DECLARATION DATA SHEET

POLYETHYLENE BRALEN FB 08-64

TIPELIN / TIPOLEN / TIPPLEN / TATREN / BRALEN
The joint product portfolio of TVK and SLOVNAFT provide infinite opportunities

FOOD CONTACT APPLICATION

The composition of this product as supplied from our factory complies with the requirements for use in contact with food of:

Commission 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,
Commission Regulation (EU) No. 10/2011 (of 14 January 2011) on plastic materials and articles intended to come into contact with food and its ammendments:
Commission Regulation (EU) No. 1282/2011 (of 28 November 2011), No. 1183/2012 (of 30 November 2012), No. 202/2014 (of 3 March 2014) on plastic materials and articles intended to come into contact with food
(Applies to all EU-Member States)

Based on migration experiments with test samples made of this polymer and carried out in the presence of the standard food simulants A (distilled water), B (3% acetic acid), C (10% ethanol) and D (olive oil) at 40°C during 10 days, it is our experience that under these conditions overall migration limits are not exceed 10 mg/dm^2.

During the production of this product we do not intentionally add primary aromatic amines (PAA) and chemical substances based on Ba, Co, Cu, Fe, Li, Mn and Zn, therefore there are not expected to be present in this product.
Based on migration experiments with test samples made of this polymer we confirm that specific migration limits of above mentioned substances (in 3% acetic acid ,10 and 95% ethanol) and PAA (3% acetic acid, 40°C, 10days) meet requirements given by EU-Directive 10/2011/EC.

We draw your attention to the fact that the EU-Directive 10/2011/EC, which applies to all EU-Member States, includes a limit of 10 mg/dm^2 on the overall migration from finished plastic articles into food. In accordance with EU-Directive 10/2011/EC the migration should be measured on finished articles placed into contact with the foodstuff or appropriate food simulants for a period and at the temperature which are chosen by reference to the contact conditions in actual use according to the rules laid down in EU-Directives 97/48/EC (amending 82/711/EEC) and 85/572/EEC.

There are no SMLs specified by the regulations for the components (monomers/additives) of this resin.

EU-Directive 10/2011/EC does not specify residual quantity **(QM)** limitations on the individual components of this resin.

Dual Use Additives: Dual use additives are not used for production of this product. The information provided concerning additives which are also food additives and flavouring is based on our current knowledge.

Please note it is responsibility of both the manufacturers of finishing contact articles as well as the industrial food packers to make sure that these articles in their actual use are in compliance with requirements given by above mentioned regulations.

REGULATION (EC) NO 2023/2006 (OF 22 DECEMBER 2006) ON GOOD MANUFACTURING PRACTICE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

Above mentioned polymer meets the requirements of Regulations (EC) No 1935/2004 and 2023/2006 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

We declare that production of this product runs under established, implemented and observed effective and documented quality assurance system certified by ISO 9001, ISO 14001 and OHSAS 18001.

We fulfill the general rules on GMP as laid down in the Articles 5, 6 and 7 of above mentioned commission regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

US FOOD AND DRUG ADMINISTRATION (FDA)

This product meets requirements given by FDA (Food and Drug Administration) Title 21 CFR (Code of Federal Regulations) § 177.1520: Indirect food additives: Polymers: Olefin polymers; (c) Specifications: 2.1 Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking and 2.2 Polyethylene for use in articles used for packing or holding food during cooking.

BfR (BUNDESINSTITUT FÜR RISIKOBEWERTUNG), III. POLYETHYLENE

This product meets requirements given by BfR (Bundesinstitut für Risikobewertung), III. Polyethylene Recommendation for the materials intended to come into contact with food.

RESIDUAL PEROXIDES

Content of residual peroxides for this polymer was below detection limit (limit 6,4 mg/kg according to BfR (Bundesinstitut für Risikobewertung), III. Polyethylene.

EUROPEAN PHARMACOPOEIA (EP), 8th EDITION

This product complies (according to the laboratory test results) to EP requirements for European Pharmacopoeia, 8th Edition, Chapter 3.1.4. Polyethylene without additives for containers for preparations for parenteral use and for ophthalmic preparations.

