Product Specification and Certificate

Product no.	031050-0000
Product name	Duma Standard 50 ml
Product description	44 mm round plastic container with a snap-on neck to be provided with Duma Handy Cap 2813. Index in the bottom. Intended for the packing of tablets and powder.
Design	• Regulatory drawing A031050 Regulatory • Standard drawing B031050
Raw material	Purell PE GF 4760, High-density polyethylene (HDPE) in compliance with Regulation (EU) 10/2011 and FDA title 21 CFR § 177.1520, LyondellBasell Industries. Coloured with 3.0-4.5% white masterbatch, containing about 59% titanium dioxide. Purell GF4760 Declaration 2016
Colour	PE 22305+ Remafin-White, Low-density polyethylene (LDPE) in compliance with Regulation (EU) 10/2011, FDA title 21 CFR § 178.3297 and BfR recommendation IX, Clariant Plastics & Coatings (Italia) S.p.A. PE 22305+ Declaration
Production	**Facility:** Vaerloese, Denmark **Process:** The containers are injection blow moulded **Hygiene:** The production takes place in clean room **Sterilisation:** N/A

Measures and Properties

Dimensions: Container:		Neck:	
Outside height	61.0 +1.0/-1.0 mm	Inside diameter	21.4 +0.2/-0.2 mm
Outside diameter	44.5 +0.5/-0.5 mm	Upper outside diameter	28.0 +0.3/-0.3 mm
		Neck ring diameter	30.6 +0.3/-0.3 mm
Wall thickness	Min. 0.4 mm		
Other dimensions:			
Label height	Max. 33 mm	Volume	Max. 67 ml
Label width	Max. 139 mm	Shelf life	5 years
Weight	8.0 +0.8/-0.6 gr	Bioburden	Max. 50 CFU

Test Results

The container and cap comply with all demands for Moisture Vapour Transmission and Light Transmission and are in accordance with USP <671>. Documentation enclosed.
WVP - 031050-0000/002813-2000/JUL2014

LT - 031050-0000/SEP2013

The container and cap comply with all demands for Multiple Internal Reflectance and Differential Scanning Calorimetry and are in accordance with USP <661>. Documentation enclosed.
IR - GF4760 / PE22305+
DSC HDPE/AUG2016

The container and cap comply with all demands for Physicochemical and Biological Reactivity and are in accordance with USP <661>. Documentation enclosed.
Physico - PE22305+/PEZ121818X/21156601/AUG2016
In vitro - GF4760/PE22305+/JUN2016

Packing and Way of Delivery

The products are packed in 1 LDPE bag, which is then heat-sealed. The LDPE bag is put into a cardboard carton, which is sealed with 2 PP-straps. The cartons are packed on pallets, which are 1200 x 800 x 140 mm and weight approximately 23 kg.

Carton dimensions:
Height (mm): 350 Length (mm): 780 Width (mm): 600

Packing information:
Number of items per carton: 1200 Volume per carton (m³): 0.163
Max. number of cartons per pallet: 12 Weight per carton (kg.): 11.1
Max. height of the pallet (mm): 2300

Labelling

Each carton is provided with a label with the following information:
- Product name and no.
- Quantity
- Machine no.
- Production date / Batch no.

The bags in the carton is also marked with date and machine no.

Recommendation to Storage, Handling and Transportation

Stored inside in clean conditions in its original un-open packaging, protected from direct sunlight and with a temperature between 5 - 35° C and Relative Humidity between 30 - 70 %.

Quality Control

All products are quality controlled according to instructions specified in our quality control system. We therefore guarantee that all deliveries from Gerresheimer Plastic Packaging have passed our control procedures and comply with the quality demands mentioned below. If required a certificate of conformance can be issued. The classification of defects and specifications of AQL values are based on ISO 2859 and Quality Assurance of Pharmaceutical and Cosmetic Packaging Materials:
Defect Evaluation List for Blow-moulded Plastic Containers Vol. 23 - ISBN 3-87193-405-6.
Defect Evaluation List for Injection-moulded parts made of Plastic: Closures, Sealing Disks and dosage aids (droppers, etc.) Vol. 22 - ISBN 3-87193-182-9.
Documentation enclosed.
Quality Control - IBM Containers

Declaration of Conformity

DoC EP (GF 4760 & 22305)
DoC Food Law (GF 4760 & PE22305+)
DoC TSE/BSE
DoC Allergens, Phthalates, BPA, Latex, Melamine

Information on Packaging and Packaging Waste Directive 94/62/EC and/or CONEG

Both container, cap and bag are produced from material, which complies with the directions for plastics material in contact with foodstuffs. The content of heavy metals in the products, the inner bag, and the carton is less than 100 ppm.

The products can be utilised by recovery of material and because of a high heating value by recovery of energy.

REACH

We can confirm that the raw materials used in the product are either pre-registered or exempted from pre-registration.

Complaint Handling

In case that the delivered products are outside specification, complaint must be send in writing to daily contact person in Customer Care Center.

In order to ensure a thorough investigation it is important to send the following basic information:

- Article number
- Batch number
- Cavity number (if related to specific cavities)
- Number of defective items
- Defect observed in
  - a) incoming control including sample size
  - b) production including quantity of items used
  - c) final products including quantity of items used
  - d) market complaint
- Defect found in
  - a) one carton
  - b) several cartons - please specify quantity
- Exact production date/time from carton/bag or carton/bag/pallet number products in quarantine:
  - a) Filled products - Quantity
  - b) Not filled products - Quantity
  - c) No products left
- Description of the defect

The following standard form can be used: 3.1 Customer Complaint Report.

Depending on the defect, additional information will be requested as described in the attached standard forms: 2.5 Information requested in relation to complaints.

It is very important to send samples at the time a complaint is filed, as any delay in these can have an impact on time of investigation. An investigation report is send to Customer within 21 days counting from when complaint, relevant information and samples are received.

Important !
Filled or empty products involved in a complaint to Gerresheimer Plastic Packaging, must only be destroyed by Customer after written approval from Gerresheimer. Any activity in connection with a complaint where Customer expect Gerresheimer to cover the costs must be approved by Gerresheimer in writing before initiation of the activity.

Complaint report
Labelling
Loose silica gel-loose desiccant-defect on desiccant
Mix-up
Partly- or disconnected TE-rings
Product defect
Transport

Registrations and Certifications

Gerresheimer Plastic Packaging was established in January 2006. Before that time the company was working under the following names: Superfos Pharma, Superfos Pharma Pack, Dudek Plast and Duma.

Documentation, i.e. test reports, certificates etc. issued before January 2006 will be with reference to one of the names above.

Gerresheimer Vaerloese A/S has obtained the following registrations and certifications for Vaerloese and Haarby, Denmark:
ISO 9001, no. 160454-2014-AQ-DEN-DANAK
ISO 14001, no. 156579-2014-AE-DEN-DANAK
ISO 15378, no. 160455-2014-Q-DEN-DNV

The product is FDA registered in US with the following DMF number:
DMF 12077 – DMF type III Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is TPD registered in Canada with the following DMF number:
DMF 2000-108 - Packaging material – Drug Master File. Packaging material, Manufactured in Vaerloese - Denmark, Haarby - Denmark.

The product is SFDA registered in China with the following license number:
J20050032 - Duma Twist-Off.

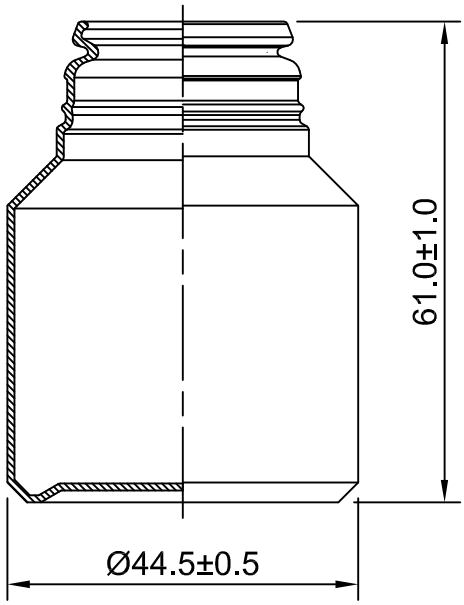
The product is registered in Russia with the following number:
C3 2011/11203 – plastic packages in size between 3ml to 3000 ml with accessories.

The product is registered in Ukraine with one of the following numbers:
10787/2011
10785/2011
10786/2011
14788/2015
14789/2015

Revisions

Version:	Implementation:	Revision information:
1	08.02.2010	Transfer to new system, additional information and change in dimensions/tolerances of inside diameter, upper outside diameter and neck ring diameter
2.1	23.11.2010	Updated GF 4760 declaration, weight per carton changed from 11.2 to 11.7 and recorrection of version number from 1.0 to 2.1
2.2	13.07.2011	GF 4760 Declaration 2011: Updated GF4760 declaration GF 4760: Updated Regulation (EU) 10/2011 Clariant PE 22305+: Updated with Regulation (EU) 10/2011
2.3	14.07.2011	PE22305 Declaration 2011
2.4	31.01.2012	Registrations and Certifications: More precise description of registrations
2.5	15.03.2012	GF 4760 Declaration 2012: Updated
2.6	29.05.2012	IR - GF4760 / PE22305+: Updated
2.7	09.08.2012	Purell PE GF 4760 declaration 2012: Updated
3	24.10.2012	Number of items per carton changed from 1275 to 1200 and weight per carton changed from 11.7 to 11.1
3.1	03.01.2013	PE 22305+ Declaration 2012: PE 22305+ declaration updated
3.2	28.02.2013	Migr. - GF4760/PE 22305+/JUN2012: Updated
3.3	08.04.2013	PE 22305+ Declaration 2013: Updated Purell GF4760 Declaration 2013: Updated
3.4	18.04.2013	PE 22305+ Declaration 2013: Updated
3.5	24.07.2013	IR - GF4760 / PE22305+: Updated

4	17.09.2013	Coloured with 3.0-4.5% white masterbatch
4.1	17.09.2013	LT - 031050-0000/SEP2013: Updated
4.2	05.12.2013	Purell GF4760 Declaration 2013: Updated
4.3	13.01.2014	PE 22305+ Declaration 2013: Updated
4.4	25.02.2014	Purell GF4760 Declaration 2014: Updated
4.5	10.06.2014	PE 22305+ Declaration: Updated
4.6	09.07.2014	Purell GF4760 Declaration 2014: Updated
4.7	04.08.2014	WVP - 031050-0000/002813-2000/JUL2014: Updated
4.8	23.03.2015	Purell GF4760 Declaration 2015: Updated
4.9	17.09.2015	PE 22305+ Declaration: Updated
4.10	11.01.2016	Purell GF4760 Declaration 2016: New SVHC list - 17.12.2015
4.11	08.04.2016	Clariant PE 22305+: Clariant new company name
4.12	10.05.2016	Registrations and Certifications: Updated
4.13	14.06.2016	PE 22305+ Declaration: Updated
5	29.06.2016	Regulatory drawing, Declaration of Conformity and Complaint handling added
5.1	29.06.2016	Quality Control - General text: New classification of defects Quality Control - IBM Containers: Updated
5.2	03.08.2016	Purell GF4760 Declaration 2016: New SVHC list 20.06.2016 IR - GF4760 / PE22305+: Updated
6	16.09.2016	USP tests updated
6.1	28.09.2016	Purell GF4760 Declaration 2016: Updated with 1416/2016



