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Regulatory Information Sheet (RIS)

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General absence declaration for all CONSTAB Products

According to the information provided by our suppliers we herewith confirm that the substances mentioned below are not intentionally used or added(*) during manufacturing of the products produced by CONSTAB Polyolefin Additives GmbH.

For the mentioned substances no chemical analyses have been performed so trace levels cannot be excluded.

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Substances / description	CAS numbers
Acetyl acetone	123-54-6
Acrylamide	79-06-1
Acrylonitrile	107-13-1
Aldrin	309-00-2
Allergens as covered by the requirements in point 1:	
1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except: a. wheat based glucose syrups including dextrose; b. wheat based maltodextrins; c. glucose syrups based on barley; d. cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;	
2. Crustaceans and products thereof;	
3. Eggs and products thereof;	
4. Fish and products thereof, except: a. fish gelatin used as carrier for vitamin or carotenoid preparations; b. fish gelatin or Isinglass used as fining agent in beer and wine;	
5. Peanuts and products thereof;	
6. Soybeans and products thereof, except: a. fully refined soybean oil and fat; b. natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; c. vegetable oils derived phytosterols and phytosterol esters from soybean sources; d. plant stanol ester produced from vegetable oil sterols from soybean sources;	
7. Milk and products thereof (including lactose), except: a. whey used for making alcoholic distillates including ethyl alcohol of agricultural origin; b. lactitol;	
8. Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), pinoli	

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(pinus), chestnuts (castanea) and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;	
9.	Celery and products thereof;
10.	Mustard and products thereof;
11.	Sesame seeds and products thereof;
12.	Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;
13.	Lupin and products thereof;
14.	Molluscs and products thereof;
15.	Natural rubber latex
Anthraquinone	84-65-1
Aromatic amines (as restricted in Regulation EC 1907/2006 - Annex XVII)	
Arsenic and Arsenic compounds	7440-38-2
Artificial musk	
Asbestos	
Aziridine	151-56-4
Azocolorants (as restricted in Regulation EC 1907/2006 - Annex XVII)	
Azodicarbonamide	123-77-3
Benzophenones like	119-61-9
• 2,3,4,4-Tetrahydroxybenzophenone	31127-54-5
• 2,4-dihydroxybenzophenone	131-56-6
• 2-hydroxybenzophenone	117-99-7
• 3-hydroxybenzophenone	13020-57-0
• 4-Hydroxybenzophenone	1137-42-4
• 4 Methylbenzophenone	134-84-9
• 4,4'-dihydroxybenzophenone	611-99-4
Benzotriazoles like	95-14-7
• UV-320	3846-71-7
• UV-327	3864-99-1
• UV-328	25973-55-1
• UV-350	36437-37-3

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Beryllium and Beryllium compounds	7440-41-7
Biocidal products as defined in point 2	
Bismuth	7440-69-9
Bisphenols like • Bisphenol A • Bisphenol B • Bisphenol F • Bisphenol S	80-05-7 77-40-7 620-92-8 80-09-1
Boric acid	10043-35-3 / 11113-50-1
Butyl acetate	123-86-4
Butylated hydroxyanisole (BHA)	121-00-6 / 25013-16-5
Cellulose, acetate	9004-35-7
Chlordane	57-74-9
Chlordecone	143-50-0
Chlorofluorocarbons (CFC), hydrogenated chlorofluorocarbons (HCFC) and halones	
CMR substances categories 1A, 1B according to EC 1272/2008	
Colophony (rosin)	8050-09-7
Conflict Minerals as mentioned in point 3: • Gold • Tantalum • Tin • Tungsten	7440-57-5 7440-25-7 7440-31-5 7440-33-7
Cyanuric acid	108-80-5
Dichloro diphenyltrichlorethane (DDT)	50-29-3
Dieldrin	60-57-1
Diethylhexyl maleate (DEHM)	142-16-5
Dimethyl fumarate (DMF)	624-49-7
Dioxins like • 1,2 dioxin • 1,4 dioxin	289-87-2 290-67-5
Edetic acid	60-00-4
Endosulfan	115-29-7 / 959-98-8 / 33213-65-9