REGULATION (EC) NO 1272/2008 (OF 16 DECEMBER 2008) ON CLASSIFICATION, LABELING AND PACKAGING OF SUBSTANCES AND MIXTURES, AMENDING AND REPEALING DIRECTIVES 67/548/EEC AND 1999/45/EC, AND AMENDING REGULATION (EC) NO 1907/2006 CLP – CLASSIFICATION, LABELLING AND PACKAGING REGULATION

This product is not classified as dangerous substance according to the Directive CLP 1272/2008/EC and Legal Act of the National Council of SR No. 67/2010 Coll. of Law.

DECLARATION OF CODE OF FEDERAL REGULATIONS TITLE 16 CHAPTER II. CONSUMER PRODUCT SAFETY COMMISSION PART 1500 (HAZARDOUS SUBSTANCES AND ARTICLES)

This product is not classified as hazardous substance (see § 1500.3 Definitions). Waste of this product is not hazardous and can be re-processed by recycling and reused as raw material.

DIRECTIVE 94/62/EC (OF 20 DECEMBER 1994) ON PACKAGING AND PACKAGING WASTE AND ITS AMENDMENT 2005/20/EC AND 2013/2/EU

Heavy metals like cadmium, lead, mercury, hexavalent chromium (Cr^{VI}) and their compounds are not used in manufacturing and therefore are not expected to be present in this polymer.
Therefore it can be declared that this product, as well as the product packaging material, is in compliance with the concentration levels of heavy metals specified in Article 11, item 1 of EU-Directive 94/62/EC. This product meets requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury. In addition, this product has the potential to be recycled according to these requirements.

REGULATION (EC) NO 850/2004 (OF 29 APRIL 2004) ON PERSISTENT ORGANIC POLLUTANTS AND AMENDING DIRECTIVE 79/117/EEC

We declare that during production of this product, we do not intentionally add into this product, any of the chemicals as restricted by ANNEX I – IV. of this regulation. According to this fact it is not reasonable to expect any of such substances to be present in this product. However, this product has not been tested for presence of these chemical substances.

DIRECTIVE 2011/65/EC (OF 8 JUNE 2011) ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS)

Heavy metals like cadmium, lead, mercury, hexavalent chromium (Cr^{VI}) and their compounds, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) restricted by this regulation are not intentionally add during the production of this product. However this product has never been tested for presence of mentioned substances.

DIRECTIVE 2000/53/EC (OF 18 SEPTEMBER 2000) ON END-OF-LIFE VEHICLES (ELV)

Heavy metals like cadmium, lead, mercury, hexavalent chromium (Cr^{VI}) and their compounds restricted by this regulation are not incorporated into this polymer intentionally during production. However, this product has not been tested for presence of these chemical substances.

REGULATION (EC) NO 1895/2005 (OF 18 NOVEMBER 2005) ON THE RESTRICTION OF USE OF CERTAIN EPOXY DERIVATIVES IN MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

BADGE, BFDGE and NOGE are not used in manufacturing of this product therefore it is not reasonable to expect any of such substances to be present in this product. However, this product has not been tested for presence of these chemical substances:

- 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, referred to as 'BADGE'
  (CAS No: 001675-54-3)
- bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, referred to as 'BFDGE'
  (CAS No: 039817-09-9)
- other novolac glycidyl ethers, referred to as 'NOGE'

DIRECTIVE 2009/48/EC (OF 18 JUNE 2009) ON THE SAFETY OF TOYS

We certify that during manufacturing of this product, we do not intentionally add into this product, any of the chemicals as restricted by 2009/48/EC ANNEX II. Part III.Chemical properties, Tables No.11 and No.13. According to this fact it is not reasonable to expect any of such substances to be present in this product. However, this product has not been tested for presence of these chemical substances.

