



# Discussion on "Hazardous Substances" Criterion Investigation of Request for Derogation

DRAFT - WORK IN PROGRESS

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# 1 POINT FOR DISCUSSION – DEROGATION REQUESTS

## Methodological approach

In accordance with Paragraph 6 of Article 6 of the Ecolabel Regulation 66/2010, the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures that meet certain specified classification criteria. However, according to Article 6(7) of this Regulation, the Commission may under certain conditions grant derogations from Paragraph 6<sup>1</sup>. Therefore, stakeholders were invited to submit specific reasoned requests for derogation from this criterion.

In this process of development of EU Ecolabel criteria for imaging equipment the JRC-IPTS received the following derogation requests:

1. (1-methylethylidene)di-4.1-phenylenetetraphenyl diphosphate
2. 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol
3. Triphenylphosphine
4. Nickel in Stainless Steel

In addition to the above listed substances a derogation request for Antimony trioxide was submitted to the DG ENV in a later stage. This request does not specifically refer to the development of EU Ecolabel criteria for imaging equipment but is addressed in general for all product groups for which EU Ecolabel criteria are developed. As this request came in the last phase of the development of the EU Ecolabel criteria for imaging equipment, the investigation of this derogation request is still ongoing and thus is not presented in the presented here analysis. this would be possible in a later phase.

The methodological approach regarding the investigation of the request of derogations is carried as follows.

For each substance the following information and data is gathered:

- General physical and chemical properties, functionality of the substance and of the materials in which it is used, and its overall mass or concentration found in the product.
- Health and direct environmental impacts

In this phase scientific information reveals the importance on how the hazardous effects of the substance take place and in what are the potential health impacts. Moreover, potential direct environmental impacts due to the substance are also investigated in this phase.

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<sup>1</sup> According to Article 6(7) of Regulation No 66/2010 on the EU Ecolabel, no derogation from the exclusion in Article 6(6) shall be given concerning substances identified as substances of very high concern (SVHC) and included in the list foreseen in Article 59 of REACH, present in mixtures, in an article or in any homogenous part of a complex article in concentrations higher than 0,1 % (w/w). Specific concentration limits determined in accordance with Article 10 of CLP Regulation No1272/2008 shall apply in case it is lower than 0, 1% (w/w).

- Life cycle considerations and indirect environmental impacts related to the use of this substance are further investigated.

This information indicates/reveals whether the use of the substance raises high environmental concerns along the life cycle of the product, e.g. in stages like production, raw material extraction, recycling, thermal recovery or disposal on a landfill.

- Potential substitutes

In this phase the potential substitutes of this substance are investigated. It is important to identify whether safer – from the health and environmental viewpoint – substances are available. In this phase it can be also considered whether alternative materials can be used, thus preventing the use of the investigated hazardous substance.

Based on the overall information gathered for the given substance and on the decisiveness of each input it is determined whether a derogation shall be granted or not.

In this phase we shall highlight that the aforementioned approach in which these four elements of information are collected has to be adapted to the particular characteristics and case-specific conditions. Depending on what type of substance is investigated one information piece may be more significant than another. For example the life cycle considerations and the indirect environmental impacts are more relevant in the case of chemical additives which are related to the formation of dioxins than the case of Ni in stainless steel for which less significant indirect environmental impacts could be identified in the production or recycling phases.

Another important aspect in this respect is the availability of information. When the investigation covers a broad spectrum of aspects for one specific substance the availability of information cannot be taken for granted. Data gaps can be expected. The lack of data is especially important regarding the question of substitution.

Furthermore, investigating substitutes is in general a complex issue. The potential alternatives shall be evaluated as better options than the requested for derogation substance in order to be characterised/indicated as substitutes. However, this implies that a similar investigation of the potential substitutes (like for the substance of interest) shall be carried out, i.e. including information on health and direct impacts, indirect environmental impacts in a life cycle perspective and functionality of the substances. Furthermore, a detailed investigation on the substitutes shall also contain economic and technical consideration in order to explore if it is feasible in the current conditions to recommend them. Nevertheless, an indication on the potential of the substitution, especially when this is accessible and known, is important and therefore it was included to the appropriate extent in this investigation.

Concluding based on the current knowledge and the availability of information regarding the requests for derogations the investigation conducted covers the following issues:

- What is the function of the substance, how high is its content in the product, in which product's parts it is contained and in which form?
- What are the health impacts of the substance and what is the exposure path. Apart from the health impacts, what other direct environmental concern are of relevance?

- What are the indirect environmental concerns related to the use of this substance in other life cycle phases of the product than the use phase, i.e. dioxin formation during thermal treatment, high environmental impacts in the production phase, etc.
- What are the potential substitutes and whether the use of the investigated substance can be avoided if another material or another technology is applied?

The following sections presents the information collected in the frame of the study together with external expertise received for the above listed substances, requested to be derogated from the hazardous substances criterion.

## 1.1 (1-methylethylidene)di-4.1-phenylenetetraphenyl diphosphate

### 1.1.1 Background information, physical and chemical properties

(1-methylethylidene)di-4.1-phenylenetetraphenyl diphosphate, or also called bis bisphenol A bis(biphenyl) phosphate (BDP), belongs to a group of substances used as flame retardants called aryl phosphates. This is a large group of organophosphorus flame retardants, which includes triphenyl, isopropyl – and t-butylsubstituted triaryl and cresyl phosphates.

Aryl phosphates are used as flame retardants in polycarbonate, polycarbonate blends with acrylonitrile butadiene styrene terpolymer (ABS), and/or styrene acrylonitrile copolymer (SAN) and/or polyester (PET). These materials are applied in imaging equipment for external housing parts (e.g. control panel cover, front, back and side housing panel) with a maximum load of 20 % (w/w).

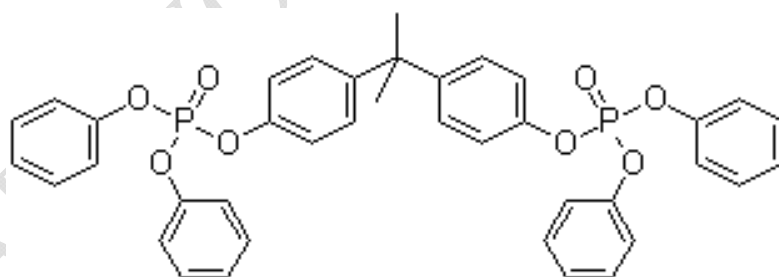


Figure 1 Chemical structure of (1-methylethylidene)di-4.1-phenylenetetraphenyl diphosphate (CAS 5945-33-5 and 181020-79-5), also called Bis phenolA bis (biphenyl) phosphate (BDP)

The physical and chemical properties of BDP are summarised in the Table 1. The respective information sources are given in Table 2.

