



Association de Recherche Clinique
en Allergologie et Asthmologie

SPECIFICATIONS



DETERGENTS

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DISCLAIMER

1. Introduction

The company that submits its products or services for approval will have previously fulfilled all its duties in terms of compliance with the regulations in force.

The specifications are based on a partnership between health professionals specialized in allergic pathologies, gathered in an associative group representing the French allergists' community (ARCAA: Clinical Research Association in Allergology and Asthmology) and the R-LAB consulting company to develop a preventive approach and "controlled allergens" approval of industrial products for a reduction of their allergenic potential.

It aims to address the **following issues**:

- The difficulty for consumers suffering from contact skin allergy to have safe products available on the French market for use in domestic and professional environments.
- the willingness to support detergent manufacturers who focus on the prevention of allergic skin diseases or relapses, a common source of disability among home users and cleaning professionals.
- Finally, it is a matter of recognizing the know-how of manufacturers and ensuring greater transparency on the composition of their products for the consumer.

2. Main Objective

Set a higher level of quality than that established by French and European legislation.

3. Basis of the Specifications

- 3.1** Adopt transparency with regard to the consumer, using a communication method that does not mislead them
- 3.2** Evolutionary approval process: vintage principle, according to the most recent international literature in the field of skin and respiratory allergy and the regulation.
- 3.3** Leave enough space to constantly adapt to the requirements of technical progress and the evolution of European legislation on allergenic substances
- 3.4** Apply the precautionary principle to questions raised by the allergological scientific community, which have not found scientifically validated answers or are awaiting validation.

4. Regulatory Basis

4.1 Specifications

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The specifications, without prejudice to the regulatory provisions, shall govern the manufacture, control, packaging, placing on the market, labelling, import and distribution of detergent products, in particular, with regard to the classification, packaging and labelling of dangerous preparations.

4.2 Detergent regulations

- ✓ At the European level: It must respect the detergents regulation 648/2004 and its adaptations of the European Parliament and the Council of March 31, 2004 relating to the detergents recommendation of the **regulation N°648/2004 of the European Parliament of October 2005** relating to the labeling of the detergents and cleaning products.

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1. Proponent

ARCAA (Association de Recherche Clinique en Allergologie et Asthmatologie - Clinical Research Association in Allergology and Asthmatology) representing the French allergology community

2. Sources

Literature and professional experience on the allergic risk of detergents.

3. Business Target

Manufacturers of cleaning products wishing to be labelled "allergens controlled".

4. Relevant Public

General public, professional interior cleaning environment.

5. Selection of Files

Detergents and laundry products:

- The evaluation covers the composition of substances in a range of labellable products, likely to contain substances with known allergenic potential and which are often a source of allergic symptoms.
- The prospective method has been chosen. It is necessary to proceed with this evaluation in the presence of representatives of the relevant industries, of a panel of users for the technical aspects, as it will be necessary to check with them certain information on the offered products (or the absence of certain information).

6. Field of Application

This specification applies to detergents as defined by **Regulation 648/2004 of the European Parliament and of the Council.**

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Detergent is therefore defined here as "any substance containing soaps or other surfactants intended for washing or cleaning purposes.

Detergents can be presented in any form (liquid, powder, paste, bar, moulded piece, brick, etc.), and can be marketed or used for domestic, institutional or industrial purposes.

Cleaning aids, fabric softeners, all-purpose cleaning preparations and other cleaning or washing preparations are also covered by this regulation.

7. Labelling and Communication

- 7.1 Designations allowing the identification of the specifications: The products defined in the present specifications and meeting its requirements benefit from the "**controlled allergens**" designation.
- 7.2 References to the control body: The reference to the control body is in the form and wording "**Approved HQE-A by the ARCAA allergists**".
- 7.3 Obligation of transparency on the composition: The display of the complete composition is done in accordance with Appendix VII of the **EC regulation n°648/2004**:
All components are listed in **INCI** for chemical ingredients, and in latin, for plant ingredients.

8. Good Practice Objectives Evaluated

Holding the manufacturer accountable to ensure the absence of officially recognized allergenic or sensitizing substances.

Specify on the packaging the absence of officially recognized allergenic or sensitizing substances (see Appendices I and II of these specifications)

Indicate in the instructions for use: the actions to avoid and the protections to use (see Appendix III).

9. Important warnings

Allergists **cannot guarantee the safety of allergenic compounds in the long term** because it depends very much on the way (**direct contact or not**) the product is used and the frequency (**repeated contact or not**) of use of the product. This will have an **essential impact on the approval and the level of approval** of the product.

