

Analysis Certificate

Version: 001

Project Number: 17/EA/06/23A
Date received: 20th June 2017
Purchase order: 135291

Client: Gwalia Healthcare Ltd.
Subject: E1186-15:2002 LDPE Drinking Bottle compliance testing

1815-20-401810-
55-401814-20-02
1814-20-401814-
20-701815-20-40

Introduction:

Gwalia Healthcare Ltd. Offer bespoke manufacturing and such Edwards' Analytical were appointed to test LDPE drinking bottle compliance to EN1186 food contact standards.

SAMPLE	Sample details:
A	QTY x 10 of 750ml LDPE drinking bottles

Methods of Analysis:

The samples were tested in accordance with EN1186-15:2002.

- FTIR confirmation of polymer type.
- Determination of extracted substances.

Results:

The results are detailed on pages 2 through to 9 of this report.

Conclusion:

Based upon the samples provided at the time of testing the LDPE bottles were found to be within the EN1186-15:2002 test limit of 10mg/dm² and therefore are compliant.

Certificate

Author:

W S Cullen

01 August 2017

W S Cullen

Business Manager

Certificate

Authorised:

J H Edwards

01 August 2017

J H Edwards

Quality Manager

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Pertaining Worksheets:

WS 13413

To

WS13416

Edwards' Analytical contract laboratory is considered to comply with the principles of Good Manufacturing Practice as detailed in Directive 2003/94/EC.



Edwards Analytical



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Results:

FTIR confirmation of polymer type.

Each Sample was tested in triplicate.

Figure 1 illustrates the FTIR spectrum for LDPE reference material.

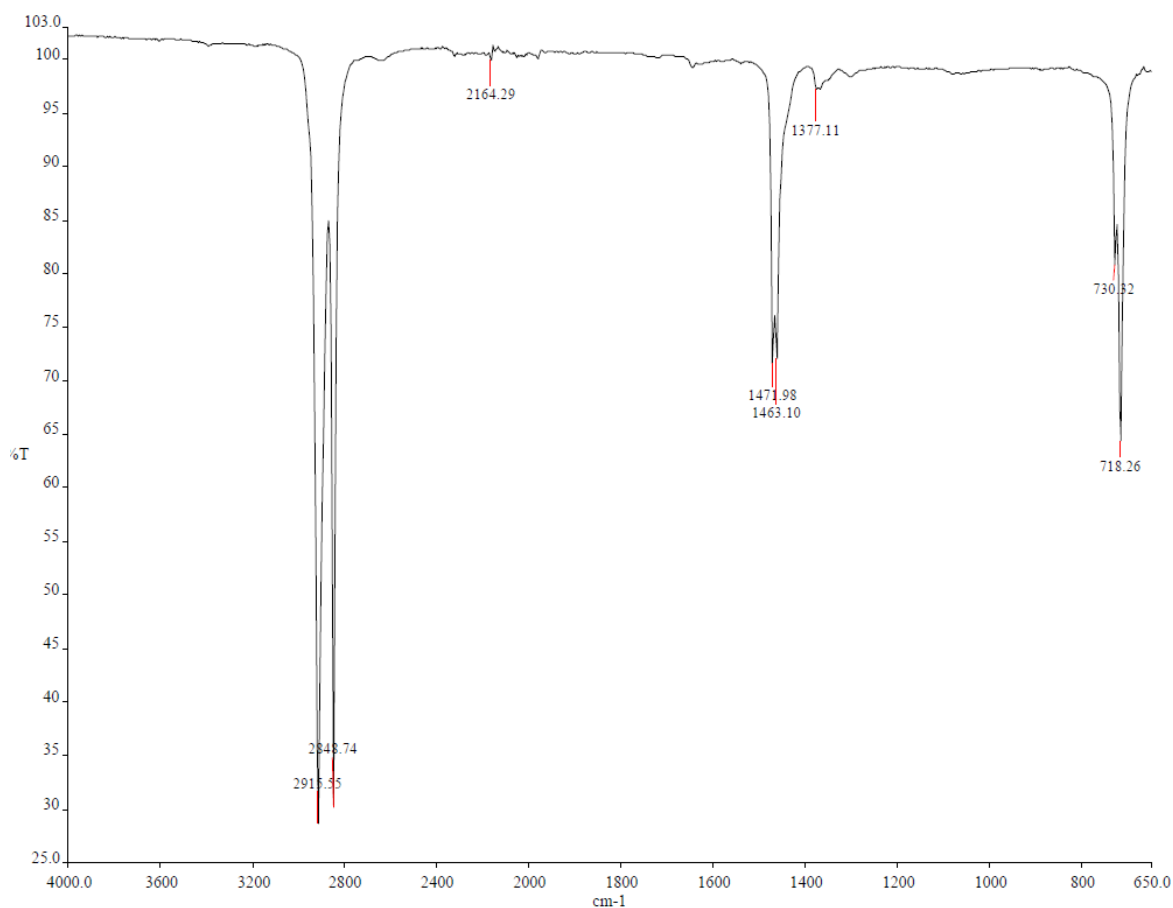




FIGURE 1: LDPE reference material FITR spectrum.