Round 50ml		
Replaced drawing		
Designer	Hek	09.01.2015
Released	BS	09.01.2015
Scale	Drawing Type	Size
1 : 1	Regulatory	A4

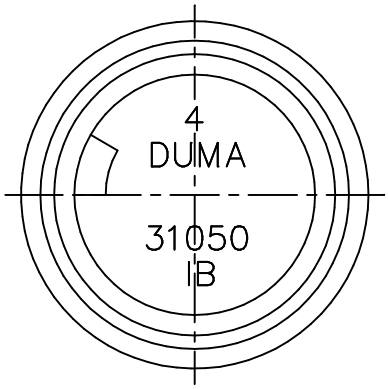
GERRESHEIMER

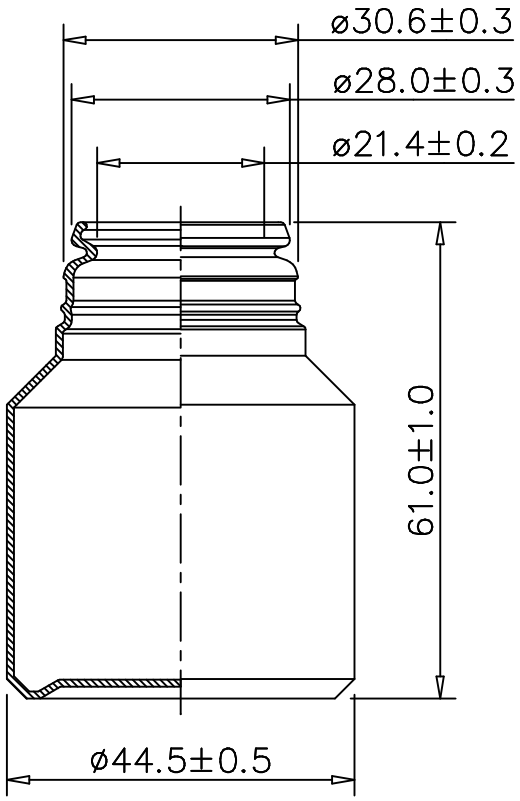
Gerresheimer Vaerloese A/S
Walgerholm 2-8, Postbox 229
DK-3500 Vaerloese

Phone +45 4477 7888
Fax. +45 4477 7892

This drawing may not be handed over, copied or used by others

Item	No.
Duma Standard 031050	A031050
	Vers. no.: 1





Tolerance changed	29.12.2009	MG	29.12.2009	
Tolerance changed	25.09.2009	MG	25.09.2009	
Logo changed	19.06.2009	JJ	19.06.2009	
No. and logo changed	17.03.2006	JJ	17.03.2006	
Created	05.2000	JJ	05.2000	
Created / Correction	Date	Sign.	Appr. Date	Sign.

GERRESHEIMER
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Fax. +45 4477 7892

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Item
Duma Standard
031050 50ml.

No.
B031050

Vers. no.: 1

September 15, 2016

Katarzyna Jawor
Gerresheimer
Gerresheimer Boleslawiec S.A.
Plastic Packaging
Boleslawa Chrobrego 15
59-700 Boleslawiec, Poland

Purell **PE GF4760**

A product of Basell Sales & Marketing Company B.V.

Dear Katarzyna Jawor:

The following is in response to your request for Product Stewardship Information (PSInfo) for the product listed above. The attached Product Stewardship Bulletin (PSB) details the regulatory status of this product.

LyondellBasell Industries responds to product stewardship requests with a standardized Product Stewardship Bulletin (PSB) which summarizes the global regulatory status of a product. LyondellBasell Industries will not complete customers' forms or questionnaires. Standardized responses provide each customer with consistent information in a timely fashion. Each request is reviewed to ensure our response documents provide relevant information.

Please note that compliance with these regulations should not be interpreted to guarantee that the product, will, in fact, perform in a particular application. Your Technical Service Representative can help you determine that the characteristics of the product are compatible with the desired conditions of use.

Should you have any further questions concerning a LyondellBasell product, or if we can assist in any other way, please do not hesitate to contact us.

Best regards,

Micaela Poltronieri
Product Safety Specialist
+39 0532 46 8087
micaela.poltronieri@lyondellbasell.com

Product Stewardship Bulletin

Purell PE GF4760

A product of Basell Sales & Marketing Company B.V.

Global Food Contact Status:

European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP) and as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm2 as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

SML Components

This product contains one or more components with Specific Migration Limits (SMLs).

93280; distearylthiodipropionate; SML(T) = 5 mg/kg (14).

68320; Octadecyl 3(3,5-Di-tert-butyl-4-hydroxyphenyl) propionate; SML = 6 mg/kg

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.

- E 470a Calcium salts of fatty acids

United States

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.2a.

This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, the substances used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

Allergen Statements

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Biomedical Policy

This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices, without prior notification to Seller for each specific product and application; or (ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: (1) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (2) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; (3) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (4) tobacco related products and applications; (5) electronic cigarettes and similar devices.

(iii) Additionally, the product(s) may not be used in: (1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; (2) applications involving permanent implantation into the body; (3) life-sustaining medical applications.

All references to U.S. FDA, Health Canada, and European Union regulations include other country's equivalent regulatory classifications.

Animal Based Raw-Materials (BSE/TSE)

Tallow

Tallow derived additives may be used in the manufacture of this product.

Europe - BSE/TSE - "Mad Cow"

Tallow derived materials used in this product fullfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3".

Epoxy Derivatives

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act - September, 2010)

Please see link below for the position of LyondellBasell concerning this Act:

https://www.lyondellbasell.com/en/investors/corporate-governance/?id=52

The link to this document is located in the right margin under the heading "Corporate Governance Documents" titled "Conflict Minerals Policy".

Genetically Modified Organisms (GMO)

Additives derived from Genetically Modified Organisms (GMO's) are not intentionally used in the formulation of this product.

Halal Certification

This product is not certified as Halal.

Kosher Certification

This product is not certified Kosher.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

Medical

European Pharmacopeia (EP)

This product meets the EP requirements for 3.1.3, Polyolefins - 8th Edition of European Pharmacopeia.

ISO 10993

Biological reactivity evaluations have been performed on representative samples of this product, specifically the Chapter 88 USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). These USP tests may fit the requirements of certain sections of 10993-10 (tests for irritation and skin sensitization) and 10993-11 (tests for systemic toxicity). Despite this, the manufacturer of a medical device made with this product must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of ISO 10993.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

US Pharmacopeia (USP)

Representative samples of this product have passed the Chapter 88; USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). In addition, the Physico-chemical testing of this product met the USP limits defined in Chapter 661.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

US FDA Drug Master File (DMF)

Information on this product is listed in DMF N. 5654. Contact LyondellBasell for a DMF authorization letter to be sent to FDA.

Metals Content

US CONEG

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and its following amendments concerning the defined limit(s)of heavy metals.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

Nanomaterials

Nanomaterials (defined as natural, incidental or manufactured materials containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm) are not used in the manufacture of or the formulation of this grade. However, this product has not been tested for these chemical substances.

Other Chemicals

The chemical materials listed below are not used in the manufacture or the formulation of this product and are not expected to be present. However, this product has not been tested for these chemical materials.

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;

2,4,4'-trichloro-2'-hydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5;

2-mercaptobenzothiazole; MBT; CAS# 149-30-4;

Acrolein; (propenal); (CAS# 107-02-8);

Acrylamide; CAS# 79-06-1;

Aromatic amines;

Asbestos;

Azo Dyes and Pigments;

Polyaromatic Hydrocarbons - PAHs:

1,2-dihydro-acenaphthene; (CAS# 83-32-9);
9H-Fluorene; (CAS# 86-73-7);
Acenaphthylene; (CAS# 208-96-8);
Anthracene; (CAS# 120-12-7);
Benz(a)anthracene; (CAS# 56-55-3);
Benzo(a)pyrene; (CAS# 50-32-8);
Benzo(b)fluoranthene; (CAS# 205-99-2);
Benzo(e)pyrene; (CAS# 192-97-2);
Benzo(ghi)perylene; (CAS# 191-24-2);
Benzo(j)fluoranthene; (CAS# 205-82-3);
Benzo(k)fluoranthene; (CAS# 207-08-9);
Chrysene; (CAS# 218-01-9);
Dibenz(a,h)anthracene; (CAS# 53-70-3);
Fluoranthene; (CAS# 206-44-0);
Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5);
Naphthalene; (CAS# 91-20-3);
Phenanthrene; (CAS# 85-01-8);
Pyrene; (CAS# 129-00-0);

Benzophenone; CAS RN 119-61-9;

Bisphenol A; (BPA); CAS# 80-05-7;

Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;

Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6;

Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;

Butylated hydroxytoluene; (BHT); CAS# 128-37-0

Chlorinated paraffins;

Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5;

Dimethyl fumarate; (DMF); CAS# 624-49-7;

Dioxins;

Epichlorohydrin; (ECH); CAS# 106-89-8;

Fluorocarbons;

Fluorotelomers

Formaldehyde; CAS# 50-00-0;

- Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)

Gold(Au); CAS# 7440-57-5;

Halogenated Flame Retardants

Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;

Nonylphenol; CAS# 25154-52-3;

Nonylphenol ethoxylates;

Novolac glycidyl ether;

Organotin compounds;

Perfluorochemicals; (PFCs);

Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1;

Perfluorooctanoic acid; (PFOA); CAS# 335-67-1;

Plasticizers (e.g. DEHA, DINCH, BTHC, TOTM, etc.):
DEHA bis(2-ethylhexyl) adipate; CASRN: 103-23-1
DINCH 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester, CASRN: 166412-78-8
BTHC butyryl tri-n-hexyl citrate; CASRN: 82469-79-2;
TOTM tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; CASRN: 3319-31-1
DINP; Diisononyl Phthalate; CASRN: 28553-12-0;
DEHP; di(2-ethylhexyl) phthalate
DOP; di-octyl phthalate; CASRN: 117-81-7;
DIDP; di-iso-decyl phthalate; CASRN: 26761-40-0;
DBP; di-butyl phthalate; or DNBP; di-n-butyl phthalate; CASRN 84-74-2;
BBP; butyl benzyl phthalate; CASRN 85-68-7;
DNOP; di-n-octyl phthalate; CASRN: 117-84-0;
Glycerides, castor-oil mono-, hydrogenated, acetates; CASRN: 736150-63-3

Polybrominated biphenyls; (PBBs);

Polybrominated diphenyl ethers; (PDBEs);

Polybrominated terphenyls; (PBTs);

Polychlorinated biphenyls; (PCBs);

Polychlorinated naphthalenes; (PCNs);

Polychlorinated terphenyls; (PCTs);

Polystyrene;

Polyvinyl chloride; (PVC); CAS# 9002-86-2;

Radioactive substances;

Radon; CAS# 10043-92-2;

Styrene monomer; CAS# 100-42-5;

Sulphur dioxide; CAS# 7446-09-5;

Tin oxide (SnO2); (Cassiterite); CAS# 8062-08-6;

Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;

Vinyl chloride; CAS# 75-01-4;

Wolframite; Tungsten (W); CAS# 1332-08-7;

Ozone Depleting Substances

European Union

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation (EC) No 1005/2009 of 16 September 2009, are not intentionally used in the manufacture of or formulation of this product.

