

**Visottica Industrie Spa Informative Report according to the provisions of European Regulation (EC) No. 1907/2006 (REACH)**

Dear Customer,

since June 1<sup>st</sup> 2007 the **REACH European Regulation (EC) No. 1907/2006** concerning the Registration, Evaluation, Authorization and Restriction of Chemicals produced or commercialized within the European Community became effective. The aim of this Regulation is to allow the responsible use of chemicals and to this end REACH provides for the registration at the European Community both for new chemicals and for those already existing on the market.

Visottica Industrie Spa, as “manufacturer of articles” (and therefore “downstream user”, as defined by Art. 3 clause 13 of REACH Regulation) has no obligation of pre-registration or registration, because the conditions requiring these fulfillments according to Art. 7 of the Regulation (Registration and notification of substances in articles) are not present.

Moreover, Visottica Industrie Spa, with the aim of making the REACH enforcement easier in the private sector establishing some communication standards in the supply chain and in voluntary compliance with Art. 32 and 33 of the same, has arranged for its Customers this Informative Report and the related Technical Datasheets (containing the information extracted from the Safety Data Sheets arranged by suppliers of metal alloys) identifying the chemical composition of alloys used for glasses components.

Visottica Industrie Spa specifies that according to REACH Regulation (EC) No. 1907/2006 and up to the date of revision of this document, the spectacles components produced and/or commercialized:

- do not contain chemicals listed in the **Annex XIV** (List of Substances subject to Authorization);
- can contain chemicals present in the attached “**Candidate List**” of the Substances of Very High Concern (SVHC), and in particular:
  - 4,4'-isopropylidenediphenol (CAS No. 80-05-7), or BpA, that can be present in trace levels in the polymer matrix of Polycarbonate material, since BpA is the monomeric building block used during chemical process of polymerization. About BpA, its effects and its possible presence in Visottica Comotec articles please see the attached Visottica REACH/Bisphenol A Informative Note.
- can contain substances present in the **Annex XVII** (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles)., and in particular:
  - Nickel (CAS No. 7440-02-0), which can be present (6÷65% w/w) in the metal alloys constituting its articles and by those could be released in case of direct and prolonged contact with skin, with standards higher than the restrictions reported at point No. 27 of Annex XVII.  
To this end Visottica Industrie Spa reaffirms that the correct use of its components, intended for a professional user for the production of spectacle frames, requires not to put them in direct and prolonged contact with skin if they haven't been covered with appropriate Nickel-free coating guaranteeing a release not exceeding the limits imposed by Annex XVII of REACH Regulation.
  - Lead (CAS No. 7439-92-1), which is present in a concentration (0.5÷3.5% w/w) above the restrictions reported at point No. 63 of Annex XVII of REACH Regulation in the following standard articles of 2017 Visottica Comotec catalogues:

Nuts	01DA26010000	01DA26010001	01DA26020000	01DA26020001
	01DA20022000	01DA20022001	01DA22020000	01DA22020001
	01DA20010001	01DA20010000	01DA22011000	

At the same time, Visottica Industrie Spa wants to clarify that also some of the articles that are not present in 2017 Visottica Comotec catalogues but that could be still provided to its customers may contain Lead with higher amounts than the restrictions reported in Annex XVII. In case of specific request made by the customer, Visottica Industrie Spa will be pleased to answer to any additional question the customers may have about the possible Lead presence in these articles.

Considering the dynamic nature of the Candidate List of SVHC substances, as well as of Annexes XIV and XVII of REACH Regulation No. 1907/2006, Visottica Industrie Spa will keep on monitoring them periodically and informing the downstream users should there be any necessity to use such substances.

This Informative Report complies with Standards and Regulations in force on the date in which it has been issued. An updated copy of this Informative Report and of the mentioned Technical Datasheets are downloadable from the website [visotticacomotec.com](http://visotticacomotec.com).

