Product Specification and Certificate

Product no.	002813-2000
Product name	Duma Handy Cap 2813
Product description	32 mm round plastic push-fit tamper-evident cap with a short opening tear-band and frangible connecting bridges. Intended for the sealing of: - Duma Special 30 ml HDPE Containers - Duma Standard 50 - 125 ml HDPE Containers
Design	· Regulatory drawing A002813 Regulatory · Standard drawing B002813
Raw material	LD 653, Low-density polyethylene (LDPE) in compliance with Commision Regulation (EU) No 10/2011, FDA title 21 CFR § 177.1520 "Olefin Polymers" and BfR recommendation III "Polyethylen", ExxonMobil. Coloured with white masterbatch, containing titanium dioxide. LD653 Declaration
Colour	21156601, Polyethylene (PE), in compliance with Commision Regulation (EU) No 10/2011 and FDA title 21 CFR §§ 177.1520 & 178.3297, A. Schulman or PEZ121818X Remafin-White/LUB, Polyethylene (PE), in compliance with Commision Regulation (EU) No 10/2011, FDA title 21 CFR §§ 177.1520 & 178.3297 and BfR recommendation IX, Clariant Plastics & Coatings (Nordic) AB. 21156601 Declaration 2016 PEZ121818X Declaration
Production	**Facility:** Vaerloese, Denmark **Process:** The caps are injection moulded **Hygiene:** The production takes place in clean room **Sterilisation:** N/A

Measures and Properties

Dimensions:

External:		Internal:	
Height	15.4 +0.5/-0.5 mm	Diameter	27.2 +0.15/-0.15 mm
Diameter	32.5 +0.2/-0.2 mm	Base ring	28.6 +0.15/-0.15 mm
Max. width	36.0 mm	Sealing plug	21.75 +0.15/-0.15 mm

Other dimensions:

Weight	2.9 +0.3/-0.3 gr	Shelf life	5 years
		Bioburden	Max. 50 CFU

Test Results

The container and cap comply with all demands for Water Vapour Permeability and Light Transmission and are in accordance with USP. Documentation enclosed.
WVP - 031030-0000/002813-2000/JUN2012
LT - 002813-4000/MAY2013

The container and cap comply with all demands for Multiple Internal Reflectance and fulfil the conditions regarding Heavy Metals and Non-volatile Residue and are in accordance with USP. Documentation enclosed.
IR - LD653 / PEZ121818X / PE1324184
Migr. - LD653/PE1324184/JUN2012

Packing and Way of Delivery

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

Carton dimensions:
Height (mm): 340 Length (mm): 580 Width (mm): 385

Packing information:
Number of items per carton: 3500 Volume per carton (m^3): 0.08
Max. number of cartons per pallet: 20 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 - 35º 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 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 Plastic Blow-moulded containers Vol. 23 - ISBN 3-87193-159-4.
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 - Duma Handy Cap - Vaerloese

Declaration of Conformity

DoC EP (LD653 White)
DoC Food Law (LD653)
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.

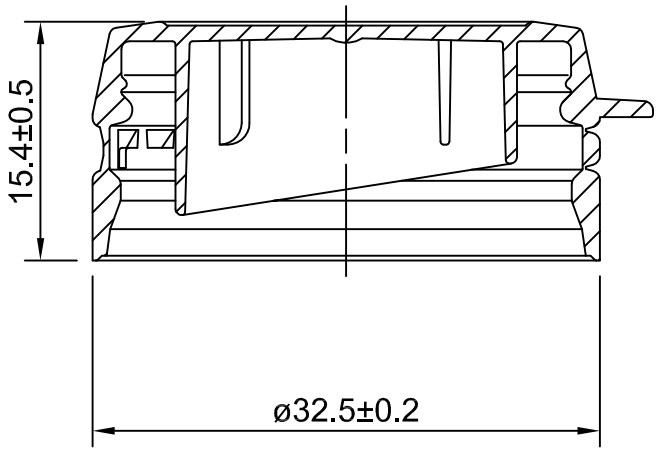
The product is registered in Ukraine with one of the following numbers:
10787/2011
10785/2011
10786/2011
14788/2015
14789/2015