Table 1 Physical-chemical properties of bisphenolA bis(biphenylphosphate) [CAS5945-33-5]

Property	Value/statement
Physical state at 20 OC) and 101.3 KPa	Solid
Melting point (OC)	41 - 90 °C
Boiling point (OC)	> 400°C
Vapour pressure	20e-3 Pa and 1.33e-3 Pa
Water solubility	2.74e-4 and 7.07e-4 mol/m3
Partition coefficient n-octanol/water (log value)	4.5 or 6
Partition coefficient air/water (log value)	-15.75 to -14.54

Table 2 Reference list for physical/chemical data for bis phenol A bis (biphenylphosphate)

1	Cole, G.J. and Mackay, D., Correlating Environmental Partitioning Properties of Organic Compounds: The Three Solubility Approach, Environmental Toxicology and Chemistry, Vol. 19, No.2, 2000, pp. 265-270,.
2	Dobry, A. and Keller R., Vapor Pressures of Some Phosphate and Phosphonate Esters." The Journal of Physical Chemistry 61(10), 1957, pp. 1448-1449. Karickhoff, S.W., Carreira, L.A., and Hilal, S.H. Sparc On-Line Calculator 4.5. University of Georgia, 2009.
3	Kollig, H.P., Criteria for evaluating the reliability of literature data on environmental process constants. Toxicology and Environmental Chemistry, 1988-17, pp. 287-311.
4	Leisewitz, A., Kruse, H., Schramm, E., Substituting environmentally relevant flame retardants: Assessment fundamentals. Results and summary overview. Environmental research plan of the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Research Report 297 44 542, 2000.
5	Mackay, D., Multimedia Environmental Models. The Fugacity Approach. Second Edition. Lewis Publishers, Boca Raton, 2001.
6	Meylan, W. M. and P. H. Howard, Bond contribution method for estimating henry's law constants." Environmental Toxicology and Chemistry 10(10), 1991, pp. 1283-1293.
7	RSC. ChemSpider – Database of Chemical Structures and Property Predictions. Royal Society of Chemistry, Cambridge, United Kingdom, 2010.
8	SRC. Interactive PhysProp Database (Demo). Syracuse Research Corporation, New York, United States, 2010.
9	U.S. EPA. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency, Washington, DC, USA, 2009.

### 1.1.2 Hazardous properties and health impact

BDP showed no mutagenic (Illinois EPA, 2007; WS Ecological Health, 2006). No incidences of chromosomal aberrations in hamster lung cells were observed (Pakalin et al., 2007). The No Observed Effect Level (NOEL) for developmental effects of rats was high (1000 mg/kg/d). No data on reproduction toxicity was available. Data on carcinogenic activity and reproduction toxicity could not be found.

The degradation products from the chemical components of BPADP are phenol, bisphenol A, and diphenyl phosphate (Maine 2007, Washington State 2006). It is unclear from these references under what conditions and to what extent this degradation into bisphenol A may appear.

The European Union risk assessment report on bisphenol A concluded that this chemical poses the following health effects: “eye and respiratory tract irritation, skin sensitisation, repeat dose toxicity to the respiratory tract, effects on the liver and reproductive toxicity (effects on fertility and on development)”; with the most sensitive effects on aquatic organisms appear to be related to endocrine disruption (European Commission, 2003).

Due to the potential for endocrine disruption by bisphenol A, (BPADP) was scored as high for the endocrine disrupting attribute based on its degradation products. The values for the persistence for CAS RN 83029-72-5 and CAS RN 5945-33-5 were raised from high to very high using the revised thresholds (European Commission, 2003).

The respective information sources are given in Table 3.

Table 3 Reference list for toxicity for bis phenolA bis(biphenylphosphate)

1	European Commission, Joint Research Centre, European Chemicals Bureau, European Union Risk Assessment Report - 4,4'-isopropylidenediphenlo (bisphenol-A), 2003.
2	Illinois Environmental Protection Agency. Report on Alternatives to the Flame Retardant DecaBDE.
3	Evaluation of Toxicity, Availability, Affordability, and Fire Safety Issues A. 2007. Report to the Governor and the General Assembly Illinois Environmental Protection Agency, 2007.
4	Maine, Brominated Flame Retardants: Third annual report to the Maine Legislature. Augusta, Maine: Maine Department of Environmental Protection and Maine Center for Disease Control & Prevention, 2007.
5	Pakalin, S., Cole, T., Steinkellner, J., Nicolas, R., Tissier, C., Munn, S., Eisenreich, S., Review on production processes of decabromodiphenyl ether (decaBDE) used in polymeric applications in electrical and electronic equipment, and assessment of the availability of potential alternatives to decaBDE, European report EUR 22693 EN (2007), Brussel, Belgium. <a href="http://ecb.jrc.it/Documents/Existing-Chemicals/Review_on_production_process_of_decaBDE.pdf">http://ecb.jrc.it/Documents/Existing-Chemicals/Review_on_production_process_of_decaBDE.pdf</a> .
6	Washington State 2006, Department of Ecology and Department of Health, Flame Retardant Alternatives (prepared by Syracuse Research Corporation), February 2006.

### 1.1.3 Direct environmental impacts

The direct environmental impacts are summarised in Table 4 to Table 6.

Table 4 Persistency of bisphenolA bis(biphenylphosphate) [5945-33-5]

Persistence	Data	Reference list in Table 7
High	DT <sub>50</sub> >1 year (pH 4.0, 7.0 & 9.0, 25°C),	[3]
	not ready biodegradable DT <sub>6</sub> =28 days	[6]
High to Low	DT <sub>50</sub> = 1 day - 1 year	[3]
Low	-not specified, primary source not found-	[5]



<sup>1</sup>Italic values are predicted.

Table 5 Bioaccumulation of bis phenol A bis(biphenylphosphate) [5945-33-5]

Bioaccumulation	Data	Reference list in Table 7
High to Moderate	BCF= 360-3000 <sup>1</sup>	[4]
	BCF=3.16 (high log K <sub>ow</sub> =4.5-6 <sup>1</sup> ) <sup>2</sup>	[3]
	- not specified -	[6]
Low	-not specified-	[5]

<sup>1</sup>Italic values are predicted.