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Figure 2 illustrates the FTIR spectrum for Sample A, the drinking bottle.

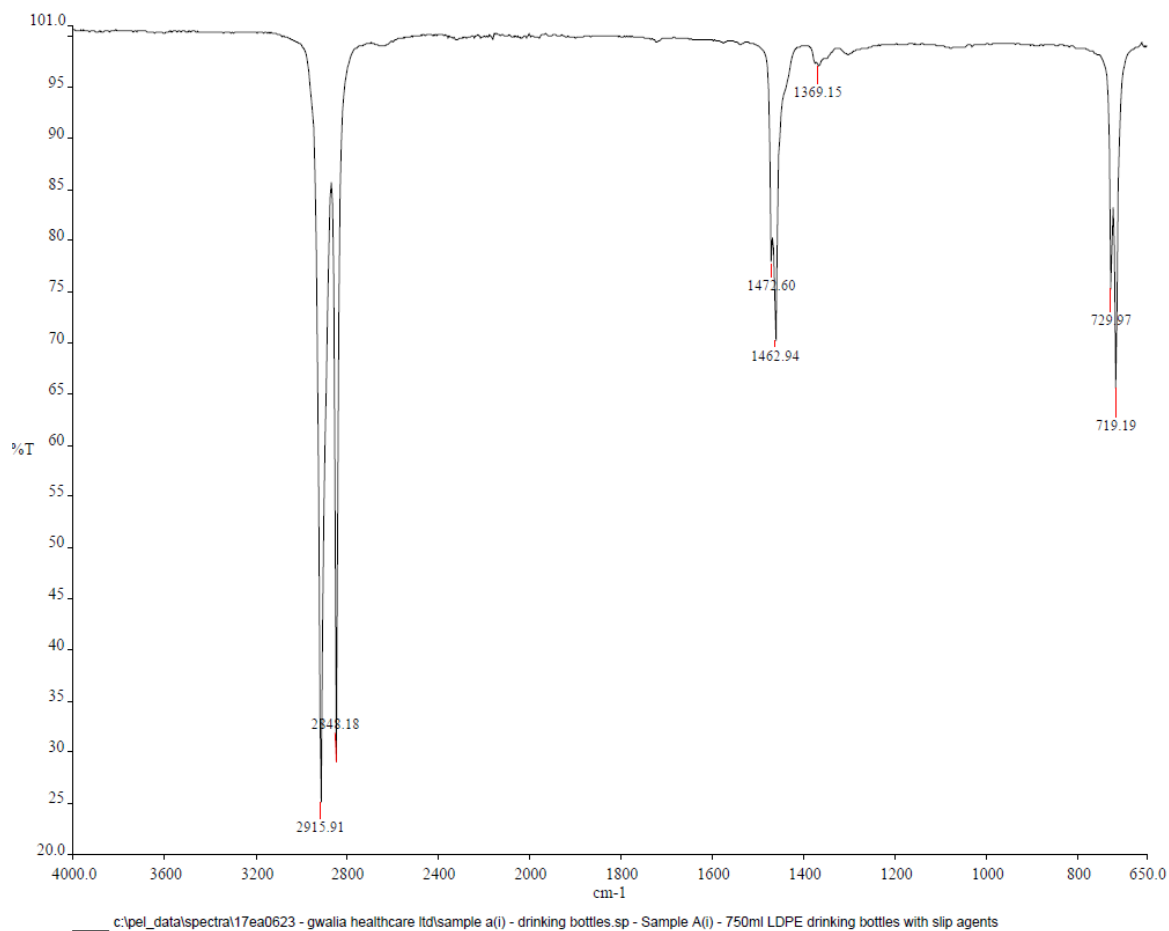


FIGURE 2: Sample Ai, Drinking bottle FITR spectrum.

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Figure 3 illustrates the FTIR overlay for the LDPE reference material and Sample Ai, the drinking bottle.