Best regards,

**VISOTTICA INDUSTRIE Spa**

Chief Operations Officer

Mr. Daniele Angeli

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**Attached:** Candidate List of SVHC Substances  
Visottica Industrie Spa REACH/Bisphenol A Informative Note

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Cap. Soc. € 3.452.540 i.v.  
Registro Imprese  
TV 01531210308  
R.E.A. TV - 275318 - M 044040  
Part.IVA IT03486160264  
Codice Fiscale 01531210308

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## **Candidate List of Substances of Very High Concern**

	Substance identification		Date of inclusion	Reason for inclusion
	Substance name	EC (CAS No.)		
1	Anthracene	204-371-1	28.10.08	PBT (art. 57d)
2	4,4'-Diaminodiphenylmethane (MDA)	202-974-4	28.10.08	Carcinogenic (art. 57a)
3	Dibutyl phthalate (DBP) (added to Annex XIV – Substances subject to Authorization)	201-557-4	28.10.08	Toxic for reproduction (art. 57c)
4	Cobalt dichloride	231-589-4	28.10.08 20.06.11	Carcinogenic and toxic for reproduction (art. 57a and c)
5	Diarsenic pentaoxide (added to Annex XIV – Substances subject to Authorization)	215-116-9	28.10.08	Carcinogenic (art. 57a)
6	Diarsenic trioxide (added to Annex XIV – Substances subject to Authorization)	215-481-4	28.10.08	Carcinogenic (art. 57a)
7	Sodium dichromate (added to Annex XIV – Substances subject to Authorization)	234-190-3 (7789-12-0 and 10588-01-9)	28.10.08	Carcinogenic, mutagenic and toxic for reproduction (art. 57a, 57b and 57c)
8	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) (added to Annex XIV – Substances subject to Authorization)	201-329-4	28.10.08	vPvB (art. 57e)
9	Bis (2-ethylhexyl)phthalate (DEHP) (added to Annex XIV – Substances subject to Authorization)	204-211-0	28.10.08 17.12.14	Toxic for reproduction (art. 57c); Equivalent level of concern having probable serious effects to the environment (art. 57f)
10	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: α-hexabromocyclododecane β-hexabromocyclododecane γ-hexabromocyclododecane (added to Annex XIV – Substances subject to Authorization)	247-148-4 and 221-695-9 (134237-50-6) (134237-51-7) (134237-52-8)	28.10.08	PBT (art. 57d)
11	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) (added to Annex XIV – Substances subject to Authorization)	287-476-5	28.10.08	PBT and vPvB (art. 57d - e)
12	Bis(tributyltin)oxide (TBTO)	200-268-0	28.10.08	PBT (art. 57d)
13	Lead hydrogen arsenate	232-064-2	28.10.08	Carcinogenic and toxic for reproduction (art. 57a and c)
14	Benzyl butyl phthalate (BBP) (added to Annex XIV – Substances subject to Authorization)	201-622-7	28.10.08	Toxic for reproduction (art. 57c)
15	Triethyl arsenate	427-700-2	28.10.08	Carcinogenic (art. 57a)
16	2,4-Dinitrotoluene (added to Annex XIV – Substances subject to Authorization)	204-450-0	13.01.10	Carcinogenic (art. 57a)
17	Anthracene oil	292-602-7	13.01.10	Carcinogenic, mutagenic, PBT and vPvB (art. 57a, 57d, 57e)
18	Anthracene oil, anthracene paste, anthracene fraction	295-275-9	13.01.10	Carcinogenic, mutagenic, PBT and vPvB (art. 57a, 57d, 57e)
19	Anthracene oil, anthracene-low	292-604-8	13.01.10	Carcinogenic, mutagenic, PBT and vPvB (art. 57a, 57b, 57d, 57e)
20	Anthracene oil, anthracene paste	292-603-2	13.01.10	Carcinogenic, mutagenic, PBT and vPvB (art. 57a, 57b, 57d, 57e)
21	Anthracene oil, anthracene paste, distr. lights	295-278-5	13.01.10	Carcinogenic, mutagenic, PBT and vPvB (art. 57a, 57b, 57d, 57e)
22	Diisobutyl phthalate (DIBP) (added to Annex XIV – Substances subject to Authorization)	201-553-2	13.01.10	Toxic for reproduction (art. 57c)
23	Lead chromate (added to Annex XIV – Substances subject to Authorization)	231-846-0	13.01.10	Carcinogenic and toxic for reproduction (art. 57a and c)
24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) (added to Annex XIV – Substances subject to Authorization)	235-759-9	13.01.10	Carcinogenic and toxic for reproduction (art. 57a and c)

