make sure that the request is communicated within the supply chain without delay. The data owner will have to send it within three weeks to the CAs identified by the detergent manufacturer.

In order to ensure a speedy process, the inspected company should ask the inspector for an e-mail address which can be used by the surfactant supplier to send the data supporting the biodegradability of the surfactants in question.

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<sup>1</sup> Only publications in peer-reviewed scientific literature, giving full experimental details, are considered as data "being in the public domain".



Appendix 3 shows a template on how this request from the detergent manufacturer to the surfactant supplier can be phrased.

Appendix 4 shows a template on how a request from a surfactant trader to its supplier can be phrased.

## **Appendix 1**

### Translations of the sentences for the SDS (sections 12 and/or 15) in application of Article 9(2) of Regulation (EC) No 648/2004 on Detergents.

Language	Option 1	Option 2
English  (reference language for the translation)	<b>The surfactant(s) contained in this preparation complies (comply) with</b> the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.	<b>This surfactant complies with the</b> biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.
Bulgarian	Повърхностно активното/ните вещество/ва, съдържащо/и се в този препарат, отговаря (отговарят) на критериите за биологична разградимост, посочени в Регламент (ЕК)№648/2004 относно детергентите. Данните, потвърждаващи това твърдение са на разположение на компетентните органи на страните -членки и може да им бъдат предоставени при тяхна директна молба или при молба от страна на производител на детергент.	Това повърхностно активно вещество отговаря на критериите за биологична разградимост, посочени в Регламент (ЕК) №648/2004 относно детергентите. Данните, потвърждаващи това твърдение са на разположение на компетентните органи на страните -членки и може да им бъдат предоставени при тяхна директна молба или при молба от страна на производител на детергент.
Czech	<b>Povrchově aktivní látka(y) obsažena(y) v tomto přípravku je (jsou) v souladu s</b> kritérii biodegradability podle Směrnici (EÚ) No. 648/2004 o detergentech. Údaje potvrzující toto prohlášení jsou k dispozici kompetentním institucím členských států Unie na jejich přímou žádost, nebo na žádost výrobce detergentu.	<b>Povrchově aktivní látka je v souladu s</b> kritérii biodegradability podle Směrnice (EÚ) No.648/2004 o detergentech. Údaje potvrzující toto prohlášení jsou k dispozici kompetentním institucím členských států Unie na jejich přímou žádost, nebo na žádost výrobce detergentu.
Danish	<b>Preparatets tensid(er)opfylder</b> kriterierne for biologisk nedbrydelighed i henhold til Regulering (EF) nr. 648/2004 om vaske- og rengøringsmidler. Data til bekræftelse af dette er til disposition for medlemsstaternes kompetente myndigheder og vil kunne stilles til rådighed på direkte forespørgsel herfra eller på forespørgsel fra fabrikanten af vaske- og rengøringsmidler.	<b>Dette tensid opfylder</b> kriterierne for biologisk nedbrydelighed i henhold til Regulering (EF) nr. 648/2004 om vaske- og rengøringsmidler. Data til bekræftelse af dette er til disposition for medlemsstaternes kompetente myndigheder og vil kunne stilles til rådighed på direkte forespørgsel herfra eller på forespørgsel fra fabrikanten af vaske- og rengøringsmidler.