United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II, HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

Phthalates

Phthalates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for phthalates.

REACh Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of June 20, 2016) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing. The current list of all SVHCs can be found at ECHA website link listed below:

http://echa.europa.eu/web/guest/candidate-list-table

Global Chemical Control Regulations

All ingredients in this product are in compliance with the following chemical inventories:

See Section 15, of the SDS (Safety Data Sheet) for Global Chemical Inventories.

Global Toy Regulations:

CEN EN Standards refer to safety of toys and not specifically to plastic raw materials. According to the information provided by our raw material suppliers, we deem this product should comply with the requirements of CEN standards EN71-3 / EN71-9 (as amended) as applicable to plastic raw materials (pellets, powder, flakes). However, this product has not been tested according to these CEN Standards.

VOC Content

Switzerland VOC Declaration

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

CEN Standard prEN 13432

This product is not suitable for composting.

Energy Recovery - CEN Standard prEN 13431

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg.

Disclaimer

The information in this document is, to our knowledge, true and accurate at the time and date of issue. However, information in this document may be updated periodically due to changes in the laws and regulations, or for other reasons, therefore we cannot guarantee that the status of this product will remain unchanged. Users are expected to regularly visit the PSInfo Website to obtain the most current information on this product. Product Stewardship Bulletins not directly received from the PSInfo system are uncontrolled documents.

Before using a product sold by a company of the LyondellBasell family of companies, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.
SELLER MAKES NO WARRANTY; EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY) OTHER THAN AS SEPARATELY AGREED TO BY THE PARTIES IN A CONTRACT.

Users should review the applicable Safety Data Sheet before handling the product.
This product(s) may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application:
(i) U.S. FDA Class I or II Medical Devices; Health Canada Class I, II or III Medical Devices; European Union Class I or II Medical Devices;
(ii) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices;
(iii) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; tobacco related products and applications, electronic cigarettes and similar devices.

The product(s) may not be used in:
(i) U.S. FDA Class III Medical Devices; Health Canada Class IV Medical Devices; European Class III Medical Devices;
(ii) applications involving permanent implantation into the body;
(iii) life-sustaining medical applications.

All references to U.S. FDA, Health Canada, and European Union regulations include another country's equivalent regulatory classification.
In addition to the above, LyondellBasell may further prohibit or restrict the use of its products in certain applications. For further information, please contact a LyondellBasell representative.

Addhere, Adflex, Adstif, Adsyl, Akoafloor, Akoalit, Alathon, Amazing Chemistry, Aquamarine, Aquathene, Avant, Catalloy, Clyrell, CRP, Crystex, Dexflex, Explore & Experiment, Flexathene, Glacido, Hifax, Histif, Hostacom, Hostalen, Ideal, Integrate, Koattro, LIPP, Lucalen, Luflexen, Lupolen, Lupolex, Luposim, Lupostress, Lupotech, Metocene, Microthene, Moplen, Nerolex, Nexprene, Petrothene, Plexar, Pristene, Prodflex, Pro-Fax, Purell, Sequel, Softell, Spherilene, Spheripol, Spherizone, Starflex, Stretchene, Superflex, Toppyl, Trans4m, Ultrathene, Vacido and *Valtec* are trademarks owned or used by the LyondellBasell family of companies.

Adsyl, Akoafloor, Akoalit, Alathon, Aquamarine, Avant, CRP, Crystex, Dexflex, Explore & Experiment, Flexathene, Hifax, Hostacom, Hostalen, Ideal, Integrate, Koattro, Lucalen, Lupolen, Microthene, Moplen, Nexprene, Petrothene, Plexar, Pristene, Pro-Fax, Purell, Sequel, Softell, Spheripol, Spherizone, Starflex, Toppyl, and *Ultrathene* are registered in the U.S. Patent and Trademark Office.

Clariant Masterbatches

CLARIANT

Gerresheimer Boleslawiec S.A

ul. Boleslawa Chrobrego 15
PL - 59-700 Boleslawiec
Poland

0000145632 26358650 25.08.2015

Declaration

Remafin White 22305+

Introduction

This declaration applies exclusively to the above mentioned product when used as colouring or additive agent of a plastic food contact material and article. Our mixture is not intended to come directly in contact with food in its original form: therefore, since Clariant has no influence on subsequent processing, this declaration can not be extended to the finished material or article. Indeed, the compliance of the end material or article with the food contact regulations is the responsibility of the converter. He is committed to meet all relevant legal requirements and to test the migration limits according the conditions of use (temperature, time, simulants) of the article in its finished form (e.g. volume, geometry, thickness). These conditions are not part of our knowledge and therefore are not under Clariant's control.

Framework Regulation (EC) No. 1935/2004 and GMP Regulation No 2023/2006

Framework Regulation (EC) No. 1935/2004 sets out the general rules that must be met by all classes of food contact materials without giving any specific rule of how to prove the safety of food contact articles: plastic materials are covered by specific measures in relation to component types used in the formulation of our mixtures:

- polymers and additives are regulated by Regulation (EU) No 10/2011 and its amendments.
- colourants (including dyes, organic and inorganic pigments) must not migrate and must also comply with the purity requirements laid down in the national laws of Member States. General requirements for colourants are listed in the EU Resolution of the Council of Europe, AP (89) 1 though this is not legally binding.
- catalysts, solvents and polymer production aids (not yet listed at EU level) shall be assessed with general rules of the Framework Regulation by the substance manufacturer and/or shall comply with the national legislations provisions.

The product is not expected to cause any contravention to the Framework Regulation since the subsequent stages of manufacture, processing and distribution of the end article are in line with the Good Manufacturing Practices (GMP) applicable to food contact materials and article's supply chain, as listed in Regulation (EC) No 2023/2006. In addition, we would declare that our own production process, as a part of this supply chain will conform to the provisions of GMP.

Hereafter the status of the different component types is given according to their applicable legislation and based on the declarations received by Clariant from starting materials suppliers:

Commission Regulation (EU) No 10/2011 and its amendments

The reproduction, entirely or partially, of this declaration or any deductive reasoning derived from it is not under Clariant's responsibility. The validity of these statements is twelve months.

All the carriers and the intentionally added additives comply with the requirements of Regulation (EU) No 10/2011 and its amendments published before the release date of this certificate. We would like to remind you that the assessment of overall migration limit and other release restrictions such as those found in Annex II (e.g. the release of aromatic amines in a detectable quantity) is the responsibility of the producer of the finished article (converter). Information regarding components subjected to further specific limitations and concerning the presence of dual-use additives is given hereunder.

Restrictions and Limitations

- Barium sulphate: SML (T) = 1 mg/Kg expressed as Barium.
- Zinc sulfide: SML(T) = 25 mg/kg (as zinc) see also note (38)
- Triethanolamine, SML = 0.05 mg/kg, SML expressed as the sum of triethanolamine and of hydrochloride adduct expressed as triethanolamine.
- Zinc salts (including double salts and acid salts) of authorised acids, phenols or alcohols: SML = 25 mg/kg (expressed as Zn)
- 1,1,1-Trimethylolpropane: SML = 6mg/kg

Please note, that the following dual-use-additives are contained:

FCM number / name of the additive / content of the additive (given in range)

106	Stearic acid & derivatives	1 - 2,5 %
610	Titanium dioxide	40 - 60 %

SML	Specific Migration Limit	SML(T)	Specific Migration Limit expressed as Total
DL/LR/NG	Detection Limit	FP/PF/BG	Finished Product or Article

European Resolution AP (89) 1

All the colourants used meet the requirements established in European Resolution AP(89) 1 in regard to the maximum permissible levels of heavy metals, primary aromatic amines, sulphonated aromatic amines and polychlorinated biphenyls.

Belgium: Arrêté Royal from 11.05.1992 of the Moniteur Belge 24.07.1992

All the colourants used meet the purity requirements listed in the Arrêté Royal from 11.05.1992 of the Moniteur Belge 24.07.1992 and its amendments.

France: Jorf

All the colorants fulfil the applicable requirements and restrictions for food contact applications.

Germany: BfR Recommendation IX

There are no objections to the use of the colourants in this product according to the Recommendation IX of the BfR (Federal Institute for Risk Assessment).

Italy: Decreto Ministeriale

All the colourants used, meet the purity requirements listed in the Decreto Ministeriale of 21.03.1973 and its amendments.

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The Netherlands: Warenwet

All the colourants used meet the purity requirements listed in the Dutch regulation Warenwet and its amendments.

Spain: Real Decreto 847/2011 (subsecretaria para Sanidad)

All the colourants used meet the purity requirements listed in Annex II of Real Decreto 847/2011 (subsecretaria para Sanidad) and its amendments.

Turkey: Food Codex Regulation

All the components used meet the requirements of Turkish Food Codex Regulation on materials and articles which are intended to come into contact with foodstuffs issued in December 29th 2011 and its amendments.

We would also like to inform you of the status of our product in regard to the Directive 94/62/EC, CONEG (Regulation status and the content of diarylide pigments):

Directive 94/62/EC and CONEG

Based on the knowledge of the raw materials as well as of the manufacturing process, we are able to confirm that the product does not contain intentionally added heavy metals. The product meets the requirements of the Directive 94/62/EC and the CONEG regulation which limits the content of heavy metals up to 100 ppm (Cd, Pb, Hg, Cr(VI)). National regulations such as D.L.22 del 5/02/97 (IT), Ley de envases y residuos de envases 11/97 (ES) are also satisfied.

Diarylide Pigments

The product does not contain any intentionally added diarylide pigment in its chemical composition.

Clariant Polska Spółka z o.o.

This information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. Clariant makes no warranties, express or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of Clariant's products for its particular application. Nothing included in this information waives any of Clariant's General Terms and Conditions of Sale, which control unless it agrees otherwise in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing Clariant products, are available upon request and are provided in compliance with applicable law. You should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact Clariant.
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NO EXPRESS OR IMPLIED WARRANTY IS MADE OF THE MERCHANTABILITY, SUITABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE OF ANY PRODUCT OR SERVICE.
9/2010

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Clariant Masterbatches

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

27392830 07.06.2016

Declaration

REMAFIN-WHITE PE 22305+

Introduction

This document is intended to provide information on the current status of the above-referenced material under certain regulatory programs. Please review this document carefully and contact your Clariant representative if you have any questions.
All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field. Due to the broad range of possible applications we make no warranty that the actual use of the product in the finished article is comprised by the information below.

Hereafter the status of the different component types is given according to their applicable legislation and based on the declarations received by Clariant from starting materials suppliers:

USA Food and Drug Administration

In the USA substances used as a component of articles intended to come into contact with food are regulated by Food and Drug Administration FDA 21 CFR Title 21. Specific limitations and conditions of use, as set forth in these regulations, are specified below.Please note the maximum use rate specified below must be met to ensure regulatory compliance.

