

Declaration of Compliance

For articles intended to come into contact with food

Identity and trade name of the article(s)

Item No	Name	Colour	Material
3191090	SmartStore™ Pro 15	Black / Orange	PP
3193090	SmartStore™ Pro 31	Black / Orange	PP
3196090	SmartStore™ Pro 45	Black / Orange	PP
3191010	SmartStore™ Pro 15	White / Blue	PP
3193010	SmartStore™ Pro 31	White / Blue	PP
3196010	SmartStore™ Pro 45	White / Blue	PP
3195010	SmartStore™ Pro 15 w inserts		PP
3523513	SmartStore Pro 15 insert	Orange	PP
3190090	SmartStore™ Pro 15 w inserts	Black / Orange	PP
3196269	SmartStore™ Pro 45	Black / Orange	PP

We hereby declare, on behalf of Orthex Group Ab and its subsidiaries, Suomalaistentie 7, FI-02270 Espoo, that the product(s) mentioned above comply (ies) with the provisions of:

- Framework Materials and Articles Intended to Come into Contact with Food Regulation (EC) No 1935/2004, as amended
- Plastic Materials and Articles Intended to Come into Contact with Food Regulation (EU) No 10/2011, as amended.

Plastic materials and articles are produced in accordance with Good Manufacturing Practice for Materials and Articles Intended to Come into Contact with Food Regulation (EC) No 2023/2006

When used as specified, the overall migration, as well as the specific migration of the substances listed below (where applicable), do not exceed the legal limits. The testing was performed according to Regulation (EU) No 10/2011 (Annex V).

None of the substances in this/these product(s) are classified as dual-use substances.

A functional barrier made from plastic is not used in the above mentioned product(s).

The following substances are used and subject to restrictions and/or specifications under Regulation (EU) No 10/2011:

Name of substance	CAS no.	Restriction
N/A		

Specification of the intended use or restrictions:

- Type of food or process for which the material is suitable:
All
- Type or types of food or processes for which the material is not suitable:
Max 100° C Min -40° C
- Test conditions:
40° C 10 days
100° C 2 h

Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article: 1 dm²/L



Peter Ottosson

Factory Manager

Signature

Name

Job title

July 5, 2020

Tingsryd

Date

Place

Manufacture site / Issuer:

Orthex Group

☐ Orthex Sweden AB
Gnosjö

☒ Orthex Sweden AB
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☐ Oy Orthex Finland Ab

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03.08.2020

Report No. 0003332333/30 AZ 381650-1/2

Test item: Storage box black

Identification: Storage box with lid, black SmartStore Pro 15
Material: PP
Item no.: TBA
Material no.: 42822

Condition at delivery: No claim, Test item without sales packaging

Date of delivery: 15.07.2020

Place of testing: Cologne

Test period: 16.07.2020 to 03.08.2020

Test scope: Parameters selected by customer

Test specification: § 31 LFGB (German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch)
French DGCCRF, French LOI n° 2012 1442

Test result: Pass - According to the kind and extent of tests performed the test item meets the requirements of the test specification.

Cologne, 03.08.2020

X 

Sachverständige(r)/Expert
Signiert von: Andrea Collmann

X 

Sachverständige(r)/Expert
Signiert von: Klaus Kaiser

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Photo documentation

Picture 1: Storage box black



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List of materials

Article	Article name
1	Storage box black

Mat.No.	Article	Component	Material	Colour
001	1	basic material	polypropylene	black

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Results

Sensory analysis

Sample No.	381650-001				
Sample composition	Mat. 001				
Unit	.				
Organoleptic test					
Contact medium	H2O				
Test conditions	10 d, 40°C				
Migration preparation	1,18dm²/200 ml				
Smell transfer	0				
Transfer of taste	0,5				

H2O water

If the evaluation is between 0 to 2.5 no sensory deviation is indicated and the sample fulfils the requirements of § 31 LFGB respectively article 3 of the regulation (EC) 1935/2004 (61. Mitteilung Bundesgesundheitsbl. - Gesundheitsforsch - Gesundheitsschutz 46 (2003) 363).