Dutch	<b>De oppervlakteactieve stof(fen) in dit preparaat voldoet(n)</b> aan de criteria voor biologische afbreekbaarheid zoals vastgelegd in Verordening (EG) nr. 648/2004 betreffende detergentia. Gegevens ter ondersteuning van deze bewering worden ter beschikking van de bevoegde autoriteiten van de lidstaten gehouden en zullen aan hen beschikbaar worden gesteld na een rechtstreeks verzoek of op verzoek van een producent van detergentia.	<b>Deze oppervlakteactieve stof voldoet</b> aan de criteria voor biologische afbreekbaarheid zoals vastgelegd in Verordening (EG) nr. 648/2004 betreffende detergentia. Gegevens ter ondersteuning van deze bewering worden ter beschikking van de bevoegde autoriteiten van de lidstaten gehouden en zullen aan hen beschikbaar worden gesteld na een rechtstreeks verzoek of op verzoek van een producent van detergentia.
Estonian	<b>Antud valmistis(t)es sisalduvate pindaktiivsete ainete</b> biolagundatavus vastab biolagundatavuse kriteeriumidele, mis on detergentidele sätestatud EÜ määruses nr.648/2004. Antud kinnitust toetavad andmed on liikmesriikide pädevate asutuste valduses ning antakse liikmesriikidele nende vahetu taotluse alusel või detergentide tootja taotluse alusel.	<b>Pindaktiivsete ainete</b> biolagundatavus vastab biolagundatavuse kriteeriumidele, mis on detergentidele sätestatud EÜ määruses nr. 648/2004. Antud kinnitust toetavad andmed on liikmesriikide pädevate asutuste valduses ning antakse liikmesriikidele nende vahetu taotluse alusel või detergentide tootja taotluse alusel.
Finnish	<b>Valmisteeseen sisältämä pinta-aktiivinen aine (aineeet) täyttää</b> pesuaineista annetun (EY):n asetuksen N:o 648/2004 mukaiset biologisen hajoavuuden kriteerit. Tiedot, jotka tukevat edellistä väittämää, pidetään jäsenmaiden toimivaltaisten viranomaisten saatavilla ja ne toimitetaan heille heidän pyynnöstään tai pesuainevalmistajan pyynnöstä.	<b>Pinta-aktiivinen aine täyttää</b> pesuaineista annetun (EY):n asetuksen N:o 648/2004 mukaiset biologisen hajoavuuden kriteerit. Tiedot, jotka tukevat edellistä väittämää, pidetään jäsenmaiden toimivaltaisten viranomaisten saatavilla ja ne toimitetaan heille heidän pyynnöstään tai pesuainevalmistajan pyynnöstä.
French	<b>Le(s) agent(s) de surface contenu(s) dans cette préparation respecte(nt)</b> les critères de biodégradabilité définis dans le règlement (CE) n° 648/2004 relatif aux détergents. Les données prouvant cette affirmation sont tenues à la disposition des autorités compétentes des Etats Membres et leur seront fournies à leur demande expresse ou à la demande du producteur de détergents.	<b>Cet agent de surface respecte</b> les critères de biodégradabilité définis dans le règlement (CE) n° 648/2004 relatif aux détergents. Les données prouvant cette affirmation sont tenues à la disposition des autorités compétentes des Etats Membres et leur seront fournies à leur demande expresse ou à la demande du producteur de détergents.
German	<b>Das in dieser Zubereitung enthaltene Tensid erfüllt (Die in dieser Zubereitung enthaltenen Tenside erfüllen)</b> die Bedingungen der biologischen Abbaubarkeit wie sie in der Verordnung (EG) Nr. 648/2004 über Detergenzien festgelegt sind. Unterlagen, die dies bestätigen, werden für die zuständigen Behörden der Mitgliedsstaaten bereit gehalten und nur diesen entweder auf ihre direkte oder auf Bitte eines Detergentienherstellers hin zur Verfügung gestellt.	<b>Dieses Tensid erfüllt</b> die Bedingungen der biologischen Abbaubarkeit wie sie in der Verordnung (EG) Nr. 648/2004 über Detergenzien festgelegt sind. Unterlagen, die dies bestätigen, werden für die zuständigen Behörden der Mitgliedsstaaten bereit gehalten und nur diesen entweder auf ihre direkte oder auf Bitte eines Detergentienherstellers hin zur Verfügung gestellt.