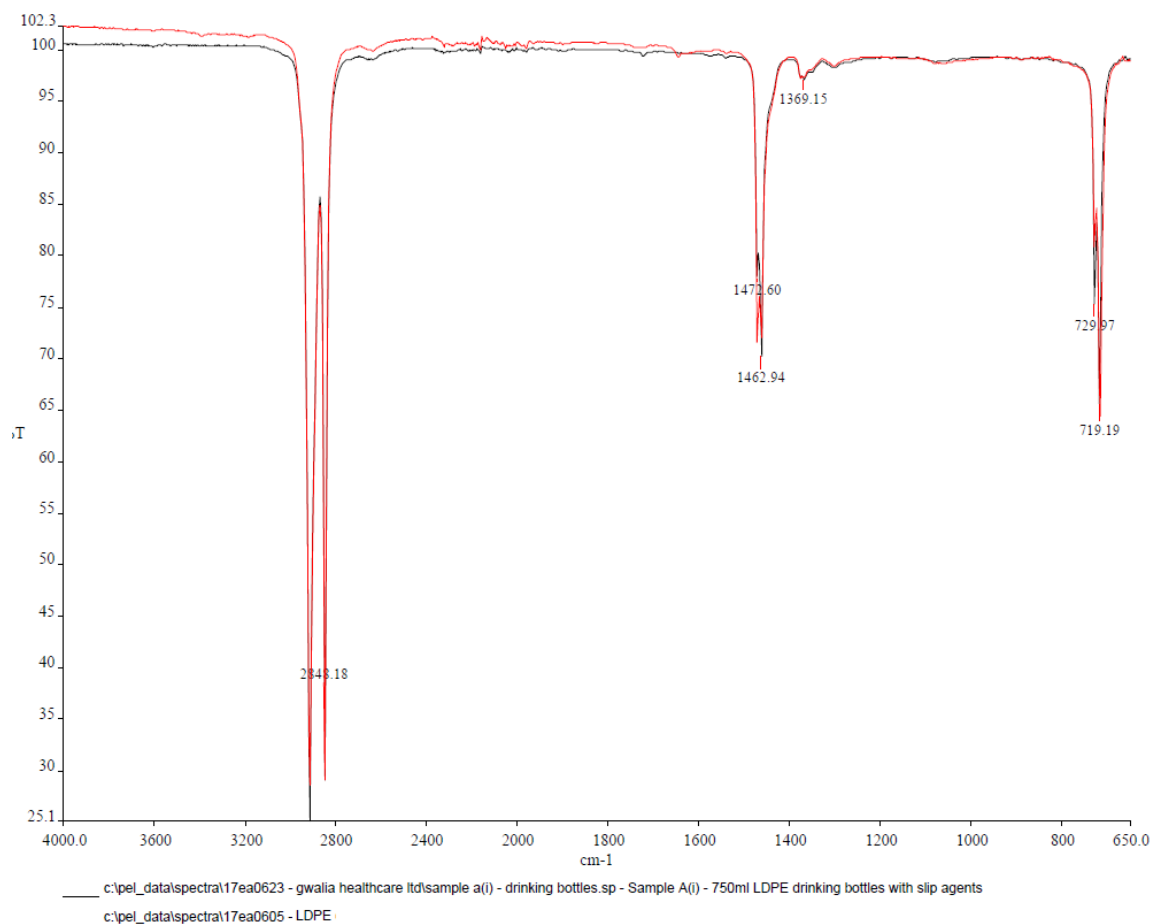




FIGURE 3: FTIR overlay for the LDPE reference material and Sample Ai, the drinking bottle.

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Figure 4 illustrates the FTIR spectrum for Sample Aii, the drinking bottle with slip agent.

