

# Polypropylene H03-N

# SECTION 1. REACH

- With respect to REACH Registration / SVHC / ANNEX XIV / ANNEX XVII the following will be stated by GRUPA AZOTY Polyolefins:
- According to Article 2(9) of the Regulation (EC) 1907/2006 of December 18, 2006 and amendments (hereinafter referred to as REACH regulation), polymers are exempted from the Titles II (Registration of substances) and VI (Evaluation).
- According to the requirements of Article 6(3) of the REACH regulation, any manufacturer or importer of a polymer that comprises more than 2% of (a) chemically bound monomer(s) (b) in a volume exceeding 1000 kg per year must register the monomer(s) used.
  We can inform you that GRUPA AZOTY Polyolefins has successfully registered its monomer(s) used in the our products under REACH.
- Polymers, such as produced by GRUPA AZOTY Polyolefins are mixtures (preparations consisting of the polymer part, residual monomer, additives, etc.). According to the REACH regulation, preparations do not need to be registered separately, provided that the individual parts of the mixture are (pre)-registered.
- For substances used for which GRUPA AZOTY Polyolefins is a Downstream User, and therefore has no obligation to register, GRUPA AZOTY Polyolefins has contacted its suppliers and confirmed that all their registration obligations under REACH have been met. GRUPA AZOTY Polyolefins will not use any product or will do business with a supplier that is not in compliance with the REACH regulation.
- GRUPA AZOTY Polyolefins has registered all substances for which it had a registration obligation, and will continue to ensure regulatory compliance with the REACH regulation.
- It has to be noted that the REACH registration of the substance(s) subject to registration in this GRUPA AZOTY Polyolefins product is restricted to the product as manufactured by GRUPA AZOTY Polyolefins and cannot be used by any other party outside the supply chain.
- We can further inform you that GRUPA AZOTY Polyolefins polymers are not dangerous preparations according to the requirements of the Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures and therefore is not subject to the requirements of Article 31(1) and (2) of the REACH regulation. Based on that, there is no legal obligation to set up a Safety Data Sheet according to the requirements of Article 31 (6) and Annex II of the REACH Regulation. Therefore, the Safety Data Sheet as supplied by GRUPA AZOTY Polyolefins, does not need to contain any mandatory information on the use of the GRUPA AZOTY Polyolefins polymers or other information derived from the REACH notification.

# SECTION 2. Substances of Very High Concern (SVHC)



According to the recipe in the production of GRUPA AZOTY Polyolefins products, following SVHC are not intentionally added:

- Substances of Very High Concern (SVHC), included in the most recent and authentic "Candidate List of Substances of Very High Concern for Authorisation", in a concentration above the threshold limit of 0.1%, as published by the European Chemicals Agency (ECHA) on http://echa.europa.eu/web/guest/candidate-list-table, dated June 14, 2023.
- Substances subject to the provisions of Annex XIV or Annex XVII of EU Regulation (EC) 1907/2006 incl. amendments.
- Substances listed at the UK REACH Candidate List of Substances of Very High Concern (SVHCs) for Authorisation in accordance with Article 59(10) of UK REACH.

## SECTION 3. Food Contact

#### **European Union**

- This GRUPA AZOTY Polyolefins product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).
- This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP) and as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). GRUPA AZOTY Polyolefins operates ISO 9001, ISO 14001 and ISO 45001 certified management systems.
- The monomer and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EU and subsequent amendments.
- EU Regulation 10/2011 specifies 10 mg/dm2 as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011 and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food. The OML and SML tests have not been conducted by GRUPA AZOTY Polyolefins.

#### SML Components:

- Ref. No. 45704 which is regulated with SML = 5 mg/kg
- Ref. No. 89040, with Zinc salts having an SML = 5mg/kg
- This product contains traces of a substance which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Annex II).
  SML = 1 mg/kg (expressed as Aluminium)

#### Dual Use Additives:

• E 470 Salts of fatty acids

#### **United States of America**

- The base resin in this product is listed in the Code of Federal Regulations (CFR), Title 21, paragraph 177.1520 (olefin polymers), issued by the Food and Drug Administration (FDA).
- This product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, these substances used in this product meet the requirements of their respective FDA regulations.



• Extraction tests according to FDA regulations have not been conducted by GRUPA AZOTY Polyolefins.

#### China

• GB4806.1-2016 - Food Contact Material & Articles General Safety Requirements

The migration tests have not been conducted by GRUPA AZOTY Polyolefins.