The components entering into the formulation of the above-referenced product are approved under one or more of the specific FDA paragraphs or have other clearances listed below:

1. Colorants listed in 21 CFR 178.3297 "Colorants for Polymers."
2. Components that are exempt from regulation under 21 CFR 170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
3. Polymers and/or additives listed in the appropriate parts of 21 CFR (174, 175, 176, 177, 178, 181, 182, 184 and 186).
4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.

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5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
6. Substances that are "Prior Sanctioned" for use in this application.
7. Substances that are the subject of applicable Food Contact Substance Notifications.

The above statement is valid only if the dosage ratio listed below is not exceeded in the application polymer:

Application polymer	Max. let-down ratio (w/w)
HDPE	No limitation.
The above-mentioned declaration is only valid if the finished article is not used for packing or containing food during cooking (conditions of use C through G described in title 21 CFR, §176.170(c)).	
LLDPE	No limitation.
The above-mentioned declaration is only valid if the finished article is not used for packing or containing food during cooking (conditions of use C through G described in title 21 CFR, §176.170(c)).	
LDPE	No limitation.
The above-mentioned declaration is only valid if the finished article is not used for packing or containing food during cooking (conditions of use C through G described in title 21 CFR, §176.170(c)).	
PP	No limitation.
The above-mentioned declaration is only valid if the finished article is not used for packing or containing food during cooking (conditions of use C through G described in title 21 CFR, §176.170(c)).	

If you do not find your application polymer, please contact your Clariant product safety representative.

We would also like to inform you of the status of our product in regard to the Directive 94/62/EC, CONEG (Regulation status and the content of diarylide pigments):

Directive 94/62/EC and CONEG

Based on the knowledge of the raw materials as well as of the manufacturing process, we are able to confirm that the product does not contain intentionally added heavy metals. The product meets the requirements of the Directive 94/62/EC and the CONEG regulation which limits the content of heavy metals up to 100 ppm (Cd, Pb, Hg, Cr(VI)). National regulations such as D.L.22 del 5/02/97 (IT), Ley de envases y residuos de envases 11/97 (ES) are also satisfied.

Diarylide Pigments

The product does not contain any intentionally added diarylide pigment in its chemical composition.

Clariant Plastics & Coatings (Nordic) AB

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Country Product Stewardship

This declaration was produced automatically and therefore does not have an original signature.

This information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. Clariant makes no warranties, express or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of Clariant's products for its particular application. Nothing included in this information waives any of Clariant's General Terms and Conditions of Sale, which control unless it agrees otherwise in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing Clariant products, are available upon request and are provided in compliance with applicable law. You should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact Clariant.

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Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

27392821 07.06.2016

Declaration

REMAFIN-WHITE PE 22305+

Introduction

All statements refer exclusively to the named product in its current formulation: they are based on the present state of our knowledge and experience and concern the product in its original form and packaging as supplied from our factory.
Since the masterbatch and compound manufacturer has no influence on subsequent processing, the processor himself is responsible for ensuring that the finished article is suitable for the intended use, and is also responsible for ascertaining the compliance of the end article with the national and international regulations and laws concerning its application field.

Additional information

- Based on the current formulation of the above mentioned product, the following substances have not been intentionally added during its production:

  Allergens, Melamine, Latex, Phthalates, Bisphenol A

  These substances were not used as starting materials during the mixing phase of our product but, on the basis of our current knowledge, we cannot give you any warranty they are not constitutionally contained (or are present at level of ubiquitous(**) traces) in raw materials.
  Please note that, in any case our Company does not carry out any specific analysis in order to detect the presence of above mentioned substances.
  (**)Ubiquitous in regard to a chemical substance means that this substance is omnipresent (occurs literally everywhere) and its occurrence in this "ubiquitous" traces cannot be avoided by any technical, physical or chemical measure.

Additional information

In addition be informed that, in case here above was not clearly mentioned, you can find the following information into the Safety Data Sheet you already got by us:
- the ingredients that may be classified as dangerous for health and environment;
- information on restriction on use that we are aware of and that could be relevant for plastic applications.

The reproduction, entirely or partially, of this declaration or any deductive reasoning derived from it is not under Clariant's responsibility. The validity of these statements is twelve months.

Clariant Plastics & Coatings (Nordic) AB

Country Product Stewardship

This declaration was produced automatically and therefore does not have an original signature

This information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. Clariant makes no warranties, express or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of Clariant's products for its particular application. Nothing included in this information waives any of Clariant's General Terms and Conditions of Sale, which control unless it agrees otherwise in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing Clariant products, are available upon request and are provided in compliance with applicable law. You should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact Clariant.

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TEST REPORT

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 603427/4

1347624
4 July 2014
HEAN

Specifications

Closure

Type:	Duma Handy Cap 2813
Number:	002813-2000
Raw material:	LD 653 (PE-LD)
Colour:	White, PEZ121818X
Cavity:	1 - 12 (Mould B)

Container

Type:	Duma Standard 50 ml
Number:	031050-0000
Raw material:	GF4760 (PE-HD)
Colour:	White, PE 22305+
Cavity:	1-4 (Mould 1)

Test period: 13 June – 27 June 2014

Water Vapour Permeation

10 specimens of containers and closures have been tested according to USP 37 <671>. For containers used for drugs being dispensed on prescription, the containers so tested are *tight containers* if not more than one of the *10 test containers* exceeds 100 mg per day per litre in moisture permeability, and none exceeds 200 mg per day per litre.

The work has been carried out according to the General Terms and Conditions regarding commissioned work accepted by the Danish Technological Institute.

Results

mg water vapour per day per litre container-volume:

No 1	No 2	No 3	No 4	No 5	No 6	No 7	No 8	No 9	No 10
4.1	5.5	4.6	9.1	7.4	6.3	6.2	5.9	6.0	10.0

Average: 6.5 mg/d/l

Conclusion
The tested containers comply with the requirement of USP 37 <671> test for tight containers used for drugs being dispensed on prescription.

Centre: Packaging and Logistics

Helle Antvorskov, Senior Consultant
Phone: +45 72 20 31 69
e-mail: hean@dti.dk

Test responsible

Søren R. Østergaard, Head of Section Packaging
Phone: +45 72 20 31 80
e-mail: sos@dti.dk

Co-reader

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TEST REPORT

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 568694/1

4 September 2013
1347624
HEAN

Specifications

Container

Type:	Duma Standard 50 ml
Number:	031050-0000
Raw material:	GF4760 (HDPE)
Colour:	White, PE 22305+
Cavity:	2-3 (Mould 1)

Date of receipt: 3 September 2013
Test period: 3 September 2013

Light Transmission

Samples from the container have been tested according to USP 36 <671>. Requirement: The light transmission must not exceed 10 % in the range from 290 to 450 nm. Enclosure 1 shows the spectra from 290 to 450 nm of the samples from the container.

Results

maximum % light transmission:

Sample No 1	Sample No 2
7.4	6.4

Conclusion
The tested container complies with the requirement of USP 36 <671>.

