

**FOOD CONTACT STATUS DOCUMENT - EUROPE**

**POLYGLAS D4218/M**

**Inventory Status**

POLYGLAS D4218/M is compliant with following inventories.

<b>COUNTRY</b>	<b>INVENTORY</b>	<b>STATUS</b>
Australia	AICS	Conforms
Canada	DSL	All components of this product are on the Canadian DSL list
China	IECSC	Conforms
Europe	EINECS	Conforms
Japan	ENCS	Conforms
Korea	KECI	Conforms
New Zealand	NZIOC	Conforms
Philippines	PICCS	Conforms
United States	TSCA	Conforms

**Statement for Food contact application**

The above product is intended to be used as glass coating for food contact applications. It should be applied to the non-food contact side of glass bottles and containers. However, the applicator should take all appropriate technical measures to minimise the quantity of product sprayed into the interior of the food-contact glass containers.

The above-mentioned product contains only substances authorized and comply with the following EU commission, FDA regulations and directives:

• **FOOD AND DRUG ADMINISTRATION (FDA) REGULATION**

The Cold End Coating comply with the FDA requirements for use in direct food contact application as container glass. The individual substances present in this product that are reasonable expected to migrate to food are covered by the following regulation:

- Adhesives and Components of Coatings 21 CFR 175-105,
- Listed as GRAS, Generally Recognized As Safe notices (21CFR 182-186)

• **STATE OF CALIFORNIA:**

Proposition 65 list : None of the ingredients of this product is on the California Proposition 65 list

• **EU :**

- By the resolution of the Council of Europe AP (2004) 1 – Version N° 3 – 12-02-2009 – on coatings intended to come into contact with foodstuffs. All substances are listed in the technical document No. 1:
  - ✓ A - List1: Monomers.
  - ✓ C - List 1: Additives.
- By the framework Regulation (EC) 1935/2004 (as amended)

✓ Article 3 (safety clause) :

It is the responsibility of the end-use manufacturer to verify the compliance of the finished materials or articles at the specific real and/or foreseeable conditions of use, based on the information disclosed in this document.

✓ Article 17 (traceability) :

The product is manufactured under a quality management system certified to be in compliance with ISO 9001:2015 and in accordance with Company Corporate Standards on hygiene and housekeeping. The requirements of article 17 of Regulation (EC) 1935/2004 on traceability are fulfilled by the adherence to the clause 7.5.3 (Identification and traceability) of the ISO 9001:2015 standard.

- Our Quality Assurance System covers the requirements of the EU regulation on good manufacturing practice for materials and articles intended to come into contact with food (Regulation (EC) No 2023/2006)
- By the Commission Regulation (EU) N° 10/2011 (14.01.2011) on plastic materials and articles intended to come into contact with food, Annex I, Table 1, included latest subsequent amendments that is valid at the document date.

The following restrictions apply under Regulation (EC) 10/2011 or as differently specified:

PM ref	Substance name	Content in product as supplied	Restrictions and/or specifications
77708	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary alcohols (C8-C22)	< 10 %	SML(*) = 1.8 mg/kg
80077	Polyethylene waxes, oxidized	< 15%	SML(*) = 60 mg/kg
86480	Sodium Bisulfite	<900 ppm	SML(T)(*) = 10mg/kg
37520	1,2-benzisothiazolin-3-one  (#) According to the 16th list of substances for food contact materials adopted on 25-26 September 2007 by the AFC panel. The opinions of the AFC panel are available on the EFSA website	< 200 ppm	SML(*) = 0.5 mg/kg (#) (SCF list 3) under EFSA evaluation . Only to be used in aqueous polymer dispersion and emulsions and at concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself.  <b>Germany:</b> Recommendation BfR XIV-A (plastic dispersion) with a max. level of 80µg/dm <sup>2</sup> .  <b>The Netherlands:</b> Commodities Act Regulation on packaging and consumer articles Chap. I (plastics) as polymerization aids and additives. Restriction: SML(*) =0,5 mg/kg.
43730	CMIT/MIT	< 50 ppm	EFSA Opinion: SCF List3, maximum residual amount in the finished product: 25 µg/dm <sup>2</sup>

			<p>Only to be used in aqueous polymer dispersion and emulsions and at concentrations which do not result in an anti-microbial effect on the surface of the polymer or on the food itself.</p> <p><b>Germany:</b> Recommendation BfR XIV-A (plastic dispersion) with a max. level of 4 µg/dm<sup>2</sup>.</p>
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(\*) Legenda: SML = Specific migration limit;

SML(T) = Specific migration limit expressed as total of moiety or substance(s) indicated.