Revisions

Version:	Implementation:	Revision information:
1	08.02.2010	Transfer to new system and additional information
2.1	04.10.2010	Weight per carton changed from 12.5 to 11.1 and recorrection of version number from 1.0 to 2.1
2.2	01.03.2011	LD653 Declaration 2010: Updated LD653 declaration
2.3	05.10.2011	LD653 Declaration 2011: Updated LD653 declaration LD 653: LD 653 declaration updated
2.4	31.01.2012	Registrations and Certifications: More precise description of registrations
2.5	29.05.2012	IR - LD653 / PE1324184: Updated
2.6	01.02.2013	EP Statement - LD653 / PPH 10012 / PPC 10712: Declaration of Conformity updated
2.7	05.03.2013	Migr. - LD653/PE1324184/JUN2012: Updated
2.8	08.04.2013	LD653 Declaration 2013: Updated
2.9	07.05.2013	PEZ121818X Declaration 2013: Updated
2.10	23.05.2013	Ferro PE 1324184 + Clariant PEZ121818X Remafin: Updated Regulation (EU) 10/2011
3	24.05.2013	1324184 declaration updated
3.1	24.07.2013	IR - LD653 / PEZ121818X / PE1324184: Updated
3.2	30.08.2013	WVP test updated

3.3	13.01.2014	PEZ121818X Declaration 2013: Updated with additional inform.
3.4	21.01.2014	PEZ121818X Declaration 2013: Updated
3.5	25.02.2014	LT - 002813-4000/MAY2013: Updated
3.6	07.08.2014	LD653 Declaration 2014: Updated
3.7	03.11.2014	1324184 Declaration 2014: Updated A. Schulman 1324184 + Clariant PEZ121818X: Ferro changed name to A. Schulman
3.8	23.03.2015	1324184 Declaration 2015: Updated with 174/2015/CE LD653 Declaration: Updated with Reg. (EU) No 2015/174
3.9	30.10.2015	PEZ121818X Declaration: Updated
3.10	08.04.2016	A. Schulman 1324184 + Clariant PEZ121818X: Clariant new company name
3.11	10.05.2016	Registrations and Certifications: Updated
3.12	19.05.2016	21156601 Declaration 2016: Updated A. Schulman 21156601 + Clariant PEZ121818X: White colour A. Schulman new article number
3.13	14.06.2016	PEZ121818X Declaration: Updated
4	24.06.2016	Regulatory drawing, Declaration of Conformity and Complaint handling added

2:1



Replaced drawing		
Designer	Hek	27.11.2014
Released	BS	17.12.2014
Scale	Drawing Type	Size
2 : 1	Regulatory	A4

GERRESHEIMER

Gerresheimer Vaerloese A/S
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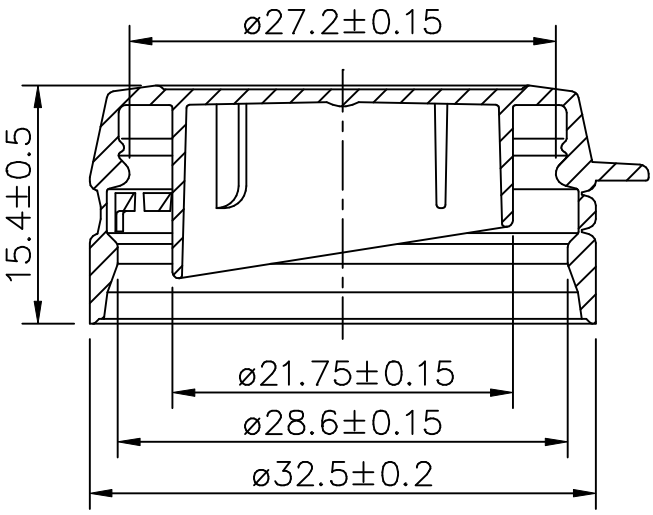
Phone +45 4477 7888
Fax. +45 4477 7892

Item	No.
Duma Handy Cap 002813	A002813
	Vers. no.: 1

2:1



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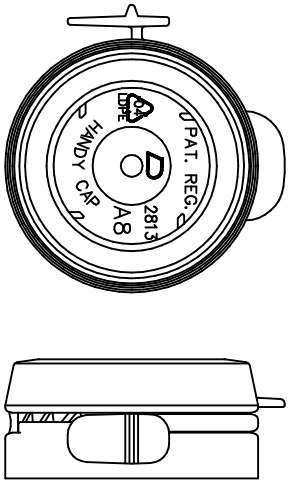

Logo changed	19.06.2009	JJ	19.06.2009	A
No. and logo changed	15.03.2006	JJ	15.03.2006	A
2000 added	12.2002	JJ	12.2002	A
Engravement	12.2001	JJ	12.2001	A
Created	07.2000	JJ	07.2000	A
Created / Correction	Date	Sign.	Appr. Date	Sign.