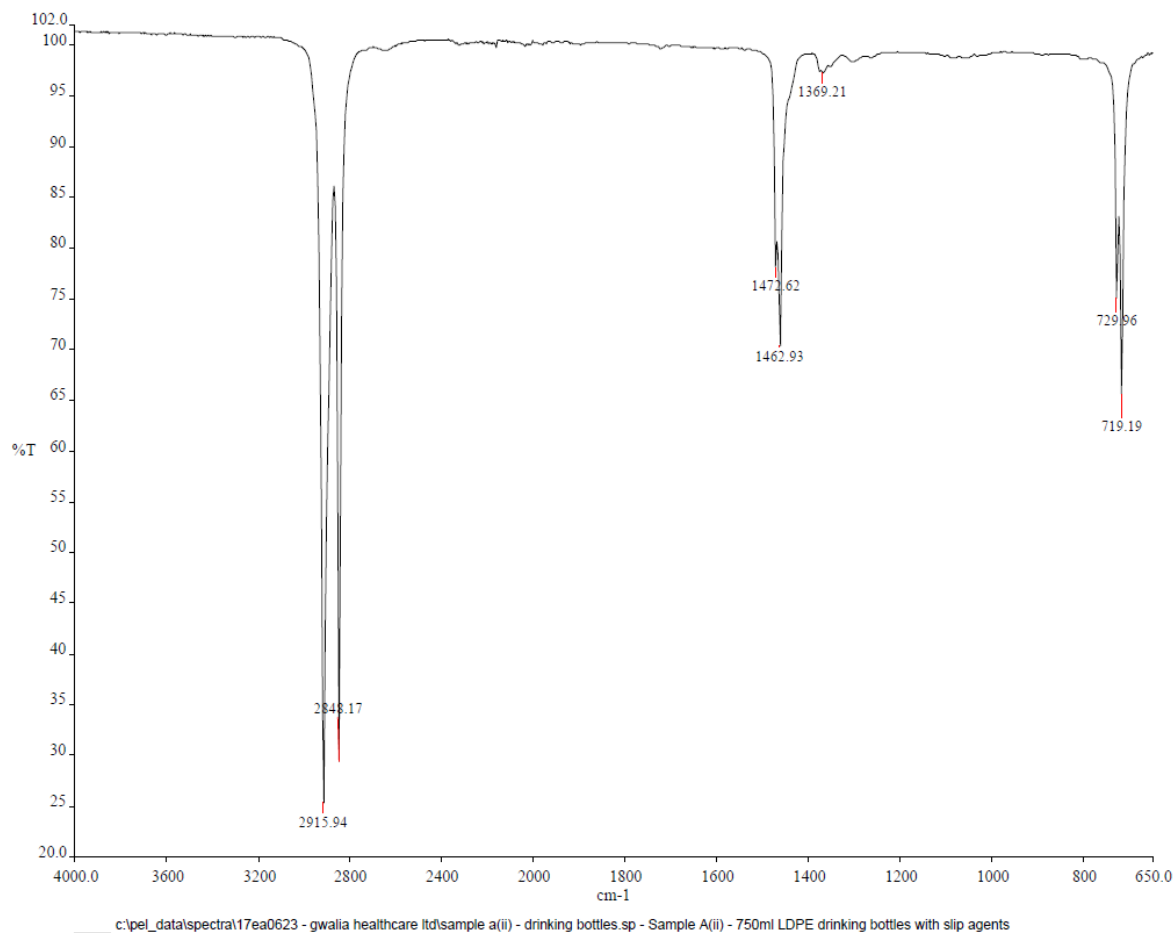



FIGURE 4: Sample Aii, Drinking bottle FITR spectrum.

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Figure 5 illustrates the FTIR overlay for the LDPE reference material and Sample Aii, the drinking bottle.

