

## Statement on Conformance

Mixing ratio [REDACTED] Internal liner, gold  
with [REDACTED] component for [REDACTED]

**Intended use:** [REDACTED]-component internal spray application of extruded monobloc aerosol cans and tubes made of aluminium. Suitable for pharmaceutical and cosmetic products and as food contact surface.

### Assessment:

#### **9 EU: Regulation (EC) No. 1935/2004**

The **European Union Regulation (EC) No. 1935/2004** "concerns materials and articles intended to come into contact with food" and repeals **Directive 80/590/EEC** and **Directive 89/109/EEC**.

If applied and cured for the intended end-use following our recommendations of our datasheets, the product [REDACTED] will comply with the requirements set out in **Article 3 of Regulation (EC) No. 1935/2004**. Namely that the product is sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health, or bring about an unacceptable change in the composition of the food, or a deterioration in its organoleptic properties.

The physiological harmlessness was confirmed by the examinations with respect to food legislation, which has been carried out in accordance with the German Code of Law for Food and Feeds **LFGB § 64** (the LFGB, has repealed the German Food and Commodities Law LMBG as valid national law on September 1, 2005) and the US **FDA Code of Federal Regulations Title 21, Subpart 175.300 "Resinous and polymeric coatings"** (Institute Nehring, Braunschweig, Germany, Reference-No. STGM38-026 (8510600)(EN), dated 2006-02-23).

The dry residues of the migrates are low and below the levels which are considered as tolerable in the **Resolution ResAP(2004)1**. They are also considerable lower than those levels which are mentioned in **US FDA Regulation 21 CFR § 175.300 "Resinous and polymeric coatings"**.

The product is listed by the FDA (Food and Drug Administration) in Washington under the **Drug Master File number DMF 6612 Type III Packaging Material**.

**\*Germany: LFGB**

In the circumstances of the destined and expected usage the product [REDACTED] complies with the requirements of the § 31 paragraph 1 of the LFGB -and is eligible for the manufacture of commodities as defined by § 5 paragraph 1 No. 1. The LFGB (German Code of Law for Food and Feeds) has repealed the LMBG (German Food and Commodities Law) as valid national law on September 1, 2005.

**\* EU: Commission Regulation (EC) No. 1895/2005**

To avoid risks to human health the **Commission Regulation (EC) No. 1895/2005** lays down specific migration limits for **BADGE** (Bisphenol-A DiGlycidyl Ether), BFDGE (Bisphenol-F DiGlycidyl Ether) as well as for **NOGE** (novolac glycidyl ethers) and some of their derivatives.

We hereby declare, that in the manufacture of the above mentioned product no **Novolac resin** is used. Further, none of the constituent raw materials is specified by its supplier to contain **Novolac** as an impurity.

• **EU: Directive 2004/1/EC – Use of Azodicarbonamide (ADC), Semicarbazide (SEM)** We hereby declare, that the product [REDACTED] is free of **Azodicarbonamide** and therewith free of **Semicarbazide**. Further, none of the constituent raw materials is specified by its supplier to contain Azodicarbonamide or Semicarbazide as an impurity. Thus the above mentioned product meets the compositional requirements of the Commission Directive 2004/1/EC of 6 January 2004, amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent.

**a Organotin compounds**

We hereby declare, that the product [REDACTED] is free of **Organotin compounds** such as **Monobutyltin (MBT)**, **Dibutyltin (DBT)** and **Tributyltin (TBT)**. Further, none of the constituent raw materials is specified by its supplier to contain any of the above mentioned substances as an impurity.

**9 Ethylene Glycols**

We hereby declare, that the product [REDACTED] is free of **Ethylene glycol methyl ether (EGME, CAS-No. 109-86-4)**, **Ethylene glycol ethyl ether (EGEE, CAS-No. 110-80-5)**, **Ethylene glycol methyl ether acetate (EGMEA, CAS-No. 110-49-6)**, **Ethylene glycol ethyl ether acetate (EGEEA, CAS-No. 111-15-9)**, **Ethylene glycol dimethyl ether (EGDME, CAS-No. 110-71-4)**,

Triethylene glycol dimethyl ether (TEGDME, CAS-No. 112-49-2), Diethylene glycol monomethyl ether (DEGME, CAS-Nr. 111-77-3), Diethylene glycol dimethyl ether (DEGDME, CAS-No. 111-96-6), 1-Propylene glycol 2-methyl ether (1PG2ME, CAS-No. 1589-47-5) and 1-Propylene glycol 2-methyl ether acetate (1PG2MEA, CAS-Nr. 70657-70-4). Further, none of the constituent raw materials is specified by its supplier to contain the above mentioned ethylene glycols as an impurity.

