



Association de Recherche Clinique  
en Allergologie et Asthmologie

## SPECIFICATIONS



## - AEROSOL PRODUCTS -

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# FORWARD

## 1. Introduction

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: association of clinical research in allergology and asthmology) and the R-LAB consulting company to develop a preventive approach and "controlled allergen" approval of industrial products for a reduction of their allergenic potential.

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

- the lack of approval of hypo-allergenicity in France by an independent agency of the production industry.
- considering indoor air pollution, which is a public health problem.
- the difficulties for consumers suffering from contact skin allergy and respiratory allergy (nasal and bronchial) to have products of maximum safety available on the French market for use in the domestic and professional environment.
- the willingness to support manufacturers of airborne substances who focus on the prevention of skin and respiratory allergic diseases, as well as on the prevention of relapses in sensitized subjects, a common source of disability among domestic users and cleaning professionals.
- Finally, the know-how of manufacturers must be recognized, and consumers must be given greater transparency on the composition of their products.

It is **not intended** to analyse the **carcinogenic** and **endocrine disrupting potential** of the ingredients studied.

## 2. Main Objective

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

## 3. Basic Principles of the Specifications

- 3.1 Adopt transparency with regard to the consumer, using a communication method that does not mislead them.
- 3.2 The certification process will be evolutionary, adopting the **vintage** principle, according to the **most recent data** in international literature in the field of skin and respiratory allergy.
- 3.3 Leave enough space to constantly adapt to the requirements of technical progress and the evolution of European legislation on allergenic and airway-damaging 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.
- 3.5 Change the behavior of the population by optimizing the use of manufactured products to reduce the effect of indoor pollution.
- 3.6 In no case promote products delivered in aerosols.

#### 4. **Regulatory Basis**

The specifications, apart from the regulatory provisions, shall govern the manufacture, control, packaging, placing on the market, labelling, import and distribution of aerosols for indoor environmental sanitation, in particular with regard to the classification, packaging and labelling of dangerous preparations.

Compliance with the various regulations and recommendations is a prerequisite for labelling: it is the manufacturer's responsibility to ensure that the product will comply with all relevant regulations.

Any amendment to an EC regulation described in this chapter will be applicable according to its date of entry into force, even before the updating of this specification:

1. At European level: It must comply with the Regulation on classification, labelling and packaging of substances and mixtures EC 1272/2008 (CLP) and its annual adaptations (adaptation to technical and scientific progress)
2. At French level: All members, including France, are subject to the CLP regulation EC 1272/2008.
3. Especially allow access to the full composition, through the website "allergens-controlled.com", which will be specified on the product packaging, and by creating a link to the manufacturer's website which will allow easier updates (put the link of the manufacturer's website).

#### **Other regulations and recommendations**

- Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 (misleading and comparative advertising).
- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.
- Articles L.115-27 to L. 115-33 and R. 115-1 to R. 115-3 of the Consumer Code.
- The First and Second Opinions of the National Consumer Council on the clarification of Environmental Claims, dated 6 July and 15 December 2010 respectively.
- CSHPF (French High Council for Public Hygiene) recommendations.
- IFRA (International Fragrance Association) guidelines.

# SPECIFICATIONS ARTICLES

## 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 experiments** on the allergic risk of aerosols.

## 3. Business Target

**Manufacturers of aerosol products** wishing to be labelled "allergen controlled".

## 4. Relevant Public

**General public, professional interior cleaning environment.**

## 5. Selection of Files

**Aerosols:**

- The evaluation covers the composition of substances in a range of labellable products, likely to contain substances with known allergenic and/or irritant 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, as it will be necessary to check with them certain information on the offered products (or the absence of certain information).

**NB:** only products containing substances that have not been found to be carcinogenic or endocrine disrupting will be evaluated.

## 6. Field of Application

This specification applies to indoor air fresheners in aerosols or non-pressurized spray form. For the definition of aerosols, we use the definition of the **European Directive n° 75/324/EEC**:

Aerosol dispenser, within the meaning of this Directive, means the assembly consisting of a single-use metal, glass or plastic container containing a compressed, liquefied or dissolved gas under pressure, with or without a liquid, paste or powder, and provided with a sampling device allowing the contents to be discharged in the form of solid or liquid particles in gas suspension, or in the form of a foam, paste or powder, or in the liquid state. Aerosols may be marketed or used for domestic, institutional, or industrial purposes.