<sup>2</sup> As the log K<sub>ow</sub> is 4.5 to 6 it is very unlikely that the BCF is 3.16; it is suspected that the authors meant log BCF=3.16. Because of the high K<sub>pw</sub> the substance is assigned to the category high to moderate bioaccumulativity.

Table 6 Toxicity of bisphenolA bis(biphenylphosphate) [5945-33-5]

Toxicity	Data	Reference list in Table 7
High	acute & chronic (because of bisphenolA breakdown product which is potentially developmentally- and, reproductive toxic, also an endocrine disruptor)	[5]
Presumably Moderate to Low Aquatic Toxicity	Aquatic Algal Inhibition: EC50> 1 mg L <sup>-1</sup> EC50 >100 ppm (mg L <sup>-1</sup> ) Fish: NOEC = 5 mg L <sup>-1</sup>	[2]
	Fish, Daphnia & Algae NOEC >1 mg/L (EC50 exceeds solubility)	[4, 6]
Low Terrestrial Toxicity	Rat: LD50>2000 mg kg <sup>-1</sup> bw	[2, 3, 4, 6]
Insufficient Data	Low aquatic	[2]

<sup>1</sup>Italic values are predicted.

The respective information sources are given in Table 7.

Table 7 Reference list for persistency, bioaccumulation and toxicity of bisphenolA bis(biphenylphosphate)

1	U.K. Environment Agency, et al., Prioritization of flame retardants for environmental risk assessment, UK Environment Agency, 2003, pp. 129.
2	Washington State Department of Ecology and Washington State Department of Health, Washington State Polybrominated Diphenyl Ether (PBDE) Chemical Action Plan: Final Plan, Department of Ecology Publication No. 05-07-048, Department of Health Publication No. 334-079, Olympia, WA, USA, 2006, pp. 307.
3	European Chemicals Bureau, et al., Review on production processes of decabromodiphenyl ether (decaBDE) used in polymeric applications in electrical and electronic equipment, and

	assessment of the availability of potential alternatives to decaBDE, E.C. Bureau, Editor, European Chemicals Bureau, Institute of Health and Consumer Protection, Joint Research Centre, JRC, European Commission: Brussel, Belgium, 2007.
4	Illinois Environmental Protection Agency, Report on Alternatives to the FlameRetardant DecaBDE: Evaluation of Toxicity, Availability, Affordability, and Fire
5	Clean Production Action, M. Rossi, and L. Heine, The Green Screen for SaferChemicals: Evaluating Flame Retardants for TV Enclosures, C.P. Action, Editor, 2007, p. 17.
6	Australian Department of Health and Ageing, Phosphoric acid, (1-methylethylidene) di-4,1-phenylene tetraphenyl ester (Fyrolflex BDP), in National industrial chemicals notification and assessment scheme, NICNAS - Full public reports, A.D.o.H.a.A. (administration), Editor, 2000.

#### 1.1.4 Life cycle considerations for bisphenolA bis(biphenylphosphate)

BDP is added in external housing parts (e.g. control panel cover, front, back and side housing panel) that consist polycarbonate, and polycarbonate blends with acrylonitrile butadiene styrene terpolymer (ABS), and/or styrene acrylonitrile copolymer (SAN) and/or polyester (PET) with a maximum load is 20 % (w/w).

During the product's use phase it is not expected for BDP to be emitted to the environment due to its very low volatility.

Since BDP has very low water solubility and high bioaccumulation potential the environmental fate of the substance is expected to be through particles. Therefore, it is very likely that BDP is emitted through plastic particles during recycling of external housing parts. If the housings are incinerated according to BAT than BDP is irreversible eliminated.

#### 1.1.5 Potential substitutes of bisphenolA bis(biphenyl) phosphate

The issue of alternative flame retardants to BDP is only briefly and indicative presented here. In general, the determination of potential substitutes especially for BDP is considered complex.

Alternative substances which can be used as flame retardants (FR) instead of BDP are indicatively presented In

Table 8. All the presented potential substitutes are non-halogenated aromatic FR applicable to each specific material matrix, where BDP is solely feasible for polycarbonate and its blends.

Also halogenated aromatic flame retardants can be used instead of BDP. However, halogenated aromatic FR can raise various environmental concerns and therefore their use is restricted in the MS Ecolabels.

This thematic is complex and thus addressed and analysed in depth in another part of the work of the development of the Ecolabel criteria for imaging equipment. Hence, for the needs of investigating the derogation requests and in particular the potential substitutes of BDP the halogenated aromatic flame retardants were not be on the focus of this analysis. In general halogenated aromatic flame retardants are not considered to be potential substitutes of BDP which could contribute to improved environmental performance of products.

Question to the stakeholders:

Stakeholders are asked to comment and complement the available information on the substitutes for BDP.

Table 8 Non halogenated Flame retardants commercially used in PC, PC blends, ABS, SAN and PET

Flame retardant Chemical name	CAS RN	Poly carbonate (PC)	Poly carbonate blends (PC/ABS)	Acrylo nitrile butadiene styrene terpolymer (ABS)	Styrene acrylo nitrile copolymer (SAN)	Poly ester (PET)
NON HALOGENATED FLAME RETARDANTS (HFFR)						
Bis phenol A bis (biphenyl) phosphate (BDP)	5945-33-5 and 181020-79-5	X	X			
Boehmite (Aluminiumhydroxide oxide)	1318-23-6	X		X		X
Diethylphosphinate, aluminium salt (with or without synergist <sup>(2)</sup> )	225789-38-8					X
Hypophosphite calcium salt (with or without synergist)	7789-79-9	X	X			
Melamine polyphosphate	218768-84-4					X
Resorcinol bis (diphenyl diphosphate) (RDP)	57583-54-7	X	X			X
Triphenylphosphate (TPP)	115-86-6		X			
Zinhydrostannate (ZnHS)	12027-96-2			X		
Zincstannate (ZnS)	12036-37-2			X		

Source: Pinfa, Table of Flame retardants Product Selector and Regulatory Information (2010)

<sup>2</sup> Synergistic effects mean that two or more components interact in such a way that their effect is greater than each component working separately.