25	Lead sulfochromate yellow (C.I. Pigment Yellow 34) (added to Annex XIV – Substances subject to Authorization)	215-693-7	13.01.10	Carcinogenic and toxic for reproduction (art. 57a and c)
26	Tris(2-chloroethyl)phosphate (added to Annex XIV – Substances subject to Authorization)	204-118-5	13.01.10	Toxic for reproduction (art. 57c)
27	Coal tar pitch, high temperature	266-028-2	13.01.10	Carcinogenic, PBT and vPvB (art. 57a, 57d and 57e)
28	Acrylamide	201-173-7	30.03.10	Carcinogenic and mutagenic (art. 57a and 57b)
29	Boric acid	233-139-2 234-343-4	18.06.10	Toxic for reproduction (art. 57c)
30	Ammonium dichromate (added to Annex XIV – Substances subject to Authorization)	232-143-1	18.06.10	Carcinogenic, mutagenic and toxic for reproduction (art. 57a, 57b and 57c)
31	Disodium tetraborate, anhydrous	215-540-4	18.06.10	Toxic for reproduction (art. 57c)
32	Potassium chromate (added to Annex XIV – Substances subject to Authorization)	232-140-5	18.06.10	Carcinogenic and mutagenic (art. 57a and 57b)
33	Potassium dichromate (added to Annex XIV – Substances subject to Authorization)	231-906-6	18.06.10	Carcinogenic, mutagenic and toxic for reproduction (art. 57a, 57b and 57c)
34	Sodium chromate (added to Annex XIV – Substances subject to Authorization)	231-889-5	18.06.10	Carcinogenic, mutagenic and toxic for reproduction (art. 57a, 57b and 57c)
35	Tetraboron disodium heptaoxide, hydrate	235-541-3	18.06.10	Toxic for reproduction (art. 57c)
36	Trichloroethylene (added to Annex XIV – Substances subject to Authorization)	201-167-4	18.06.10	Carcinogenic (art. 57a)
37	2-Ethoxyethanol	203-804-1	15.12.10	Toxic for reproduction (art. 57c)
38	2-Methoxyethanol	203-713-7	15.12.10	Toxic for reproduction (art. 57c)
39	Chromic acid Dichromic acid Oligomers of chromic and dichromic acid (added to Annex XIV – Substances subject to Authorization)	231-801-5 236-881-5 -	15.12.10	Carcinogenic (art. 57a)
40	Chromium trioxide (added to Annex XIV – Substances subject to Authorization)	215-607-8	15.12.10	Carcinogenic and mutagenic (art. 57a and 57b)
41	Cobalt(II) carbonate	208-169-4	15.12.10	Carcinogenic and toxic for reproduction (art. 57a and c)
42	Cobalt(II) diacetate	200-755-8	15.12.10	Carcinogenic and toxic for reproduction (art. 57a and c)
43	Cobalt(II) dinitrate	233-402-1	15.12.10	Carcinogenic and toxic for reproduction (art. 57a and c)
44	Cobalt(II) sulphate	233-334-2	15.12.10	Carcinogenic and toxic for reproduction (art. 57a and c)
45	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	276-158-1	20.06.11	Toxic for reproduction (art. 57c)
46	1,2,3-Trichloropropane	202-486-1	20.06.11	Carcinogenic and toxic for reproduction (art. 57a and c)
47	1-Methyl-2-pyrrolidone	212-828-1	20.06.11	Toxic for reproduction (art. 57c)
48	Hydrazine	206-114-9	20.06.11	Carcinogenic (art. 57a)
49	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	271-084-6	20.06.11	Toxic for reproduction (art. 57c)
50	Strontium chromate (added to Annex XIV – Substances subject to Authorization)	232-142-6	20.06.11	Carcinogenic (art. 57a)
51	2-Ethoxyethyl acetate	203-839-2	20.06.11	Toxic for reproduction (art. 57c)
52	Zirconia Aluminosilicate Refractory Ceramic Fibres <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:</i> a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na <sub>2</sub> O+K <sub>2</sub> O+CaO+MgO+BaO) content less or equal to 18% by weight	-	19.12.11	Carcinogenic (art. 57a)
53	Calcium arsenate	231-904-5	19.12.11	Carcinogenic (art. 57a)