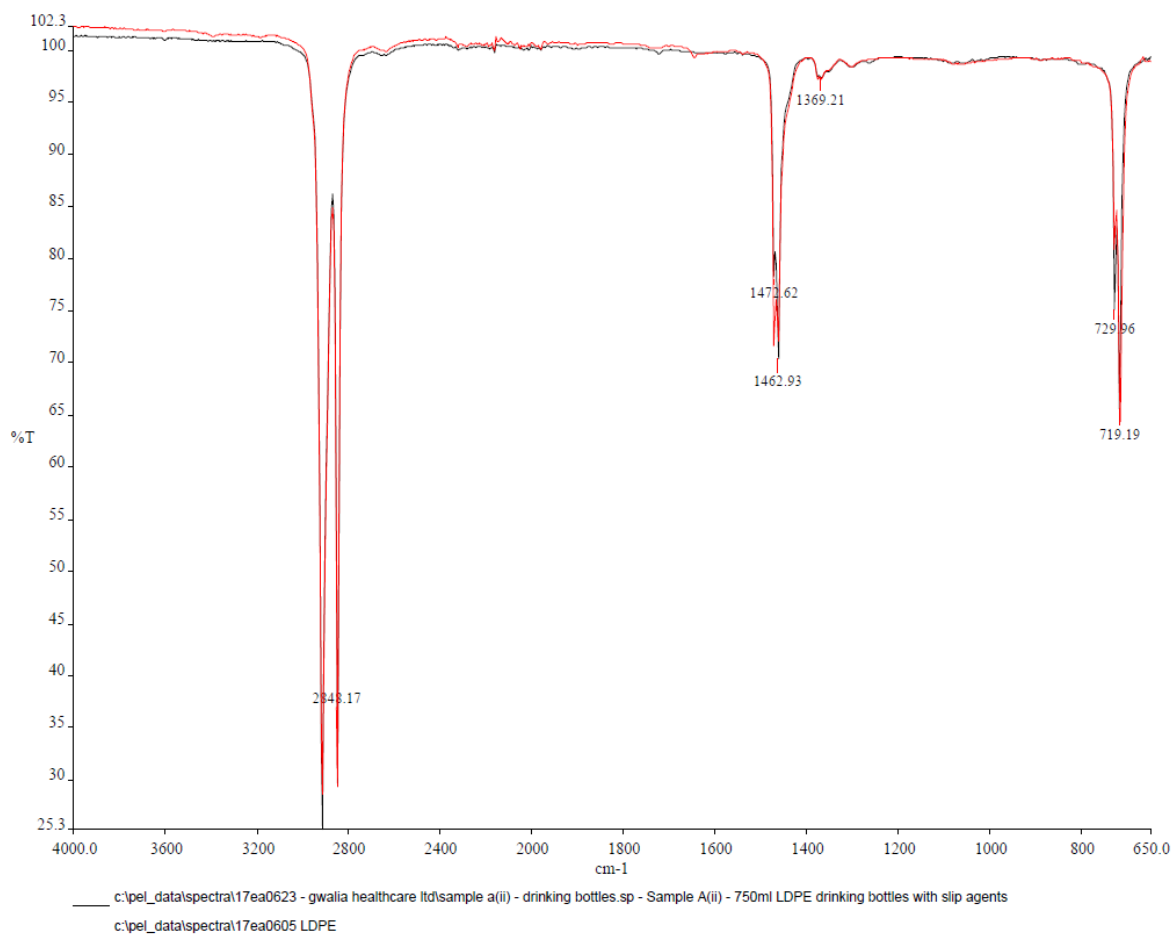



FIGURE 5: FTIR overlay for the LDPE reference material and Sample Aii, the drinking bottle.

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Figure 6 illustrates the FTIR spectrum for Sample Aiii, the drinking bottle.

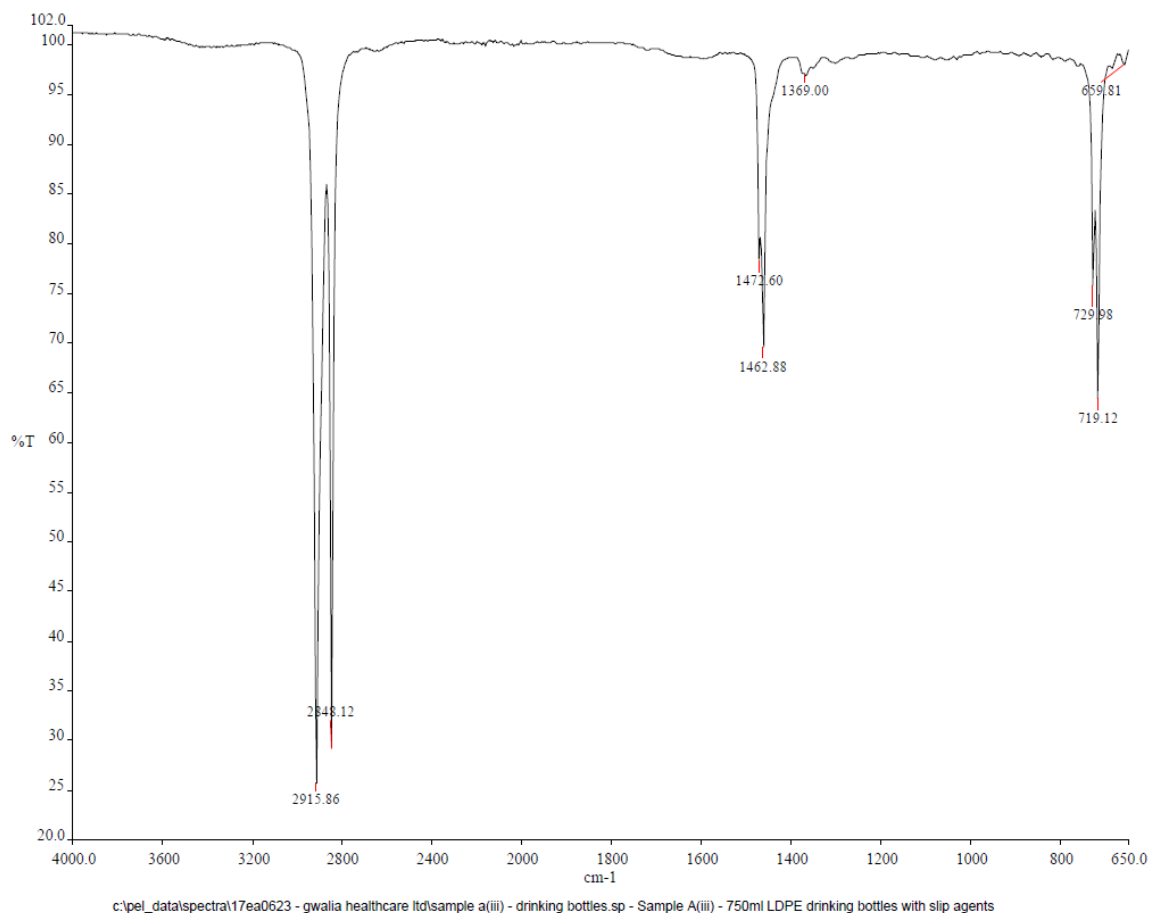


FIGURE 6: Sample Aiii, Drinking bottle with slip agent FITR spectrum.

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Figure 7 illustrates the FTIR overlay for the LDPE reference material and Sample Aiii, the drinking bottle.