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Endrin	72-20-8
Epichlorohydrine	106-89-8
Epoxidised Soybean oil (ESBO)	8013-07-8
Epoxy derivatives (BADGE, BFDGE and NOGE as defined in (EC) 1895/2005)	
Ethanol	64-17-5
Ethoxyquin	91-53-2
Ethyl acetate	141-78-6
2-ethyl-hexanoic acid	149-57-5
Formaldehyde	50-00-0
Furan	110-00-9
Furfural	98-01-1
Glycol ethers like - Ethylene glycol dimethyl ether (EGDME) - Ethylene glycol monomethyl ether (EGME) - Ethylene glycol monomethyl ether acetate (EGMEA)	110-71-4 109-86-4 110-49-6
Glyoxal	107-22-2
Heavy metals as mentioned in point 4: - Cadmium - Hexavalent chromium - Lead - Mercury	7440-43-9 7440-47-3 7439-92-1 7439-97-6
Heptachlor	76-44-8
Hexabromo-1,1'-biphenyl	36355-01-8
Hexabromocyclododecane (HBCD) like - Alpha-HBCD - Beta-HBCD - Gamma-HBCD	25637-99-4 / 3194-55-6 134237-50-6 134237-51-7 134237-52-8
Hexachlorobenzene (HCB)	118-74-1
Hexachlorobutadiene	87-68-3
Hexachlorocyclohexanes, including lindane - BHC or HCH γ-HCH or γ-BHC (lindane) (1α,2β,3α,4β,5α,6β)-1,2,3,4,5,6-hexachlorocyclohexane (1α,2α,3β,4α,5β,6β)-1,2,3,4,5,6-hexachlorocyclohexane	608-73-1 58-89-9 319-85-7 319-84-6

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Indium	7440-74-6
Isopropylthioxanthone (ITX)	5495-84-1 / 83846-86-0
Melamine	108-78-1
4,4'-methylenedianiline (MDA)	101-77-9
Mineral Oils as mentioned in point 5: - Mineral oil / Mineral oil hydrocarbons (MOH) - Mineral oil saturated hydrocarbons (MOSH) - Mineral oil aromatic hydrocarbons (MOAH) - Polyolefin Oligomeric Saturated hydrocarbons (POSH) - Low molecular weight poly alpha olefines like lubricants (PAO)	
Mirex	2385-85-5
Natural rubber latex	
N-ethyl-o(or p)-toluenesulphonamide (NETSA)	8047-99-2
N,N-diethylhydroxylamine (NEPTSA)	3710-84-7
Nitrosamines	
Nonylphenol	25154-52-3
Nonylphenol, ethoxylated	9016-45-9 / 26027-38-3
Octylphenol	67554-50-1
Octylphenol, ethoxylated	9002-93-1
Organic peroxides	
Organotin compounds like - Dibutyltin (DBT) - Dioctyltin (DOT) - Tributyltin (TBT) - Tributyltin oxide (TBTO) - Triphenyltin (TPT) - Monobutyltin (MBT)	56-35-9
Ozone depleting substances as covered by the requirements in point 7	
Palladium	7440-05-3
Parabene like - Butylparaben - Ethylparaben - Methylparaben	94-26-8 120-47-8 99-76-3