- **Germany :**

By the Bundesinstitut für Risikobewertung (BfR) and in conformity with specifications in force for the manufacture of materials intended for food contact, namely:

- Empfehlung XLVIII " MATERIALS FOR COATING THE OUTSIDE OF HOLLOW GLASSWARE". Bgb Nr.18, 1975 (Heft Nr.10, Seite 173).

**REACH – Annex XVII (Includes the latest updated list of candidates)**

All substances listed in the Regulation (EC) N°. 1907/2006 Annex XVII and amendments are not intentionally added in the manufacture process of POLYGLAS D4218/M. Their presence is therefore not expected in this product.

**COMMISSION REGULATION (EU) 2023/2055 (Synthetic polymer microparticles)**

Some of our raw materials are microplastic synthetic polymers as defined in the regulation UE2023/2055. [Regulation - 2023/2055 - EN - EUR-Lex](#)

Nevertheless, we confirm that our customers are allowed to use our cold end coating as:

- They are using it on industrial site.
- the synthetic polymer microparticles are modified during our process of emulsification.

Concerning our customers, they modify permanently the synthetics polymers contained in our emulsion to form a coating on the bottle surface. By this process, the polymer no longer falls in the scope of this regulation.

**STATEMENT OF HEAVY METAL**

- **CONEG and Packaging Waste**

Following heavy metal compounds are not used and not expected in the manufacture of POLYGLAS D4218/M:

- Antimony
- Arsenic
- Barium
- Cadmium
- Chromium
- Copper
- Mercury
- Lead
- Selenium

- Tin
- Zinc

This product conforms to the CONEG standard and to the requirements of the Directive 94/62/EC (Packaging Waste) and amendments (Article 11).

- **RoHS**

Lead, mercury, hexavalent chromium, Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE) are not used and not intentionally introduced in the manufacture of POLYGLAS D4218/M.

This product meets the criteria of the first article of the Directive 2011/65/EU relative to the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- **BIOCIDAL PRODUCT REGULATION N°528/2012**

Following the European regulation above-mentioned, our product formulation contains exclusively biocidal product authorized to be used on the market.

## **ABSENCE OF CHEMICALS**

- **Substances of very high concern (SVHC) - Candidate List and REACH Annex XVII - Decree n°2021-1285 and decree of 30 August 2023**

This product is free from any substances identified as "SVHC" (Substances of Very High Concern) which are referred to the "candidate list" as published by ECHA in the context of the REACH Regulation (EC) No 1907/2006. This statement includes all substances listed by ECHA, decree of 30 August 2023 and its amendments based on the latest list available at the date of this food statement.

([Identification of substances of very high concern \(SVHC\) - ECHA CHEM](#)).

- **Endocrine disruptors List (ED List & decree of 28 September 2023)**

POLYGLAS D4218/M doesn't contain any substances added intentionally that are listed in ED list I : Substances identified as endocrine disruptors at EU level and in the decree of 28 September 2023 and its amendments available at date of this document.

(<https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu>)

([Decree of 28 September 2023](#))

This product is also free from any substances added intentionally that are listed by ANSES in the "Elaboration of a list of substances of interest as regards to a potential endocrine activity and prioritisation strategy for assessment", Table 7: Substances prioritized to enter the ranking methodology. For the detail of substances, see the [Table 7 in the document below](#).

<https://www.anses.fr/system/files/REACH2019SA0179Ra-1.pdf>

- **Non-intentionally added substances (NIAS)- REGULATION (EU) 2025/351**

NIAS could come from various sources: side product, breakdown products and contaminants. We can confirm that the quantity of potential NIAS will not exceed 0.001% in our product. As specified in Regulation (EU) No 10/2011, unauthorized substances may be used in plastic FCMs behind a functional barrier, provided they do not migrate at levels above 10 µg/kg food. In consequence the user of our cold end coating should verify that unauthorized substances will not exceed a level of 10µg/Kg of food, by

using a worst case scenario.