TALLOW AND ITS DERIVATES (BSE/TSE)

The concerns relative to BSE/TSE in the context of plastics materials used in contact with food are linked to the use of additives of animal origin: tallow derivatives. During the production of above mentioned polymer we do not use tallow derived additives. Above mentioned polymer is not TSE/BSE dangerous product.

NANOTECHNOLOGY

We certify that during manufacturing of this product, we do not use Nanotechnology or any nanomaterials according to COMISSION RECOMMENDATION 2011/696/EU (of 18 October 2011) ON THE DEFINITION OF NANOMATERIAL.

DECLARATION OF OTHER CHEMICAL ELEMENTS

As a producer of this product we confirm that during production of this product we do not use below mentioned elements and their derivatives therefore are not expected to be present in this product. However, this product has not been tested for presence of these chemical elements.

- Antimony (Sb)
- Arsenic (As)
- Gold (Au)
- Halogens (fluorine, chlorine, bromine, iodine)
- Nickel (Ni)
- Phosphorus (yellow and red)
- Selenium (Se)
- Sulphur (S)
- Tantalum (Ta)
- Tin (Sn)
- Titanium (Ti)
- Tungsten (W)
- Uranium (U)

DECLARATION OF OTHER SUBSTANCES

We confirm that during manufacturing of this product, we do not intentionally add into product any of the chemicals listed below and therefore are not expected to be present in this product. However, this product has not been tested for presence of below mentioned substances.

- Acetyl Acetone (ACAC) [CAS No: 123-54-6]
- Acrylamide [CAS No : 79-06-1]
- Aromatic Amines (restricted by Directive 2002/61/EC)
- 4-Aminobiphenyl [CAS No. 92-67-1] and its salts
- Amonium Nitrate [CAS No: 6484-52-2]
- Asbestos [Chryolite CAS No: 12001-29-5, Amosite CAS No: 12172-73-5, Anthophyllite CAS No: 77536-67-5, Actinolite CAS No: 77536-66-4, Tremolite CAS No: 77536-68-6]
- Alkyl phenol Ethoxylates (APE)
- Azocolorants (restricted by Directive 2002/61/EC)
- Azodicarbonamide [CAS No: 123 -77-3]
- Bisphenol A (BPA) [CAS No: 80-05-7], S [CAS No: 80-09-1] and Bisphenol F (BPF) [CAS No: 620-92-8]
- Benzene [CAS No: 71-43-2]
- Benzidine [CAS No: 92-87-15] and its salts
- Benzoic Acid [CAS No: 65-85-0]
- Benzotriazole [CAS No.: 95-14-7]
- Benzophenone [CAS No: 119-61-9]

- Beryllium compounds (including: beryllium-oxide) and beryllium alloy
- Biocides
- Bis(chloromethyl)ether (BCME) [CAS No: 542-88-1]
- Bis(2-butoxyethyl) adipate [CAS No: 141-18-4]
- Blue colorants
- Butylated Hydroxytoluene (BHT) [CAS No: 128-37-0]
- Butylated Hydroxyanisole (BHA) [CAS No: 25013-16-5]
- Cellulose Acetate [CAS No: 9004-35-7]
- Cobalt-dicloride [CAS No: 7646-79-9]
- Dichlorodiphenyltrichloroethane [CAS No: 50-29-3]
- Dimethylacetamide [CAS No: 127-19-5]
- Dimethylfumarate [CAS No: 624-49-7]
- Dimethylformamide (DMF) [CAS No: 68-12-2]
- Dioxin [CAS No: 290-67-5] and its derivatives
- Epichlorohydrin [CAS No: 106-89-8]
- Epoxidised Soy-Bean Oil (ESBO)
- Ethylenediaminetetraacetic acid (EDTA) [CAS No: 60-00-4]
- Ethyl-acetone (methyl-propyl-ketone) [CAS No: 107-87-9]
- Ethylene glycol dimethylacrylate (EGDMA) [CAS No:97-90-5]
- Fluoroelastomers
- Furfural [CAS No: 98-01-1]
- Glycerol[CAS No: 56-81-5]
- Glycols ethylene [CAS No: 107-21-1] and propylene [CAS No: 57-55-6]
- Herbicides
- Hexachlorobenzene (HCB) [CAS No: 118-74-1]
- Halogenated HydroCarbons
- Flame retardants
- Formaldehyde [CAS No: 50-00-0]
- Furan [CAS No: 110-00-09] and its derivatives
- Insecticides
- Isopropyl thioxanthone (ITX) [CAS No: 83846-86-0, 5495-84-1 and 75081-21-9]
- Latex
- Lithium Hydroxide (LiOH) [CAS No: 1310-65-2]
- N-Methylpyrrolidone (NMP) [CAS No: 872-50-4]
- Nanomaterials (including Nanoclay, Nanosilver)