Evaluation scheme:

- 0 = no perceptible difference
- 1 = just perceptible difference (still difficult to define)
- 2 = slight difference
- 3 = marked difference
- 4 = strong difference

Overall migration

Sample No.	381650-002				
Sample composition	Mat. 001				
Unit	mg/dm²				
Conditions of migration acetic acid 3%	10 d, 40°C				
Migration preparation	1,10dm²/180 mL				
Overall migration	<2				

Sample No.	381650-003				
Sample composition	Mat. 001				
Unit	mg/dm²				
Conditions of migration 95%-EtOH	10 d, 40°C				
Migration preparation	0,60dm²/100 mL				
Overall migration	5				

Limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and if applicable amendments:

Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²).

By derogation from this, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC and 2006/125/EC, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

This limit is also relevant for articles where a calculation of the surface to volume ratio cannot be determined exactly.

If not further specified the 1st migrate is reported.

* Acc. to. EN 1186 the following analytical tolerances have been observed:

20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes.

6 mg/kg or 1 mg/dm² in migration tests using the aqueous simulant.

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Migration of heavy metals, plastic

Sample No.	381650-005				
Sample composition	Mat. 001				
Unit	mg/kg food simulant				
Soluble heavy metals					
Migration solution	3 % HAC				
Conditions of migration	10 d, 40°C				
Migration preparation	1,10dm ² /180 mL				
Barium	<0,3				
Cobalt	<0,01				
Copper	<1				
Iron	<5				
Lithium	<0,1				
Manganese	<0,05				
Zinc	<1				
Aluminium	<0,2				
Lead	<0,07				
Nickel	<0,01				

3 % HAC

3 % acetic acid

Limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011, DM/4B/COM/003 and if applicable amendments:

Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Aluminium = 1 mg/kg Lebensmittel oder Lebensmittelsimulanz.

Barium = 1 mg/kg food or food simulant,

Cobalt = 0,05 mg/kg food or food simulant,

Copper = 5 mg/kg food or food simulant,

Iron = 48 mg/kg food or food simulant,

Lithium = 0,6 mg/kg food or food simulant,

Manganese = 0,6 mg/kg food or food simulant,

Zinc = 5 mg/kg food or food simulant.

Nickel = 0,02 mg/kg food or food simulant.

Limits for colored products in contact with foodstuffs according French DM/4B/COM/003 and if applicable amendments:

Colored plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Barium = 1 mg/kg food or food simulant,

Lead = 0,07 mg/kg food or food simulant,

Nickel = 1 mg/kg food or food simulant.

If not further specified the 1st migrate is reported.

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Color migration of pigmented plastics

Sample No.	381650-006				
Sample composition	Mat. 001				
Unit	.				
Colour fastness					
Water	pass				
3% Acetic acid	pass				
50% Ethanol	pass				
Coconut oil	pass				

According to the recommendation of the BfR part IX "Farbstoffe zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände", "Kunststoffe im Lebensmittelverkehr" (synthetic material in contact with food) respectively Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food, no traces of colour may migrate into the food simulant.

*at silicone vegetable oil

Bisphenol-A, extractable

Sample No.	381650-010				
Sample composition	Mat. 001				
Unit	mg/kg				
Bisphenol-A	<0,1				

Limit in France acc. to LOI n° 2012-1442: <0,1 mg/kg

Metals, total content at decomposition

Sample No.	381650-009				
Sample composition	Mat. 001				
Unit	mg/kg				
Cadmium	<5				
Lead	<5				

Requirements for cadmium according to Regulation (EC) No 1907/2006 Annex XVII entry 23 (including amending regulations):

- Articles and mixtures of plastics < 0.01% (100 mg/kg)
- Coated / painted articles < 0.1% (1000 mg/kg)
- Jewelry components < 0.01% (100 mg/kg)
- Paints and varnishes (excluding the applicable exemptions) < 0.01% (100 mg/kg)

Legal limit value for lead in jewellery according to Regulation (EC) No. 1907/2006 Annex XVII incl. amendment by Regulation (EU) No. 836/2012: 500 mg/kg.

This limit value does not apply to crystal glass according to annex I (list of crystal glass categories 1, 2, 3 and 4) of the directive 69/493/EEC.

Consumer products which under normal and foreseeable conditions of use be placed in the mouth by children:

Limit value for lead according to Regulation (EC) No. 1907/2006 Annex XVII incl. amendment by Regulation (EU) No. 628/2015: <500 mg/kg.

This limit value does not apply to articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight.

That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article does not exceed 0,05 µg/cm² per hour (equivalent to 0,05 µg/cm²/h) and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

Requirement according to Regulation (EC) No. 1907/2006 (REACH):

Duty to communicate on SVHC, if the concentration of elementary lead or cadmium in the article is higher than 0.1 % (m/m).