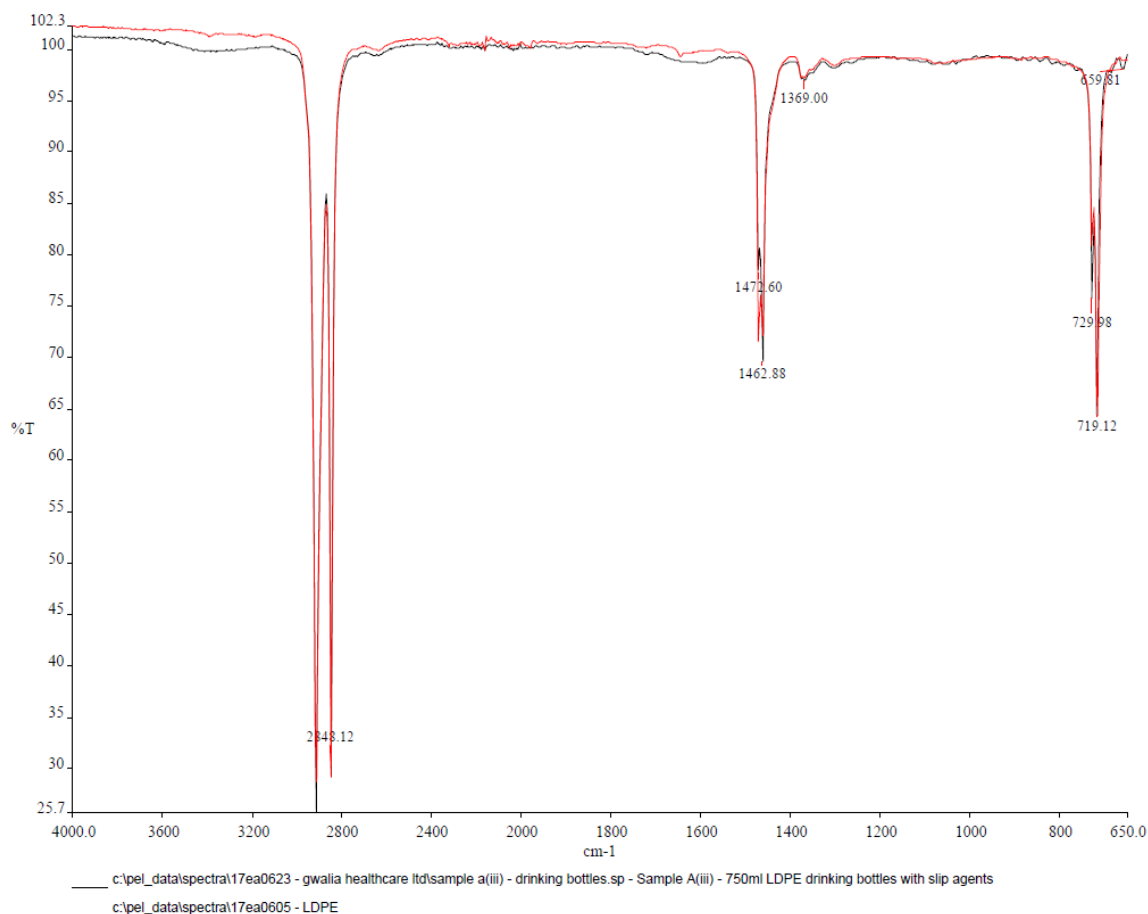


FIGURE 7: FTIR overlay for the LDPE reference material and Sample Aiii, the drinking bottle.

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Determination of extracted substances.



Table 2, below provides a summary of the determination of extracted substances.

Sample	Initial mass of evaporating basin (g)	Mass After Evaporation (g)	Mass of residue (g)	Mass of residue (mg)	Mass extracted into Solvent (mg/dm ²)	Test Limits (mg/dm ²)	Result
Ai	58.7007	58.70909	0.00839	8.39			
Aii	67.4562	67.46995	0.01375	13.75			
Aiii	66.26804	66.28025	0.01221	12.21			
Mean A	64.14164667	64.15309667	0.01145	11.45	1.76	10	PASS
Blank 1	67.24817	67.2487	0.00053	0.53			
Blank 2	55.35587	55.37121	0.01534	15.34			
Mean Blank	61.30202	61.309955	0.007935	7.935			

TABLE 2: Summary of extracted substances.

Conclusion

The pass / fail criteria of the EN 1196-15:2002 migration testing is set to less than 10mg/dm², based upon the samples provided at the time of testing the bottles were found to be within the test limits and therefore pass.

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FOOD CONTACT DECLARATION

It is the responsibility of our customers to check if the materials supplied by SABIC and articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.

