

**DECLARATION DATASHEET OF POLYETHYLENE TIPELIN 6000B**

**DECLARATION DATASHEET**

**Product Trigger Spray bottles – Product code P5061**

**Polyethylene TIPELIN 6000B / Original Document date 07-11-16**

**Supplier Cambrian**

**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 January 2011) on plastic materials and articles intended to come into contact with food,**

(applies to all EU-Member States)

We declare that we use monomers and additives in our production only which are listed in union list of authorized monomers, other starting substances, additives, and polymer production aids of Directive 10/2011/EC ANNEX I.

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 and D at 40°C during 10 days, it is our experience that under these conditions overall migration limits are not exceed 10 mg/dm<sup>2</sup>.

Furthermore, we declare that this product does not release substances in detectable quantity listed in 10/2011/EC ANNEX II.

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 do not use any SML specified additives according to EU-Directive 10/2011/EC.

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

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.

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.

**Regulation (EC) No 2023/2006 (22 December 2006) on good manufacturing practice for 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, ISO14001 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

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change in the composition of the food or bring about deterioration in the organoleptic characteristics.

We fulfil 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.

Moreover, we declare that our production process is in harmony with requirements of **Directive 1999/92/EC (16 December 1999)** on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres.

**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 (a)(3)(i)(c1) related specification: 2.1 and 2.2

**European Pharmacopoeia (EP), 7 th Edition**

This product complies (according to the laboratory test results) to EP requirements for 3.1.3. Polyolefines – 6 th Edition of European Pharmacopoeia.

considering that 3.1.3 chapter of 6th edition of EP was not modified in 7th edition, it may be assumed the conformity with 7th edition

**Directive 2007/68/EC ( 27 November 2007) amending Annex IIIa to Directive 2000/13/EC regards certain food ingredients (Allergens)**

We certify, that during manufacturing of this product, we do not use or intentionally incorporate into this product , any of the substances are listed in ANNEX IIIa of this directive. 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.

Note: 2000/13/EC, 2003/89/EC, 2006/142/EC has been amended by 2007/68/EC

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

This product is not classified as dangerous substance according to the Directive 67/548/EEC and 1999/45/EC, Legal Act of National Council of HU No. 2000/XXV. Law, Publication date: 26/04/2000, Reference: (MNE(2003)54491)

Note(1): 78/631/EEC; 88/379/EEC; 89/178/EEC; 90/492/EEC; 93/18/EEC; 96/65/EC has been repealed by Directive 1999/45/EC acc.to ANNEX VIII.

Note(2): 67/548/EEC and 1999/45/EC will be repealed by Directive 1272/2008/EC (16 Dec 2008) with effect from 1 June 2015

**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.

**Directive 94/62/EC (20 December 1994) on packaging and packaging and its amendment 2004/12/EC**

Heavy metals (like cadmium, lead, mercury, hexavalent chromium (CrVI)) 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 packaging material, is in compliance with the concentration levels of heavy metals specified in Article 11, item1 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.

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**Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products**

We certify, that during manufacturing of this product, we do not use or intentionally incorporate into this product, any of the chemicals are listed ANNEX II and ANNEX III part 1 of this directive. 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 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 June 2000) on substances that deplete the ozone layer (Ozone Depleting Chemicals such as CFC's, HCFC's, Halons, CCl4, Trichloroethane, HBFC's)**

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 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.

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 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 (CrVI) 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.

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**Directive 2000/53/EC (18 September 2000) on end-of life vehicles (ELV)**

Heavy metals (like cadmium, lead, mercury, hexavalent chromium (CrVI)) and their compounds restricted by this regulation are not incorporated into this polymer intentionally during production.

**GADSL Declaration**

Hereby following substances are listed below which are indicated in Global Automotive Declarable Substance List (2011 GADSL v1.0, Released 01.02.2011).and they are present in this polymer product:

There is not GADSL substance in formulation of this product

*Note: in Aug 2005, VDA list of VDA 232-101 regulation (VDA = Verband der Automobilindustrie) has been replaced by the GADSL.*

**Regulation (EC) No 1895/2005 (18 November 2005) on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food**

- 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',

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 2003/11/EC (6 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.

*Note: Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and Part 3 of Annex II thereto are repealed with effect from 20 July 2013.*

According to the analytical test results of more polymer material produced by TVK Plc. we certify that this product fulfils the requirements of European Standard EN 71 "Safety of Toys", Part 3 (2002): "Migration of certain elements" - (Sb< 60; As<25; Ba<1000; Cd< 75; Cr< 60; Pb< 90; Hg< 60; Se< 500 mg/kg toy material).

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 substances to be present in this product. However, this product has not been tested for 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. Tallow derived additive may be used in manufacturing of this product. We have certificate issued by Supplier that their additives

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are not BSE/TSE dangerous products.

### BIFMA (Business and Institutional Furniture Manufacturers Association) declaration

We certify, that during manufacturing of this product, we do not intentionally incorporate into this product, any of the chemicals as listed by BIFMA e3-2008 Furniture Sustainability Standard ANNEX B (Chemicals of concern list). 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.

### 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 ( fluor, brom, iod )
- Phosphorous (yellow and red)
- Selenium (Se)
- Uranium (U)

We must call your attention that this product may contain chlorine compounds in negligible quantities (<100ppM)

### 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)
- 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] and Bisphenol F (BPF) [CAS No.: 620-92-8]
- Benzene [CAS No. 71-43-2]
- Benzoic Acid
- Benzotriazole [CAS No. 95-14-7]
- Benzophenone [CAS No. 119-61-9]
- Beryllium compounds (including: beryllium-oxide) and beryllium alloy
- Bis(chloromethyl)ether (BCME) [CAS No. 542-88-1]
- Bis(2-butoxyethyl) adipate [CAS No. 141-18-4]
- Butylated Hydroxytoluene (BHT) [CAS No. 128-37-0]
- Butylated Hydroxyanisole (BHA) [CAS No. 25013-16-5]
- Cellulose Acetate
- Cobalt-dicloride [CAS No. 7646-79-9]
- Dimethylfumarat [CAS No. 624-49-7]
- Dimethylformamide (DMF) [CAS No. 68-12-2]

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- 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]
- Glycols ethylene [CAS No. 107-21-1] and propylene [CAS No. 57-55-6]
- Hexachlorobenzene (HCB) [CAS No. 118-74-1]
- Halogenated HydroCarbons
- 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]
- 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),
- Polychlorinated Terphenyls (PCTs),
- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polycyclic aromatic hydrocarbons (PAHs)
- PolytetrafluoroEthylene (PTFE, TEFLON) [CAS No. 9002-84-0]
- PVC and PVDC
- Rosin from wood [CAS No. 8050-09-7]
- Silicone and silica gel
- Softeners
- Styrene [CAS No. 100-42-5]
- Vinyl Chloride [CAS No. 75-01-4]
- 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]

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## Disclaimer

The information provided in this publication has been compiled to the best of our present knowledge as of the date of publication however TVK Plc. as supplier of this product does not assume any liability whatever for the accuracy and completeness of such information.

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 request a current copy of this declaration regularly.

Sheena Britton  
 Technical Compliance Manager  
 Klipspringer Ltd



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