- Nitrite derivatives
- 4-Nitro-BiPhenyl [CAS No: 92-93-3]
- Melamine [CAS No: 108-78-1]
- Methylene-Diphenyl-Diisocyanate (MDI) [CAS No: 101-68-8]
- 4-Methylbenzophenone [CAS No: 134-84-9]
- 2-Naphthylamine [CAS No. 91-59-8] and its salts
- NETSA (N-Ethyl-o-toluenesulfonamide [CAS No: 1077-66-1]
- N-Ethyl-p-toluenesulfonamide [CAS No: 80-39-7]
- Nonylphenolethoxylate
- Octylphenols [CAS No.: 27193-28-8] and Nonylphenol [CAS No: 25154-52-3]
- o-Phenylphenol (OPP) [CAS No: 90-43-7]
- Oleamide [CAS No: 301-02-0]
- Oxalic Acid [CAS No: 144-62-7] and its derivatives
- Palm oil, Coconut Oil and Palm Kernel Oil
- Parabenes (Esters of Para-hydroxybenzoic-acid)
- Phthalates : DEHP, DBP, BBP, DINP, DIDP, DEP, DCHP, DMEP, DMCHP, Di-benzyl phthalate
- PentaBDE (pentabromodiphenyl ether) and octaBDE(octabromodiphenyl ether)
- Perfluorooctannoic acid (PFOA) [CAS No: 68141-02-6] and Perfluorooctanesulfonic acid (PFOS) [CAS No: 1763-23-1]
- Pesticides
- Polychlorinated Biphenyls (PCBs)
- Polybrominated Biphenyls (PBBs)
- Polychlorinated Terphenyls (PCTs)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polytetrafluorethylene (PTFE, TEFLON) [CAS No: 9002-84-0]
- Proteins
- PVC [CAS No : 9002-86-2] and PVDC [CAS No: 9002-85-1]
- Rosin from wood [CAS No: 8050-09-7]
- Rubber (Synthetic and Natural)
- Silicone [CAS No: 90337-93-2] and silica gel [CAS No: 99439-28-2]
- Softeners
- Styrene [CAS No: 100-42-5]
- Vinyl Chloride [CAS No: 75-01-4]

- **Tetraethyleneglycol dimethacrylate (TEGDMA) [CAS No:109-16-0]**
- **TBT (tributyl-tin), DBT (dibutyl-tin) and MBT (monobutyl-tin) and dioctyl-tin compounds (DOT) and other organo-tin compounds**
- **Titanium acetyl acetonate (TAA) [CAS No: 17501-79-0]**
- **Triclosan [CAS No: 3380-34-5]**
- **Trichlorbenzene [CAS No: 12002-48-1]**
- **tris(2-butoxyethyl) phosphate (TBEP) [CAS No: 78-51-3]**
- **tris(2-nonylphenyl) phosphite [CAS No: 26523-78-4]**
- **Toluene [CAS No: 108-88-3]**

DISCLAIMER

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It is the responsibility of those to whom we supply this product to inspect and test our products in order to satisfy itself as to the suitability of this product for particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of this product.

This product is under continuous development, therefore we reserve the right to change the information presented in this publication at our own discretion. It is the responsibility of those to whom we supply this product to check and to download the newest Declaration Data Sheet on www.slovnaft.sk website.

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