### 1.1.6 Conclusions regarding derogation request of bisphenolA bis(biphenylphosphate)

The assessment of bisphenolA bis(biphenylphosphate) consist of data gaps and contradictory data. Nevertheless, there is enough data that indicates persistency, bioaccumulation and toxicity, as well as endocrine toxic properties for BDP. There are references indicating that BDP is biologically transformed into bisphenolA, which is a known endocrine disrupting substance.

Table 8 above indicates that non halogenated FRs are applicable to each specific material matrix, where BDP is solely feasible for polycarbonate and its blends. Thus, substitutes are considered to be available.

It is important to emphasise that the issue of alternative flame retardants to BDP is complex. Therefore this topic needs to be discussed further with stakeholders during the progress of this study.

Conclusively, applying the precaution principle, it is suggested based on the hazardous properties of bisphenolA bis(biphenylphosphate) it cannot be derogated as requested by the industry.

## 1.2 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol

### 1.2.1 Background information and physical and chemical properties

2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol is mainly used as UV stabilizer in polycarbonate, and polycarbonate blends with ABS, and/or SAN and/or PET that is used in external housing parts (e.g. control panel cover, front, back and side housing panel), internal mechanical parts (e.g. paper guider, knobs, levers) and internal optical parts (e.g. light guide) with maximum load to 0,4 % (w/w) <sup>(3)</sup>.

2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol is added in external housing parts (e.g. control panel cover, front, back and side housing panel) in imaging equipment with a maximum load is 0,4 % (w/w).

Its physical and chemical properties are given in Table 9.

Table 9 Physical and chemical properties of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol

Property	Value/statement
Physical state at 20 °C) and 101.3 kPa	Solid
Melting point (°C)	106 - 108

3 Hazard Characterization Document, "Screening –level hazard characterization sponsored chemicals Phenolic Benzotriazoles Category: 2-(2'-Hydroxy-5'-methylphenyl) benzotriazole (CASRN 2440-22-4), 2-(2'-Hydroxy-5'-octylphenyl) benzotriazole (CASRN 3147-75-9), 2-(2'-Hydroxy-3',5'-di-t-amylphenyl) benzotriazole (CASRN 25973-55-1), 2-(2H-Benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl) phenol (CASRN 70321-86-7), U.S. Environmental Protection Agency September, 2009, available online at: [http://www.epa.gov/chemrtk/hpvis/hazchar/Category\\_Phenolic%20Benzotriazoles\\_Sept2009.pdf](http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Phenolic%20Benzotriazoles_Sept2009.pdf).

Property	Value/statement
Boiling point (°C)	454,6 (estimated)
Vapour pressure	9.8×10 <sup>-9</sup> mm Hg (estimated)
Water solubility (20 °C)	<1 mg/L (measured) 0.274 mg/L (estimated)
Henry's Law Constant	4.45×10 <sup>-13</sup> atm-m <sup>3</sup> /mole (estimated)
Partition coefficient n-octanol/water (log value)	6.2 (estimated)

### 1.2.2 Hazardous properties and health impact

The main data regarding hazardous properties and health impacts of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol are summarised in Table 10.

Table 10 Hazardous properties and health impacts of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol

Property	Value/statement
Acute oral toxicity	Male rats. No mortality was observed. LD50 > 1000 mg/kg-bw
Repeated dose toxicity	Rats. There were no deaths and no effect on body weight or food consumption during the test period. NOAEL = 5658 mg/kg-bw/day (highest dose tested)  Rats. No mortality occurred. LOAEL ~ 40 mg/kg-bw/day (based on blood, liver and kidney effects) NOAEL ~ 20 mg/kg-bw/day
Genetic Toxicity – Gene Mutation	A reverse mutation assay was conducted using <i>S. typhimurium</i> strains TA 98, TA100, TA 1535 and TA 1537 and <i>E. coli</i> . 2-(2'-Hydroxy-5'-octylphenyl) benzotriazole was not mutagenic in this assay.
Reproductive toxicity	No data
Developmental Toxicity NOAEL/LOAEL (mg/kg-bw/day) Maternal Toxicity Developmental Toxicity	No Data NOAEL = 1000 (RA) NOAEL = 1000 (RA)
Genetic Toxicity – Gene Mutation In vitro	Negative
Genetic Toxicity – Chromosomal Aberrations In vivo	No Data Negative (RA)
Carcinogenicity	No data

Source: Hazard Characterization Document, U.S. Environmental Protection Agency September, 2009 [3]

### 1.2.3 Direct Environmental impacts

The main environmental relevant properties of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol are summarised in Table 11 .

Table 11 Main properties and direct environmental impacts of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol

Property	Value/statement
Photo degradation, half -life	4.02 hours (estimated)
Hydrolysis Half-life	Cannot be determined due to low water solubility
Biodegradation	0–1% after 28 days (not readily biodegradable)
Bioconcentration	BCF = $1.21 \times 10^4$ (estimated)
Log $K_{oc}$	6.6 (estimated)
Fugacity (Level III Model)	
Air (%)	$4.0 \times 10^{-5}$
Water (%)	3.5
Soil (%)	44.6
Sediment (%)	51.9
Persistence	High
Bioaccumulation	High

Source: Hazard Characterization Document, U.S. Environmental Protection Agency September, 2009 [3]

### 1.2.4 Life cycle considerations for 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol

2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol is used in imaging equipment in external housing parts (e.g. control panel cover, front, back and side housing panel) with a maximum load of 0,4 % (w/w).

During the product's use phase it is not expected for 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol to be emitted to the environment due to its very low volatility and low load in the imaging equipment.

Since 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol has very low water solubility and high bioaccumulation potential the environmental fate of the substance is expected to be through particles. Due to the low load in housings and similar parts any potential emissions to the environment of this substance are negligible.

Therefore, it is likely that 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol is emitted through plastic particles during recycling of external housing parts. If the housings are incinerated above 500°C then all 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol is irreversibly eliminated.

### **1.2.5 Potential substitution for 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol**

There is no information available regarding potential substitutes. Therefore this topic needs to be discussed with stakeholders during the development of these criteria.

Question to the stakeholders:

Stakeholders are asked to comment and complement the available information concerning the potential substitutes for 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol.

### **1.2.6 Conclusions regarding derogation request of 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol**

Based on the findings presented above it is suggested that 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol may be as requested by the industry.