9.1 Detergent products in direct and repeated contact (e.g. hand dishwashing liquid)

This category of products for which the contact is direct and repeated, the sensitizing character of certain ingredients will increase the existing pathology or initiate a beginning of pathology.

9.2 Detergent products for machines (e.g. washing machines, dishwashers, ...)

This category of products for which the contact is limited and not repeated, the sensitizing character of certain ingredients will have a **lesser impact** on the allergic user of the product.

9.3 Detergent products in the form of non-pressurized spray (e.g. window cleaner, descaler...)

Because of the method of diffusion of the product (in the form of spray), the latter is delivered in the form of droplets whose size may impact their degree of penetration into the deep

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bronchial tubes of the allergic user and consequently, increase, to a greater or lesser extent, his/her pathology.

These substances can be responsible, in the form of airborne diffusion, of **cutaneous allergenic sensitization** when **deposited repeatedly and/or cumulatively on exposed areas** (face, hands, forearms).

Particles at risk of nasal and bronchial deposition should be specified by their particle diameter (if less than **2.5 μ m**), as harmful effects through the respiratory system may occur in confined areas for cumulative use of these substances.

9.4 Approval and Rating Level

The level of approval depends on the presence of allergenic substances (essentially or potentially, see Appendix 1) and their number in the product:

- **More than one allergen substance present**, the product **will not be approved**.
- If **only one allergenic substance** is present, the product **can be approved** with a **star** rating (*) and the **obligation** to indicate the offending substance on the label.
- **No allergenic substances present**, the product **can be approved** with a **two star** rating (**).

NB: Allergenic substances that **have been the subject of rare sensitization observations and are not yet** standardized for allergological exploration are also **accepted** (INCI nomenclature).

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10. Evaluation criteria

| |
|--|
| Questions to determine if the criteria are present. |
|--|

1. **The safety data sheet lists the complete composition of all components of the submitted product.**

- Perfumers must provide the chromatography of the fragrances.
- Preservers must be specified.
- In the case of non-pressurized spray:
 - If the data sheet indicates particles smaller than 2.5 microns in diameter in sprays, the product should be monitored for safety as scientific data evolve.
 - If an ingredient with sensitizing potential or known allergenic potential is present, it must be listed. The ingredient will not be listed on the label if it is below the thresholds that made the safety study on sensitizing potential
 - If the sheet indicates **allergens > 10 ppm** in the fragrances, the product will not be allowed to apply for HQE-A approval and ARCAA "allergen controlled" labelling.

Question 1: Do one or more of the additional data sheets for fragrance substances indicate the official list of allergens with the notation "absence" or "below 10 ppm"?

2. **An instructions for proper use is specified: instructions for use, means of personal protection, reminder of non-use in skin hygiene.**

In the case of TV advertising: the means of protection must be clearly seen.

Question 2: Is the correct use of the presented products indicated?

11. Data Collection Grid

Mark only one answer per product:

1 or O if the answer is YES

ID N°:

2 or N if the answer is NO

Date:

3 or N/A if not applicable

Time spent on this audit:

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| | QUESTION 1 | QUESTION 2 |
|---|---|---|
| | Do one or more of the additional data sheets for fragrance substances indicate the official list of allergens with the marking "absence" or "below 10 ppm"? | Is the correct use of the presented products indicated? |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

| | | |
|------------|--|--|
| Total of 1 | | |
| Total of 2 | | |
| Total of 3 | | |

YOUR COMMENTS FOR THIS SELF-EVALUATION

| | Observation per product |
|---|-------------------------|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |

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12. Interpretation of Results

- What do you think of the results? Are they in line with what is expected?
- How do you explain, for certain criteria, the possible differences observed?
- Do you think that corrective measures could be put in place? If so, which ones?

13. Renewal of Approval

The approval procedure **must** be renewed for **any approved product** for which **modifications have been made by the manufacturer**.

14. Use of the "Controlled Allergens" Label and Territory

- Following this approval, the manufacturer is granted the right to use the label in advertising after payment of an **annual license fee**.
- Label Territory**
 - The Label is **legitimate and valid throughout the French territory**.
 - However, **medical expertise, being universal, gives the community** of allergists the legitimacy **to export their approach and their Label to other countries** and to take its full validity after signing a specific contract for each territory.

15. Evolution of the Specifications

- ARCAA's allergists **cannot guarantee the long-term safety of the compounds**.