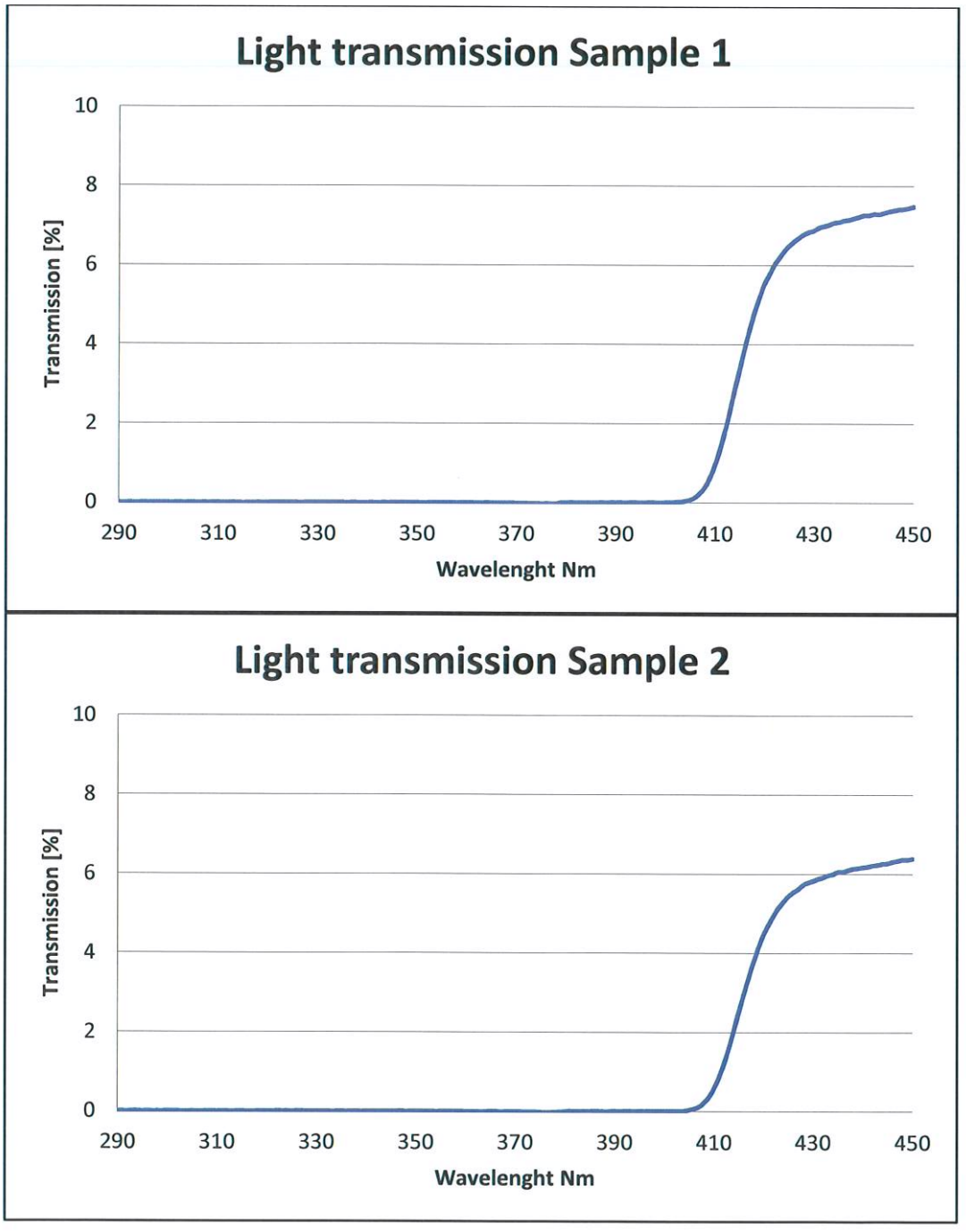
Centre: Packaging and Logistics

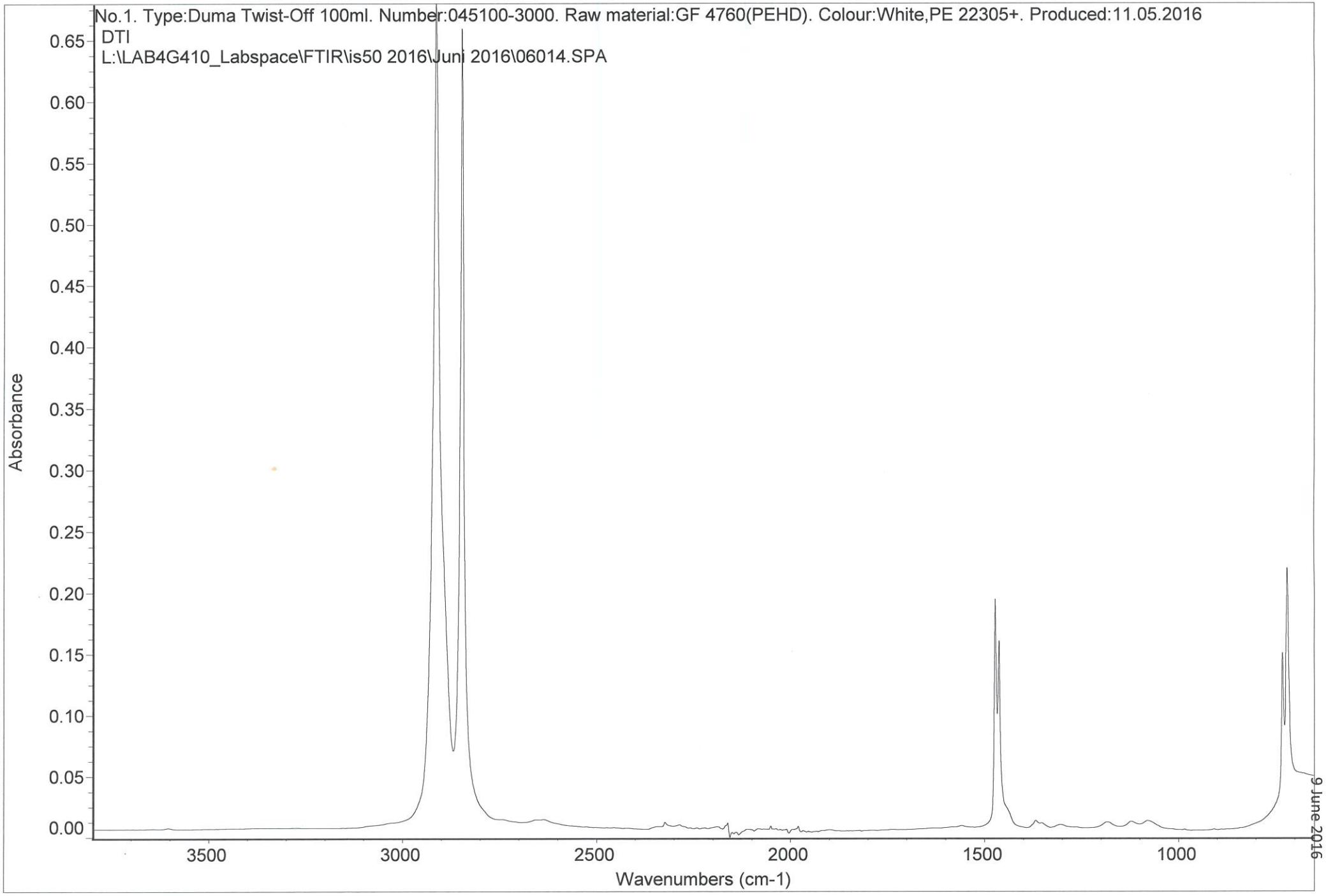
Maria Kisbæk
Consultant

Helle Antvorskov
Senior consultant

Gerresheimer Vaerloese

Type: Duma Standard 50 ml
Number: 031050-0000




No.1. Type:Duma Twist-Off 100ml. Number:045100-3000. Raw material:GF 4760(PEHD). Colour:White,PE 22305+. Produced:11.05.2016
DTI
L:\LAB4G410_Labspace\FTIR\is50 2016\Juni 2016\06014.SPA
Absorbance
0.65
0.60
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)
9 June 2016
Encl. 1

DANAK

TEST Reg. no. 127

1 August 2016
ten-decr
Rev. 1

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Test report

Customer

Gerresheimer Vaerloese A/S
Walgerholm 2-8
DK-3500 Vaerloese

Rep. no.: 139/16-2

No. of encl.: 1
Cosign:

Test

Thermal analysis

Sample

Raw material sent to our laboratory on 22 June 2016 bearing the following ID

DSC sample no. 1
Raw material: GF 4760 (HDPE)
Batch no.: SD 1042201

DSC sample no. 6
Raw material: GB 7250 (HDPE)
Batch no.: SC 2942101

Test method

The DSC (thermal analysis) is based on

USP 39 <661> *Containers - Plastics / Physical Tests*, which refers to
USP 39 <891> *Thermal Analysis*

One spot sample (approx. 12 mg) was taken from the raw material.
The following conditions were used for the comparative DSC analysis:

Heating	40 °C to +200 °C at 10 °C/min in nitrogen (80 ml/min)
Cooling	200 °C to 40 °C at 10°C/min in nitrogen (80 ml/min)

The peak values of the Onset temperature are compared.

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Test equipment

32T07.02	Calorimeter, Differential Scanning Calorimetry, DSC 823e from Mettler-Toledo
32T14.60	Analytical balance XS 105 from Mettler-Toledo
32T07.03	Reference sample of High density polyethylene from USP (Rockville)
Purge gas	Nitrogen (purity grading: 5) from Aga

Test results

Sample	Melting Peak °C	Onset °C	Difference between values (Onset temperature) °C
Ref sample of high density polyethylene	136.3	124.8	-
DSC sample no. 1 Raw material: GF 4760 (HDPE) Batch no.: SD 1042201	133.4	122.8	2.0
DSC sample no. 6 Raw material: GB 7250 (HDPE) Batch no.: SC 2942101	128.7	121.7	3.1

Acceptance criteria: Difference between values (Onset temperature) ≤ 6.0 °C
Test result: *Pass*

Rev. 1: The report has been revised because the ID of the samples in the results has been changed.

Yours sincerely
Centre for Plastics Technology

Tina Elmer Nielsen
Laboratory Technician

Phone: +45 72 20 31 13 (direct)
Email: ten@teknologisk.dk

Conditions: The test results are solely referring to the tested (examined) materials. The testing has been performed in compliance with an accreditation from the Danish Accreditation Scheme.
Enclosed are the General Terms and Conditions regarding Commissioned Work accepted by the Danish Technological Institute (DTI)
Publication of the Test Report in full is allowed. Publication of extracts from the Test Report is allowed, if the testing laboratory has given a written approval.

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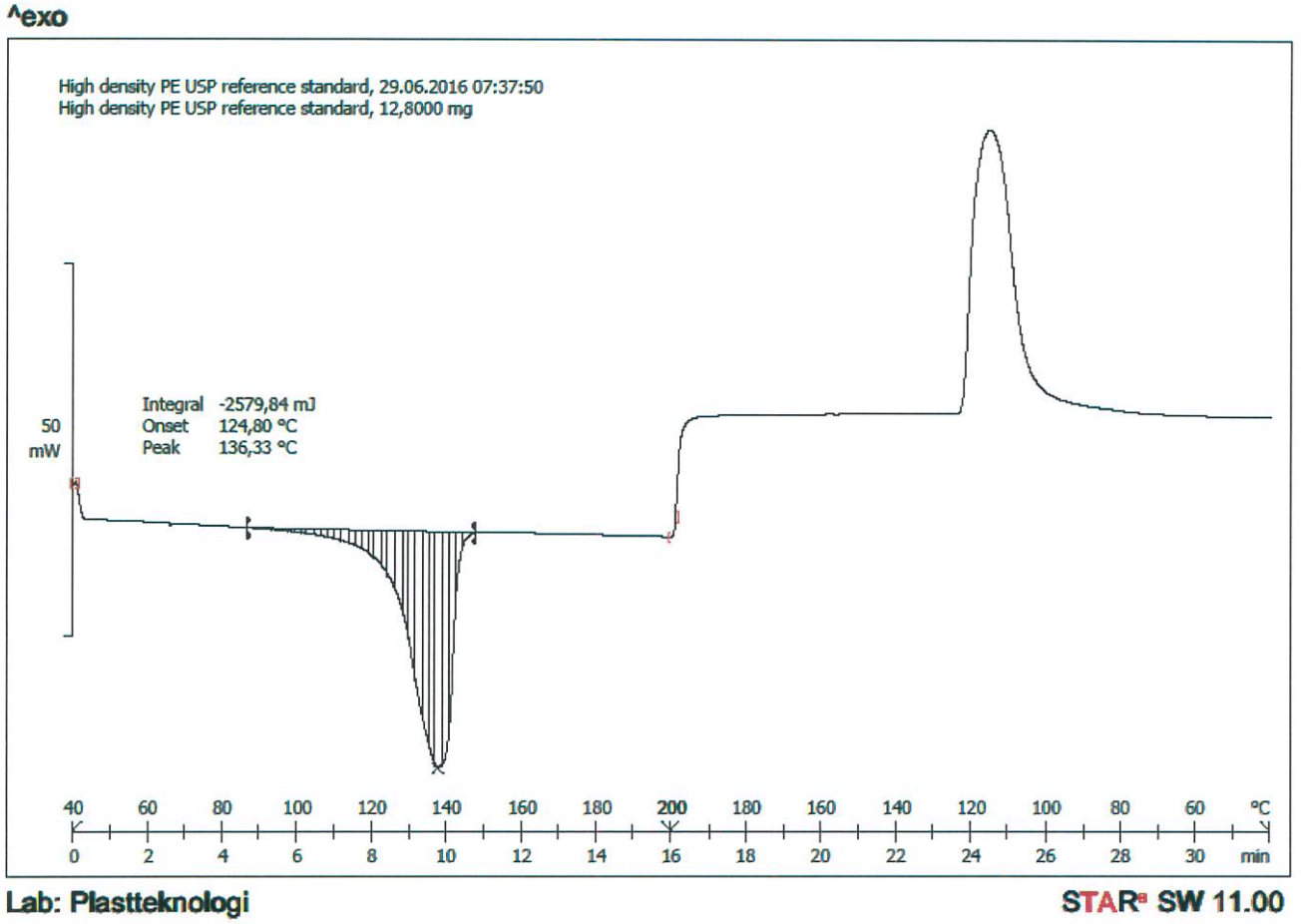