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• Propylparaben	94-13-3
Pentachlorobenzene (PeCB)	608-93-5
Pentachlorophenol and its salts and esters	87-86-5
• Pentachlorophenyl laurate	3772-94-9
• Perchlorophenyl 5-oxo-L-prolinate	28990-85-4
• Potassium pentachlorophenolate	7778-73-6
• Sodium pentachlorophenolate	131-52-2
• Zinc bis(pentachlorophenolate)	2917-32-0
Perfluorinated compounds like	
• Perfluorobutanesulfonic acid (PFBS)	375-73-5 / 59933-66-3
• Perfluorononanoic acid (PFNA)	375-95-1
• Perfluorooctanoic acid (PFOA)	335-67-1
• Perfluorooctanoic acid, ammonium salt (APFO)	3825-26-1
• Perfluorooctane sulfonic acid	
• Perfluorooctane sulfonamides	
• Perfluorooctane sulfonates (PFOS)	
• Perfluorooctane sulfonyls	
Persistent Organic Pollutants as covered by the requirements in point 8	
Phthalates as covered by the requirements in point 9 and expanded with further phthalates:	
• Di(2-ethylhexyl)phthalate (DEHP)	117-81-7
• Dibutylphthalate (DBP)	84-74-2
• Benzylbutylphthalate (BBP)	85-68-7
• Di-,isononyl'phthalate (DINP)	28553-12-0 / 68515-48-0
• Di-,isoderyl'phthalate (DIDP)	26761-40-0 / 68515-49-1
• Di-noctylphthalate (DNOP)	117-84-0
• Butyl cyclohexyl phthalate (BCP)	84-64-0
• Butyl decyl phthalate (BDP)	89-19-0
• Di(2-propylheptyl) phthalate (DPHP)	53306-54-0
• Di-n-hexyl phthalate (DNHP)	84-75-3
• Di-n-pentyl phthalate (DNPP)	131-18-0
• Di-n-propyl phthalate (DPP)	131-16-8
• Diallyl phthalate (DAP)	131-17-9
• Dicyclohexyl phthalate (DCP)	84-61-7

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• Diethyl phthalate (DEP) • Diisobutyl phthalate (DIBP) • Diisoheptyl phthalate (DIHpP) • Diisohexyl phthalate (DIHxP) • Diisooctyl phthalate (DIOP) • Diisotridecyl phthalate (DIUP) • Diisoundecyl phthalate (DIUP) • Dimethyl phthalate (DMP) • Ditridecyl phthalate (DTDP) • Diundecyl phthalate (DUP) • n-Octyl n-decyl phthalate (ODP)	84-66-2 84-69-5 41451-28-9 146-50-9 27554-26-3 68515-47-9 85507-79-5 131-11-3 119-06-2 3648-20-2 119-07-3
Plant Protection Products as defined in point 10	
Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE) • Bis(pentabromophenyl) ether • Heptabromodiphenyl ether • Hexabromodiphenyl ether • Pentabromodiphenyl ether • Tetrabromodiphenyl ether	1163-19-5 68928-80-3 36483-60-0 32534-81-9 / 60348-60-9 40088-47-9 / 5436-43-1
Polychlorinated dibenzo-p-dioxins (PCDD)	
Polychlorinated dibenzofurans (PCDF)	
Polychlorinated biphenyls (PCB) like • 2,2',4,4',6,6'-hexachlorobiphenyl • 2,2',4,4'-tetrachlorobiphenyl • 2,4,4'-trichlorobiphenyl • 2-chlorobiphenyl • 3-chlorobiphenyl • 4,4'-dichlorobiphenyl • 4-chlorobiphenyl • Chloro-1,1'-biphenyl • Decachloro-1,1'-biphenyl • Dichlorobiphenyl • Heptachloro-1,1'-biphenyl • Nonachloro-1,1'-biphenyl • Pentachloro[1,1'-biphenyl]	1336-36-3 33979-03-2 2437-79-8 7012-37-5 2051-60-7 2051-61-8 2050-68-2 2051-62-9 27323-18-8 2051-24-3 25512-42-9 28655-71-2 53742-07-7 25429-29-2

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• Tetrachloro(tetrachlorophenyl)benzene	31472-83-0
Polychlorinated naphthalenes (PCN)	70776-03-3
Polychlorinated terphenyls (PCT)	61788-33-8
Polycyclic aromatic hydrocarbons (PAHs) like	
• Naphthalene	91-20-3
• Phenanthrene	85-01-8
• Anthracene	120-12-7
• Fluoranthene	206-44-0
• Pyrene	129-00-0
• Chrysen (CHR)	218-01-9
• Benzo[a]anthracene (BaA)	56-55-3
• Benzo[a]pyrene (BaP)	50-32-8
• Benzo[b]fluoranthene (BbFA)	205-99-2
• Benzo[e]pyrene (BeP)	192-97-2
• Benzo[j]fluoranthene (BjFA)	205-82-3
• Benzo[k]fluoranthene (BkFA)	207-08-9
• Dibenzo[a,h]anthracene (DBAhA)	53-70-3
• Indeno[1,2,3-cd]pyrene	193-39-5
• Benzo(g,h,i)perylene	191-24-2
Polyvinyl chloride (PVC)	9002-86-2
Polyvinylidene chloride (PVDC)	9002-85-1
Quaternary ammonium compounds	
Radioactive substances	
Recycled Materials as described in point 11	
RoHS annex II substances as defined in point 12	
Selenium and selenium compounds	7782-49-2
Semicarbazide	57-56-7
Short-chain chlorinated paraffins (SCCP)	85535-84-8
Silver and silver compounds	7440-22-4
Styrene	100-42-5
Titanium Acetyl Acetate (TAA)	17927-72-9
Toxaphene	8001-35-2
Triclosan	3380-34-5
Vanadium	7440-62-2
Vinyl chloride / Vinylidene chloride	75-01-4 / 75-35-4