54	Bis(2-methoxyethyl) ether (added to Annex XIV – Substances subject to Authorization)	203-924-4	19.12.11	Toxic for reproduction (art. 57c)
55	Potassium hydroxyoctaoxodizincatedichromate (added to Annex XIV – Substances subject to Authorization)	234-329-8	19.12.11	Carcinogenic (art. 57a)
56	Lead dipicrate	229-335-2	19.12.11	Toxic for reproduction (art. 57c)
57	N,N-dimethylacetamide	204-826-4	19.12.11	Toxic for reproduction (art. 57c)
58	Aluminosilicate Refractory Ceramic Fibres <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:</i> a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na <sub>2</sub> O+K <sub>2</sub> O+CaO+MgO+BaO) content less or equal to 18% by weight	-	19.12.11	Carcinogenic (art. 57a)
59	Arsenic acid (added to Annex XIV – Substances subject to Authorization)	231-901-9	19.12.11	Carcinogenic (art. 57a)
60	2-Methoxyaniline; o-Anisidine	201-963-1	19.12.11	Carcinogenic (art. 57a)
61	Trilead diarsenate	222-979-5	19.12.11	Carcinogenic and toxic for reproduction (art. 57a and c)
62	1,2-dichloroethane (EDC) (added to Annex XIV – Substances subject to Authorization)	203-458-1	19.12.11	Carcinogenic (art. 57a)
63	Pentazinc chromate octahydroxide (added to Annex XIV – Substances subject to Authorization)	256-418-0	19.12.11	Carcinogenic (art. 57a)
64	Formaldehyde, oligomeric reaction products with aniline (added to Annex XIV – Substances subject to Authorization)	500-036-1	19.12.11	Carcinogenic (art. 57a)
65	Bis(2-methoxyethyl) phthalate (DMEP)	204-212-6	19.12.11	Toxic for reproduction (art. 57c)
66	4-(1,1,3,3-tetramethylbutyl)phenol	205-426-2	19.12.11	Equivalent level of concern having probable serious effects to the environment (art. 57f)
67	Lead diazide, Lead azide	236-542-1	19.12.11	Toxic for reproduction (art. 57c)
68	Phenolphthalein	201-004-7	19.12.11	Carcinogenic (art. 57a)
69	Dichromium tris(chromate) (added to Annex XIV – Substances subject to Authorization)	246-356-2	19.12.11	Carcinogenic (art. 57a)
70	Lead styphnate	239-290-0	19.12.11	Toxic for reproduction (art. 57c)
71	2,2'-dichloro-4,4'-methylenedianiline (MOCA) (added to Annex XIV – Substances subject to Authorization)	202-918-9	19.12.11	Carcinogenic (art. 57a)
72	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) <i>[with ≥0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]</i>	208-953-6	18.06.12	Carcinogenic (art. 57a)
73	α,α-Bis[4-(dimethylamino)phenyl]-4(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) <i>[with ≥0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]</i>	229-851-8	18.06.12	Carcinogenic (art. 57a)
74	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	202-959-2	18.06.12	Carcinogenic (art. 57a)
75	1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	423-400-0	18.06.12	Mutagenic (art. 57b)
76	Diboron trioxide	215-125-8	18.06.12	Toxic for reproduction (art. 57c)
77	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	203-977-3	18.06.12	Toxic for reproduction (art. 57c)
78	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol <i>[with ≥0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]</i>	209-218-2	18.06.12	Carcinogenic (art. 57a)
79	Lead(II) bis(methanesulfonate)	401-750-5	18.06.12	Toxic for reproduction (art. 57c)
80	Formamide	200-842-0	18.06.12	Toxic for reproduction (art. 57c)