Greek	<b>Τα τασιενεργά που περιέχονται στο συγκεκριμένο παρασκεύασμα συμμορφώνονται με τα κριτήρια βιοδιασπασιμότητας τα οποία ορίζονται στον Κανονισμό (ΕΚ) Νο.648/2004 για απορρυπαντικά. Τα δεδομένα που υποστηρίζουν τη δήλωση αυτή βρίσκονται στη διάθεση των αρμόδιων αρχών των Κρατών Μελών και θα παρέχονται σε αυτές κατόπιν άμεσου αιτήματός τους ή κατόπιν αιτήματος του κατασκευαστή του απορρυπαντικού.</b>	<b>Αυτό το τασιενεργό συμμορφώνεται με τα κριτήρια βιοδιασπασιμότητας τα οποία ορίζονται στον Κανονισμό (ΕΚ) Νο.648/2004 για απορρυπαντικά. Τα δεδομένα που υποστηρίζουν τη δήλωση αυτή βρίσκονται στη διάθεση των αρμόδιων αρχών των Κρατών Μελών και θα παρέχονται σε αυτές κατόπιν άμεσου αιτήματός τους ή κατόπιν αιτήματος του κατασκευαστή του απορρυπαντικού.</b>
Hungarian	<b>A preparátumban található felületaktív anyagok(k) megfelel(nek) a tisztítószerekre vonatkozó, (EC) No.648/2004 számú szabályzatban lefektetett biológiai lebomlási kritériumoknak. Az ezt alátámasztó adatok mindenkor a Tagállamok illetékes szerveinek a rendelkezésére állnak, és közvetlen kérésükre vagy a tisztítószer gyártó kérésére megtekinthetők.</b>	<b>Ez a felületaktív anyag megfelel a tisztítószerekre vonatkozó, (EC) No.648/2004 számú szabályzatban lefektetett biológiai lebomlási kritériumoknak. Az ezt alátámasztó adatok mindenkor a Tagállamok illetékes szerveinek a rendelkezésére állnak, és közvetlen kérésükre vagy a tisztítószer gyártó kérésére megtekinthetők.</b>
Italian	<b>Il(i) tensioattivo(i) contenuto(i) in questo formulato è (sono) conforme(i) ai criteri di biodegradabilità stabiliti dal regolamento (CE) n. 648/2004 relativo ai detersivi. Tutti i dati di supporto sono tenuti a disposizione delle autorità competenti degli Stati Membri e saranno forniti, su loro esplicita richiesta o su richiesta di un produttore del formulato, alle suddette autorità.</b>	<b>Questo tensioattivo è conforme ai criteri di biodegradabilità stabiliti dal regolamento (CE) n. 648/2004 relativo ai detersivi. Tutti i dati di supporto sono tenuti a disposizione delle autorità competenti degli Stati membri e saranno forniti, su loro esplicita richiesta o su richiesta di un produttore del formulato, alle suddette autorità.</b>
Latvian	<b>Virsmas aktīvs(i), kas iekļauts šajā preparātā, atbilst biodegradabilitātes kritērijiem, kas noteikti Regulā (EC) Nr.648/2004 par šķīdumiem. Dati, kas apstiprina šo pieņēmumu tiek glabāti, lai uzrādītu Dalībvalstu attiecīgām institūcijām, un tie tiks iesniegti pēc tieša pieprasījuma vai šķīduma ražotāja pieprasījuma.</b>	<b>Šis virsmas aktīvs atbilst biodegradabilitātes kritērijiem, kas noteikti Regulā (EC) No.648/2004 par šķīdumiem. Dati, kas apstiprina šo pieņēmumu tiek glabāti, lai uzrādītu Dalībvalstu attiecīgām institūcijām, un tie tiks iesniegti pēc tieša pieprasījuma vai šķīduma ražotāja pieprasījuma.</b>
Lithuanian	<b>Surfaktantas (-ai)esantis (-ys) šiame preparate atitinka biodegradavimo kriterijus detergentams, nustatytus Reglamente (EB) Nr.648/2004. Duomenys, patvirtinantys šį teiginį, yra kompetetingų valdžios atstovų iš ES šalių žinioje ir bus prienami pastariesiems tiesiogiai pareikalavus arba pareikalavus detergentų gamintojui.</b>	<b>Šis surfaktantas atitinka biodegradavimo kriterijus detergentams, nustatytus Reglamente (EB) No.648/2004. Duomenys, patvirtinantys šį teiginį, yra kompetetingų valdžios atstovų iš ES šalių žinioje ir bus prienami pastariesiems tiesiogiai pareikalavus arba pareikalavus detergentų gamintojui.</b>
Maltese	N/A	N/A

