

Evonik Operations GmbH
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Product Safety Information

INFINAM® PA 6002 P

1. Conformity with legislation for contact with foodstuffs

1.1. Europe

1.1.1. Regulation (EU) No 10/2011 and Regulation (EC) No 1935/2004

INFINAM® PA 6002 P is listed with respect to its monomer and additives in Regulation (EU) No 10/2011 on plastics materials and articles intended to come into contact with food and its amendments, implementing Regulation (EC) No 1935/2004 for plastics. These monomers / additives may be used in the manufacture of plastic materials and articles intended to come into contact with food in the European Union.

INFINAM® PA 6002 P contains intentionally added dual-use additives.

Colorants are excluded from the Union list of Regulation (EU) No 10/2011. They may be used in the manufacture of plastic layers in plastic materials and articles subject to national law. Colorants used during the manufacturing process of INFINAM® PA 6002 P meet the requirements of Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.

Regulation (EU) No 10/2011 obligates suppliers to disclose monomers / additives with restricted limit values as well as dual-use additives to the supply chain. This requires Evonik to disclose confidential information, which might be harmful to our business and is therefore not in the best interest of our customers. However, we recognize the importance of this regulation and have an alternative procedure to assure the protection and compliance of confidential information. It is important to notice, that restricted limit values are based on releases of components from the finished article, not simply with the components of the raw material INFINAM® PA 6002 P. Upon request, we will submit the identities of monomer / additives of our INFINAM® PA 6002 P to an independent laboratory, where the specific migration of the restricted monomers / additives will be measured and the compliance of the final article with the regulation can be confirmed.

1.1.2. Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

Below listed substances mentioned in Commission Regulation (EC) No 1895/2005 are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

Substance	CAS-No.
2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE)	1675-54-3
Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE)	39817-09-9
Novolac glycidyl ethers (NOGE)	-

INFINAM® PA 6002 P is made of raw materials of technical purity. The occurrence of above listed substances can be excluded, except negligible amounts on the level of natural/ technical impurities. Please notice that INFINAM® PA 6002 P is not routinely analysed for those substances listed above.

1.1.3. Regulation (EU) No 1169/2011 on the provision of food information to consumers

Allergens as mentioned in Annex II – Substances or Products Causing Allergies or Intolerances of Regulation (EU) No 1169/2011 and its amendments are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

INFINAM® PA 6002 P is made of raw materials of technical purity. The occurrence of allergens listed in Annex II of Regulation (EU) No 1169/2011 and its amendments can be excluded, except negligible amounts on the level of natural/ technical impurities. Please notice that INFINAM® PA 6002 P is not routinely analysed for those allergens listed in Annex II of Regulation (EU) No 1169/2011 and its amendments.

1.2. The USA

1.2.1. Food and Drug Administration (FDA), Code of Federal Regulation (CFR), 21

INFINAM® PA 6002 P complies with respect to its polymeric composition and additives with the following sections of food contact regulations in the USA (Food and Drug Administration (FDA), Code of Federal Regulation (CFR), 21):

- FDA, 21 CFR, §175.300 (b)(3)(xxxii) (Resinous and polymeric coatings);
- FDA, 21 CFR, §177.1500 (a)(9) (Nylon resins) **only for non-alcoholic foods with restrictions** as mentioned in §177.1500 (b)(9)(a) and (b).

There are restrictions in each of the regulations that must be taken into account by INFINAM® PA 6002 P users. Users must review all applicable regulations and restrictions to assure compliance.

2. Biocompatibility

The following biocompatibility tests were performed on parts laser sintered from INFINAM® PA 6002 P.

2.1. ISO 10993

2.1.1. In Vitro Cytotoxicity Test (ISO 10993-5)

INFINAM® PA 6002 P meets the requirements of the test and is considered to have no cytotoxic potential.