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VOC > 3% w/w (Volatile Organic Compounds) according to Swiss SR 814.018	
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The above general absence declaration cover all relevant substances mentioned in the regulations, definitions, standards and norms in the annex

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ANNEX

1. Allergens

FALCPA - The Food Allergen Labeling and Consumer Protection Act

Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA) – (Last update July 18, 2006)

Allergens – Regulation (EU) No 1169/2011

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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 – (ANNEX II)

ANVISA - RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC N° 26, DE 2 DE JULHO DE 2015

This resolution establishes requirements for mandatory labelling of the main food responsible for causing food allergy.

2. Biocidal Products

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (replace directive 98/8/EC)

Article 3, 1. (a) 'biocidal product' means - any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

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3. Conflict Minerals

US-Dodd-Frank Consumer Protection Act - Section 1502 -The term "conflict minerals" is defined as columbite-tantalite, also known as coltan (from which tantalum is derived); cassiterite (tin); gold; wolframite (tungsten); or their derivatives; or any other mineral or its derivatives determined by the Secretary of State to be financing conflict in the Democratic Republic of the Congo or an adjoining country.

REGULATION (EU) 2017/821 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas.

4. Heavy metals – Cd, Cr(VI), Hg and Pb

2000/53/EC – End-of life vehicles - Directive 2000/53/EC of the European Parliament and of the council of 18 September 2000 on end-of life vehicles

CONEG - Coalition of Northeastern Governors - The Toxics in Packaging Clearinghouse (TPCH) was established by the Coalition of Northeastern Governors (CONEG) in 1992 to assist states that adopted the CONEG-developed Model Toxics in Packaging Legislation.

5. Mineral Oil (MOH (MOSH/MOAH) / POSH / PAO)

There are no standard methods for the determination of MOAH, MOSH and POSH. It is currently not possible to analytically differentiate MOSH / MOAH with many other substances that have similar chemical structures. These substances are partly natural products such as e.g. Beeswax (on gummy bears). Positive signals in the analysis are therefore not to be equated in principle with the contamination of mineral oils.

Mineral oil / Mineral oil hydrocarbons (MOH)

Mineral oil is an extremely complex mixture of hydrocarbons with varying carbon numbers and structures. It is a raw material for a large number of applications for example lipstick, detergents, tyres, plastic, petrol and heating oil. Especially primary or secondary packaging made of cardboard with recycled paper as sources of contamination has become public in

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this way. Known causes in this case are the residues of mineral oil-containing offset printing inks. However, plastic packaging is usually printed in flexographic or special gravure printing. The corresponding printing inks for both printing processes are formulated according to the state of the art mineral oil-free.

Fractions of mineral oil are mineral oil hydrocarbons (MOH = MOSH/MOAH).

MOSHs are saturated hydrocarbons from mineral oil based on open-chained and cyclic hydrocarbons (paraffins and naphthenes). MOAHs do not contain saturated hydrocarbons; they are mostly alkylated polycyclic compounds (with one to five aromatic rings).

Polyolefin Oligomeric Saturated hydrocarbons (POSH)

POSH are oligomeric substances from polyolefins (polypropylene and polyethylene) that consist of saturated and branched hydrocarbons and are formed during the polymerization reaction as a by-product. They are not intentionally added(*) to the polymer.

Poly Alpha Olefine (PAO)

Poly-alpha-olefin (or poly- α -olefin) is a polymer made by polymerizing an alpha-olefin. It is a specific type of olefin (organic) that is used as a base stock in the production of some synthetic lubricants.