We confirm that **SABIC[®] LDPE 2801H0W 00900** has been formulated and manufactured in accordance with the compositional requirements of the following food contact recommendations or regulations:

Germany

Empfehlung III "Polyäthylen" of Kunststoffe im Lebensmittelverkehr: Empfehlungen des Bundesinstituts für Risikobewertung (BfR) (former BgVV).
Status: March 2011.

Bedarfsgegenständeverordnung in der Fassung der Bekanntmachung vom 23 December 1997, latest amendment February 15, 2016 (BGBl. I S. 198)

UK

Plastics for food applications: A code of practice for safety in use, issued by BPF/BIBRA. 1991 Edition.

Statutory Instruments 1998 No.1376, 2000 No.3162, 2002 No.2364, 2002 No.3008, 2005 No.325 and 2006 No.1401, 2009 No.205, 2011 No.231, 2012 No. 2619.
Status: June 2016.

Netherlands

Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen).
Chapter 1 – Kunststoffen.

Belgium

Arrêté royal du 3 juillet 2005 relatif aux matériaux et aux objets en matière plastique destinés à entrer en contact avec les denrées alimentaires, amended by Arrêté royal du 10 février 2011.

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France

Brochure n°. 1227 du Journal Officiel de la République Française; Matériaux au contact des denrées alimentaires, produits de nettoyage de ces matériaux.
Edition July 2002.

Arrêté du 2 janvier 2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires (arrêtés modificatifs: arrêté du 29 mars 2005, arrêté du 9 août 2005, arrêté du 19 octobre 2006, arrêté du 25 avril 2008, arrêté du 19 novembre 2008, arrêté du 3 Septembre 2010 et arrêté du 1 Avril 2011).

Spain

Real Decreto 847/2011, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos (*BOE número 161 de 11/7/2011*).

Real Decreto número 103/2009, de 6 de febrero, por el que se modifica el Real Decreto 866/2008, de 23 de mayo, por el que se aprueba la lista de sustancias permitidas para la fabricación de materiales y objetos plásticos destinados a entrar en contacto con los alimentos y se regulan determinadas condiciones de ensayo (*BOE número 41 de 17/02/2009*).

Italy

Decreto Ministeriale No 227 del 04.05.2006.

Regolamento recante aggiornamento del decreto ministeriale 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari e con sostanze d'uso personale, and subsequent amendments up to and including Decreto 23.04.2009, published in the Gazzetta Ufficiale – G.U. Serie Generale n. 144 del 24-6-2009-.

Norway

Forskrift om materialer og gjenstander i kontakt med næringsmidler.
Status: January 2003.

Finland

Maa- ja metsätalousministeriön asetus eräiden elintarvikkeiden kanssa kosketuksiin joutuvista aineista annettujen säädösten kumoamisesta (497/2011) 12.5.2011.

Kauppa- ja teollisuusministeriön asetus 141/2005; 24.2.2005 elintarvikkeen kanssa kosketukseen joutuvista muovisista tarvikkeista.

Kauppa- ja teollisuusministeriön asetus 181/2005; 10.3.2005 elintarvikkeen kanssa kosketukseen joutuvista muovisista tarvikkeista.

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Denmark

Fødevarekontaktmaterialebekendtgørelsen BEK nr. 822 af 26/06/2013 gældende om materialer og genstande bestemt til kontakt med fødevarer; Fødevarerministeriet.

Sweden

Statens livsmedelsverks kungörelse om ändring i kungörelsen (SLV FS 1993:18) med föreskrifter och allmänna råd om material och produkter avsedda att komma i kontakt med livsmedel.

Status: February 2004.

Austria

Kunststoff-Verordnung (KVO), über Gebrauchsgegenstände aus Kunststoff, die für die Verwendung bei Lebensmitteln und Nahrungsergänzungsmitteln bestimmt sind BGBl. II Nr. 476/2003 of 14/10/2003, zuletzt geändert durch die Verordnung BGBl II Nr. 45/2011 of 14.02.2011.

Switzerland

Verordnung des EDI SR 817.023.21 über Bedarfsgegenstände (Ordinance on materials and objects) of 16. December 2016.

Status: 1. May 2017.

EC

Commission Regulation (EU) No. 10/2011 of January 14, 2011, including its amendments (EU) No. 1282/2011 of November 28, 2011, (EU) No. 1183/2012 of November 30, 2012, (EU) No. 202/2014 of 3 March 2014, (EU) No. 2015/174 of 5 February 2015, (EU) No. 2016/1416 of 24 August 2016 and (EU) 2017/752 of 28 April 2017.

This material contains no monomers which are regulated with a restriction in their use.

This material does not contain additives which are regulated with a restriction in their use.

This material does not contain intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex IV of Commission Regulation (EU) 10/2011.