Norwegian	<b>Tensidet(ene) som inngår i denne blandingen oppfyller</b> kriteriene for biologisk nedbrytning i EU regulativ nr. 648/2004 som omhandler vaske- og rengjøringsmidler. Data som underbygger denne påstanden er tilgjengelige for medlemsstatenes rette myndighet og vil bli gjort tilgjengelige for dem ved direkte forespørsel, eller på forespørsel fra en produsent av vaske- og rengjøringsmidler.	<b>Dette tensidet oppfyller</b> kriteriene for biologisk nedbrytning i EU regulativ nr. 648/2004 om vaske- og rengjøringsmidler. Data som underbygger denne påstanden er tilgjengelige for medlemsstatenes rette myndighet og vil bli gjort tilgjengelige for dem ved direkte forespørsel, eller på forespørsel fra en produsent av vaske- og rengjøringsmidler.
Polish	<b>Środek powierzchniowo czynny / środki powierzchniowo czynne zawarte w tym preparacie jest/są zgodny/e</b> z kryteriami podatności na biodegradację zawartymi w dyrektywie (WE) nr 648/2004 dotyczącej detergentów. Dane potwierdzające ten fakt są do dyspozycji właściwych władz państw członkowskich i będą im udostępniane na ich bezpośrednią prośbę lub na prośbę producenta detergentów.	<b>Ten środek powierzchniowo czynny jest zgodny</b> z kryteriami podatności na biodegradację zawartymi w dyrektywie (WE) nr 648/2004 dotyczącej detergentów. Dane potwierdzające ten fakt są do dyspozycji właściwych władz państw członkowskich i będą im udostępniane na ich bezpośrednią prośbę lub na prośbę producenta detergentów.
Portuguese	<b>O(s) tensioactivo(s) contido(s) nesta preparação(ões) cumpre(m) com</b> os critérios de biodegradabilidade segundo o Regulamento (EC) n° 648/2004 relativo aos detergentes. Dados que apoiam esta afirmação estão à disposição das autoridades competentes dos Estados Membros e serão disponibilizados a seu pedido directo ou através do pedido de um produtor de detergentes”.	<b>Este tensioactivo cumpre com</b> os critérios de biodegradabilidade segundo o Regulamento (EC) n° 648/2004 relativo aos detergentes. Dados que apoiam esta afirmação estão à disposição das autoridades competentes dos Estados Membros e serão disponibilizados a seu pedido directo ou através do pedido de um produtor de detergentes”.
Romanian	<b>Agentul/Agentii tensioactiv(i) continut(ți) în acest preparat corespunde/corespund</b> criteriilor de biodegradabilitate prevăzute de Reglementarea (CE) Nr.648/2004 privind detergentii. Datele care susțin această afirmație sunt ținute la dispoziția autorităților competente ale Statelor Membre și le vor fi furnizate la cererea directă a acestora sau la cererea unui producător de detergenți.	<b>Acest agent tensioactiv corespunde</b> criteriilor de biodegradabilitate prevăzute de Reglementarea (CE) Nr.648/2004 privind detergentii. Datele care susțin această afirmație sunt ținute la dispoziția autorităților competente ale Statelor Membre și le vor fi furnizate la cererea directă a acestora sau la cererea unui producător de detergenți.
Slovak	<b>Povrchovo aktívna(e) látka(y) obsiahnutá(é) v tomto prípravku je (sú) v súlade s</b> kritériami biodegradability podľa Smernice (EÚ) No.648/2004. Údaje potvrdzujúce toto prehlásenie sú k dispozícii kompetentným inštitúciám členských štátov Únie na ich priamu žiadosť, alebo na žiadosť výrobcu detergentu	<b>Povrchovo aktívna látka je v súlade s</b> kritériami biodegradability podľa Smernice (EÚ) No. 648/2004. Údaje potvrdzujúce toto prehlásenie sú k dispozícii kompetentným inštitúciám členských štátov Únie na ich priamu žiadosť, alebo na žiadosť výrobcu detergentu