Additional information regarding alternative stabilizers to 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3,-tetramethylbutyl)phenol could complement the current findings. Stakeholders are asked to complement the available information on this aspect.

## **1.3 Triphenylphosphine**

### **1.3.1 Background information, physical and chemical properties**

Triphenylphosphine (TPP), IUPAC name triphenylphosphane, is a highly efficient intermediate that is used in many applications, including vitamin synthesis, for the production of pharmaceutical active ingredients, crop protection products and coatings, co-catalyst in isobutanol and n-butanol production, initiator of several polymerization reactions and as UV stabilizer in plastics<sup>(4)</sup>.

It is used in plastics such as polycarbonate, and polycarbonate blends with ABS, and/or SAN and/or PET which are applied in external housing parts (e.g. control panel cover, front, back and side housing panel), internal mechanical parts (e.g. paper guider, knobs, levers) and internal optical parts (e.g. light guide) with maximum load to 0,25 % (w/w).

The main physical and chemical properties of triphenylphosphine (TPP) are summarised in Table 12.

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4 <http://www.basf.de/en/intermed/products/triphenylphosphine/>

Table 12 Physical and chemical properties of triphenylphosphine (TPP)

Property	Value/statement	Reference	Comments
Physical state at 20 °C) and 101.3 KPa	Solid Crystalline white	IUCLID dataset 18 <sup>th</sup> February 2000 MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011	
Melting point (°C)	78.5 – 81.5	IUCLID dataset 18 <sup>th</sup> February 2000	
Boiling point (°C)	195 °C – 205 °C at 7hPa  377 °C at 1,013 hPa (760 mmHg)	IUCLID dataset 18 <sup>th</sup> February 2000 MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011	
Relative density (20 °C)	1.194 g/cm <sup>3</sup>	IUCLID dataset 18 <sup>th</sup> February 2000	
Vapour pressure	0.01 hPa at 88 °C 0.1 hPa at 117 °C	IUCLID dataset 18 <sup>th</sup> February 2000	Very low volatility  Remark: Likely with exposure through particles and dust
Water solubility (25 °C)	0.09 mg/L	IUCLID dataset 18 <sup>th</sup> February 2000	Remark: Likely that the substance is bound to particles and dust if released.

### 1.3.2 Hazardous properties and health impact

The main hazardous property of triphenylphosphine are summarised in Table 13.

Table 13 Hazardous properties of triphenylphosphine

Property	Value/statement	Reference	Comments
Partition coefficient n-octanol/water (log value)	4.5  > 2.587 at 25 °C	MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011 IUCLID dataset 18 <sup>th</sup> February 2000	Borderline bioaccumulative



Property	Value/statement	Reference	Comments
Chemical dangers	The substance decomposes on heating producing highly toxic fumes of phosphorus oxides and phosphine. Reacts with strong acids and strong oxidants.	IPCS Inchem ICSC: 0700 Date of Peer Review: April 1994	
Allergy	May cause allergic skin reaction	MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011  Merck chemicals, see link <a href="http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEfVhTI">http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEfVhTI</a>	Not in conflict with requirements for H-statements for the current Ecolabel criteria for similar applications (laptops etc).

### 1.3.3 Direct environmental impacts

The main environmental relevant properties of triphenylphosphine are summarised in Table 14.

Table 14 Main properties and direct environmental impacts of triphenylphosphine

Property	Value/statement	Reference	Comments
Cut off values OSPAR see annex 1.	The substance does not meet the T-acute criterion and the B-criterion is not met either.  The substance is an intermediate used in closed systems and it is therefore not considered to be a risk for the marine environment.  Furthermore, it is not suspected to have endocrine disrupting effects. Based on this the OSPAR Commission concluded to delete the substance from the OSPAR List of Chemicals for Priority Action and to update the List of Substances of Possible Concern accordingly.	OSPAR, See link; <a href="http://www.ospar.org/content/content.asp?menu=00960304100000_000000_000000#350">http://www.ospar.org/content/content.asp?menu=00960304100000_000000_000000#350</a>	The substance is not an environmental hazard under controlled conditions.  The substance is consequently an environmental hazard during unprofessional handling or disposal.

Property	Value/statement	Reference	Comments
Aquatic impact	May cause long-term adverse effects in the aquatic environment.	MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011  Merck chemicals, see link <a href="http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEFvHtI">http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEFvHtI</a>	
Partition coefficient n-octanol/water (log value)	4,5  > 2,587 at 25 °C	MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011  IUCLID dataset 18th February 2000	Borderline bioaccumulative

### 1.3.4 Life cycle considerations for triphenylphosphine

Triphenylphosphine is added in external housing parts (e.g. control panel cover, front, back and side housing panel) with a maximum load of 0,25% (w/w).

During the product's use phase it is not expected for triphenylphosphine to be emitted to the environment due to its very low volatility and low load in the imaging equipment devices.

Since triphenylphosphine has very low water solubility and high bioaccumulation potential the environmental, the fate of the substance is expected to be through particles. Due to the low load in housings and similar parts, any potential emissions to the environment of this substance are negligible.

Therefore, it is likely that triphenylphosphine is emitted through plastic particles during recycling of external housing parts. If the housings are incinerated above 500°C then all triphenylphosphine is irreversibly eliminated.

The information sources about this substance are indicated in Table 15.

Table 15 Reference list for triphenylphosphine

IPCS Inchem, ICSC: 0700, Date of Peer Review: April 1994
MSDS Sigma Aldrich Version 3.2, Revision Date 01/11/2008, Print Date 03/06/2011 MERCK, <a href="http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEFvHtI">http://www.merck-chemicals.com/sweden/triphenylphosphine/MDA_CHEM-808270/p_9HCb.s1LdHwAAAEWouEFvHtI</a>
European Commission, JRC, IUCLID dataset , (18th February 2000)

### 1.3.5 Potential substitution for triphenylphosphine

There is no information available regarding potential substitutes. Therefore this topic needs to be discussed with stakeholders during the development of these criteria.

Question to the stakeholders:

Stakeholders are asked to comment and complement the available information on the available substitutes for triphenylphosphine.

### 1.3.6 Conclusions regarding derogation request for triphenylphosphine

Based on the findings presented it is suggested that triphenylphosphine may be derogated as requested by the industry.

In accordance with the available knowledge the derogation seems substantiated as triphenylphosphine does not pose environmental and health risks if handled under controlled and normal foreseeable conditions.