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Nonylphenol, content

Sample No.	381650-007				
Sample composition	Mat. 001				
Unit	mg/kg				
Nonylphenol	<5				

Plasticizer, screening

Sample No.	381650-011				
Sample composition	Mat. 001				
Unit	%				
Plasticizer-screening					
Bis-(2-ethylhexyl)phthalate, DEHP	<0,01				
Dibutylphthalate, DBP	<0,01				
Benzylbutylphthalate, BBP	<0,01				
Diisononylphthalate, DINP	<0,01				
Diisodecylphthalate, DIDP	<0,01				
Di-n-octylphthalate, DNOP	<0,01				
Dimethylphthalate, DMP	<0,01				
Diethylphthalate, DEP	<0,01				
Butyl-i-butylphthalate	n.n.				
Trimethylpentandiolisobutyrate, TXIB	<0,01				
Diisononyladipate, DINA	n.n.				
Acetyl tributyl citrate, ATBC	<0,01				
Diethylhexyladipate, DEHA	<0,01				
Hexamoll®	<0,01				
Mesamoll®	<0,01				
Triphenylphosphate (TPP)	<0,01				
Tri-o-kresylphosphate	<0,01				
Tri-m-kresylphosphate	<0,01				
Tri-p-kresylphosphate	<0,01				
Butyl benzoate	<0,01				
Di(propylene glycol) dibenzoate, DPGDB	<0,01				
Di(ethylene glycol) dibenzoate, DEGDB	<0,01				
Tri(ethylhexyl)trimellitate, TOTM	<0,01				
2-Ethylhexyl diphenyl phosphate	<0,01				
1,2-Benzenedicarboxylic acid, di-C6 -8-branched alkyl esters, C7-rich, DIHP	n.n.				
1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl ester, DHNUP	n.n.				
Diisooctylphthalate	n.n.				
Diisobutylphthalate, DIBP	<0,01				
Di-n-pentylphthalate, DnPP	<0,01				
Diisopentylphthalate DiPP	n.n.				
n-Pentyl-isopentyl phthalate, PiPP	n.n.				
Bis-(2-methoxyethyl) phthalate, BMEP	<0,01				

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Diethylhexylterephthalate, DEHT	<0,01				
Bis(2-n-butoxyethyl)phthalate, BBEP	<0,01				
Diallyl phthalate	<0,01				
Dicyclohexylphthalate, DCHP	<0,01				
Bis-(3,5,5-trimethylhexyl) phthalate	n.n.				
Di-n-butyl maleate, DBM	<0,01				
Di-(2-ethylhexyl) maleate	<0,01				
Butyl stearate	<0,01				
Dimethyl adipate	<0,01				
Dibutyl adipate	<0,01				
Diisodecyl adipate	<0,01				
Dicapryl adipate	n.n.				
Di(2-(2-butoxyethoxy)ethyl) adipate	<0,01				
Bis(2-butoxyethyl) adipate	<0,01				
Stearylstearat	n.n.				
Dipropylphthalate, DPP	<0,01				
Di-n-hexyl phthalate, DnHP	<0,01				
Di-n-heptyl phthalate	<0,01				
Di-n-nonyl phthalate, DnNP	n.n.				
Di-n-decyl phthalate	n.n.				
Di-n-undecyl phthalate	n.n.				
Diisoundecylphthalate, DIUP	n.n.				
Di(2-propylheptyl)phthalate, DPHP	n.n.				
Divinyladipat	n.n.				

n.n. Not detectable

Requirements according to REACH-regulation no. 1907/2006/EC Annex XVII:

- Entry 51: General ban (sum < 0.1 %) on DEHP, DBP, BBP and DIBP in toys and childcare articles
- Entry 52: Prohibition (sum ≤ 0.1 %) of DINP, DIDP and DNOP in toys and childcare articles that can be placed in the mouth

Requirement according to the toy safety-directive 2009/48/EC:

Prohibition of the use of CMR substances (categories 1A, 1B and 2) above the concentration of the respective classification limit according to CLP-regulation no. 1272/2008/EC. Several phthalates are classified as reprotoxic category 1B (H360D: "May damage the unborn child.") the generic concentration limit therefore is 0.3 % (3.000 mg/kg).