• GB31603-2015: General Hygiene Standard for Production of Food Contact Materials and Articles

This material has been manufactured outside the People's Republic of China, but in accordance with the relevant requirements of the European Comission Regulation (EC) no. 2023/2006 on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food. These requirements are similar to the reqirements of PRC National Standard GB31603-2015 (Chinese GMP Standard).

• GB4806.6-2016 - National Food Safety Standard: Food Contact Plastic Resins

The base resin in this product is listed in GB4806.6-2016, National Food Safety Standard: Food Contact Plastic Resins, Appendix A.1, Serial Number 74, resin type: PP. No monomer with SMLs is present in this base resin. The migration tests have not been conducted by GRUPA AZOTY Polyolefins.

• GB9685-2016 - National Food Safety Standard: Additives for use in Food Contact Materials and Articles

The additives used in this product are listed in "GB9685-2016 National Food Safety Standard: Additives for use in Food Contact Materials and Articles and relevant approval announcements". This product contains one or more components with SML (Specific Migration Limits).

#### Japan

• Food Contact Positive Lists by Japan's Ministry of Health, Labour and Welfare (MHLW)

The base polymer and monomer of this product are listed in the Positive List of Base Polymers and Monomers.

The additives used in this product are listed in the Positive List of Additives authorized for use in the Base Resin of this product.

#### South America

MERCOSUR

This product contains only monomer listed in Part 1 of the Annex, of MERCOSUR GMC RES. No. 2/12, Positive list of monomers and polymers to be used in packaging in contact with food up to and including MERCOSUR GMC RES. No. 19/21.

This product contains only additives included in Table 1, of the MERCOSUR GMC RES. No. 39/19, Positive list of additives to be used in packaging in contact with food.

This product contains components with SML (Specific Migration Limits).

The migration tests have not been conducted by GRUPA AZOTY Polyolefins. The manufacturers of the final article must verify that the final article does not exceed overall migration limits that apply to the finished food packaging material.



ANVISA

The base polymer of this product is listed in Annex II Positive List of Polymers and Resins for Plastic Packaging and Equipment in Contact with Foodstuff of Resolution RDC No. 56/2012, as amended.

This product contains only additives listed in Resolution RDC No. 326/2019.

This product contains components with SML (Specific Migration Limits).

The migration tests have not been conducted by GRUPA AZOTY Polyolefins

#### SECTION 4. Phthalates

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, phthalates are not intentionally added.

The product is manufactured using a phthalate-free catalyst system

SECTION 5. Endocrine Disruptors

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, any substances considered to be endocrine disruptors are not intentionally added to this product.

#### SECTION 6. CMR Substances

GRUPA AZOTY Polyolefins does not intentionally add substances classified as CMR (all categories) according to the Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures and its amendments.

#### SECTION 7. Cosmetic Regulation

"Substances prohibited in cosmetic products" as listed in Annex II or "Substances which cosmetic products must not contain except subject to the restrictions laid down" as listed in Annex III of Regulation (EC) No 1223/2009 on cosmetic products and its amendments are not intentionally added to GRUPA AZOTY Polyolefins products.

#### SECTION 8. EuPIA Exclusion Policy

Substances (Group A – G) as listed in the EuPIA Exclusion Policy for printing inks and related products, are not intentionally added to GRUPA AZOTY Polyolefins products.

#### SECTION 9. California Proposition 65

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, substances (at levels resulting in exceedance of indicated safe harbor levels) mentioned in the list of chemicals known to cause cancer or reproductive toxicity (Safe Drinking Water and Toxic Enforcement Act of 1986) of the California Proposition 65, updated August 11th, 2023 are not intentionally used or added.

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# SECTION 10. Animal origin (TSE/BSE)

We state that manufacturing this product, we incorporate small amounts of additives derived from fatty acids that can be of animal origin.

The plastic material is exposed to temperatures above 200 °C during the extrusion step in the plastic manufacturing process. Under the described conditions any virus, bacteria or substance causing immunological diseases (TSE; BSE, CJD) is destroyed.

We therefore state that our product is to be considered safe with respect to BSE and TSE transmissions.

## SECTION 11. Halal

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, the following substances as such are not intentionally added to this product:

Alcohol

The absence has not been tested.

This product does not have an official Halal certification.

# SECTION 12. Kosher

This product does not have an official Kosher certification.