## 1.4 Nickel in stainless steel

### 1.4.1 Background information for nickel in stainless steel <sup>5</sup>

All stainless steels contain a minimum of 10.5% chromium. At this content level chromium reacts with oxygen and moisture in the environment and form a protective, adherent and coherent oxide film which envelopes its entire surface. This oxide film (known as passive or boundary layer) is very thin, 2-3 nm<sup>6</sup>). The passive layer on stainless steels exhibits a truly remarkable property – when damaged (e.g. abraded), it self-repairs as chromium in the steel reacts rapidly with oxygen and moisture in the environment to reform the oxide layer.

Increasing the chromium content beyond 10.5% confers still greater corrosion resistance. Corrosion resistance may be further improved (providing also a wide range of other properties) by the addition of 8 % or more of nickel.

Regarding other substances, the addition of molybdenum further increases corrosion resistance (in particular, resistance to pitting), while nitrogen increases mechanical strength.

It is important to mention also the effect of Alloying on Structure and Properties. Nickel improves general corrosion resistance and prompts the formation of austenite (i.e. stabiliser). Stainless steels with 8-9% nickel have a fully austenitic structure and exhibit superior welding and working characteristics to ferrite stainless steels. Increasing nickel content beyond 8-9% further improves both corrosion resistance (especially in acids) and workability.

<sup>5</sup> The Stainless Steel Family and Basic Alloy Design, Tony Newson, European confederation of Iron and Steel Industries, May 2010

<sup>6</sup> 1 nanometre = 10<sup>-9</sup> meter

From a regulatory perspective, nickel in stainless steel is the main substance of concern. Chromium is released in the trivalent form, which is not classified as hazardous.

- Nickel (metal) has the following CLP harmonized classifications:-
- Carc. 2 H351 (R45)
- Skin Sens. 1 H317 (R43)
- STOT RE 1 H372

In accordance with the CLP, mixtures containing 1% or more of nickel are classified with the same hazards as nickel metal. Many stainless steels contain nickel as a deliberate alloying addition. The most commonly used stainless steels contain ~10% nickel. However, the range covers 0 – 32% nickel and even many of the so-called nickel-free stainless steels contain up to 1% nickel as an impurity.

In the recent Directive 2009/48/EC on the safety of toys also similar provisions regarding the use of hazardous substances are made as in the case of Article 6(6) of Ecolabel Regulation 66/2010.

It is explicitly stated in this Directive that for the safety of toys new essential safety requirements are adopted. The respective excerpt is given below:

"It is also necessary to adopt new essential safety requirements. In order to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances, in particular substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), and allergenic substances and certain metals, should be subject to careful attention. It is therefore in particular necessary to complete and update the provisions on chemical substances in toys to specify that toys should comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

Therefore, new restrictions on CMR substances, in accordance with applicable Community legislation on the classification, labelling and packaging of substances and mixtures, and on fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. Nickel in stainless steel has proven to be safe, and consequently it is appropriate that it can be used in toys"<sup>(7)</sup>.

Conclusively, for the needs of Directive 2009/48/EC and the safety on toys nickel in stainless steel was regarded to be safe.

#### **1.4.2 Hazardous properties and health impact of nickel in stainless steel**

In this chapter relevant information regarding nickel sensitisation and its release from stainless steel, based mainly on scientific publications, is presented. Nickel sensitisation and release into artificial biological fluids has been tested and verified as presented in more detail later. The release of nickel from stainless steel and the related consequences regarding health and environmental impacts are influenced by several parameters, such as the elemental composition of stainless steel, its grade and its size or surface area. For the needs

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<sup>7</sup> Directive 2009/48/EC on the safety of toys, p. 3 section (21).

of a better readable of this section the reference list regarding nickel in stainless steel is given in Annex 2.2.

The most recent study found, conducted by the Finnish Institute of Occupational Health is the "Review on toxicity of Stainless Steel"<sup>(8)</sup>. In this study it is concluded that: metallic stainless steel is likely to exert very low toxicity. Based on GHS-CLP classification and labelling criteria for mixtures, many stainless steels should be classified as specific target organ toxicants and/or category 2 carcinogens because of their nickel content.

However, available stainless steel specific data provide enough evidence to show that this kind of classification is misleading. In vitro release tests show that the nickel release from stainless steel in artificial lung fluids is substantially lower than from nickel particles due to chromium (III) oxide enrichment at the surface. No classification for target organ toxicity in repeated exposure to stainless steel is proposed. In addition, based on the low dissolution of nickel from stainless steel and that the available stainless steel specific data raised no concerns for carcinogenicity, no classification for carcinogenicity is proposed.

Certain stainless steels with a sulphur addition (for example, AISI 303) may release nickel in artificial sweat at more than 0.5 µg/cm<sup>2</sup>/week. The actual threshold for the induction of nickel allergy is unknown. In the case of sulphurated stainless steels like AISI 303, the risk of skin sensitization after prolonged skin contact is higher.

Therefore, these grades should be considered potentially sensitizing in situations of continuous skin contact. The data presented by the Finnish Institute clearly show that the toxicity of stainless steel cannot be predicted solely on the basis of the bulk concentration of elemental constituents, but that the release of the constituents plays an essential role in the toxicity of stainless steel. This has to be taken into account in the hazard assessment and classification of stainless steel, as indicated above. However, the applicability of a similar approach to other alloys must be considered separately by evaluating the specific properties of the alloy. This demands further studies and validation of release tests for different kinds of alloys.

Moreover, Cross et al. (1999) have carried out a review of nickel sensitisation and the release of nickel from stainless steel. They report that in many of the studies of nickel release from stainless steel into artificial sweat and other biological fluids, such as blood, plasma and saliva, the stainless steel is poorly characterised in terms of grade, elemental composition, size or surface area. Therefore, although nickel release has been demonstrated under various experimental conditions, the results are difficult to interpret.

The most reliable data on the release of nickel from stainless steel comes from the following studies where the stainless steels are fairly well defined.

Haudrechy et al. (1994) showed that particular examples (all containing 0.007% of sulphur or less) of stainless steel grades AISI 304, 316L and 430 released less than 0.03 µg/cm<sup>2</sup>/week of nickel into artificial sweat at pH 4.5. These samples elicited no skin reactions in patients already sensitised to nickel. In contrast, nickel plated samples released around 100 µg/cm<sup>2</sup>/week of nickel and samples of resulphurised stainless steel (AISI 303), containing approximately 0.3% sulphur, released about 1 µg/cm<sup>2</sup>/week of nickel under the same conditions. These samples also elicited positive reactions (96% and 14%, respectively) in clinical patch tests on patients already sensitised to nickel.