2.1.2. Irritation and Skin Sensitization Tests (ISO 10993-10)

The sites injected with the extracts of INFINAM® PA 6002 P did not show a significantly greater biological reaction than the sites injected with the control article. INFINAM® PA 6002 P meets the requirements of ISO 10993-10 guidelines for the Intracutaneous Reactivity Test.

The extracts of INFINAM® PA 6002 P elicited no reaction at the challenge (0% sensitization), following the indication phase (according to Kligman Maximization Test). INFINAM® PA 6002 P is classified as a non-sensitizer.

2.1.3. Systemic Injection Tests (ISO 10993-11)

The animals treated with extracts of INFINAM® PA 6002 P did not induce a significantly greater biological reaction than the control extracts.

INFINAM® PA 6002 P meets the requirements of ISO 10993-11 guidelines for the Systemic Injection Test.

2.2. USP Class VI

The following biocompatibility tests in accordance with USP Class VI were performed with INFINAM® PA 6002 P:

- Systemic injection test in mice
- Intracutaneous test in rabbits
- Implantation test in the rabbit

None of the above-mentioned tests with INFINAM® PA 6002 P produced a biological response. INFINAM® PA 6002 P meets the requirements of USP Class VI Plastic.

3. Additional Regulations

3.1. General

INFINAM® PA 6002 P is made of raw materials of technical purity. The occurrence of substances that are not intentionally used in the manufacturing process (see subsections 3.2 – 3.11 of current document) can be excluded, except negligible

amounts on the level of natural/ technical impurities. Please notice that INFINAM® PA 6002 P is not routinely analysed for those substances.

3.2. Directive 94/62/EC on packaging and packaging waste

Substances mentioned in Directive 94/62/EC and its amendments (lead, mercury, cadmium and their compounds, and chromium (VI) compounds) are not intentionally used in our recipes to produce INFINAM® PA 6002 P.

3.3. Directive 2011/65/EU on the restriction of certain hazardous substances in electrical and electronic equipment (RoHS)

Below listed substances and heavy metals listed in Directive 2011/65/EU and its amendments are not intentionally used in our recipes during the manufacturing process of INFINAM® PA 6002 P.

Substance	Maximum concentration values tolerated by weight in homogeneous material
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %
Bis(2-ethylhexyl) phthalate (DEHP)	0,1 %
Butyl benzyl phthalate (BBP)	0,1 %
Dibutyl phthalate (DBP)	0,1 %
Diisobutyl phthalate (DIBP)	0,1 %

3.4. Coalition of Northeastern Governors (CONEG)

Heavy metals mentioned in CONEG-Regulation (lead and compounds, mercury and compounds, cadmium and compounds, chromium (VI) and compounds) are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.5. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Below listed substances mentioned in Annex XVII – Restrictions of the REACH Regulation are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

- Asbestos fibers (Pos. 6);
- Arylamines (Pos. 12, 13, 15);
- Organostannic Compounds (Pos. 20);
- Chlorinated Phenols (Pos. 22);
- Azocolorants /dyestuffs (Pos. 43);
- Nonylphenol and Nonylphenol ethoxylates (Pos. 46);
- Chlorinated Benzenes (Pos. 49, 64);
- Polycyclic aromatic hydrocarbons (PAHs) (Pos. 50);
- Phthalates (Pos. 51, 52);
- Dimethylfumarate (DMF) CAS-No. 624-49-7 (Pos. 61);
- Bisphenol A (Pos. 66);
- Perfluorooctanoic acid (PFOA) and its salts (Pos. 68).

Additionally, please refer to the Section 15 of the EU Safety Data Sheet.

3.6. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Biocidal products authorised according to Regulation (EU) No 528/2012 and its amendments are not intentionally used to produce INFINAM® PA 6002 P.

3.7. Regulation (EC) No 1005/2009 on substances that deplete the ozone layer and the Clean Air Act

Ozone depleting substances mentioned in Regulation (EC) No 1005/2009 as well as substances listed as Class I and Class II in section 602 of the Clean Air Act (adoption of “The Montreal Protocol on Substances that Deplete the Ozone Layer” into legislation) are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.8. Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products

INFINAM® PA 6002 P does not contain intentionally added volatile organic compounds (VOC) as defined by Directive 2004/42/EC. Additionally, please refer to the SDS and Technical Data Sheet.