# SECTION 13. PPW

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, lead, mercury, cadmium or hexavalent chromium are not intentionally added to this product. Thus, this product complies with the Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (PPW), up to and including Directive 2018/852/EU of 30 May 2018, concerning the defined limits of heavy metals.

# SECTION 14. ELV

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, lead, mercury, cadmium or hexavalent chromium are not intentionally added to this product. Thus, this product complies with Directive 2000/53/EC of 18 September 2000 on end-of life vehicles (ELV), as amended concerning the defined limits of heavy metals.

# SECTION 15. ROHS

Heavy metals and chemical substances restricted by Directive 2011/65/EU (RoHS 2), amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS 3) are not intentionally added to this product. Thus, this product complies with directives mentioned above, concerning the defined limits of heavy metals and restricted chemical substances.

## SECTION 16. WEEE



The GRUPA AZOTY Polyolefins product complies with Directive 2012/19/EU as amended (Waste Electrical & Electronic Equipment - WEEE). None of the substances listed in Annex VII (selective treatment of the waste) are intentionally added or used in this grade.

# SECTION 17. CONEG

According to the recipe in the production of the GRUPA AZOTY Polyolefins polymer, lead, mercury, cadmium or hexavalent chromium are not intentionally added to this product. Thus, this product complies with Model Toxics in Packaging Legislation, concerning the defined limits of heavy metals.

## SECTION 18. Restricted Substances

In the production of the GRUPA AZOTY Polyolefins product, the following restricted substances are not intentionally added:

- Acetone
- Acetyl tributyl citrate (ATBC)
- Acrylamide(s)
- Acrylonitrile
- Active and intelligent materials as defined in Commission Regulation (EC) No 450/2009 of 29 May 2009
- AlkylPhenols (AP) and AlkylPhenol Ethoxylates (APE) (e.g. nonylphenol or nonylphenol ethoxylates)
- Amide solvents such as, but not limited to, N,N-dimethylformamide (DMF), N,N-dimethylacetamide (DMA) and N-methyl-2-pyrrolidone (NMP)
- Amine catalysts, amine reagents, amine solvents
- Anisoles (incl. chloro and bromo anisoles)
- Anthraquinone and its derivatives
- Antimicrobials (antibiotics, disinfectants, antiseptics)
- Antimony trioxide, antimony pentoxide
- (Aromatic) diamines (e.g. benzidine, 4,4'-methylenedianiline (MDA))
- Asbestos
- Azides
- Aziridine(s)
- Azodicarbonamide(s), hydrazine(s)
- Azo-dyes, azo-pigments and azo-colorants
- BADGE, BFDGE or NOGE and derivatives as referred to in Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy Derivatives
- Benzene
- Benzophenone and its derivatives
- Benzo[a]pyrene, benzo[e]pyrene
- Benzotriazole (BTA)
- Biocides (preservatives, insecticides, disinfectants, antiseptics, pesticides, fumigants)
- Bisphenol-A, -AP, -AF, -B, -BP, -C, -C2, -E, -F, -G, -M- S, -P, -PH, -TMC, -Z
- Boric acid; diboron trioxide; tetraboron disodium heptaoxide, hydrate; disodium tetraborate, anhydrous; orthoboric acid sodium salt; disodium tetraborate decahydrate; disodium tetraborate pentahydrate
- Butylated hydroxyanisole (BHA)
- Butylated hydroxytoluene (BHT)
- Carbamates
- Chlorinated paraffins (SCCP, MCCP, LCCP)
- Chlorobenzene
- Chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs)
- Chlorophenols (e.g. pentachlorophenol)
- 2-Chloro-propanol
- 3-Chloro-1,2-propanediol (3-MCPD)