The product [REDACTED] contains only a very small amount (≤ 0.01 %) of 1-Propylene glycol 2-methyl ether acetate (1PG2MEA, CAS-Nr. 70657-70-4) as an impurity of the solvent Propylene glycol methyl ether acetate (CAS-No. 108-65-6).

- **Phthalates**

We hereby declare, that the above mentioned product is free of **Phthalates**, in particular also free of **Dibutylphthalate (DBP)**, **Diethylphthalate (DEP)**, **Diisononyl phthalate (DINP)**, **Diethylhexylphthalate (DEHP)**, **Di-isodecyl phthalate (DIDP)**, **Di-n-octylphthalate (DNOP)** and **Benzylbutylphthalate (BBP)**. Further, none of the constituent raw materials is specified by its supplier to contain phthalates as an impurity.

- **Polybrominated biphenyls (PBB), polybrominated diphenyl ether (PBDE), polychlorinated biphenyls (PCB):**

We hereby declare, that the above mentioned product is free of **polybrominated biphenyls (PBB)**, **polybrominated diphenyl ether (PBDE)** and **polychlorinated biphenyls (PCB)**. Further, none of the constituent raw materials is specified by its supplier to contain PBB, PBDE or PCB as an impurity.

- **EU/USA: Directive 94/62/EC, CONEG**

We hereby declare, that in the manufacture of [REDACTED] no deliberate or knowing addition of **toxic metals** or **heavy metals**, specifically lead, cadmium, mercury and chrome (VI), is made and the product does therefore constitutionally not contain any **heavy metals**. Furthermore, none of the raw materials purchased for the production of the above named product is specified by its supplier to contain any toxic metals or heavy metals as significant impurities.

The total content of all elements combined is in summary less than 100 ppm by weight and thus complies with the limit specified by the **European Council and Parliament Directive on Packaging and Packaging Waste 94/62/EC** (December 1994) as well as the **American CONEG Regulation** (January 1994).

- **BSE (Bovine Spongiform Encephalopathy) / TSE (Transmissible Spongiform Encephalopathy)** We hereby declare that for the product [REDACTED] no deliberate or knowing addition of raw materials of animal origin is made in its manufacture. Further, none of the raw materials purchased for the production of the above named product are specified by its supplier to contain any substances of animal origin as significant impurities.

Therefore it can be precluded, that the product contains any substances, that cause **bovine spongiform encephalopathy (BSE)**, that belongs to a group of diseases known as **transmissible spongiform encephalopathies (TSE)**.

\* Use of **halogenated hydrocarbons**

Halogenated hydrocarbons are generally not used in the manufacture of our products.

**References**

**Regulation (EC) No. 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

LFGB - German Code of Law for Food and Feeds (repealed the LMBG (German Food and Commodities Law) as valid national law on September 1, 2005)

**Regulation (EC) No. 1895/2005** of the European Parliament and of the Council of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

**Framework Resolution ResAP(2004)1** on coatings intended to come into contact with Foodstuffs of 10 June 2004, adopted by the Committee of Ministers on 1 December 2004

**Commission Directive 2004/1/EC** of 6 January 2004, amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent.

**US FDA 21 CFR § 175.300** „Resinous and polymeric coatings”  
CONEG, issued January 1994

**Directive 94/62/EC** of the European Parliament and of the Council on packaging and packaging waste of December 1994

Technical Administrator

San Ginés, Murcia, 2008-22-04

\* Validity

This assessment refers exclusively to the product [REDACTED]. In the case of a change of the raw materials, the raw material composition of the product, the legal regulations or new toxicological realizations it loses its validity.

## Statement on Bisphenol A in Packaging Coatings

████████████████████, gold

████████ Internal liner ██████

████ with ██████

We hereby declare, that in the manufacture of the above mentioned product no Bisphenol A or any material known to contain it is used. Further, none of the constituent raw materials is specified by its supplier to contain Bisphenol A as an impurity.

We anticipate therefore, that Bisphenol A will remain undetectable in any extraction or migration check.

Technical Administrator