GERRESHEIMER

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Item
Duma Handy Cap
002813

No.
B002813

Vers. no.: 1

ExxonMobil Chemical Belgium
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GERRESHEIMER PHARMASYSTEMS
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Email Address: k.jawor@gerresheimer.com

Issue Date: 26 FEB 2015

Subject: Regulatory Declaration and/or Product Stewardship Information Statement(s) - Request

Dear Sir/Madam:

In response to your request, please find enclosed the regulatory declaration and/or product stewardship information statement(s) for the following product(s):

EXXONMOBIL LD653

These statements are provided by or on behalf of the above referenced ExxonMobil selling affiliate.

If you have any questions or need additional information please contact your ExxonMobil sales representative.

Enclosure(s):

EXXONMOBIL LD653 - EUROPEAN FOOD LAW
Reference Number: 0191403

STATEMENT

Issue Date: 26 FEB 2015
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

EU FOOD-CONTACT REGULATION

The monomer(s) and the additive(s) intentionally used in the above polymer grade are listed in Annex 1 or are authorized in accordance with the requirements of Commission Regulation (EU) No 10/2011 of 14 January 2011, as amended up to Regulation (EU) No 2015/174, on plastic materials and articles intended to come into contact with food.

The above polymer grade complies with the relevant requirements of Regulation (EC) No 1935/2004 in as far as:

* the grade is produced using Good Manufacturing Practice as required in article 3.1 of Regulation (EC) No 1935/2004 and meets the guidelines for Good Manufacturing Practice as specified in Regulation (EC) No 2023/2006 (on good manufacturing practice for materials and articles intended to come in contact with food).
* the production of the above grade ensures traceability as required in article 17.1 of Regulation (EC) No 1935/2004.
* the polymer production aids and aids to polymerization are either permitted in one or more EU Member State(s) and/or have been risk assessed based on the following assumptions:

  100% migration, 1kg/food packed with 6dm2 of packaging, article thickness of 250 microns

EU MEMBER STATES

As for the compliance status with EU Member States laws and/or recommendations where specific requirements exist for substances other than monomers and additives, the following can be stated:

The polymer production aids ("PPA")* and/or aids to polymerization ("AP") possibly present in the above polymer are permitted in the following countries.

* Solvents are excluded from the "polymerisation production aids" definition.

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", as amended up to "Arrêté royal du 10 février 2011"

France
- "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", as amended up to "Arrêté du 1er avril 2011"

Germany
- "Bedarfsgegenständeverordnung in der Fassung der Bekanntmachung vom 23. Dezember 1997 (BGBl. 1998 I S. 5)", as amended up to "Verordnung vom 24.6.2013 (BGBl. I S. 1682)"

- BfR Empfehlung III "Polyethylen" from the Bundesinstitut fuer Risikobewertung "BfR". 01.03.2011

Italy
- "Decreto 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale", as amended up to "Decreto 04 febbraio 2013, n. 23 (G.U. Serie Generale, n. 71 del 25 marzo 2013)"

Spain
- "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", as amended up to "Orden PRE/628/2011, de 22 de marzo"

The Netherlands
- "Regeling Verpakkingen- en gebruiksartikelen (Warenwet)" as amended up to "Regeling Verpakkingen- en gebruiksartikelen Staatscourant Nr VGP/VC 3048441" from February 14, 2011
  Hoofdstuk 1 - Kunststof

SWITZERLAND:

The composition of the above polymer grade meets the requirements of the Swiss Ordinance on material and objects in Plastic, SR 817.023.21 of 23 Nov 2005 (stand 1 April 2013).

- The composition of the base polymeric component(s) in this polymer grade complies with the positive lists for allowed monomers in the above referenced legislation.
- The additives that may be present comply with the lists for additives in the above referenced legislation, unless explicitly referred to in the additives note below. Information regarding additives subject to a restriction in food (dual use additives) and information on lipophilic substances are not applicable in Switzerland.

Monomer restrictions:

None of the monomers used in the production of this polymer is subject to a Specific Migration Limit (SML).