- **Persistent organic pollutants (POP) - REGULATION (EU) 2019/1021 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019**

Polyglas D4218/M doesn't contain any substances added intentionally that are listed in the annex I, II and IV in regulation EU 2019/1021 based the latest list available at the date of this food statement.

<http://data.europa.eu/eli/reg/2019/1021/oj>  
[Substances proposed as POPs - ECHA CHEM](#)

- **NF EN 71-12 Safety of toys - Part 12 : N-Nitrosamines and N-nitrosatable substances**

POLYGLAS D4218/M doesn't contain N-Nitrosamine or nitrosable substances added intentionally.

- **SIN list chemicals**

POLYGLAS D4218/M doesn't contain any substances added intentionally that are listed in the SIN list of hazardous chemicals for the food contact materials based on the latest list available at the date of this food statement.

- **Bisphenol A (BPA) and other bisphenols and bisphenol derivatives – REGULATION (EU) 2024/3190**

POLYGLAS D4218/M doesn't contain or added intentionally any Bisphenol A, B, F and S and derivatives structures as defined in the Regulation (EU) No 2024/3190

- **PFAS, Per- and polyfluoroalkyl substances (PFASs) – REGULATION 2025/40**

Per- and polyfluoroalkyl substances (PFASs), as per list included in UE Directive 2020/2184, annex III, Part B, Paragraph 3 are not intentionally used in the process of POLYGLAS D4218/M. Their presence is therefore not expected in this product.

However, we do not systematically perform specific tests to verify the absence of these substances

- **Other chemicals**

None of the following substances is intentionally used in the process of POLYGLAS D4218/M. Their presence is therefore not expected in this product.

However, we do not systematically perform specific tests to verify the absence of these substances:

- 1,4 Dioxane
- Alkylphenol and Alkylphenol ethoxylates (APEO)
- Aromatic amines
- Azo dyestuffs
- Azodicarbonamide or semi-carbazide compounds
- Benzophenone, hydroxybenzophenone and 4-methyl benzophenone
- Brominated flame retardants
- Calcium carbonate
- Carbon black pigment
- Decabromodiphenylether ( decaBDE)
- 2-Ethylhexanoic Acid (2-EHA)
- Di(ethylhexyl) adipate (DEHA) and di(ethylhexyl) maleate (DEHM)
- Dimethyl fumarate (DMF)
- Dioxins and furans
- Epoxy derivatives as defined in the [Regulation 1895/2005/EC](#).

-BADGE (2,2-bis(4-hydroxyphenyl)propane bis (2,3 epoxypropyl)ether),

-BFDGE (bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether),

-NOGE (novolac glycidyl ether),

- Epoxidized Soya Bean Oil
- Ethanol
- Isopropyltioxanthone (ITX)
- Latex
- Melamine
- Natamycine
- Oxygen absorber
- Polyethylene Glycol (PEG)
- Polyglycolique Acid
- Polytrimethylene naphthalate (PTN) (CAS#28779-81-9)
- Polyvinyl chloride (PVC)
- Styrene (N°CAS 100-42-5)
  
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Titanium dioxide
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS: 3380-34-5).
- Tris (nonylphenyl) phosphite (TNPP)
- TXIB (2,2,4-triméthyl-1,3-pentanediol diisobutyrate)

- **Phthalates**

None of the following substances is intentionally used in the process of POLYGLAS D4218/M