The main conclusion of this study was that low-sulphur stainless steels like AISI 304, 316L and 430 showed no evidence of the potential to elicit nickel contact dermatitis in nickel-

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8 Tiina Santonen, Helene Stockmann, Juvala Zitting, Antti Zitting, "Review on toxicity of Stainless Steel" Finnish Institute of occupational health, 2010.

sensitised individuals and, therefore, can be used without any problem in prolonged contact with skin.

The relatively poor resistance of AISI 303 steel to pitting corrosion is a consequence of its sulphur content, which, in combination with manganese, initiates pitting corrosion sites. This pitting corrosion accounts for the elevated levels of nickel release relative to the other steels tested. Therefore, it is suggested that the use of high-sulphur stainless steel (e.g. AISI 303) should be avoided if prolonged skin contact might occur.

Later Haudrechy et al. (1997) followed up their earlier work with a study of stainless steels with an intermediate sulphur content of approximately 0.03%. Three stainless steels complying with the specifications for AISI 304L, AISI 304L + Ca, and AISI 304L + Cu were tested. A low-sulphur AISI 304 and a high-sulphur AISI 303 were used as a reference.

Nickel release tests showed that the three intermediate-sulphur grades released less than 0.3 µg/cm<sup>2</sup>/week in artificial sweat at pH 4.5, and less than the detection limit (0.09 µg/cm<sup>2</sup>/week) at pH 6.6. The high-sulphur AISI 303 released 1.4 µg/cm<sup>2</sup>/week of nickel at pH 4.5 and 0.3 µg/cm<sup>2</sup>/week – at pH 6.6. Clinical patch tests again showed that some (4%) of nickel-sensitised patients reacted to AISI 303, while none reacted to the other grades. Thus, this study confirms that low- and intermediate-sulphur stainless steels (Sulphur content of 0.03%) like AISI 304 and 304L should not elicit contact dermatitis in people already sensitised to nickel, while the high-sulphur grades (S > 0.1%) should be avoided.

In another (unpublished) study by Haudrechy and Pédarrie in 1997, the nickel release of a more extensive range of stainless steels was investigated using the then latest version of prEN 1811<sup>(9)</sup>. The pH of the synthetic sweat was 6.5, the value in the current standard.

These results demonstrate that, under the conditions specified in EN 1811, the nickel release rates of these steels, with the exception of AISI 303, are negligible. Prolonged skin contact with these particular grades of stainless steel (excluding AISI 303) is unlikely to result in skin reactions in nickel-sensitised subjects.

In a short study in 2001 (unpublished), Sheffield Analytical Services were commissioned to carry out the European Standard nickel content and nickel release test methods on twenty samples of AISI 316L stainless steel and twenty samples of gold-plated AISI 316L stainless steel ear piercing post assemblies.

Following the method described in EN 1811, the mean nickel release rate (uncorrected) into artificial sweat was 0.12 µg/cm<sup>2</sup>/week for both the gold-plated and non-coated 316L stainless steel post assemblies. The mean nickel content of the gold-plated and non-coated post assemblies was found to be 10.1% and 9.9%, respectively.

Menné et al. (1987) tested subjects previously sensitised to nickel in a patch-testing study using discs of stainless steel containing 18% chromium, 9% nickel and 70% iron. Nickel release from these discs into artificial sweat was approximately 0.04 µg/cm<sup>2</sup>/week. The subjects were exposed to the discs for 48 hours and the response assessed after 48 and/or 72 hours. Two out of 66 subjects gave a positive response to the stainless steel. The results from this study indicate that the stainless steel tested elicits a weak response from people with prior sensitisation to nickel. Nickel release and patch test results from other nickel alloys, including stainless steel, tested in this study showed the following trend:

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<sup>9</sup> EN 1811, "Reference test method for release of nickel from post assemblies which are inserted into pierced parts of the human body and products intended to come into direct and prolonged contact with the skin", Edition, 2009, <https://www.astandis.at/shopV5/Preview.action;jsessionid=7526CA850994F2FE493CC8A10D2E4824?preview=&dokkey=340252&selectedLocale=en>

Alloys with a nickel release  $>1.0 \mu\text{g}/\text{cm}^2/\text{week}$  elicit a positive skin reaction in  $>50\%$  of subjects with prior sensitisation,

Alloys with a nickel release  $<0.5 \mu\text{g}/\text{cm}^2/\text{week}$  elicit a positive skin reaction in  $<30\%$  of subjects with prior sensitisation.

Other relevant studies confirm or complement the above findings with more details. They are listed in Annex 2.2.

#### **1.4.3 Life cycle considerations for nickel in stainless steel**

Nickel is embedded in the stainless steel and, if handled along the life cycle under foreseeable conditions (i.e. BAT conditions), it is considered that it is not released to the environment. Apart from Nickel's inherent hazardous properties (as described in the previous section) no other significant environmental concern was identified from the life cycle perspective of Ni in Stainless steel.

The steel industry and the metal sector as a whole have well-established recycling markets. All stainless steels produced in the EU (and much of the stainless steel produced globally) rely heavily on the use of steel scrap. In fact, every production batch of stainless steel in the EU contains on average 50% of steel scrap. However, as there are more than 200 commercial grades of stainless steel, the actual percentage of scrap varies from steel grade to steel grade depending upon the level of alloying additions required.

[Question to the stakeholders:](#)

[Stakeholders are asked to comment and complement the available information on the health relevance of the nickel in sulphurised stainless steel, and whether additional provisions in this respect shall be included in the EU Ecolabel criteria](#)

#### **1.4.4 Potential substitution of nickel in stainless steel**

As described above, the passive layer on stainless steels exhibits a remarkable property – when damaged (i.e. abraded), it self-repairs as chromium in the steel reacts rapidly with oxygen and moisture in the environment to reform the oxide layer. Corrosion resistance may be further improved. Further, several properties can be provided by the addition of 8% or more of nickel.

Currently, the available information does not unveil that there is available any substitute for nickel in stainless steel which could ensure comparable properties in the end-product and have less hazard and environmental concerns.