#### **Airborne Particles:**

- PM - (particulate matter): fine particles (aerodynamic diameter less than 2.5µm).
- Ultra-fine particles (UFP less than 0.1µm in diameter): the size and composition of PM play a key role, the smaller they are, the more dangerous they are).

**Respiratory risk:** The use of **two or more types of simultaneous aerosol sprays** has been associated with asthma. Further analysis is needed to understand the underlying mechanisms that may lead to a harmful effect of sprays on asthma.

#### **Skin risk**

- a hydrophobic coating could enhance skin penetration due to a greater affinity for stratum corneum lipids).
- pores are a way of penetration.
- the presence of sweat which can alter the surface of the particles.
- a study allowed the sensitization potentiality to be evaluated according to the **concentration** of an ingredient with known sensitizing power, present in a cleaning aerosol: it was retained that a concentration equal to or lower than a certain percentage (examples: 0.021% for benzisothiazolinone, 0.1% for cyclodextrins), did not induce skin sensitization.

There is also the question of whether the **combination** of the active ingredient with the fragrance **substance** during collection **can cause sensitization**. This possibility is monitored in the scientific literature.

## **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 preservatives, the list is subdivided into the following ranges, expressed in weight percentage:

- less than 5%
- 5% or more

Particles likely to cause nasal and bronchial deposits must be specified by their particle diameter (less than **2.5µm**).

**Allergenic or known sensitizing substances** must appear on the label according to the thresholds defined by CLP EC 1272/2008.

In addition, benzisothiazolinone whose concentrations must appear on the label if they are higher than 0.021%, and cyclodextrins if the concentrations are higher than 0.1%.

**Allergenic or known sensitizing substances** must appear on the label. If there is a literature allowing to know the allergenic or sensitizing thresholds, as for example for Benzisothiazolinone for concentrations higher than 0,021%, that is to say less than 210 ppm, and cyclodextrins if the concentrations are higher than 0.1%, that is to say 1000 ppm, an indication will be added, stating that the concentration of the agent(s) contained in the aerosol is lower than X times the dose known to be allergenic/sensitizing.

## 8. Good Practice Objectives Evaluated

### **Aim:**

Holding the manufacturer accountable to ensure the absence of officially recognized allergenic or sensitizing substances and/or having a harmful effect on the distal bronchial airways.

Specify on the packaging:

- The substances officially recognized as allergens, when present above the threshold established by the CLP regulation EC 1272/2008.
- Specify the precaution of avoiding the simultaneous use of 2 or more airborne substances with potentially harmful health effects (see bibliography - Le Moual N & al 2012 Eur Resp J)
- Implement general preventive recommendations on good practices for the use of airborne substances in an indoor environment.
- Indicate in the instructions for use: the actions to be avoided and the recommendations for use (see Appendix IV)

## 9. Evaluation criteria

<b>Questions to determine if the criteria are present</b>
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### 1. **The safety data sheet lists the complete composition of all components of the submitted product.**

- Perfumers must provide the chromatography of the fragrances.
- If the sheet indicates particles smaller than **2.5 microns** in diameter in aerosols, the product will not be allowed to apply for HQE-A approval and ARCAA "allergen controlled" labelling.
- 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
- Preservers must be specified.

**2. The product submitted for labelling must guarantee good long-term performance to prevent users from having problems with a product that has been poorly preserved.**

Aerosols require the use of ingredients that promote good preservation.

These ingredients may or may not be substances officially classified as "preservatives". Should there be none, it will be necessary to know, under the seal of confidentiality, what preserves the product.

The company is committed to ensuring that the safety data sheet is updated in accordance with European regulations

**3. An instruction of good use is specified:** instructions for use, means of personal protection in the case of TV advertising: do not show misuse of the product

**10. 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:** .....

	<b>QUESTION 1</b>	<b>QUESTION 2</b>	<b>QUESTION</b>
	Do one or more additional sheets indicate the rating "above" or "below" 2.5 microns for airborne particles?	Do one or more of the additional sheets indicate the rating "above" or "below" the critical threshold for sensitizing ingredients?	Are the proper use of the products displayed mentioned?
<b>1</b>			
<b>2</b>			
<b>3</b>			
<b>4</b>			
<b>5</b>			

<b>Total of 1</b>			
<b>Total of 2</b>			
<b>Total of 3</b>			



Observation per product	
1	
2	
3	
4	
5	

## 11. 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?

## 12. Labelling levels

*1 star (standard):* particles larger than 2.5 microns in diameter, indication of the presence of allergen(s) or potentially sensitizing ingredient(s) on the label if the sensitizing thresholds are not known. If the allergenic/sensitizing thresholds are known, indication of the presence of the allergen(s) or ingredient(s) on the label, mentioning that the concentration of the agent(s) contained in the aerosol is less than X times the dose known to be allergenic/sensitizing.

