



## DECLARATION DATA SHEET

### Polyethylene BRALEN VA 20-60

#### 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 (14<sup>th</sup> of January 2011) 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, B, C at 40°C during 10 days, it is our experience that under these conditions overall migration limits do not exceed 10 mg/dm<sup>2</sup>.

The migration into food simulant D at migration conditions (40°C for 10 days, 100 cm<sup>2</sup>/100 ml of food simulant) exceeds 10 mg/dm<sup>2</sup>. The usage of this product at other conditions (shorter contact period, lower temperature, more favourable migration ratio) or contact with foodstuffs having the migration test results divided by the correction factor before comparing with the migration limits is possible. The migration shall be verified at a final product according to the real conditions of use.

As a producer of this product we confirm that during production of this product we do not intentionally add primary aromatic amines and chemical substances based on Ba, Co, Cu, Li, Mn and Zn, therefore there are not expected to be present in this product. However, this product has not been tested for presence of these chemical elements.

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<sup>2</sup> 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.

During production of above mentioned product we do not use any SML specified monomers and SML specified additives according to EU-Directive 10/2011/EC.

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

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

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 the imposed overall migration requirements.

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### **Regulation (EC) No 2023/2006 (22<sup>nd</sup> of 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 so that, under normal or foreseeable conditions of use, its constituents can not transfer to food in quantities which could endanger human health or bring about an unacceptable change in the composition of the food or bring about deterioration in the organoleptic characteristics. 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 corresponds FDA (Food and Drug Administration of the USA) – Code of Federal Regulations – Title 21 § 177.1520: Indirect food additives: Polymers (c) Specifications: 2.1 Polyethylene.

### **European Pharmacopoeia (EP), 7<sup>th</sup> Edition**

This product complies (according to the laboratory test results) to EP requirements for European Pharmacopoeia, 7<sup>th</sup> Edition, Chapter 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations.

### **Directive 67/548/EEC (27<sup>th</sup> of June 1967) with pertaining 29 amendments and Directive 1999/45/EC (31<sup>st</sup> of May 1999) relating to the classification, packaging and labelling of dangerous substances**

#### **CLP – CLASSIFICATION, LABELLING AND PACKAGING REGULATION 1272/2008/EC**

This product is not classified as dangerous substance according to the Directive 67/548/EEC, 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) and does not contain any hazardous substances which are mentioned in CFR 16 Part 1500. Waste of this product is not hazardous and can be re-processed by recycling and reused as raw material.

### **Directive 94/62/EC (20<sup>th</sup> of December 1994) on packaging and packaging waste and its amendment 2004/12/EC**

Heavy metals (like cadmium, lead, mercury, hexavalent chromium (Cr(VI))) and their compounds are not used in manufacturing of, and therefore are not expected to be present in the above mentioned polymer. Therefore it can be declared that this product, as well as the product

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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 the year 2001 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.

### **Directive 76/769/EEC (27 July 1976) relating to restrictions on the marketing and use of certain dangerous substances and preparations and its amendments**

Polychlorinated biphenyls (PCB) and Polychlorinated ter-phenyls (PCT) are not used in our production technologies and they are not intentionally incorporated into this polymer mentioned by EU-Directive 76/769/EEC. However, this product has not been tested for these chemical substances.

Note: Directive 76/769/EEC is superseded by Annex XVII of the REACH Regulation 1907/2006/EC - restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles

### **Regulation (EC) No 2037/2000 (29<sup>th</sup> of June 2000) on substances that deplete the ozone layer (Ozone Depleting Chemicals such as CFC's, HCFC's, Halons, CCl<sub>4</sub>, Trichloroethane, HBFC's)**

Class I and Class II ODCs (according to Montreal Protocol) are not used in manufacturing of this product.

This product does not contain fully halogenated chlorofluorocarbons (CFC's) including Trichlorofluoromethane (CFC-11), Dichlorodifluoromethane (CFC-12), Trichlorotrifluoroethane (CFC-113), Dichlorotetrafluoroethane (CFC-114), Chloropentafluoroethane (CFC-115).

This product does not contain Tetrachloromethane and Trichloroethane.

This product does not contain fully halogenated bromofluorocarbons, bromochlorocarbons and bromochlorofluorocarbons including Bromochlorodifluoromethane (halon-1211), Bromofluoromethane (halon-1301), Dibromotetrafluoroethane (halon-2402).

This product does not contain hydrobromofluorocarbons (HBFC's) and hydrochlorofluorocarbons (HCFC's) including Chlorodifluoromethane (HCFC-22), Dichlorotrifluoroethane (HCFC-123), Dichlorofluoroethane (HCFC-141), Chlorodifluoroethane (HCFC-142).