From a more holistic perspective it could be also relevant to address whether there are substitutes of the material as a whole (in this case stainless steel) and not only of the substance (in this case Nickel). But even in this more broad approach a general substitution of stainless steel from another material is not considered feasible.

[Question to the stakeholders:](#)

[Stakeholders are asked to comment and complement the available information on the potential substitutes and its relevance.](#)

#### **1.4.5 Conclusions regarding derogation request for nickel in stainless steel**

In general metallic stainless steel is likely to exert very low toxicity. Nickel in stainless steel was regarded to be safe for the use in toys (Directive 2009/48/EC).

Nonetheless, certain stainless steels with a sulphur addition (for example, AISI 303) may release nickel. The actual threshold for the induction of nickel allergy is unknown. In the case of sulphurated stainless steels like AISI 303, the risk of skin sensitization after prolonged skin contact is higher.

Nickel is embedded in the stainless steel and, if handled along the life cycle under foreseeable conditions (i.e. BAT conditions), it is considered that it is not released to the environment.

Further, the available information does not unveil that there is available any substitute for nickel in stainless steel which could ensure comparable properties in the end-product and have less hazard and environmental concerns.

In conclusion, based on the findings presented it is suggested that Nickel in stainless steel may be as requested by the industry. Considerations are only raised when nickel is used in stainless steel of high-sulphur grades ( $S > 0.1\%$ ).

Questions to the stakeholders:

The stakeholders are asked for their feedback whether derogation for Ni in high sulphur grade stainless steel shall be accepted.



## 2 ANNEXES

### 2.1 Annex additional studies regarding the health impacts of Ni in stainless steel

Lidén et al. (1996) carried out a series of patch-testing experiments using a range of nickel-containing alloys including stainless steel. The study involved 100 nickel sensitized subjects and 20 non-nickel-sensitized subjects acting as controls. The latter subjects were confirmed to be non-sensitive to nickel by patch testing. Three stainless steels were tested: surgical grade ISO 5832) 13-15% nickel AISI 317; 18/8 grade ISO 683 XIII 6.5-9.5% nickel AISI 304; and stainless steel SS 142382, <0.5% nickel (probably a martensitic or ferritic stainless steel).

A gold-plated version of the 18/8 stainless steel was also tested. Samples were applied to the upper back of each subject for 48 hours and the skin response was assessed after the third day. The three stainless steels were negative in all nickel-sensitized and non-nickel-sensitive subjects. The gold-plated stainless steel gave 4 positive responses out of 100 but was not statistically significant. The three stainless steels were then tested in 20 of the nickel-sensitive subjects by using the ear lobe as the exposure site over a 7-day period. No positive responses occurred with any of these stainless steels. This study also investigated the types of objects that had caused dermatitis, as reported by nickel-positive subjects. Eighty-eight per cent had had their ears pierced, but only 23% of these suspected that they had been sensitized to nickel in the same year as their ears were pierced. Sixty-one per cent suspected sensitization one or more years after ear piercing, and 12% one or more years before. Four per cent were uncertain when sensitization occurred.

Räsänen et al. (1993) investigated nickel sensitivity in a group of nine volunteers who had had their ears pierced using 'stainless steel' ear piercing kits. The subjects, all females, had no reported history of nickel sensitivity, although this was not confirmed by patch testing before ear piercing. The subjects were monitored for symptoms of sensitization after ear piercing and were patch tested. Six of the females exhibited symptoms of itching, swelling or discharge within one to three weeks of piercing and gave positive responses to nickel in patch tests. The nine ear-piercing kits were tested for nickel release in plasma and distilled water. The highest nickel release occurred in plasma, although displaying wide variability, i.e. 0.03 – 104 µg/cm<sup>2</sup>/week. The maximum nickel release in distilled water was 1.39 µg/cm<sup>2</sup>/week.

In a subsequent communication (Fisher 1994), it was reported that although the ear piercing kits were all made of stainless steel, four of these were plated with gold with a layer of nickel underneath the gold. Three of the females using the gold-plated ear piercing kits showed local symptoms and patch tested positive to nickel. Because the subjects were not checked to confirm non-sensitivity to nickel before the start of the study, and because the chemical composition of the kits is not clear, this study does not allow any conclusions to be drawn regarding the potential of stainless steel to induce sensitization.

Cross et al. (1999) also reviewed a number of case-reports which have reported health effects in individuals who have received surgical or dental prosthetic devices made of stainless steel. Overall, it was considered these studies provide no reliable information on which to assess the potential of stainless steel to elicit allergic responses or induce sensitization. However, given the large number of people who are exposed to stainless steel by way of surgical implants, it is notable that so few case-reports of suspected sensitization are available.

Ingber et al. (paper submitted for publication) have recently carried out a study to investigate whether stainless steel ear-piercing post assemblies elicit an allergic response in nickel sensitive subjects. Twenty-three female and two male subjects, known to be nickel-sensitive by patch testing, had their ears pierced using AISI 316L stainless steel ear piercing post assemblies. The subjects were examined on day 7, 14, 30 and 42, and none showed any evidence of contact dermatitis during the six weeks of the study. Seven of the post assemblies were selected at random and tested for nickel content and nickel release into artificial sweat. The nickel content of the post assemblies ranged from 11.5% to 12.9% and the nickel release was below the detection limit [assumed to be 0.05  $\mu\text{g}/\text{cm}^2/\text{week}$ (uncorrected)].

Samitz and Katz (1975) examined nickel release from stainless steel prostheses and other surgical accessories into various biological fluids. The objects were immersed in physiological saline, sweat, whole blood or plasma for one week at room temperature. The lowest concentrations of nickel were measured in plasma, which gave a range of results from 'not detected' (n.d.) to 1.0 ppm, and the highest concentrations in sweat (range n.d. -99 ppm). Nickel levels in saline ranged from 'not detected' to 9.8 ppm; and in whole blood 'not detected' to 17.4 ppm. The detection limit was 1.0  $\mu\text{g}$  (which is estimated to correspond to a release rate of about 0.5  $\mu\text{g}/\text{cm}^2/\text{week}$ ). With some items tested, the type of steel was reported (AISI 302, 303 or 316L). The study shows that, under the conditions of this experiment, detectable amounts of nickel are released into biological fluids from stainless steel. However, there was insufficient information to allow the variation between different biological fluids to be explored.

## 2.2 Annex Reference list for Nickel in Stainless Steel

### Reference list for Nickel in Stainless Steel

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