- Cobalt (Co) or mica sourced from conflict-affected and high-risk areas in accordance with the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas.
- Conflict Minerals (cassiterite / tin; columbite-tantalite (coltan) / tantalum; wolframite / tungsten and gold), as referred to in Title XV, Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act
- Cyanides
- Cytotoxins, endotoxins, hormones
- 1,3-Dichloro-2-propanol (1,3-DCP)
- Dimethylfumarate (DMF)
- Dioxins and furans
- 2-Ethylhexylhexanoic acid (2-EH)
- Ethylene oxide
- Engineered nanomaterials
- Epichlorohydrin
- Formaldehyde
- Fragrances, perfumes
- Genetically Modified Organisms (GMO) or substances derived thereof
- Glycolethers
- Glyoxal (ethanedial)
- Ground bamboo, bamboo flour or fibers, corn flour
- Halogenated flame retardants
- Human pathogens
- Human substances and substances of human origin (e.g. blood, DNA, insulin)
- (lso)cyanates
- Latex, natural rubber
- Melamine
- Metals: Arsenic (As), Cadmium (Cd), hexavalent Chromium (Cr6+), Lead (Pb), Mercury (Hg), Gold (Au), Iridium (Ir), Molybdenium (Mo), Nickel (Ni), Osmium (Os), Palladium (Pd), Platinum (Pt), Rhodium (Rh), Ruthenium (Ru), Selenium (Se), Silver (Ag), Thallium (Tl), Tin (Sn), Vanadium (V)
- Methylene chloride
- Methyl Ethyl Ketone (MEK)
- Methyl IsoButyl Ketone (MIBK)
- Microorganisms / Microbes (e.g. bacteria, fungi, yeasts, moulds, archaea, protists, viruses)
- Nitrates, Nitrites, Nitric acid, Nitrous acid, Nitrosating agents, Nitrating agents
- Nitro compounds (aliphatic and aromatic) such as, but not limited to, nitrosamines,
- Nitroso compounds, nitroalkanes, nitroalkenes, nitrocellulose, nitrofurazone and nitrobenzene
- Organotin (organostannic) compounds (mono-, di-, tri-alkyltins and their derivatives, such as, but not limited to MBT, DBT, TBT, TeBT, MOT, DOT, TPhT, TcMT)
- Ozone Depleting Substances (ODS) according to the Montreal protocol or EU Regulation (EU) No 2017/605 amending Regulation (EC) No 1005/2009
- Paint-Wetting Impairment Substances (PWIS)
- Parabens
- Perfluorinated organic compounds (PFC) (Polymeric) Per- and PolyFluorinated Alkyl Substances (PFAS) including, but not limited to:
  - Per- and PolyFluorinated Carboxylic Acids (PFCA) and their derivatives (e.g. Long Chain PerFluorinated Alkyl Carboxylates (LCPFAC) and their salts and precursors, TFA, PFPA, HFBA, PFHxA, PFOA, PFNA and "GenX substances")
  - Per- and PolyFluorinated Sulfonic Acids (PFSA) and their derivatives (e.g. PFBS, PFHxS, PFOS, PFOSA)
  - PerFluoroEther Carboxylic Acids (PFECA) and their derivatives
  - PerFluoroEther Sulfonic Acids (PFESA) and their derivatives
  - PerFluoroAlkyl Phosphonic or Phosphinic Acids (PFPhA, PFPiA) and their derivatives
  - Fluorinated polymers (e.g. PTFE, FEP, PVDF, PVF)
  - PerFluoroPolyEthers (PFPE)
- (very) Persistent, (very) Bioaccumulative and/or Toxic substances (PBT and/or vPvB)
- Persistent Organic Pollutants (POP) according to the Stockholm Convention or Regulation (EU) No 2019/1021, including amendments



