

2022-01-14 No. S/22/0013

DECLARATION OF COMPLIANCE FOR A PLASTIC INTERMEDIATE MATERIAL¹ NEOPET POLYMER – POLYETHYLENE TEREPHTHALATE (PET)

NEO GROUP is a producer of plastic intermediate materials – Polyethylene terephthalate (PET) in granular form. The trade name is NEOPET (grades: AQUA NEOPET 76, NEOPET 78, NEOPET 80, NEOPET 82, NEOPET 84, NEOPET 82 FR and NEOPET 84 FR, NEOPET 82FR PLUS, NEOPET 84FR PLUS and NEOPET 82 HF). Production process in our company complies with Regulation (EC) No 2023/2006² standards on Good Manufacturing Practices for Materials and Articles intended to come into contact with food.

Monomers and Starting Substances

NEO GROUP confirms that NEOPET is manufactured only with monomers and other starting substances and additives that are authorised under the Plastics Regulation³ No 10/2011.

Intentionally Added Substances

NEO GROUP confirms that intentionally added substances in NEOPET, not subject to listing in the Union List comply with the relevant requirements of the Framework Regulation⁴ (EC) No 1935/2004 and that a risk assessment in accordance with Article 19 of the Plastics Regulation No 10/2011 has been performed.

No further risk assessment by any downstream operator is required for substances intentionally added by NEO GROUP.

NEO GROUP reminds processors of NEO GROUP plastics intermediate material that if they add any substances (i.e. colorants, processing aids, and effect additives) they must declare these in their Declaration of Compliance to their customers.

Non-Intentionally Added Substances

- 1) NEO GROUP PET is sold for use as a plastic's intermediate material.
- 2) The Committee of PET Manufacturers in Europe (CPME, <http://www.cpme-pet.org/>), of which NEO GROUP is a member, has commissioned from an independent laboratory extensive analysis of the reaction intermediates, decomposition or reaction products commonly referred to as "Non-Intentionally Added Substances" (NIAS) of all PET manufactured by its members including PET manufactured by NEO GROUP.
- 3) Following the analysis commissioned by CPME, NEO GROUP can confirm that NIAS comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation No 10/2011 has been performed.
- 4) NEO GROUP can confirm that no further NIAS risk assessments on PET sold as a plastics intermediate material will have to be performed by the downstream processor.

¹ Union Guidance on Regulation (EU) No 10/2011 with subsequent amendments on plastic materials and articles intended to come into contact with food as regards information in the supply chain, 28.11.2013 - Section 4.3.1 pp. 20 to 32

² Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food with subsequent amendments

³ REGULATION (EU) No 10/2011 with subsequent amendments on plastic materials and articles intended to come into contact with food

⁴ 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

- 5) Depending on processing conditions for NEOPET you may create more NIAS and therefore you must carry out your own NIAS analysis and then perform a risk assessment as laid down in Article 19 of Plastic Regulation No 10/2011.
- 6) NEO GROUP can confirm that details of the CPME NIAS analysis and risk assessment processes are retained by CPME for inspection by a Competent Authority as Supporting Documentation.
- 7) Information on how to carry out a PET NIAS analysis and risk assessment can be obtained by contacting CPME at info@cpme-pet.org.

Substances that are Subject to Restrictions in National Legislation

NEO GROUP does use colour modification agents and these are listed in the French Positive list (or Council of Europe (COE) Resolution AP (89) 1). This information is retained for inspection by a Competent Authority as Supporting Documentation.

Migration of Substances Subject to Restrictions in National Legislation

NEO GROUP confirms that the substances mentioned in section above (*Substances that are subject to restrictions in national legislation*) do not migrate in detectable concentrations.

Specific Migration Limits

Intentionally added substances used in the manufacture of Polyethylene terephthalate (PET) subject to Specific Migration Limits:

Substances	PM/Ref. No	CAS No	Specific migration limits (SML)
Terephthalic Acid (PTA)	24910	000100-21-0	7.5 mg/kg
Isophthalic Acid (IPA)	19150	000121-91-5	5 mg/kg
Monoethylene Glycol (MEG)	16990	000107-21-1	30 mg/kg of MEG+DEG
Diethylene Glycol (DEG)	15760	000111-46-6	
Antimony Trioxide	35760	0001309-64-4	0.04 mg/kg of Antimony

Metals

NEOPET does not intentionally contain substances listed in point 1 of Annex II of the Regulation No 10/2011.

Primary Aromatic Amines (PAAs)

NEOPET does not release PAAs covered by point 2 of Annex II of the Regulation No 10/2011. In the CPME industry test programme for NIAS no PAAs were found.

Further Compliance Work Required by Customers

There will be a need for further steps of compliance work to be performed by the downstream operator.

PET generates NIAS at all stages when processed from a plastics Intermediate material to a final article. This generation is controlled only by the processor particularly if additives such as colours, antioxidants, processing aids, recycled PET etc. are added. Downstream users are required by legislation to carry out their own risk assessment on any NIAS generated as a result of processing NEOPET from its granular form to an article.

Information on Dual Use Additives

NEO GROUP can confirm that it uses a phosphorus compound in the manufacture of NEOPET. The compound is listed in Table 6 of Section 7 of Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use

in food additives, food enzymes, food flavourings and nutrients and therefore it is a dual use additive⁵.

Column 10 Restrictions

NEOPET FR (fast reheat) grades contain Carbon Black FCM No 411 and this substance complies with the restrictions and specifications laid out in Column 10 of Annex 1 of Commission Regulation (EU) No 10/2011 on Plastics Materials and Articles Intended to come into Contact with Food.

Food Contact Uses

NEO GROUP PET is fully food contact compliant as sold and can be used for many food contact applications, however NEO GROUP is not in a position to make a specific statement about any food contact applications as NEOPET must be further processed in order to make an article.

Carcinogenic, Mutagenic, Reprotoxic (CMR) Substances

NEO GROUP confirms that the non-listed additives and monomers present in NEOPET do not meet the criteria for classification as "mutagenic" (*Category 1A, 1B and 2 mutagen*), "carcinogenic" (*Category 1A, 1B and 2 carcinogen*) or "toxic to reproduction" (*Category 1A, 1B and 2 reproductive toxicant*) in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to the CLP Regulation.⁶

Nanomaterials

NEO GROUP confirms that non-listed additives and monomers present in NEOPET are not in nanoform as defined by the Nanomaterial Recommendation.

Sincerely,

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⁵ Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006