Ref sample of High-density polyethylene

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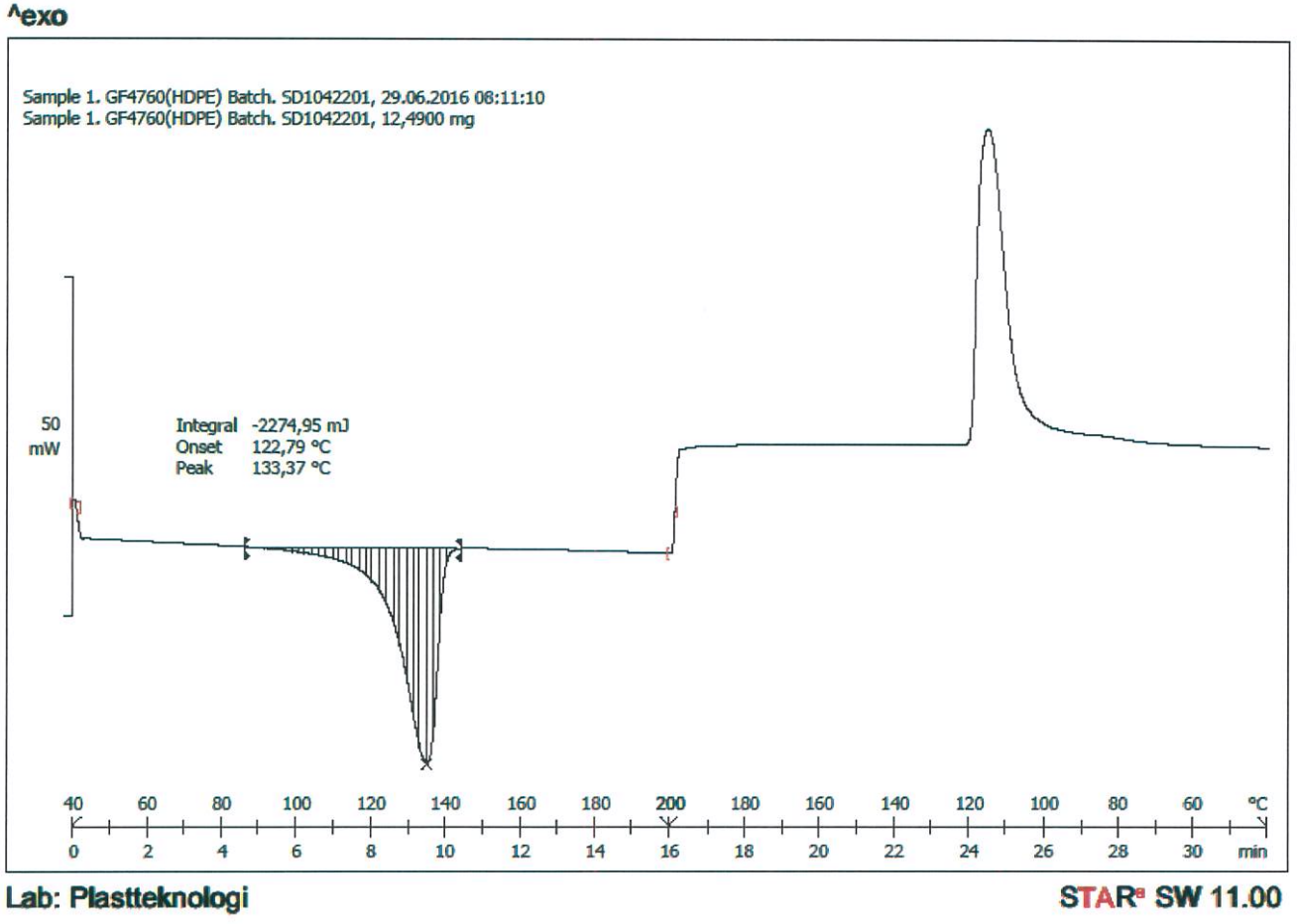

DSC sample no. 1
Raw material: GF 4760 (HDPE)
Batch no.: SD 1042201

DANISH
TECHNOLOGICAL
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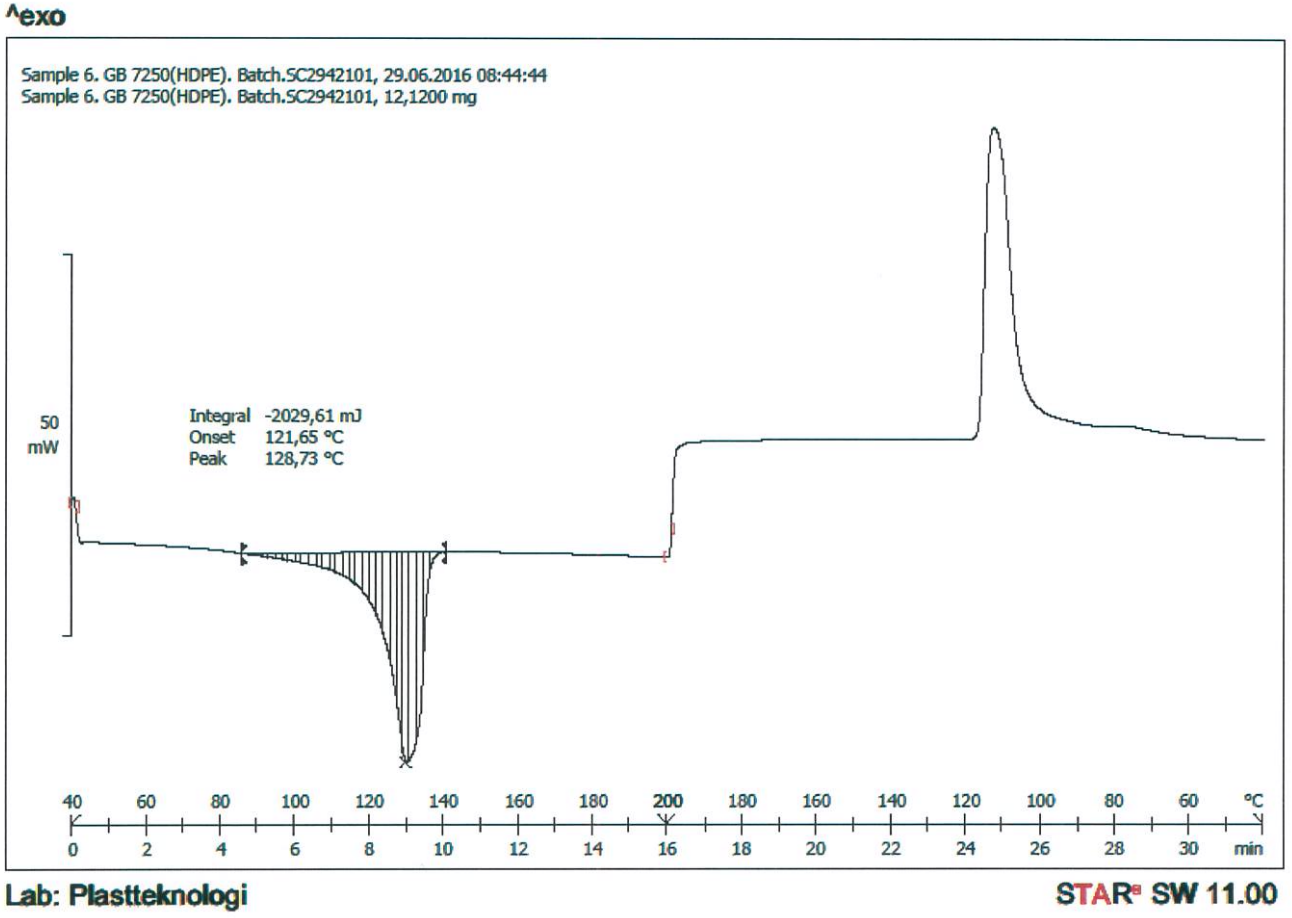

DSC sample no. 6
Raw material: GB 7250 (HDPE)
Batch no.: SC 2942101

TOXIKON
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STUDY REPORT TE161155 / 16-B3683

DUMA STANDARD 150 mL
DUMA HANDY CAP 4015

Client	:	Gerresheimer Vaerloese A/S
Contact	:	Mr. René Palmelund
Address	:	Walgerholm 2-8 DK-3500 Vaerloese Denmark

Client Purchase Order Number	:	not specified
Toxikon Quotation Number	:	1604018rev01
Date Receipt Samples	:	15 June 2016
Date Start Analysis	:	03 Aug 2016
Date Technical Completion	:	08 Aug 2016
Date Draft Report	:	09 Aug 2016
Date Final Report	:	19 Aug 2016

TESTS ON PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE: PACKAGING SYSTEM

ACCORDING TO UNITED STATES PHARMACOPOEIA 39 NF 34 GENERAL CHAPTER: 661.2, SECTION "PHYSICOCHEMICAL TESTS"

The test results on the enclosed report are only referring to the tested articles. Partly reproduction of this report can only be allowed after written permission of Toxikon. Toxikon guarantees that all results are acquired by testing according to officially accepted scientific methodology.

Iris Persy
for Frank De Smedt, PhD.
Study Director

Sofie Vercammen
Quality Assurance Unit

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1.0 OBJECTIVE OF THE STUDY

The aim of this study is to investigate if the Packaging System meets the requirements of the United States Pharmacopoeia 39 NF 34, Chapter 661.2.

2.0 REFERENCES

United States Pharmacopoeia 39 NF 34, Chapter 661.2 section "Physicochemical Tests".

3.0 TEST MATERIAL IDENTIFICATION

The following information is supplied by the Sponsor on a test requisition form or other correspondence wherever applicable; it does not apply to confidential information:

Test Material Name:	**043156-0000, 004015-2000**
Lot number:	**Sample 2**
Type Material:	**Polyethylene**
Colour:	**White**
Storage Conditions:	**Room temperature**
Nominal Volume:	**188 ml**

4.0 EXPERIMENTAL DESIGN

4.1 Sample preparation

Test Solution C1:

A container was filled till its nominal volume with Purified Water (PW) and closed. The container was subsequently **extracted at 70°C ± 2°C for 24h ± 2h**. After the extraction period, the test article was cooled till room temperature and emptied out. The emptied content is Test Solution C1.
Use Solution C1 within 4 hours of preparation.

A blank extract was prepared simultaneously using PW without any test material.

4.2 Physicochemical Tests

4.2.2 Absorbance

Within 4 hours after the preparation of Test Solution C1, an Absorbance spectrum between 230 nm and 360 nm was recorded with a Varian Cary 50 UV-VIS Spectrophotometer on Test Solution C1. The blank corrected maximum Absorbance of Test Solution C1 was 0.013 A.u.

4.2.3 Acidity or Alkalinity

To 20 mL of Test Solution C1, 0.1 mL of a Phenolphthalein Indicator Solution was added. The Test Solution C1 was colorless and turned pink when 0.4 mL 0.01 M Sodium Hydroxide Solution was added.
Subsequently 0.1 mL Methyl Red Indicator Solution was added and upon addition of 0.8 mL 0.01M Hydrochloric Acid Solution the Test Solution C1 changed color to orange-red.
Methyl Red: Test for sensitivity: Add 0.1 ml Methyl Red Indicator Solution and 0.05 ml of 0.02 M Hydrochloric Acid to 100 ml of CO2-free PW. Not more than 0.1 ml of 0.02 M Hydrochloric Acid is required to change the color from red to yellow.

4.2.4 Total Organic Carbon

Within 4 hours after the preparation Test Solution C1 was measured using a Sievers M9 Lab instrument. The measured TOC concentrations of Solution C1 are shown below in table 1.

	TOC Test result (mg/L)
Blank	< 0.2
Test Extract Solution	0.84

Table 1: TOC results

4.3 Summary of Test Results

TEST	**TEST RESULT**	**EVALUATION CRITERIA**	**Pass / Fail**
Absorbance	0.013	Maximum Absorbance between 230 nm to 360 nm ≤ 0.20 A.u.	PASS
Acidity	add 0.4 mL 0.01 M NaOH → colorless to pink	≤ 0.4 ml of 0.01 M NaOH → colorless to pink	PASS
Alkalinity	Add 0.8 mL 0.01 M HCl → pink to orange-red	≤ 0.8 ml of 0.01 M HCl → pink to orange-red	PASS
TOC	0.84 mg/L	Maximum difference between sample and blank TOC concentration ≤ 8 mg/L	PASS

Table 2: Overview of Test Result.