The specifications **may change** as a result of:

- Changes in regulations
- The progress of scientific knowledge and field feedback from the allergeo-vigilance network

- Deadline for the manufacturer to bring his products into compliance**

The manufacturer will be informed of the update of the specifications, considering these new notifications, **before the end of December of the year N** for the modification of the labels, if necessary, **on January 1st of the year N+2** (deadline for compliance and disposal of the labels).

The products, already approved and affected by this update, **must** undergo a new phase of approval for compliance.

APPENDICES

1. Appendix I: Allergenic Substances

1.1 Mainly Allergenic Substances

A **primarily** allergenic substance is one that is **known and proven to be sensitizing**.

- Quaternary ammoniums** (cationic surfactants)
- Chlorhexidine**
- Cocamidopropyl betaine** (CAPB), also called Tegobetaine: contact allergy by amidoamine and 3-dimethylaminopropylamine (DMAPA)
- Colophonium** (colophane)

- Dyes: Textile Dye Mix**
 - o Disperse Blue 35
 - o Disperse Orange 1
 - o Disperse Orange 3
 - o Disperse Red 1
 - o Disperse Red 17
 - o Disperse Yellow 3
 - o Disperse Blue 106
 - o Disperse Blue 124

- Formaldehyde and formaldehyde releasers:**
 - o Quaternium 15
 - o Diazolidinyl urea (Germall II)
 - o Imidazolidinyl urea (Germall 115)
 - o 2-Bromo-2- nitropropane-1, 3-diol (Bronopol)

- Glucosides** (decyl-, lauryl-, coco- and cetearylglucosides): allergological exploration by epidermotest with lauryl-glucoside belonging to the family.

Notes: capryl glucoside is not yet listed as a **known** sensitizing allergen in this family, but could potentially be an emerging allergen.

- Glutaraldehyde**

- 2-Hydroxyethyl methacrylate**

- Isothiazolinones :**
 - o Methylisothiazolinone (MIT)
 - o Kathon : Methylisothiazolinone + Methylchlorisothiazolinone (MCI)
 - o Benzisothiazolinone (BIT)
 - o Octylisothiazolinone (OIT)

- Lanolin Alcohol** : Lanoline

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- Metals:**
 - Nickel: sulfate hexahydrate
 - Chrome: potassium dichromate
 - Cobalt: chloride hexahydrate
- Methyldibromo glutaronitrile**
- Parabens**
- Fragrances:** 26 fragrances molecules (7th amendment by the European Commission) see appendix II
- Peru balsam**
- Propolis**
- Propylene glycol** (mono)
- Sesquiterpene lactones mix**
- Sodium Metabisulfite**

1.2 Potentially Allergenic Substances

A substance is **potentially** allergenic when the sensitizing substance:

- **Has been the subject of rare observations of sensitization and is not yet standardized** for allergological exploration (INCI Nomenclature).
- **Is hardly present** in the formulation of marketed products and its use **is very rare** by consumers (feedback from the allergeo-vigilance networks)

- Amerchol L101**
- Chloramine**
- Compositae mix II**
- hypochlorite de sodium**
- Use of sorbic acid:** ingredient referenced as having been the subject of sensitization reports [Chemotechnique diagnostics - patch-tests references 2019 and 2020], whose literature is old and currently not applicable, but which remains a potentially emerging allergen
- Phenoxy-ethanol**

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2. Appendix II: Allergenic Fragrances

- Following the directive **2003/15/CE**, since March 11, 2005, 26 substances, having among others fragrant or aromatic properties, identified as being potentially allergenic, must appear clearly in the list of ingredients, whatever their function, as soon as their **concentration exceeds 0.001%** in non-rinsed products (creams, etc...) and **0.01% in rinsed products** (shampoos, etc...).

Among these 26 substances are the 8 that are part of **Fragrance Mix**, the product that doctors use as a patch to find out if a subject is allergic to "fragrances" in general.

- **Exact composition of the standard Fragrance Mix (at 8%) called Fragrance Mix I** : 1% Amyl Cinnamal (Alpha Amyl Cinnamyl Aldehyde) - 1% Cinnamyl Alcohol - 1% Cinnamal (Cinnamic Aldehyde) - 1% Eugenol - 1% Geraniol - 1% Hydroxycitronellal - 1% Isoeugenol - 1% Oak Moss - 5% Sorbitan Sesquioleate (emulsifier)
- **Composition of Fragrance Mix II**, a new fragrance allergy test, which complements the previous one: 10% Alpha-Hexyl-Cinnamaldehyde - 5% Farnesol - 5% Coumarin - 2.5% Lyral - 2% Citral - 1% Citronellol
- **Peru Balsam**: 18 of these allergenic substances exist in their natural state. Here is the complete list (INCI name): Amyl Cinnamal, Benzyl Alcohol, Cinnamyl Alcohol, Citral, Eugenol, Hydroxycitronellal, Isoeugenol, Amylcinnamyl Alcohol, Benzyl Salicylate, Cinnamal, Coumarin, Geraniol, Hydroxyisohexyl 3-Cyclo Hexene Carboxaldehyde, Anise Alcohol, Benzyl Cinnamate, Farnesol, Butylphenyl Methylpropional, Linalool, Benzyl Benzoate, Citronellol, Hexyl Cinnamal, Limonene, Methyl 2-Octynoate, Alpha-Isomethyl Ionone, Evernia Prunastri, Evernia Furfuracea