81	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) <i>[with ≥ 0.1 % of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]</i>	219-943-6	18.06.12	Carcinogenic (art. 57a)
82	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	203-794-9	18.06.12	Toxic for reproduction (art. 57c)
83	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	219-514-3	18.06.12	Mutagenic (art. 57b)
84	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	202-027-5	18.06.12	Carcinogenic (art. 57a)
85	Pyrochlore, antimony lead yellow	232-382-1	19.12.12	Toxic for reproduction (art. 57c)
86	6-methoxy-m-toluidine (p-cresidine)	204-419-1	19.12.12	Carcinogenic (art. 57a)
87	Henicosfluoroundecanoic acid	218-165-4	19.12.12	vPvB (art. 57e)
88	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] <i>[The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]</i>	247-094-1, 243-072-0, 256-356-4, 260-566-1	19.12.12	Equivalent level of concern having probable serious effects to the environment (art. 57f)
89	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] <i>[The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]</i>	201-604-9, 236-086-3, 238-009-9	19.12.12	Equivalent level of concern having probable serious effects to the environment (art. 57f)
90	Dibutyltin dichloride (DBTC)	211-670-0	19.12.12	Toxic for reproduction (art. 57c)
91	Lead bis(tetrafluoroborate)	237-486-0	19.12.12	Toxic for reproduction (art. 57c)
92	Lead dinitrate	233-245-9	19.12.12	Toxic for reproduction (art. 57c)
93	Silicic acid, lead salt	234-363-3	19.12.12	Toxic for reproduction (art. 57c)
94	4-Aminoazobenzene	200-453-6	19.12.12	Carcinogenic (art. 57a)
95	Lead titanium zirconium oxide	235-727-4	19.12.12	Toxic for reproduction (art. 57c)
96	Lead monoxide (lead oxide)	215-267-0	19.12.12	Toxic for reproduction (art. 57c)
97	o-Toluidine	202-429-0	19.12.12	Carcinogenic (art. 57a)
98	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	19.12.12	Toxic for reproduction (art. 57c)
99	Silicic acid (H <sub>2</sub> Si <sub>2</sub> O <sub>5</sub> ), barium salt (1:1), lead-doped <i>[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]</i>	272-271-5	19.12.12	Toxic for reproduction (art. 57c)
100	Trilead bis(carbonate)dihydroxide	215-290-6	19.12.12	Toxic for reproduction (art. 57c)
101	Furan	203-727-3	19.12.12	Carcinogenic (art. 57a)
102	N,N-dimethylformamide	200-679-5	19.12.12	Toxic for reproduction (art. 57c)
103	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated <i>[covering well-defined substances and UVCB substances, polymers and homologues]</i>	-	19.12.12	Equivalent level of concern having probable serious effects to the environment (art. 57f)
104	4-Nonylphenol, branched and linear <i>[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]</i>	-	19.12.12	Equivalent level of concern having probable serious effects to the environment (art. 57f)
105	4,4'-methylenedi-o-toluidine	212-658-8	19.12.12	Carcinogenic (art. 57a)
106	Diethyl sulphate	200-589-6	19.12.12	Carcinogenic (art. 57a); Mutagenic (art. 57b)
107	Dimethyl sulphate	201-058-1	19.12.12	Carcinogenic (art. 57a)
108	Lead oxide sulfate	234-853-7	19.12.12	Toxic for reproduction (art. 57c)
109	Lead titanium trioxide	235-038-9	19.12.12	Toxic for reproduction (art. 57c)
110	Acetic acid, lead salt, basic	257-175-3	19.12.12	Toxic for reproduction (art. 57c)