This product does not contain Bromomethane.

We certify, that during manufacturing of this product, we do not intentionally incorporate into this product, any of the chemicals as restricted by 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 these chemical substances.

### **Regulation (EC) No 850/2004 (29<sup>th</sup> of April 2004) on persistent organic pollutants and amending Directive 79/117/EEC**

We certify, that during manufacturing of this product, we do not intentionally incorporate 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 these chemical substances.

### **Directive 2005/84/EC relating to restrictions on the marketing and use of phthalates in toys and childcare articles**

Phthalates such as **DEHP, DBP, BBP, DINP, DIDP, DNOP** are not used in manufacturing of, and therefore are not expected to be present in this polymer. This polymer corresponds with Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005.

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Other Phthalates listed below are not in used in manufacturing of and therefore are not expected to be present in this polymer. However, this product has not been tested for these chemical substances.

- Di-benzyl phthalate
- Di-methyl phthalate
- Di-ethyl phthalate (DEP)
- Di-cyclo-hexyl phthalate (DCHP)
- Di-methoxyl-ethyl phthalate (DMEP)
- Di-methyl-cyclo-hexyl phthalate (DMCHP)
- Other phthalates

**Directive 2002/95/EC (27<sup>th</sup> of January 2003) 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 and polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) restricted by this regulation are not incorporated into this polymer intentionally during production.

**Directive 2000/53/EC (18<sup>th</sup> of 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.

**Regulation (EC) No 1895/2005 (18<sup>th</sup> of 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 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 2003/11/EC (6<sup>th</sup> of February 2003) on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether)**

Dangerous substances pentaBDE (pentabromodiphenyl ether) and octaBDE (octabromodiphenyl ether) 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 these chemical substances.

**Directive 2009/48/EC (18 June 2009) on the safety of TOYS and EN 71-3 and EN 71-9**

We certify, that during manufacturing of this product, we do not intentionally incorporate into this product, any of the chemicals as restricted by 2009/48/EC ANNEX II. Part III. Chemical properties Tables 11 and 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 these chemical substances.

This product complies with the requirements in CEN Standard EN 71-3. Moreover EN 71- Part 9 (2005) "Organic chemical compounds - Requirements" (none of the substances listed in Tables 2 A-I are intentionally added, according to this fact it is not reasonable to expect any of such

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substances to be present in this product. However, this product has not been tested for these chemical substances.)

### Tallow and its derivatives (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.

### 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 these.

- **Antimony (Sb)**
- **Arsenic (As)**
- **Halogens (fluorine, bromine, iodine, chlorine)**
- **Phosphorus (yellow and red)**
- **Selenium (Se)**
- **Sulphur (S)**
- **Uranium (U)**

### Declaration of other substances

We certify that during manufacturing of this product, we do not intentionally incorporate into this product any of the chemicals are listed below and therefore are not expected to be present in this product. However, this product has not been tested for these chemical 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)**
- **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**

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- 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]
- 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
- Epichlorhydrin [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]
- Glycols ethylene [CAS No: 107-21-1] and propylene [CAS No: 57-55-6]
- 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
- Isopropyl thioxanthone (ITX) [CAS No: 83846-86-0]
- Latex and Natural rubbers
- 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]
- 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]
- Octylphenols [CAS NO.: 27193-28-8] and Nonylphenol [CAS No: 25154-52-3]
- o-Phenylphenol (OPP) [CAS No: 90-43-7]
- Oxalic Acid [CAS No: 144-62-7] and its derivatives
- Palm oil, Coconut Oil and Palm Kerner Oil
- Parabenes (Esters of Para-hydroxybenzoic-acid)
- Polychlorinated Biphenyls (PCBs)
- Polybrominated Biphenyls (PBBs)

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- Polychlorinated Terphenyls (PCTs)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polytetrafluoroethylene (PTFE, TEFLON) [CAS No: 9002-84-0]
- Perfluorooctanoic acid (PFOA) [CAS No: 68141-02-6] and Perfluorooctanesulfonic acid (PFOS) [CAS No: 1763-23-1]
- PVC [CAS No : 9002-86-2] and PVDC [CAS No: 9002-85-1]
- Rosin from wood [CAS No: 8050-09-7]
- 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 dioctyltin compounds (DOT) and other organo-tin compounds
- Titanium acetyl acetonate (TAA) [CAS No: 17501-79-0]
- Triclosan [CAS No: 3380-34-5]
- Toluene [CAS No: 108-88-3]

#### Disclaimer

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