NB: Plants are mixtures of these allergens, any plant used must be mentioned.

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3. Appendix III: Cleaning and Proper Use of Cleaning Products

Definition of cleaning work (1):

- ✓ Dusting, washing and polishing surfaces and walls,
- ✓ Mopping, sweeping and shining floors,
- ✓ Evacuating waste and wastewater.

☐ Relevant Public

Employees of cleaning companies, cleaning workers, surface technicians and all persons who perform these cleaning operations in their homes.

☐ Possible risks

Allergic (hives, eczema) and non-allergic (irritation) skin risks, respiratory risks (nose, bronchial tubes)

☐ Concerned substances

- ✓ Some fragrances, preservatives, surfactants, quaternary ammoniums, ammonia, alkaline components, some acids and solvents.
Use of products with a very alkaline or very acidic pH, solvent-based products.
- ✓ Allergic risk increased by skin irritation, especially if combined with the use of detergents when working in a humid environment,

Actions to avoid with cleaning products:

- ✓ **Siphoning** a product to avoid ingestion
- ✓ **Bringing** a product to the **mouth**
- ✓ **Rubbing eyes with your hands**, even if protected by gloves soiled with the cleaner
- ✓ **Directly inhaling** a product.
Use products in a well ventilated room. (9)
- ✓ **Repeated use** of hand sanitizer or "homemade" cleaning water »
- ✓ **Mix several products** without knowing their compatibility due to the **risk of toxic fumes**.
Even if you make your own household products with natural ingredients, be sure to label the finished product. Do not mix acidic preparations or products with bleach (or hypochlorite): because chlorine is released

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- ✓ **Change the conditioning or packaging** of a product - to avoid the risk of accidental ingestion of a cleaning product

- ✓ **Repeatedly use an aerosol in a confined environment** with indoor pollution (mold, passive smoking, volatile organic compounds)

Actions to take with cleaning products:

- ✓ **Ventilate your home every day: 15 minutes morning and evening.**
Because the chemicals released by the products accumulate in the indoor air.

- ✓ Before opening a product, **read the label**
 - They indicate the composition, directions for use, hazards and precautionary statements.
 - Ensure that when purchasing in bulk, compliant labeling is present. (++) (14)

- ✓ **Follow the precautionary measures on the label**
 - Wear appropriate gloves, goggles and face shield to avoid repeated and/or cumulative contact on exposed areas (face, neck, décolleté, hands, forearms)
 - Avoid contact with a wound or irritated skin.

The indication "may produce an allergic reaction" is mandatory if an ingredient has a known allergic potential.

- ✓ **Follow the manufacturer's rinsing instructions**
Additional rinsing may be advised by an allergist (wash your hands with a skin care product, rinse them well, and dry them thoroughly).

- ✓ **Alternate brands of cleaning products**
In the absence of products labeled "approved by ARCAA allergists", it is mainly the repeated use that can create a skin allergy in the medium and long term.

- ✓ **Keep EMS and poison control numbers handy**
In the event of an incident:
 - Splash on skin or eyes: rinse thoroughly with clean water.

 - Inhalation: leave the room, breathe fresh air and contact your doctor, if necessary an emergency service, the EMS and/or the relevant poison control center.

 - **Ingestion: immediately call the Poison Control Center**

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Additional preventive recommendations

- ✓ In the presence of people with known chronic respiratory pathology (COPD, asthma, rhinitis and sinusitis): the **simultaneous use of 2 or more aerosols is strongly disadvised**, because of the demonstrated risk of aggravation of the respiratory pathology.

- ✓ If the person using the aerosols, in a confined atmosphere, has an allergic skin condition, he or she is advised to:
 - Thoroughly rinse the exposed areas (face, neck, neckline, hands and forearms) and dry carefully
 - or apply a preventive cosmetic skin protection product on the exposed areas

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