- |   |                   |                  |
|---|-------------------|------------------|
| ○ Phtalate BBP (butylbenzyl phthalate)  | N°CAS 85-68-7     |                  |
| ○ Phtalate DBP (di-butyl phtalate)  | N°CAS 84-74-2     |                  |
| ○ Phtalate DEHP (di(2-éthylhexyl) phtalate)                                       | N°CAS 117-81-7    |                  |
| ○ Phtalate DIBP (diisobutyl phthalate)  | N°CAS 84-69-5     |                  |
| ○ Phtalate de di(2-méthoxyethyl) DMEP   | N°CAS 117-82-8    |                  |
| ○ Dibasic lead phthalate  | N°CAS 69011-06-9  |                  |
| ○ N-pentyl-isopentylphthalate nPiPP   | N°CAS 776297-69-9 |                  |
| ○ Diisopentyle phtalate DiPP  | N°CAS 605-50-5    |                  |
| ○ 1,2-benzenedicarboxylic acid dipentylester, branched and linear DPP             |                   | N°CAS 84777-06-0 |
| ○ 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich DIHP       |                   | N°CAS 71888-89-6 |
| ○ 1,2-Benzenedicarboxylic acid, di-C7-11 – branched and linear alkyl esters DHNUP |                   | N°CAS 68515-42-4 |
| ○ Phtalate de Dihexyle DHP, DnHP  | N°CAS 84-75-3     |                  |
| ○ Diisononyl phtalate DINP  | N° CAS 28553-12-0 |                  |
| ○ Diisodecyl phtalate DIDP  | N°CAS 26761-40-0  |                  |
| ○ Di-n-octyl phtalate DNOP  | N°CAS 117-84-0    |                  |
| ○ Diéthyl phtalate DEP  | N° CAS: 84-66-2   |                  |
| ○ Dicyclohexyl phtalate DCHP  | N° CAS: 84-61-7   |                  |

- **Allergens (as defined in the Regulation (EU) No 1169/2011)**

None of the substances or products causing allergy or intolerance, as listed in the Annex II of Regulation No 1169/2011, is intentionally used in the process of POLYGLAS D4218/M.

Their presence is therefore not expected in this product.

However, we do not systematically perform specific tests to verify the absence of these substances.

- **Genetically Modified Organisms (GMO)**

No chemical substance coming from vegetal sources or from genetically modified organisms is intentionally added in the manufacturing process of POLYGLAS D4218/M.

Their presence is therefore not expected in this product.

- **Bovine Spongiform Encephalopathy (BSE), Transmissible Spongiform Encephalopathy (TSE)**

No animal derived substances are intentionally added in the manufacturing process of POLYGLAS D4218/M.

Their presence is therefore not expected in this product.



- **Mineral oil hydrocarbons as defined in the decree of 13 April 2022.**

This product is not intentionally formulated with mineral oil hydrocarbon included MOSH or MOAH (Mineral Oil Aromatic Hydrocarbons – Mineral oil aromatic hydrocarbons)

### **MISCELLANEOUS**

- **Halal Status**

The product above-mentioned is not product under Muslim supervision. This product has not been manufactured or formulated with animal fats or ingredients derived from animal or fermentation products. We permit in case of request a Muslim inspection of the production plant.

This certificate is valid for the original product that we supply to you, but this warranty is no more valid if the composition of the original product has been modified, whatever is the nature of the added substance.

- **Nanomaterials & Nanotechnology**

Having regards to the definition of nanoparticles recommended in October 2011 by the European commission in its recommendation 2011/696/EU, our initial assessment leads us to conclude that POLYGLAS D4218/M is not a nanomaterial.

Indeed, this product is a dispersion of nanoparticles of waxes where more than 50% of the primary particles in the number size distribution have diameter above 100 nanometers.

And regarding Article 3 of the Regulation (EC) No 1907/2006 (REACH), our POLYGLAS D4218/M is not intentionally manufactured to produce nanometric particles.

### **NOTICES**

The original version of the legislations mentioned in this document should be consulted for more information.

The above-mentioned information represents our knowledge at the publication date of this statement. We remind you it is your responsibility to require an updated version of this document.

This document is exclusively established for internal use of our customers or can be made available to competent Authorities on their request. It shall not be distributed or published, whatever the form, without a preliminary written authorization of the supplier.

Our responsibility concerns the above-mentioned product as delivered and cannot be extended:

- To any further modifications in the composition of the original product, concerned by this document, whatever the nature of added substances.
- To any processing that may lead to a change of the nature of the material (if relevant for the product).
- To any checking or reciprocal compatibility of the final material with the intended uses (e.g.: respect of the taste and the odor of the food, respect of the migration limits or other restrictions).

*E. Quarleri*  
*President*