This material has been manufactured in accordance with the relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

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Migration estimations (surface area to volume ratio = 6) on test samples (monolayer films 100 µm) made of SABIC[®] LDPE 2801H0W 00900 or a comparable grade, carried out under conditions covering long term storage above 6 months at room temperature and below, including heating up to 70 °C for up to 2 hours, or heating up to 100°C for up to 15 minutes in the standard food simulants according to Table 1 of Annex III of Commission Regulation (EU) No 10/2011 have shown, that under these conditions migration limits (overall and if relevant specific see above) were not exceeded:

- in the non-fatty food simulants
- in the fatty food simulants.

USA

Code of Federal Regulations, issued by Food and Drug Administration (FDA), paragraph 21 CFR 177.1520 (olefin polymers).

Extraction experiments with test samples made of SABIC[®] LDPE 2801H0W 00900 or a comparable grade, have shown that extraction limits specified for use in articles used for packing or holding food during cooking (specification 177.1520(c)3.2a.) were not exceeded.

SABIC[®] LDPE 2801H0W 00900 does not contain intentionally incorporated additives.

Status: June 2017.

Mercosur (Argentina, Brasil, Paraguay, Uruguay, Venezuela)

Monomers in SABIC[®] LDPE 2801H0W 00900 are listed on Reglamento Técnico Mercosur sobre lista positiva de monómeros, otras sustancias de partida y polímeros autorizados para la elaboración de envases y equipamientos plásticos en contacto con alimentos; Mercosur/GMC/Res. No. 02/12.

SABIC[®] LDPE 2801H0W 00900 does not contain intentionally incorporated additives.

This material contains no monomers which are regulated with a restriction in their use.

GCC (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates).

Monomers in SABIC[®] LDPE 2801H0W 00900 are listed as authorised for materials in Table 1 of GSO standard GSO 1863-2013.

SABIC[®] LDPE 2801H0W 00900 does not contain intentionally incorporated additives.

This material contains no monomers which are regulated with a restriction in their use.

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The People's Republic of China

SABIC[®] LDPE 2801H0W 00900 comprises a resin which is listed in PRC National Standard GB 4806.6-2016, Table A.1., entry 101 (CAS 9010-79-1) and complies with any applicable requirements for that resin, as tested with the above material or a comparable grade.

All intentionally added substances used in the production of **SABIC[®] LDPE 2801H0W 00900** that are subject to PRC National Standard GB9685-2016, regulating the use of additives in food contact materials and products, are listed on this standard for the aforementioned resin or are listed on Table A.2 of PRC National Standard GB 2760-2014, regulating the use of food additives.

This material contains no monomers which are regulated with a restriction in their use.

This material does not contain additives which are regulated with a restriction in their use.

Malaysia

Monomers in **SABIC[®] LDPE 2801H0W 00900** are listed as authorised on Annex A of Malaysian standard MS 2234:2009 on Plastics materials and articles intended to come into contact with food.

SABIC[®] LDPE 2801H0W 00900 does not contain intentionally incorporated additives.

This material contains no monomers which are regulated with a restriction in their use.

We wish to stress that the migration- and extraction- test results, referred to in this declaration, may differ significantly from the performance of the final plastic material or article under the actual and foreseeable conditions of use.

SABIC has no control over final product composition nor over processing conditions. It is therefore the responsibility of the converter or food packager that markets the final material or article to check compliance with the relevant regulations and to validate material performance in the end application through proper end use testing.

Most of the recommendations or regulations mentioned above refer to the final materials and articles that directly contact the food.

This declaration however, is restricted to **SABIC[®] LDPE 2801H0W 00900** as it leaves the production facilities.

This declaration does not cover

- any substance subsequently added by the converter,
- poor material or end product due to inexpert manufacture by the converter,
- any negative influence of the finished article on the organoleptic properties of the packaged food.

Any sale of products or delivery of customer support and advice by SABIC, its subsidiaries and affiliates (each a "seller"), is made exclusively under seller's standard conditions of sale. Although any information contained herein is given in good faith, seller makes no warranty, express or implied, nor assumes any liability with respect to the performance, suitability or fitness for intended use of its products in any customer's application. Each customer should determine the suitability of seller materials for the customer's particular use through appropriate testing and analysis. No statement by Seller concerning a possible use of any product, service or design is intended, or should be construed, to grant any license under any patent or other intellectual property right of Seller or as a recommendation for the use of such product, service or design in a manner that infringes any patent or other intellectual property right. ®Trademark of SABIC Petrochemicals BV
* Trademark of SABIC Innovative Plastics BV



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As the above-mentioned Regulations develop continuously, our declarations will be adapted accordingly. Therefore we advise the receivers to ask for a new declaration periodically.

This declaration replaces all previous ones relating to this subject.

In the name of SABIC Petrochemicals BV,

A handwritten signature in black ink, appearing to be 'M. Bosma', is written over a horizontal line.

M.Bosma
Corporate Product Stewardship

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