Requirement according to the recommendation XLVII of the German federal institute for risk assessment (BfR):

Toys for children under 36 months or toys intended to be taken into the mouth must comply with the requirements applicable for foodstuff and consumer goods. Only softeners from the positive list according to Regulation no. 10/2011/EC may be used.

Following REACH-regulation no. 1907/2006/EC Annex XVII entries 51 + 52 only those substances are regarded that are present in amounts of > 0.1 % in the plasticized material.

Evaluation:

a) Allowed softeners with SML ≥ 60 mg/kg

DEHT, Hexamoll®, ATBC and Butylstearat are allowed for use in food contact materials. According to our testing experience, exceeding of this limit is not to be expected (when using the testing conditions laid down in BfR-recommendation XLVII).

b) Allowed Softeners with SML < 60 mg/kg

Mesamoll®, DEHA, TXIB and 2-ethylhexyldiphenyl phosphate are allowed for use in food contact materials. Nevertheless their specific migration limits (SML) are relatively low. A final assessment requires verification of compliance with the migration limits in form of an additional test.

c) Not listed softeners

are not allowed for use in food contact materials. Low contents up to 0.1 % can be tolerated, for higher contents the BfR-requirements are not to be regarded as fulfilled.

The use of DPHP in toys and other children's products is not regarded as acceptably safe by the German federal institute for risk assessment (BfR). Therefore, the exposition of children to DPHP from these articles should be reduced and alternative softeners should be used instead. Low contents of up to 0.1 % can be tolerated; for higher contents the BfR requirements must be regarded as not fulfilled.

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Requirements for toys with electrical function according to RoHS-Directive no. 2011/65/EU, Annex II: DEHP, DBP, BBP, DIBP each $\leq 0.1\%$

Duty to communicate according to REACH-regulation no. 1907/2006/EC for SVHC-phthalates if the concentration in the article is higher than 0.1% (1.000 mg/kg).

DEHP (CAS 117-81-7), DBP (CAS 84-74-2), BBP (CAS 85-68-79), DIBP (CAS 84-69-5), DIHP (CAS 71888-89-6), DHNUP (CAS 68515-42-4), BMEP (CAS 117-82-8), DnPP (CAS 131-18-0), PiPP (CAS 776297-69-9), DiPP (CAS 605-50-5), DnHP (CAS 84-75-3), DCHP (CAS 84-61-7), 1,2 benzenedicarboxylic acid, dipentylester branched and linear (CAS 84777-06-0), 1,2 Benzenedicarboxylic acid, dihexylester, branched and linear (CAS 68515-50-4), 1,2 Benzenedicarboxylic acid, di C6 10 alkyl esters (CAS 68515-51-5 resp. CAS 68648-93-1)

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Polycyclic aromatic hydrocarbons (PAH)

Sample No.	381650-008				
Sample composition	Mat. 001				
Unit	mg/kg				
Category *	FCM				
Acenaphthylene	<0,2				
Acenaphthene	<0,2				
Fluorene	<0,2				
Phenanthrene	<0,2				
Anthracene	<0,2				
Fluoranthene	<0,2				
Pyrene	<0,2				
Total 7 PAH	n.n./n.d.				
Naphthalene	<0,2				
Indeno(1,2,3-cd)pyrene	<0,2				
Benzo(ghi)perylene	<0,2				
Benzo(a)anthracene	<0,2				
Chrysene	<0,2				
Benzo(b)fluoranthene	<0,2				
Benzo(j)fluoranthene	<0,2				
Benzo(k)fluoranthene	<0,2				
Benzo(e)pyrene	<0,2				
Benzo(a)pyrene	<0,2				
Dibenz(ah)anthracene	<0,2				
Total 18 PAH	n.n./n.d.				

n.n./n.d. not detectable

* Assessment of the results according to "Testing and evaluation of Polycyclic Aromatic Hydrocarbons (PAH) at granting of the GS-sign", AfPS GS 2014:01 PAK (issue 04.08.2014)

Category 1 - Materials intended to be put in mouth or materials for toys intended to come into contact and with prolonged contact with the skin (longer than 30 s).

Category 2 - Materials not covered by category 1 with foreseeable contact to skin for longer than 30 seconds (long term skin contact) or repeated short term skin contact.

Category 3 - Materials not covered by category 1 or 2 with foreseeable contact to skin up to 30 seconds (short term skin contact).