3.9. Regulation (EU) No 2019/1021 on persistent organic pollutants

Substances as listed in Annex I and/or III of the Regulation (EU) No 2019/1021 and its amendments are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.10. California Proposition 65

Please refer to the US Safety Data Sheet, Section 15 Regulatory Information, State Regulations.

3.11. Certain restricted substances

3.11.1. Substances of Genetically Modified Organisms (GMO) Origin

Substances of GMO (Genetically Modified Organisms) origin are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.2. BSE / TSE risk

Substances of animal origin are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.3. Halal/Kosher Certification

Up to now INFINAM® PA 6002 P is neither Kosher, nor Halal certified.

3.11.4. Formaldehyde

Formaldehyde (CAS-No. 50-00-0) is not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.5. Elemental Chlorine

Elemental chlorine is not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.6. Natural Rubber Latex

Natural rubber latex (as defined in FDA, 21 CFR, §801.437(b)) is not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.7. Silicones

Silicones are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

3.11.8. Perfluorinated compounds

Perfluorinated compounds are not intentionally used during the manufacturing process of INFINAM® PA 6002 P.

4. Inventory Information

4.1. REACH

INFINAM® PA 6002 P purchased from Evonik Operations GmbH is in compliance with REACH in case this product is manufactured within the EU or imported into the EU by Evonik Operations GmbH. If so, all REACH relevant monomers and substances contained in this product are either registered by their suppliers or by Evonik Operations GmbH and its affiliates, or are exempt from REACH Registration. Please be aware that various exemptions are defined in REACH which may apply to our products (exempt are for example natural materials, polymers, chemicals produced or imported at less than 1 t/y). As a result, no registration number may be listed in the EU Safety Data Sheet even for REACH compliant products.

Please note that in case you are the EU importer of this product you may be obliged to register the product or its ingredients. In this case please contact us for clarification.

4.2. Substances of Very High Concern (SVHC)

Please refer to section 3 of the current EU Safety Data Sheet where Evonik Operations GmbH lists Substances of Very High Concern (SVHC) and other hazardous ingredients in its products.

The European Chemicals Agency (ECHA) publishes and regularly updates a list of SVHC ("Candidate List"). REACH obliges producers and importers to inform their customers if their products contain more than 0,1% of a substance on the Candidate List.

Evonik Operations GmbH continuously monitors the Candidate List and updates the EU Safety Data Sheets of affected products to include new SVHC. To fulfil REACH communication requirements, Evonik Operations GmbH provides updated EU Safety Data Sheets to all recorded customers who purchased affected products within the 12 months preceding the update of the EU Safety Data Sheet.

Evonik Operations GmbH encourages downstream users to ensure compliance with the requirements for communication and notification of the REACH legislation.

4.3. International Inventories

Please refer to the Safety Data Sheet, Section 15: Regulatory Information, Status of Registration.

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Information mentioned in this document is based on the current legislation and is updated periodically to include new amendments. In the case of uncertainty we recommend to consult our technical service.
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Finished food contact materials or articles containing this product as a component, need to comply inter alia with Overall Migration Limit (OML) requirements – as specified in above mention standards such as Regulation (EU) No 10/2011, Chinese Regulations GB 9685-2016, GB 4806.6-2016, GB 4806.10-2016,

Swiss Ordinance SR 817.023.21. Verification of compliance with migration limits (OML and SML) should be carried out in accordance with the rules laid down there. We would like to point out that it is in the sole responsibility of the manufacturer of the final material or article to assure the compliance with the OML requirements under actual and foreseeable conditions of use, and to check it on a regular basis. The manufacturer of food contact materials or articles, containing this product as a component, must in particular ascertain that these finished materials or articles meet the general regulatory requirement that they do not endanger human health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

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