5.0 CONCLUSION

Based on the evaluation criteria mentioned above, the test material *complies* with the requirements of the United States Pharmacopoeia 39 NF 34, Chapter 661.2 section "Physicochemical Tests".

6.0 RECORDS

The original final report and possible amended reports are forwarded to the Sponsor.

A copy of the final report and possible amended reports, original raw data and records, lab-notebooks, the sponsor signed contract, communications and documentation of deviations are archived at Toxikon Europe for a minimum of 10 years according to SOP 4.2.8 and SOP 4.2.7 Current Revisions, or will be sent to the sponsor on written request.

All unused test articles will be discarded by Toxikon Europe earliest 12 months after sample receipt, or will be sent back to the sponsor on written request.

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STUDY REPORT TE161155 / 16-B3685

DUMA SPECIAL 300 mL
DUMA HANDY CAP 6017

Client	:	Gerresheimer Vaerloese A/S
Contact	:	Mr. René Palmelund
Address	:	Walgerholm 2-8 DK-3500 Vaerloese Denmark

Client Purchase Order Number	:	not specified
Toxikon Quotation Number	:	1604018rev01
Date Receipt Samples	:	15 June 2016
Date Start Analysis	:	03 Aug 2016
Date Technical Completion	:	08 Aug 2016
Date Draft Report	:	09 Aug 2016
Date Final Report	:	19 Aug 2016

TESTS ON PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE: PACKAGING SYSTEM

ACCORDING TO UNITED STATES PHARMACOPOEIA 39 NF 34 GENERAL CHAPTER: 661.2, SECTION "PHYSICOCHEMICAL TESTS"

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for Frank De Smedt, PhD.
Study Director

Sofie Vercammen
Quality Assurance Unit

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1.0 OBJECTIVE OF THE STUDY

The aim of this study is to investigate if the Packaging System meets the requirements of the United States Pharmacopoeia 39 NF 34, Chapter 661.2.

2.0 REFERENCES

United States Pharmacopoeia 39 NF 34, Chapter 661.2 section "Physicochemical Tests".

3.0 TEST MATERIAL IDENTIFICATION

The following information is supplied by the Sponsor on a test requisition form or other correspondence wherever applicable; it does not apply to confidential information:

Test Material Name:	**065300-4000, 006017-4000**
Lot number:	**Sample 4**
Type Material:	**Polyethylene**
Colour:	**White**
Storage Conditions:	**Room temperature**
Nominal Volume:	**353 ml**

4.0 EXPERIMENTAL DESIGN

4.1 Sample preparation

Test Solution C1:

A container was filled till its nominal volume with Purified Water (PW) and closed. The container was subsequently **extracted at 70°C ± 2°C for 24h ± 2h**. After the extraction period, the test article was cooled till room temperature and emptied out. The emptied content is Test Solution C1.
Use Solution C1 within 4 hours of preparation.

A blank extract was prepared simultaneously using PW without any test material.

4.2 Physicochemical Tests

4.2.2 Absorbance

Within 4 hours after the preparation of Test Solution C1, an Absorbance spectrum between 230 nm and 360 nm was recorded with a Varian Cary 50 UV-VIS Spectrophotometer on Test Solution C1. The blank corrected maximum Absorbance of Test Solution C1 was 0.003 A.u.

4.2.3 Acidity or Alkalinity

To 20 mL of Test Solution C1, 0.1 mL of a Phenolphthalein Indicator Solution was added. The Test Solution C1 was colorless and turned pink when 0.4 mL 0.01 M Sodium Hydroxide Solution was added.
Subsequently 0.1 mL Methyl Red Indicator Solution was added and upon addition of 0.8 mL 0.01M Hydrochloric Acid Solution the Test Solution C1 changed color to orange-red.
Methyl Red: Test for sensitivity: Add 0.1 ml Methyl Red Indicator Solution and 0.05 ml of 0.02 M Hydrochloric Acid to 100 ml of CO2-free PW. Not more than 0.1 ml of 0.02 M Hydrochloric Acid is required to change the color from red to yellow.

4.2.4 Total Organic Carbon

Within 4 hours after the preparation Test Solution C1 was measured using a Sievers M9 Lab instrument. The measured TOC concentrations of Solution C1 are shown below in table 1.

	TOC Test result (mg/L)
Blank	< 0.2
Test Extract Solution	0.57

Table 1: TOC results

4.3 Summary of Test Results

TEST	**TEST RESULT**	**EVALUATION CRITERIA**	**Pass / Fail**
Absorbance	0.003	Maximum Absorbance between 230 nm to 360 nm ≤ 0.20 A.u.	PASS
Acidity	add 0.4 mL 0.01 M NaOH → colorless to pink	≤ 0.4 ml of 0.01 M NaOH → colorless to pink	PASS
Alkalinity	Add 0.8 mL 0.01 M HCl → pink to orange-red	≤ 0.8 ml of 0.01 M HCl → pink to orange-red	PASS
TOC	0.57 mg/L	Maximum difference between sample and blank TOC concentration ≤ 8 mg/L	PASS

Table 2: Overview of Test Result.

5.0 CONCLUSION

Based on the evaluation criteria mentioned above, the test material *complies* with the requirements of the United States Pharmacopoeia 39 NF 34, Chapter 661.2 section "Physicochemical Tests".

6.0 RECORDS

The original final report and possible amended reports are forwarded to the Sponsor.

A copy of the final report and possible amended reports, original raw data and records, lab-notebooks, the sponsor signed contract, communications and documentation of deviations are archived at Toxikon Europe for a minimum of 10 years according to SOP 4.2.8 and SOP 4.2.7 Current Revisions, or will be sent to the sponsor on written request.

All unused test articles will be discarded by Toxikon Europe earliest 12 months after sample receipt, or will be sent back to the sponsor on written request.

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ISO 17025 BELAC 363 - TEST

TEST RESULT REPORT: 16-B3694-N1

Project Number:	**TE161161**	**Report Date:**	**30/06/2016**
Sponsor:	**Gerresheimer Vaerloese A/S**		
Contact Person:	*René Palmelund*		
Address:	Walgerholm 2-8	Date Sample Arrival:	15/06/2016
City, State, Zip:	3500 Vaerloese	Technical Initiation:	27/06/2016
Country:	Denmark	Technical Completion:	30/06/2016

Study:	**Qualitative MEM-elution: Dye exclusion**	Temp/Time	37°C/24 hours
Test article name:	**045060-3000**	Ratio	4g/20mL
Lot number:	**Sample 1**	Vehicle	MEM-Complete

REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." and "USP 39-NF 34, 2016: <87> Biological reactivity test, in vitro." Toxikon Reference: SOP 3.1.2.3, rev. 10

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The control articles were autoclaved prior to the preparation of the extracts. Extracts were prepared at 37±1°C for 24±2 hours in a humidified atmosphere containing 5±1% carbon dioxide (static). Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The test item extract was sterile filtered. The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in triplicate and the cultures are subsequently incubated for 2 days, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity). The test item is considered to have no cytotoxic potential if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

RESULTS: No reactivity (Grade 0) was exhibited by the cell cultures exposed to the test item at the 2 days observation. Severe reactivity (Grade 4) was observed for the positive control article. The negative control article showed no signs of reactivity (Grade 0).

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered to have no cytotoxic potential.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

01 JUL 2016
Ms. Vanessa Ruymen
Study Director

04 JUL 2016
Ms. Anja De Schouwer
Quality Assurance

The test results on the enclosed report are only referring to the tested articles. Partly reproduction of this report can only be allowed after written permission of Toxikon. Toxikon guarantees that all results are acquired by testing according to officially accepted scientific methodology.

Quality Control

The quality assurance system of Gerresheimer Plastic Packaging is oriented towards a “zero defect strategy”. AQL values for dimensions must be within agreed specified limits. The necessary safety with respect to avoidance of dimensions out of specification (OOS) is achieved by means of process validation including risk analysis and/or in-line measurements and/or measurements on samples.

AQL values are defined on attributive characteristics according to below classification.

Classification of defects

Classification of defect	Effects of defects	Defect class	AQL Containers / Caps		Consequence
Critical	Critical defects are defects whose presence can have critical consequences. They can, for example: • endanger human life or health • or violate legal requirements • or lead to destruction or alteration of filling material • or seriously impair the reliability of storage • or seriously impair the efficiency of production tools, filling and packaging equipment	1	(*)	(*)	Packaging material not usable
Major	Major defects are defects whose presence can lead to considerable impairment. They can, for example: • lead to inefficient function and thus to deficiency of the packaging material/pack • or lead to consumer complaint • or lead to reduced efficiency in production • or impair the efficiency of production tools, and filling and packaging equipment	2A	0.25	0.1	Usability of packaging material markedly impaired
		2B	1.0	0.4	Usability of packaging material moderately impaired
Minor	Minor defects are defects whose presence do not have essential consequences, for instance they • represent a reduction in general quality	3	4.0	2.5	Usability of packaging material slightly impaired

(*) No AQL value is defined for defect class 1 since for this defect class, tests are done against zero defects with the greatest possible certainty and/or manufacturing process is to be correspondingly validated.
The necessary safety with respect to the avoidance of critical defects class 1 is achieved by means of process validation measures including risk analysis and/or in-line inspection and system checks. If defects of class 1 are found, it must be determined whether the entire batch or part of the batch is affected.

If a partial quantity containing a critical, major or minor defect can be clearly and reliably separated, the quality of the remainder of the batch must be evaluated separately.

AQL values for IBM containers

Defects	Defect class
- Raw material, primary packaging or labelling not according to specification - Mix-up - CFU exceeds specification - Shelf life exceeded - Moisture vapour transmission or light transmission or multiple internal reflectance or differential scanning calorimetry or physicochemical or biological reactivity – in vitro <87> OOS according to USP or EP - Migration testing exceeds requirements for food contact material - Contamination inside, contamination outside - can get into content - Tears, clefts, holes, incompletely moulded - function or tightness not ensured - Defects on sealing points - tightness impaired - Engraved/embossed text is missing or incorrect	1
- Foreign bodies incorporated in the material - Contamination outside on product - cannot get into content - Inhomogeneous colour - Deformation, not fully moulded, inhomogeneous distribution of material - usability markedly impaired - Flashes - usability markedly impaired - Wall thickness outside specifications - Black spots/degraded material ≤ 2 spots per container more than > 0.5 mm - Uneven surface - Bag with holes or incompletely welded	2A
- Defects on sealing points - tightness not impaired - Flashes - usability moderately impaired - Black spots/degraded material ≤ 2 spots per container - Black stripes in split line and bottom - Notches, clefts and roughness	2B
- Deformation - usability slightly impaired - Black spots which are only visible by the naked eye from a distance less than 1/2 m	3

If a carton is damaged or soiled upon arrival, the error must be noted at arrival on the shipping documents and the carton discarded. The remaining part of the batch is to be received as normal goods.