Limit values:

Benzo(a)pyrene, Benzo(e)pyrene, Benzo(a)anthracene, Benzo(b)fluoranthene, Benzo(j)fluoranthene, Benzo(k)fluoranthene, Chrysene, Dibenz(ah)anthracene, Benzo(ghi)perylene, Indeno(1,2,3 cd)pyrene

Category 1: <0.2 mg/kg each

Category 2: <0.5 mg/kg each

Category 3: <1 mg/kg each

Naphthalene

Category 1: <1 mg/kg

Category 2: <2 mg/kg

Category 3: <10 mg/kg

Sum of Acenaphthylene, Acenaphthene, Fluorene, Phenanthrene, Pyren, Anthracene and Fluoranthene respectively all 18 PAH each

Category 1: <1 mg/kg

Category 2: <10 mg/kg

Category 3: <50 mg/kg

Limit for 8 EU-PAHs (grey indicated substances) in rubber or plastic components of articles according to Regulation (EC) No. 1907/2006, Annex XVII, (effective from 27.12.2015):

- 1 mg/kg per substance for parts of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use

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- 0.5 mg/kg per substance for toys and childcare articles

** FCM: For any material in contact with food, Polycyclic Aromatic Hydrocarbons (PAHs) are restricted to use, either by framework Regulation (EC) No 1935/2004 article 3 or Regulation (EU) No 10/2011 Annex I (Positive list).

If being analyzed that PAH (< 0.2 mg/kg) are not present in the materials with food contact, the risk of a release of PAH under normal and foreseeable condition onto the food simulant is negligible. However, by any positive detection of any PAH above the threshold limit by total content test, a migration test is necessary.

Summary of methods

Sensory analysis	Standard: DIN 10955	Issue date: 01.06.04
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Method description:

Sensory analysis - Testing of container materials and containers for food products (Commodities), test according to: clause 11.6.3 letter c)

Overall migration	Standard: DIN EN 1186 ff.	Issue date: 01.07.02
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Method description:

According to: Determination of global migration after repeat determination from plastic materials and articles intended to come into contact with foodstuffs

Migration of heavy metals, plastic	Standard: MS-0022823*	Issue date: 10.03.20
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Method description:

Determination of metals in plastic after migration under specified conditions according to Regulation 10/2011 (EC) under consideration of all effective transitional rules. Quantification by ICP-OES according to DIN EN ISO 11885 respectively ICP-MS according to DIN EN ISO 17294-2

Notes:

* in-house working instruction

Color migration of pigmented plastics	Standard: BGESUNDHBL 15 (1972): 285	Issue date: 01.07.72
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Method description:

Examination of plastics - 24. Recommendation of the BfR commission for plastics: Testing of colour fastness of coloured commodities made of plastics and other polymers

Bisphenol-A, extractable		
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Method description:

Determination of bisphenol A, DGCCRF-method, extraction with acetonitrile, quantification by LC-MS/MS

Metals, total content at decomposition	Standard: MS-0022823*	Issue date: 10.03.20
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Method description:

In-house method - Determination of heavy metals after decomposition according to EPA 3052, quantification by ICP-OES according to DIN EN ISO 11885 respectively ICP-MS according to DIN EN ISO 17294-2

Notes:

* in-house working instruction

Nonyphenol, content	Standard: DIN EN ISO 18857-1	Issue date:
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Method description:

In-house method - Determination of alkylphenols in articles with food contact after solvent extraction, quantification by GC-MS

Plasticizer, screening		
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Method description:

In-house method - Determination of plasticizers after extraction with organic solvent, quantification by GC-MS

Notes:

Reporting limit for all quantifiable compounds 0.025 %. Not quantifiable compounds e.g. technical mixtures or isomers are marked with *. The indication of results for non quantifiable compounds is d = detected. In the report only the quantifiable respectively detected compounds are stated, however all listed compounds are analysed.

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Polycyclic aromatic hydrocarbons (PAH)	Standard: AfPS GS 2014:01 PAK	Issue date: 04.08.14
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Method description:

Harmonized Method for Determination of Polycyclic Aromatic Hydrocarbons (PAH) in polymers, gas chromatographic method with mass spectrometric detection. Limit of determination 0,2 mg/kg per component

Notes:

Single components with an amount of < 0.2 mg/kg were not considered by the calculation of the sum. In the case of all PAH were not detected, the result is stated n.n. (not detectable).

----End of report----