- Phenol, resorcinols, cresols, catechols
- Photoinitiators (e.g. isopropylthioxanthone (ITX))
- Plasticizers, softeners (Tris(2-chloroethyl) phosphate (TCEP), trimellitates, adipates, sebacates, maleates, sulfonamides)
- Polybrominated Terphenyls (PBT) / Polychlorinated Biphenyls (PCB)
- Polybrominated Biphenyls (PBB) or Polybrominated Diphenyl Ethers (PBDE)
- Polychlorinated Phenols (PCP) / Polychlorinated Naphthalenes (PCN)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Polyvinylchloride (PVC), Polyvinylidene chloride (PVDC), Chlorinated
- Polyvinylchloride (CPVC) and Polychloroprene (neoprene)
- Primary Aromatic Amines (PAA) and substances that can generate primary aromatic amines
- Pyridine(s)
- Quaternary ammonium compounds
- Radioactive substances
- Rare-earth elements: Cerium (Ce), Dysprosium (Dy), Erbium (Er), Europium (Eu), Gadolinium (Gd), Holmium (Ho), Lanthanum (La), Lutetium (Lu), Neodymium (Nd), Praseodymium (Pr), Promethium (Pm), Samarium (Sm), Scandium (Sc), Terbium (Tb), Thulium (Tm), Ytterbium (Yb), and Yttrium (Y)
- Recycled materials
- Rosin, colophony (a.k.a. colophonium) and substances derived thereof
- Semicarbazide
- Silicones, silicone oils, siloxanes
- Substances (above the mentioned concentration levels) as listed in the Global Automotive Declarable Substance List (GADSL) reference list, version V1.0, February 1st, 2023
- Substances (above limit values applying to Product class I) as listed in Annex 4 of the OEKO-TEX® Standard 100, Edition 02.2023
- "Substances causing allergies or intolerances" as listed in Annex II of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, as amended. These include: Cereals, Crustaceans, Eggs, Fish, Peanuts, Soybeans, Milk, Nuts, Celery, Mustard, Sesame seeds, Sulphur dioxide and sulphites, Lupin and Molluscs
- Substances on the OSPAR List of Chemicals for Priority Action (Revised 2013)
- Substances that could potentially be converted into nitrosamine compounds (nitrosatable substances) in any of the manufacturing steps and applied process conditions.
- Substances classified as Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under Toxic Substances Control Act (TSCA), Section 6(h), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, including those issued by the US EPA:
  - Decabromodiphenyl ether (DecaBDE) CASRN 1163-19-5
  - Phenol, isopropylated phosphate (3:1) [PIP (3:1)] CASRN 68937-41-7
  - Pentachlorothiophenol (PCTP) CASRN 133-49-3
  - Hexachlorobutadiene (HCBD) CASRN 87-68-3
  - 2,4,6-tris(tert-butyl) phenol, (2,4,6-TTBP) CASRN 732-26-3
- Thiurams
- Titanium acetylacetonate (TAA)
- Triaryl phosphites, Triclosan, Triclocarban
- Triethyl amine
- 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate (TXIB)
- Tris(nonylphenyl, branched and linear) phosphite (TNPP)
- Vinyl Chloride Monomer (VCM)
- Volatile Organic Compounds in a concentration exceeding the limit (3%) of the Swiss regulation SR 814.018: "Verordnung über die Lenkungsabgabe auf Flüchtigen Organischen Verbindungen (VOCV)" of November 12th 1997
- Xylene



# SECTION 19. Halogen Content

According to the recipe of GRUPA AZOTY Polyolefins, the following substances are not intentionally added:

• Halogens (Bromine, Fluorine, Iodine, Astatine, except for Chlorine) or halogen compounds.

The GRUPA AZOTY Polyolefins product contains trace amounts of organic or inorganic chlorine compounds, originating from the catalyst system used in the manufacturing process.

#### SECTION 20. General Information

Although several substances are declared as not been intentionally added to the GRUPA AZOTY Polyolefins Product as mentioned in sections 1-19, their absence has not been tested. This does not exclude their presence in traces as they, amongst others, may be contained as impurities in components (additives, process aids, etc.) supplied by external parties and used in the production of such components.

This declaration applies to the GRUPA AZOTY Polyolefins. It does not cover any substance(s) or preparation(s) subsequently added and/or inexpert material processing or article fabrication further down in the supply chain.

Please note carefully that regulations develop continuously and that GRUPA AZOTY Polyolefins declarations may be adapted accordingly. This declaration replaces all previous versions relating to this subject and product, and will be valid for a period of 1 (one) year, after which it will automatically expire.

If you have any further questions, or require any additional information on the above, please contact GRUPA AZOTY Polyolefins



#### DISCLAIMER

Before using any product of Grupa Azoty Polyolefins S.A., its user shall independently and at its own risk assess whether the product is suitable for the intended use and ensure whether the product may be used safely and in accordance with applicable law.

The user of the product shall read the relevant Material Safety Data Sheet before using the product.

Grupa Azoty Polyolefins S.A. gives no warranties regarding the product, except for warranties expressly agreed between Grupa Azoty Polyolefins S.A. and buyer in writing under pain of nullity. Grupa Azoty Polyolefins S.A. in particular does not provide any assurances regarding suitability of the product for a specific application and/or compliance of a specific application with applicable law.

Use of the product for certain applications is prohibited or restricted by Grupa Azoty Polyolefins S.A. In particular use of the product into any medical applications (e.g. as part of a medical device or in connection with medical devices), requires prior written approval from Grupa Azoty Polyolefins S.A.

Information on the abovementioned prohibitions and restrictions can be obtained from representative of Grupa Azoty Polyolefins S.A.

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