111	[Phthalato(2-)]dioxotrilead	273-688-5	19.12.12	Toxic for reproduction (art. 57c)
112	Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	214-604-9	19.12.12	PBT and vPvB (art. 57d - e)
113	N-methylacetamide	201-182-6	19.12.12	Toxic for reproduction (art. 57c)
114	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	201-861-7	19.12.12	Toxic for reproduction (art. 57c)
115	1,2-Diethoxyethane	211-076-1	19.12.12	Toxic for reproduction (art. 57c)
116	Tetralead trioxide sulphate	235-380-9	19.12.12	Toxic for reproduction (art. 57c)
117	N-pentyl-isopentylphthalate	-	19.12.12	Toxic for reproduction (art. 57c)
118	Dioxobis(stearato)trilead	235-702-8	19.12.12	Toxic for reproduction (art. 57c)
119	Tetraethyllead	201-075-4	19.12.12	Toxic for reproduction (art. 57c)
120	Pentalead tetraoxide sulphate	235-067-7	19.12.12	Toxic for reproduction (art. 57c)
121	Pentacosafuorotridecanoic acid	276-745-2	19.12.12	vPvB (art. 57e)
122	Tricosafuorododecanoic acid	206-203-2	19.12.12	vPvB (art. 57e)
123	Heptacosafuorotetradecanoic acid	206-803-4	19.12.12	vPvB (art. 57e)
124	1-bromopropane (n-propyl bromide)	203-445-0	19.12.12	Toxic for reproduction (art. 57c)
125	Methoxyacetic acid	210-894-6	19.12.12	Toxic for reproduction (art. 57c)
126	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	202-453-1	19.12.12	Carcinogenic (art. 57a)
127	Methyloxirane (Propylene oxide)	200-879-2	19.12.12	Carcinogenic (art. 57a); Mutagenic (art. 57b)
128	Trilead dioxide phosphonate	235-252-2	19.12.12	Toxic for reproduction (art. 57c)
129	o-aminoazotoluene	202-591-2	19.12.12	Carcinogenic (art. 57a)
130	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	19.12.12	Toxic for reproduction (art. 57c)
131	4,4'-oxydianiline and its salts	202-977-0	19.12.12	Carcinogenic (art. 57a); Mutagenic (art. 57b)
132	Orange lead (lead tetroxide)	215-235-6	19.12.12	Toxic for reproduction (art. 57c)
133	Biphenyl-4-ylamine	202-177-1	19.12.12	Carcinogenic (art. 57a)
134	Diisopentylphthalate (DiPP)	210-088-4	19.12.12	Toxic for reproduction (art. 57c)
135	Fatty acids, C16-18, lead salts	292-966-7	19.12.12	Toxic for reproduction (art. 57c)
136	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	19.12.12	Equivalent level of concern having probable serious effects to the environment (art. 57f)
137	Sulfurous acid, lead salt, dibasic	263-467-1	19.12.12	Toxic for reproduction (art. 57c)
138	Lead cyanamidate	244-073-9	19.12.12	Toxic for reproduction (art. 57c)
139	Cadmium	231-152-8	20.06.13	Carcinogenic (art. 57a); Equivalent level of concern having probable serious effects to human health (art. 57f)
140	Ammonium pentadecafluorooctanoate (APFO)	223-320-4	20.06.13	Toxic for reproduction (art. 57c); PBT (art. 57d)
141	Pentadecafluorooctanoic acid (PFOA)	206-397-9	20.06.13	Toxic for reproduction (art. 57c); PBT (art. 57d)
142	Dipentyl phthalate (DPP)	205-017-9	20.06.13	Toxic for reproduction (art. 57c)
143	4-Nonylphenol, branched and linear, ethoxylated <i>[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]</i>	-	20.06.13	Equivalent level of concern having probable serious effects to the environment (art. 57f)
144	Cadmium oxide	215-146-2	20.06.13	Carcinogenic (art. 57a); Equivalent level of concern having probable serious effects to human health (art. 57f)
145	Cadmium sulphide	215-147-8	16.12.13	Carcinogenic (art. 57a); Equivalent level of concern having probable serious effects to human health (art. 57f)
146	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	16.12.13	Carcinogenic (art. 57a)

147	Dihexyl phthalate (DnHP)	201-559-5	16.12.13	Toxic for reproduction (art. 57c)
148	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	202-506-9	16.12.13	Toxic for reproduction (art. 57c)
149	Trixylyl phosphate	246-677-8	16.12.13	Toxic for reproduction (art. 57c)
150	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	16.12.13	Carcinogenic (art. 57a)
151	Lead di(acetate)	206-104-4	16.12.13	Toxic for reproduction (art. 57c)
152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	16.06.14	Toxic for reproduction (art. 57c)
153	Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	16.06.14	Toxic for reproduction (art. 57c)
154	Sodium peroxometaborate	231-556-4	16.06.14	Toxic for reproduction (art. 57c)
155	Cadmium chloride	233-296-7	16.06.14	Carcinogenic (art. 57a); Mutagenic (art. 57b); Toxic for reproduction (art. 57c); Equivalent level of concern having probable serious effects to human health (art. 57f)
156	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	17.12.14	PBT and vPvB (art. 57d - e)
157	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	17.12.14	Toxic for reproduction (art. 57c)
158	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	17.12.14	Toxic for reproduction (art. 57c)
159	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	17.12.14	PBT (art. 57d)
160	Cadmium fluoride	232-222-0	17.12.14	Carcinogenic (art. 57a); Mutagenic (art. 57b); Toxic for reproduction (art. 57c); Equivalent level of concern having probable serious effects to human health (art. 57f)
161	Cadmium sulphate	233-331-6	17.12.14	Carcinogenic (art. 57a); Mutagenic (art. 57b); Toxic for reproduction (art. 57c); Equivalent level of concern having probable serious effects to human health (art. 57f)
162	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	15.06.15	vPvB (art. 57e)
163	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥0.3% of dihexyl phthalate (EC No. 201-559-5)	271-094-0 272-013-1	15.06.15	Toxic for reproduction (art. 57c)
164	1,3-propanesultone	214-317-9	17.12.15	Carcinogenic (art. 57a)
165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	17.12.15	vPvB (art. 57e)
166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	17.12.15	vPvB (art. 57e)
167	Nitrobenzene	202-716-0	17.12.15	Toxic for reproduction (art. 57c)
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts Ammonium salts of perfluorononan-1-oic-acid Perfluorononan-1-oic-acid Sodium salts of perfluorononan-1-oic-acid	-	17.12.15	Toxic for reproduction (art. 57c); PBT (art. 57d)
169	Benzo[def]chrysene	200-028-5	20.06.16	Carcinogenic (art. 57a); Mutagenic (art. 57b); Toxic for reproduction (art. 57c); PBT (art. 57d); vPvB (art. 57e)
170	4,4'-isopropylidenediphenol (Bisphenol-A)	201-245-8	12.01.17	Toxic for reproduction (art. 57c)
171	4-Heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	12.01.17	Equivalent level of concern having probable serious effects to the environment (art. 57f)