Slovene	<b>Tenzid (i), ki je (so) prisoten (prisotni) v tem pripravku, izpolnjuje (jo)</b> vse pravne predpise za biološko razgradnjo, kot je v Uredbi (EG) št. 648/2004 za detergente določeno. Predloge, ki se nanašajo na to potrdilo, bodo odgovornim oblastem držav članic zagotovljene – na razpolago bodo na direktno zahtevo ali na zahtevo proizvajalca detergentov.	<b>Ta tenzid izpolnjuje</b> vse pravne predpise za biološko razgradnjo, kot je v Uredbi (EG) št. 648/2004 za detergente določeno. Predloge, ki se nanašajo na to potrdilo, bodo odgovornim oblastem držav članic zagotovljene – na razpolago bodo na direktno zahtevo ali na zahtevo proizvajalca detergentov.
Spanish	<b>El tensioactivo(s) contenido(s) en esta preparación cumple(n) con</b> el criterio de biodegradabilidad estipulado en el Reglamento (CE) nº 648/2004 sobre detergentes. Los datos para justificar esta afirmación están a disposición de las autoridades competentes de los Estados Miembros y les serán mostrados bajo su requerimiento directo o bajo requerimiento de un productor de detergentes.	<b>Este tensioactivo cumple con</b> el criterio de biodegradabilidad estipulado en el Reglamento (CE) nº 648/2004 sobre detergentes. Los datos para justificar esta afirmación están a disposición de las autoridades competentes de los Estados Miembros y les serán mostrados bajo su requerimiento directo o bajo requerimiento de un productor de detergentes.
Swedish	<b>Den/de tensid(er) som ingår i denna beredning uppfyller</b> kriterierna för biologisk nedbrytning i förordning (EG) nr 648/2004 om tvätt- och rengöringsmedel. Data som stöder detta påstående finns till förfogande för medlemsstaternas behöriga myndigheter, och kommer att göras tillgängliga för dem vid direkt förfrågan, eller vid förfrågan från tillverkare av tvätt- och rengöringsmedel.	<b>Denna tensid uppfyller</b> kriterierna för biologisk nedbrytning i förordning (EG) nr 648/2004 om tvätt- och rengöringsmedel. Data som stöder detta påstående finns till förfogande för medlemsstaternas behöriga myndigheter, och kommer att göras tillgängliga för dem vid direkt förfrågan, eller vid förfrågan från tillverkare av tvätt- och rengöringsmedel.

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## Appendix 2

Translations of the sentences for the SDS (sections 12 and/or 15) in application of Article 6 of Regulation (EC) No 648/2004 on Detergents.

Language	Option 1	Option 2
English (reference language for the translation)	<b>This surfactant is being evaluated for derogation</b> according to art. 6 of Regulation No 648/2004.	<b>This surfactant has been granted derogation</b> according to art. 6 of Regulation No 648/2004.
Bulgarian	На това повърхностно активно вещество е направена оценка за дерогация съгласно член 6 на Регламент № 648/2004.	На това повърхностно активно вещество е предоставена дерогация съгласно член 6 на Регламент № 648/2004.
Czech	Táto povrchově aktivní látka je vyhodnocená pro omezení podle čl. 6 Nařízení č.648/2004.	Táto povrchově aktivní látka byla povolena omezene podle čl. 6 Nařízení č.648/2004
Danish	Dette overflade aktive stof bliver vurdret med henblik på dispensation i henhold til artikel 6 i EU direktiv nr. 648/2004.	Dette overflade aktive stof har fået dispensation i henhold til artikel 6 i EU direktiv nr. 648/2004.
Dutch	Deze surfactans wordt geëvalueerd op een afwijking volgens artikel 6 van Regulering Nr. 648/2004.	Voor deze surfactans is een uitzondering (derogatie) verleend volgens artikel 6 van reguleringsnummer 648/2004.
Estonian	Sellele pindaktiivsele ainele taotletakse eriluba vastavalt määruse nr. 648/2004 artiklile 6.	Sellele pindaktiivsele ainele on väljastatud eriluba vastavalt määruse nr. 648/2004 artiklile 6.
Finnish	Tälle pinta-aktiiviselle aineelle haetaan poikkeuslupaa asetuksen no 648/2004, artikla 6,n mukaan.	Tälle pinta-aktiiviselle aineelle on myönnetty poikkeuslupa asetuksen no 648/2004, artikla 6,n mukaan.
French	<b>Cet agent de surface</b> est en cours d'évaluation pour l'obtention d'une dérogation selon l'article 6 du Règlement No. 648/2004.	Cet agent de surface a obtenu une dérogation selon l'article 6 du Règlement No. 648/2004.
German	Dieses Tensid wird gegenwärtig zwecks Ausnahmegenehmigung gemäß Artikel 6 der Verordnung Nr. 648/2004 untersucht.	Diesem Tensid ist eine Ausnahmegenehmigung gemäß Artikel 6 der Verordnung Nr. 648/2004 erteilt worden.
Greek	Η συγκεκριμένη επιφανειοδραστική ουσία τελεί υπό αξιολόγηση αναφορικά με τη δυνατότητα παρέκκλισης, σύμφωνα με το άρθ. 6 του κανονισμού 648/2004.	Η συγκεκριμένη επιφανειοδραστική ουσία εγκρίθηκε αναφορικά με τη δυνατότητα παρέκκλισης, σύμφωνα με το άρθ. 6 του κανονισμού 648/2004.
Hungarian	E felületaktív anyagot a 648/2004. rendelet 6. cikke szerint eltérés (derogáció) szempontjából értékeli	Erre a felületaktív anyagra a 648/2004. rendelet 6. cikke szerint eltérést (derogációt) engedélyeztek.
Italian	Questo tensioattivo è attualmente in fase di valutazione per ottenere una deroga in accordo all'art. 6 del Regolamento N° 648/2004.	Questo tensioattivo ha ottenuto una deroga in accordo all'art. 6 del Regolamento N° 648/2004.
Latvian	Tiek izvērtēts, vai attiecībā uz šo virsmaktīvo vielu var piemērot izņēmuma nosacījumus saskaņā ar Regulas No.648/2004 6.pantu.	Attiecībā uz šo virsmaktīvo vielu tiek piemēroti izņēmuma nosacījumi saskaņā ar Regulas No.648/2004 6.pantu.