Presence of additives with SML

None of the additives intentionally used in this polymer grade is subject to a Specific Migration Limit (SML).

Presence of dual use additives

None of the additives intentionally used in this polymer grade is subject to a restriction in food as referred to in Article 11.3 of Regulation (EU) 10/2011.

Note on Overall Migration Limit ("OML") and on Specific Migration Limits ("SML's"), where applicable

In all EU countries and Switzerland, finished plastics food-contact materials or articles, made from or containing this product, need to comply with Overall Migration Limit ("OML") requirements and Specific Migration Limits ("SML"), where applicable and when tested on the food-contact surface with the appropriate food simulants and time/temperature test conditions.
This is the responsibility of the user of this polymer product.

In addition to the above compositional compliance status certification, the polymer user is required to carry out the appropriate overall migration ("OML") and specific migration ("SML") tests on the final material or article to determine the regulatory suitability for contact with different food-types (aqueous, fat/oil, alcoholic, etc.) and various end-use conditions (material or article thickness, pure or in blends, volume, contact time of packaging, temperature of use, etc.), all of which are beyond control of the polymer manufacturer.

GENERAL NOTE

The manufacturer of food-contact materials and articles - made from or containing this polymer grade - must ensure that the finished materials or articles meet the general regulatory requirements that they do not bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof and do not release constituents in foodstuffs in quantities that can endanger human health.

In addition, the finished food-contact material or article must be technically suitable for the intended use.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0191403

ExxonMobil Chemical Belgium
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GERRESHEIMER PHARMASYSTEMS
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Email Address: k.jawor@gerresheimer.com

Issue Date: 04 AUG 2014

Subject: Regulatory Declaration and/or Product Stewardship Information Statement(s) - Request

Dear Sir/Madam:

In response to your request, please find enclosed the regulatory declaration and/or product stewardship information statement(s) for the following product(s):

EXXONMOBIL LD653

These statements are provided by or on behalf of the above referenced ExxonMobil selling affiliate.

If you have any questions or need additional information please contact your ExxonMobil sales representative.

Enclosure(s):

EXXONMOBIL LD653 - USA FOOD LAW (FDA)
Reference Number: 0179748

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

This product complies with FDA regulation 21 CFR 177.1520 (Olefin polymers), paragraphs (c)2.1 and (c)2.2, and may be used as articles or components of articles intended for use in contact with food, including use in articles used for packing or holding food during cooking.

This product is produced under conditions of good manufacturing practice as required by 21 CFR 174.5(a) and is of a purity suitable for its intended use in food contact applications as allowed by the regulatory citations identified above. The manufacturer of any food, direct or indirect food additive, or food contact substance or article containing this product has the responsibility to ensure compliance with applicable FDA regulations and to ensure that any finished food contact article is technically suitable for the intended use.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0179748

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GERRESHEIMER PHARMASYSTEMS
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Email Address: k.jawor@gerresheimer.com

Issue Date: 04 AUG 2014

Subject: Regulatory Declaration and/or Product Stewardship Information Statement(s) - Request

Dear Sir/Madam:

In response to your request, please find enclosed the regulatory declaration and/or product stewardship information statement(s) for the following product(s):

EXXONMOBIL LD653

These statements are provided by or on behalf of the above referenced ExxonMobil selling affiliate.

If you have any questions or need additional information please contact your ExxonMobil sales representative.

Enclosure(s):

EXXONMOBIL LD653 - CONEG/WASTE PACKAGING
EXXONMOBIL LD653 - ALLERGENS IN FOOD
EXXONMOBIL LD653 - PHARMACOPOEIA STATUS (EU)
Reference Number: 0179750

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

This product is in compliance with the relevant heavy metals requirements of the following regulations:

- European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste ("Packaging and Packaging Waste Directive"), as amended up to Commission Directive 2013/2/EU of 7 February 2013.

- CONEG (Coalition of Northeastern Governors) Model Legislation.

The sum of the concentrations of the following heavy metals,
- mercury, lead, cadmium and hexavalent chromium,
in this product does not exceed 100 parts per million by weight.