172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts: Nonadecafluorodecanoic acid Ammonium nonadecafluorodecanoate Decanoic acid, nonadecafluoro-, sodium salt	206-400-3 221-470-5 -	12.01.17	Toxic for reproduction (art. 57c); PBT (art. 57d)
173	p-(1,1-dimethylpropyl)phenol	201-280-9	12.01.17	Equivalent level of concern having probable serious effects to the environment (art. 57f)

Susegana (TV), 15/03/2017

### **Visottica Industrie Spa REACH/Bisphenol A Informative Note**

#### **Background: Bisphenol A (BpA) in European Regulation No. 1907/2006 (REACH)**

In January 2017 European Chemicals Agency (ECHA) has added 4,4'-isopropylidenediphenol, better known as Bisphenol A (the monomer BpA, not the derived polymers), to the REACH Candidate List of Substances of Very High Concern (SVHC).

This means that any supplier of articles (that is the case of Visottica Industrie Spa according to European REACH Regulation) containing Bisphenol A in a concentration above 0,1% weight by weight (w/w) is obliged to provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the product itself (Art. 33 of REACH, "Duty to communicate information on substances in articles").

#### **What is Bisphenol A / Residual content and possible migration of BpA**

Bisphenol A (CAS n° 80-05-7) is an organic synthetic compound which is mainly employed to make certain plastics and epoxy resins. Among these, BpA is used as a monomeric building block for the manufacture of Polycarbonate resin. During the chemical process of polymerisation, BpA reacts and becomes firmly bound into the structure, thus actually building the polymer material.

Unavoidable technically trace levels (typically less than 100 ppm, parts per million) may remain in the polymer matrix of all Polycarbonate resins (so-called free or residual BpA) and, therefore, trace levels of BpA can be present also in all Polycarbonate articles.

BpA and articles manufactured from BpA, such as Polycarbonate, have been extensively tested for potential health effects during the years by worldwide research institutes, academic laboratories, governmental institutes and industry. All these tests asserted that there is a low-risk level of migration of BpA from Polycarbonate articles, this risk being below the safety levels set by the government agencies.

#### **Bisphenol A in Visottica Comotec products:**

Visottica Industrie Spa has made several external laboratory tests and the results have remarked that, under normal conditions of use, Polycarbonate components produced and/or commercialized perfectly comply with BpA content limits fixed by European REACH Regulation.

In addition to that, Visottica Industrie Spa wants to underline that Polycarbonate inserts are not in direct and prolonged contact with the skin, since they are embedded into PVC or Silicone nose-pads. This further reduces the risk of migration of Bisphenol A from the Polycarbonate to the skin of the user.

Referring to this last statement, Visottica Industrie Spa wants to clarify that PVC and Silicone raw materials used for the production of its nose-pads do not contain BpA, since this Chemical is not present in their formulation.

With this communication, Visottica Industrie Spa thinks to have clarified all the inquiries on this matter; in any case, Visottica Industrie Spa is fully available to give further information to its customers about Bisphenol A and its possible presence in its articles.

An updated copy of this Informative Note is downloadable from the website [visotticacomotec.com](http://visotticacomotec.com).

Best regards,

**VISOTTICA INDUSTRIE Spa**  
Chief Operations Officer  
Mr. Daniele Angeli

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**Società a socio unico**  
Cap. Soc. € 3.452.540 i.v.  
Registro Imprese  
TV 01531210308  
R.E.A. TV - 275318 - M 044040  
Part.IVA IT03486160264  
Codice Fiscale 01531210308

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