An alpha-olefin (or α -olefin) is an alkene where the carbon-carbon double bond starts at the α -carbon atom, i.e. the double bond is between the #1 and #2 carbons in the molecule.

Based on this definition Polypropylene and Polyethylene are PAO as well. Polypropylene wax and polyethylene wax can be used in masterbatches. Therefore an absence for PAO cannot be confirmed in general, only the non-intentional use of low molecular weight poly alpha olefines (like lubricants) can be declared.

6. Nanomaterials

2011/696/EU – Nanomaterials definition

'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the

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particles in the number size distribution, one or more external dimensions is in the size range 1 nm -100 nm.

The following CONSTAB-products **do contain** nanoparticles according to above-mentioned definition:

- ECOCELL P/H-1/CS
- UVA 01590 LD
- UVA 01590 PP

All other CONSTAB products remain free of nanomaterials.

7. Ozone depleting substances

Clean Air Act Title VI - Stratospheric Ozone Protection (Section 602 – US code 7671a – Listing of class I and class II substances)

MONTREAL Protocol - Chlorofluorocarbons (CFC's) and ozone depleting substances

REGULATION (EU) 2024/590 of 7 February 2024 on substances that deplete the ozone layer (repealing Regulation (EC) No 1005/2009)

Regulation EC 517/2014 - fluorinated greenhouse gases (repealing Regulation (EC) 842/2006)

8. Persistent Organic Pollutants (POP)

EU Regulation (EU) 2019/1021 - recast (formerly EC regulation 850/2004), latest amendment (EU) 2024/2570

Stockholm Convention (Annex A, B, C) - Listing of POPs

9. Phthalate

Phthalates listed in Annex XIV – REACH (Authorisation List) / Phthalates listed in Annex XVII – REACH (List of restrictions) - previous legislation: Directive 76/769/EEC (Directive 2005/84/EC) - repealed with effect from 1 June 2009

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According to the information provided by our suppliers some polyolefin manufacturer could use a catalyst system containing phthalate. The catalyst system is almost completely consumed during the polymerization process. Nevertheless, traces of catalyst residues less than 1 ppm cannot be excluded in some grades. However, the potential residual traces of the phthalates are far below the limits defined by REACH (0.1%), thus no commercial polyolefin is subject to any restriction or ban in that respect.

10. Plant Protection Products

Regulation (EC) No 1107/2009 of the European Parliament and of the council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Pesticides, fungicides, herbicides and insecticides intended for one of the following uses:

- protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;
- influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;
- preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;
- destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;
- checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

11. Recycled Materials

COMMISSION REGULATION (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008

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Article 2 - Definitions

(4) 'recycled plastic' means plastic resulting from the decontamination process of a recycling process and plastic resulting from subsequent post-processing operations and that is not yet transformed into recycled plastic materials and articles;

(5) 'recycled plastic materials and articles' means food contact materials and articles in their finished state, and that are made either fully or partly of recycled plastic;

(6) 'recycled content' refers to the amount of recycled plastic directly resulting from the decontamination process of a recycling process contained either in further post-processed recycled plastic or recycled plastic materials and articles manufactured therefrom.

12. RoHS

Directive 2011/65/EU and its amendments of the European Parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- Cr(VI), Hg, Pb, PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 %; Cd < 0.01 %

13. Active and intelligent materials

COMMISSION REGULATION (EU) 450/2009 on active and intelligent materials and articles intended to come into contact with food.

This Regulatory Information Sheet (RIS) is owned by the CONSTAB Polyolefin Additives GmbH and it is not allowed to be passed on to any third party, even not parts thereof.

(*) intentionally used or added:

Intentionally used or added means to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article.

This declaration replaces all previous ones relating to this subject.

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The above-mentioned product/-s is/are a Masterbatch/Compound for the manufacturing of articles for the plastic processing industry. This declaration is restricted to the material as it leaves the production facilities, and it does not cover any substance subsequently added by the converter.

As the above-mentioned product/-s must be further processed in order to make finished materials or articles, compliance with relevant regulatory requirements can only be demonstrated based on the complete formulation for the final article. This compliance work is the sole responsibility of the manufacturer of the finished material or article.

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