Appendix 2 (cont'd)

Lithuanian	Ši aktyvioji paviršiaus medžiaga yra įvertinta pagal Reglamento Nr. 648/2004 str.6 leidžiančią nukrypti nuostatą.	Šiai aktyviajai paviršiaus medžiagai yra suteikta leidžianti nukrypti nuostata pagal Reglamento Nr. 648/2004 str.6.
Maltese	N/A	N/A
Norwegian	Dette overflateaktive stoffet evalueres for dispensasjon i henhold til artikkel 6 i EU direktiv nr. 648/2004.	Dette overflateaktive stoffet har fått dispensasjon i henhold til artikkel 6 i EU direktiv nr. 648/2004.
Polish	Prowadzona jest ocena/analiza tego środka powierzchniowo czynnego w kontekście derogacji zgodnie z art. 6 Rozporządzenia Nr 648/2004.	Ten środek powierzchniowo czynny uzyskał derogację zgodnie z art. 6 Rozporządzenia Nr 648/2004.
Portuguese	Este tensoactivo está em processo de avaliação para efeitos de derrogação tal como previsto no Art. 6 do Regulamento nº 648/2004.	A este tensoactivo foi concedida uma derrogação nos termos previstos no art. 6 do Regulamento nº 648/2004.
Romanian	Acest surfactant este evaluat pentru derogare in conformitate cu art. 6 din Regulamentul nr. 648/2004.	Acestui surfactant i s-a acordat derogare de la art. 6 al Regulamentului nr. 648/2004.
Slovak	Táto povrchovo aktívna látka je vyhodnotená pre obmedzenie podľa čl.6 Nariadenia č.648/2004	Táto povrchovo aktívna látka bola povolená obmedzene podľa čl. 6 Nariadenia č.648/2004
Slovene	Ta površinsko aktivna snov je bila ocenjena za namen odobritve odstopanja v skladu s členom 6 Uredbe št. 648/2004.	Za to površinsko aktivno snov je bila sprejeta odobritev odstopanja v skladu s členom 6 Uredbe št. 648/2004.
Spanish	Este tensoactivo está siendo evaluado para la concesión de la excepción de acuerdo con el Artículo 6 del Reglamento (CE) nº 648/2004.	A este tensoactivo se le ha concedido la excepción de acuerdo con el Artículo 6 del Reglamento (CE) nº 648/2004..
Swedish	Denna tensid utvärderas för undantag enligt förordning nr 648/2004, artikel 6.	Denna tensid har beviljats undantag enligt förordning nr 648/2004, artikel 6.

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### **Appendix 3**

Template of the letter to be sent by the detergent manufacturer to the surfactant supplier to request the data supporting the biodegradability of a surfactant in application of Article 9(2) of Regulation (EC) No 648/2004 on Detergents. The detergent manufacturer should send a copy of this letter to the Competent Authority contact person.