Quality control for IBM containers

Activity	Control
Incoming control of raw materials	Identification of goods received and control of certificates.
Set-up new mould or change of raw materials or control specification	**Line clearance** including control of correct use of raw materials. Three samples of each cavity produced at the same time are visually controlled as well as checked for critical dimensions with plug-and ring gauges by production and QC prior to production start.
Production	QC operator performs a **visual control** of the products in accordance with ISO 2859-1. The samples are taken every hour (one sample per cavity produced at the same time). A sample of each cavity is checked for critical dimensions with plug-and ring gauges every second hour. New approval by production and QC is required after **machine stops** lasting more than one hour. In case of unplanned machine stops where products can be defected the products are 100% controlled or scrapped. If defects are detected, products are quarantine stored or 100% controlled.
Quality control	QC **reviews all the production documentation** and point out products that need additional control. This also includes follow-up on products which are quarantine stored by production. QC **controls the dimensions** of the samples from two of the in-process controls with plug-and ring gauges. QC controls the pallets for mix-up and incorrect labelling, releases the products and issue certificates with the results of the controls.

Gerresheimer Vaerloese A/S · Walgerholm 2-8 · DK-3500 Vaerloese · Denmark

GERRESHEIMER

April 08, 2016

Declaration of Conformity

European Pharmacopoeia (EP)

Declaration concerns all products manufactured in Gerresheimer Vaerloese A/S with the following composition:

- **Purell GF 4760 / White masterbatch**

Based upon certificate from our supplier of the above mentioned resin, Gerresheimer Vaerloese A/S hereby states that the resin complies with the European Pharmacopoeia, paragraph 3.1.3 "Polyolefines".

The masterbatch used during production of our products complies with the relevant regulations related to plastic materials intended to come into contact with food however the supplier does not declare the material to be in compliance with the European Pharmacopoeia.

Gerresheimer Vaerloese A/S additionally informs that our packages dedicated for solid oral dosage forms and solid active substances are tested in accordance with food law. For such substances, it has been agreed by the Joint Committee for Medicinal Products for Human Use / Committee for Medicinal Products for Veterinary Use Quality Working Party that plastic materials compliant with the relevant European Union (EU) food legislation relating to plastic materials and articles intended to come into contact with foodstuffs are considered acceptable.

Yours sincerely,

Anna Wiśniewska

Anna Wiśniewska
Regulatory Affairs Manager

Gerresheimer Plastic Packaging

GERRESHEIMER

DECLARATION OF CONFORMITY

Gerresheimer Vaerloese A/S
Walgerholm 2-8
3500 Værløse, Denmark

European Union (EU) Food Contact

Based upon the certificates from our suppliers of resin and masterbatch, product tests and our certified Quality system, Gerresheimer Vaerloese A/S hereby confirms that the below listed products comply with relevant requirements of Regulation (EC) No 1935/2004 (Framework Regulation) on materials and articles intended to come into contact with food, Regulation (EC) No 2023/2006 (GMP) on good manufacturing practice for materials and articles intended to come into contact with food and Regulation (EU) No 10/2011 (PIM) on plastic materials and articles intended to come into contact with food.

- **Duma Twist-Off Containers – White coloured products**
- **Duma Standard Containers – White coloured products**
- **Duma Special Containers – White coloured products**
- **Duma Rectangular – White coloured products**
- **Dudek Containers – White coloured products**

The intended use for the above listed products is storage of medicine and foodstuff as powder and tablets according to the product specification.

When used as specified, tests have shown that the overall migration as well as the specific migration does not exceed the legal limits.

The formulation of the raw materials used for the production of the concerned products contains the below listed substances considered to be a dual-use substance according to Regulation (EU) No 10/2011:

- Titanium Dioxide

The migration tests have been performed according to Regulation (EU) No. 10/2011 (Annex V):

- Test conditions (contact time above 30 days at room temperature):
  - Tenax / 10 days / 40°C
  - Isooctane / 2 days / 20°C
  - Acetic Acid / 10 days / 40°C

- Surface to volume ratio:
  - Tenax: According to EN 1186 & EN 14388
  - Isooctane: 1,3 dm^2 / 100 ml – 2,0 dm^2 / 100 ml
  - Acetic Acid: 1,7 dm^2 / 100 ml – 2,0 dm^2 / 100 ml

The products have been tested for contact with dry food to long time storing at room temperature.

A functional barrier made from plastic is not used in the above mentioned products.

USA Food and Drug Administration and US Pharmacopoeia (USP)

Based upon certificates from our suppliers of resin and masterbatch, we state compliance of Purell PE GF 4760 with relevant parts of FDA title 21 CFR § 177.1520 and of Remafin-White PE 22305+ with relevant parts of FDA title 21 CFR §178.3297 & 177.1520.

The products comply with the requirements defined in the USP in relation to the following tests:

- <661> Multiple Internal Reflectance
- <661> Heavy Metals and Non-volatile Residue
- <671> Moisture Vapour Transmission (Water Vapour Permeation)
- <671> Light Transmission

Værløse, November 23, 2015

Steen Jørndrup
Quality Manager

GERRESHEIMER

May 19, 2016

Declaration of Conformity

Gerresheimer Plastic Packaging requires from all raw materials suppliers to inform about any animal derived substances used for production of their products and also requests from suppliers to consider and fulfill the relevant regulations of the European Community about the avoidance of TSE/BSE contamination.

If applicable, all suppliers are requested to fulfil the requirements:

- The animal derived substances used for the manufacturing of their polymers are either produced from animals originating from BSE-free countries or are free from SRM (specified Risk Material).
- The manufacture of the animal derived substances involves rigorous processes that meet/exceed the very severe process conditions for inactivating any BSE/TSE agent.

If any of raw materials contain ancillary materials based on fatty acid, such fatty acids might have a number of origins from for example plants, animal or synthetic, where the animal origin is the most common. The use of these subsidiaries as ancillary materials, including packaging for the pharmaceutical - and the foodstuff industries, are regulated through a number of EU directives. Tallow derived materials used in some product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3". These directives regulate the general use of these products and specifically security against BSE to transmit to pharmaceutical - or foodstuff products.

Gerresheimer Plastic Packaging has received statements or certificates from all suppliers, where they state that:

- their products do not contain specific material of risk (SRM) and that infection does not transmit via their products, or
- their products fulfilled all requirements laid down in relevant regulations concerning BSE/TSE substances.

Yours sincerely,

Anna Wiśniewska

Anna Wiśniewska
Regulatory Affairs Manager

Gerresheimer Plastic Packaging

GERRESHEIMER

April 08, 2016

Declaration of Conformity

Gerresheimer Plastic Packaging only process the raw materials delivered from the suppliers and does not add any additional materials to such raw materials. Based upon the certificates from the suppliers of the raw materials, Gerresheimer Plastic Packaging hereby confirms that:

- Allergens
- Latex
- Melamine
- Bisphenol A
- Phthalates

have not been intentionally added during their production. However, the fact that these substances are not used in these products it does not exclude that trace levels of these substances may be present as a result of the specific characteristics of the raw materials and/or of the manufacturing process. Please note that, in any case suppliers do not carry out any specific analyses in order to detect the presence of the above mentioned substances.

The information is given to the best of our knowledge and does not include any warranty whatsoever. It must therefore not be misunderstood as guaranteeing specific properties.

Yours sincerely,

Anna Wiśniewska

Anna Wiśniewska
Regulatory Affairs Manager

Gerresheimer Plastic Packaging

Customer Complaint Report

GERRESHEIMER

❒ Complaint ❒ Comment / Remark Customer report No:	Established by / date:
Customers name / address / country:	Contact person / E-mail / Fax no.:
Article no.:	Date of delivery:
Batch no.:	Invoice no.:
Cavity no.:	Order no.:
Number of defective items:	Total quantity delivered:
Defect observed in: ❒ Incoming control……. Sample size: ❒ Production…….. Quantity of items used: ❒ Final product(s)…….. Quantity of items used: ❒ Complaint from end-user	
Defect found in: ❒ One carton ❒ Several cartons: Quantity _____	Exact production date/time from carton/bag or carton/bag/pallet number: ❒ Not available
Are filled/not filled products quarantined: ❒ Yes – Quantity (filled): ❒ Yes – Quantity (not filled): ❒ No ❒ N/A – no products left	Samples: ❒ Will be send ❒ Not available ❒ Additional information will be forwarded
Description of defect:	

Received by QA dept. (init. / date): _____

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Labelling

Company name:	Today's date:
❒ Wrong information ❒ Missing information ❒ Missing label ❒ Label difficult to read	
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
The defect is observed in ❒ One bag/carton ❒ Several bags/cartons - Quantity	
Exact production date and time for all concerned bags	
Exact quantity of defective items/bags/cartons	
How many bags/cartons have been controlled	
Amount of products blocked	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Loose silica gel / loose desiccant / defect on desiccant

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Defect observed in: ❒ Upon reception at your warehouse ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Defect observed in ❒ One bag ❒ Several bags - Quantity	
Exact production date and time for all concerned bags	
Exact quantity of defective items	
Are there any signs of damage to cap, desiccant or cardboard	
Are there any signs of transport damage to bag or carton	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Mix-up

Company name:	Today's date:
Ordered product	
Product received	
How many bags/cartons have been controlled	
Amount of products blocked	
Production date and time of all the concerned bags/cartons	

❒ Samples have been send
❒ Samples will be send
❒ Pictures are available
❒ No samples or pictures are available

For for mix-up - both carton label and bag label is important – and it would be helpful, if the pictures also showed the production date/time.

Comments:

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Partly- or disconnected TE-rings

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Quantity of caps with disconnected TE-rings	
Quantity of caps with partly disconnected TE-rings *Please specify quantity of broken bridges according to the AQL values/specification.*	
Specific cavity number affected	
Defect observed in: ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Defect observed in ❒ One bag/carton ❒ Several bags/cartons - Quantity	
Exact production date and time for all concerned bags	
Are there signs of damage to the cap/bag/carton	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Product defect

Company name:	Today's date:
❒ Samples have been send ❒ Samples will be send ❒ Pictures are available ❒ No samples or pictures are available	
Defect observed in: ❒ Upon reception at your warehouse ❒ Incoming inspection - sample size/plan:_____ ❒ Observed in PDS ❒ Before filling/when opening the cartons ❒ Before filling/on your line ❒ After filling ❒ Market complaint	
Exact quantity of defective items	
Specific cavity number affected	
Quantity of item used or controlled from the batch	
Amount of products blocked	
Amount of filled products blocked	
Defect observed in ❒ One bag ❒ Several bags – Quantity	
Exact production date and time for all concerned bags	
Comments:	

GERRESHEIMER

Information requested in relation to complaint investigation

We will kindly ask you to supply us with the answers to the below listed questions. The information is important for us, to make a thorough investigation.
Please return the information as soon as possible, so that we can initiate our investigation.

Transport

Company name:	Today's date:
❒ Pictures are available ❒ No pictures are available	
❒ A copy of the CMR ("Proof of delivery" from the transporter) has been forwarded ❒ A copy of the CMR ("Proof of delivery" from the transporter) will be forwarded ❒ The CMR ("Proof of delivery" from the transporter) is not available	
Defect observed on ❒ One carton ❒ Several cartons	
Exact quantity of damaged cartons	
Products can be used	❒ yes / ❒ No
Comments:	