*2 stars (premium):* particles larger than 2.5 microns in diameter, absence of allergen(s) at concentrations above a potentially sensitizing threshold if known.

*3 stars:* same as 2 stars, no emission of volatile organic compounds (as identified on the list by latest knowledge).

# APPENDICES

## 1. Appendix I

### 1.1 Potentially Allergenic Substances

- ⑩ chloramine
- ⑩ sodium hypochlorite
- ⑩ quaternary ammoniums (cationic surfactants)
- ⑩ ethalonamine
- ⑩ chloracetamide

### 1.2 Mainly Allergenic Substances

- ⑩ fragrances: 26 fragrance molecules - see appendix II
- ⑩ d-limonene
- ⑩ linacohol
- ⑩ benzisothiazolinone and methylisothiazolinone
- ⑩ alpha-hexyl-cinnamic aldehyde (HCA) propylene glycol
- ⑩ L-menthone
- ⑩ cyclodextrines
- ⑩ formaldehyde
- ⑩ phenoxy-ethanol
- ⑩ glutaraldehyde
- ⑩ lanoline colophane
- ⑩ cocamidopropyl betaine (CAPB), also called Tegobetaine: contact allergy by amidoamine and 3-dimethylaminopropylamine (DMAPA)
- ⑩ metabisulfite
- ⑩ glucosides (decyl-, lauryl-, coco- and cetearylglucosides): allergological exploration by epidermotest with lauryl-glucoside representing the family

## 2. Appendix II: Allergenic Fragrances

- The European CLP (Classification Labelling and Packaging) regulation EC1272/2008, revised annually, defines the thresholds for the labelling of allergenic ingredients, including allergenic fragrances).
- **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**: 10% Alpha-Hexyl-Cinnamaldehyde - 5% Farnesol - 5% Coumarin - 2.5% Lylal - 2% Citral - 1% Citronellol

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

### 3. Appendix III: Volatile Organic Compounds (VOC)

- ⑩ Aldehydes: formaldehyde, acetaldehyde
- ⑩ Alkanes: methyl-cyclo-pentane
- ⑩ Aromatics VOCs: benzene, toluene, ethylbenzene
- ⑩ Esters: 2,2,4-trimethyl-1,3-pentanediol di isobutyrate
- ⑩ Ethanol
- ⑩ Chlorinated hydrocarbons: chloroetheneKetone
- ⑩ Propylene glycol and glycol ethers
- ⑩ Terpenes: d-limonene

## 4. Appendix IV

### RECOMMENDATIONS FOR CLEANING AND PROPER USE OF AEROSOLS

odor sensors

#### *Definition of Sanitation Work*

##### Target Audience:

Professionals: indoor environment sanitation agents, community users private homes.

##### Relevant substances:

Some fragrances, preservatives, surfactants, quaternary ammoniums, ammonia, alkaline components, some acids, and solvents.

Use of fine-particle airborne products with cumulative effect.

#### *Allergic Risks*

- skin inflammation (hives, eczema, non-allergic irritation) especially if combined with the use of detergents when working in a humid environment.
- respiratory (nose, bronchi): aggravation of asthma if at least two aerosols are used simultaneously, persistence of rhinitis or chronic sinusitis.

#### *What to do with aerosols:*

- follow the instructions for use
- **avoid:**
  - Failure to follow manufacturer's instructions for use.
  - Repeated use of an aerosol in a confined environment with the presence of indoor pollution (mold, passive smoking, volatile organic compounds).

#### *Additional preventive recommendations*

- Ⓢ In case of people with **known chronic respiratory pathology** (COPD, asthma, rhinitis, and sinusitis):

- The simultaneous use of 2 or more aerosols is strongly discouraged, due to the demonstrated risk of aggravating the respiratory pathology.

⑩ If the person using the aerosols in a confined atmosphere has an **allergic skin condition:**

It is advised to carefully rinse the exposed areas (face, neck, hands and forearms) or apply a skin-protecting cosmetic product to the exposed areas.

## 5. Appendix V: Bibliography

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