Dear Mr. ....<sup>1</sup>

On .....<sup>2</sup> our company .....<sup>3</sup> was inspected by the .....<sup>4</sup> Competent Authorities with respect to Regulation (EC) No 648/2004 on Detergents.

Following this inspection, we have been asked in application of Article 9(2) of the above Regulation (EC) No 648/2004 to provide to the authorities data supporting the biodegradability of the following surfactant raw materials that we are purchasing from your company (.....<sup>5</sup>). Attached you will find a copy of your SDS(s) with a biodegradability compliance statement for the substance(s) in subject.

	<b>Brand name</b>	<b>Chemical name</b>	<b>CAS #</b>
<b>1</b>			
<b>2</b>			
...			

In accordance with the indications you gave us on the relevant SDSs, we would like to ask you to send to the authorities within three weeks from the date of this letter the relevant information proving the biodegradability of the above surfactants in accordance to the above Regulation (EC) No 648/2004.

All the materials should be sent at the attention of the following person .....<sup>6</sup> at this address: .....<sup>7</sup>.

I would also ask you to send me confirmation that the material has been sent at the following e-mail address: .....<sup>8</sup>.

I would like to thank you for a swift compliance and remain

Sincerely yours,

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Copy to: .....<sup>6, 7</sup>

<sup>1</sup> Insert the name of the person identified in the SDS

<sup>2</sup> Insert the date in which the CAs inspected the company

<sup>3</sup> Insert the full name of the company that has been inspected by the CAs

<sup>4</sup> Insert the indication of the Member State whose CAs made the inspection

<sup>5</sup> Insert the full name of the company supplying the surfactants in question

<sup>6</sup> Insert the name of the inspector and/or the person indicated by him/her at the CAs offices that should receive the material

<sup>7</sup> Insert the address of the CAs where the data should be sent. Ideally this should include an e-mail address to speed up the process

<sup>8</sup> Insert your own e-mail address

## **Appendix 4**

Template of the letter to be sent by a surfactant distributor to the surfactant supplier to request the data supporting the biodegradability of a surfactant in application of Article 9(2) of Regulation (EC) No 648/2004 on Detergents. The surfactant distributor should send a copy of this letter to the Competent Authority contact person.

Dear Mr. ....<sup>1</sup>

On .....<sup>2</sup>, one of our customers sent us a letter indicating that his company had been inspected by the .....<sup>3</sup> Competent Authorities with respect to Regulation (EC) No 648/2004 on Detergents.

Following this inspection, they have been asked in application of Article 9(2) of the above Regulation (EC) No 648/2004 to provide to the authorities data supporting the biodegradability of the following surfactant raw materials that we have been supplying to them and which we are purchasing from your company (.....<sup>4</sup>). Attached you will find a copy of your SDS(s) with a biodegradability compliance statement for the substance(s) in subject.

	<b>Brand name</b>	<b>Chemical name</b>	<b>CAS #</b>
<b>1</b>			
<b>2</b>			
<b>...</b>			

In accordance with the indications you gave us on the relevant SDSs, we would like to ask you to send to the authorities within three weeks from .....<sup>2</sup> the relevant information proving the biodegradability of the above surfactants in accordance to the above Regulation (EC) No 648/2004.

All the materials should be sent at the attention of the following person .....<sup>5</sup> at this address: .....<sup>6</sup>.

I would also ask you to send me confirmation that the material has been sent at the following e-mail address: .....<sup>7</sup>.

I would like to thank you for a swift compliance and remain

Sincerely yours,

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Copy to: .....<sup>5, 6</sup>

<sup>1</sup> Insert the name of the person identified in the SDS

<sup>2</sup> Insert the date in which the detergent manufacturer sent his letter to your company

<sup>3</sup> Insert the indication of the Member State whose CAs made the inspection

<sup>4</sup> Insert the full name of the company supplying the surfactants in question

<sup>5</sup> Insert the name of the inspector and/or the person indicated by him/her at the CAs offices that should receive the material

<sup>6</sup> Insert the address of the CAs where the data should be sent. Ideally this should include an e-mail address to speed up the process

<sup>7</sup> Insert your own e-mail address