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.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0179750

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

With regards to the presence of food allergens:

EUROPE:

The following substances or products causing allergies or intolerances (as listed in annex II of regulation (EU) No 1169/2011 on the provision of food information to consumers), amended by Commission Delegated Regulation (EU) No 1155/2013):

- Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof,
- Crustaceans and products thereof,
- Eggs and products thereof,
- Fish and products thereof,
- Peanuts and products thereof,
- Soybeans and products thereof,
- Milk and products thereof (including lactose),
- Nuts, i.e., Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia), and products thereof,
- Celery and products thereof,
- Mustard and products thereof,
- Sesame seeds and products thereof,
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO2,
- Lupin and products thereof, and
- Molluscs and products thereof,

are not intentionally used by ExxonMobil in this product.

USA:

The following food allergens (as referred to in the Allergen Labeling and Consumer Protection Act of 2004. 21 note- FALCPA))

(1) Milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat # containing gluten- , peanuts,

and soybeans.
(2) Food ingredient that contains protein derived from a food specified in paragraph above

are not intentionally used by ExxonMobil in this product.

Although this product is not routinely tested for their presence, based on product composition knowledge these substances are not expected to be present. However, the fact that these substances are not intentionally used by ExxonMobil in this product 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.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0179750

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

With regard to the compliance status of the ExxonMobil Chemical product referenced above with the regulation(s) identified below the following can be declared:

This product is not intended for or supported by ExxonMobil Chemical for use in pharmaceutical or medical applications requiring compliance with European Pharmacopoeia.

VALIDITY DATE: This document is valid until the next relevant legislative and/or regulatory change with a maximum of one year as of the date of issue of the statement.

Reference Number: 0179750

ExxonMobil Chemical Belgium
A Division of ExxonMobil Petroleum & Chemical, BVBA
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GERRESHEIMER PHARMASYSTEMS
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DK-3500 VAERLOESE, DENMARK

Email Address: k.jawor@gerresheimer.com

Issue Date: 04 AUG 2014

Subject: Regulatory Declaration and/or Product Stewardship Information Statement(s) - Request

Dear Sir/Madam:

In response to your request, please find enclosed the regulatory declaration and/or product stewardship information statement(s) for the following product(s):

EXXONMOBIL LD653

These statements are provided by or on behalf of the above referenced ExxonMobil selling affiliate.

If you have any questions or need additional information please contact your ExxonMobil sales representative.

Enclosure(s):

EXXONMOBIL LD653 - PHTHALATES/ADIPATES
EXXONMOBIL LD653 - LATEX / NATURAL RUBBER
EXXONMOBIL LD653 - BISPHENOL A & F & S
EXXONMOBIL LD653 - MELAMINE
EXXONMOBIL LD653 - ANIMAL DERIVED SUBSTANCES
Reference Number: 0179749

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

We are pleased to provide the following information concerning the absence or presence of certain substances in the ExxonMobil Chemical product referenced above:

Phthalate esters, such as benzyl butylphthalate, dibutyl phthalate, di-(2-ethylhexyl) phthalate, diisononyl phthalate, diisodecyl phthalate and di-n-octyl phthalate
and
Adipates such as Bis(2-ethylhexyl) adipate (DEHA), Dimethyl adipate (DMAD), Dioctyl adipate (DOA),

are not intentionally used by ExxonMobil in this product. Although this product is not routinely tested for their presence, based on product composition knowledge these substances are not expected to be present. However, the fact that these substances are not intentionally used by ExxonMobil in this product 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.

VALIDITY DATE: This document is valid for a maximum of one year as of the date of issue of the statement.

Reference Number: 0179749

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

We are pleased to provide the following information concerning the absence or presence of certain substances in the ExxonMobil Chemical product referenced above:

Latex / Natural rubber is not intentionally used by ExxonMobil in this product. Although this product is not routinely tested for its presence, based on product composition knowledge this substance is not expected to be present. However, the fact that this substance is not intentionally used by ExxonMobil in this product does not exclude that trace levels of this substance may be present as a result of the specific characteristics of the raw materials and/or of the manufacturing process.

VALIDITY DATE: This document is valid for a maximum of one year as of the date of issue of the statement.

Reference Number: 0179749

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

We are pleased to provide the following information concerning the absence or presence of certain substances in the ExxonMobil Chemical product referenced above:

Bisphenol A (BPA CAS number: 80-05-7), Bisphenol F (CAS number: 87139-40-0) and Bisphenol S (BPS CAS number: 80-09-1) are not intentionally used by ExxonMobil in this product.
Although this product is not routinely tested for its presence, based on product composition knowledge this substance is not expected to be present. However, the fact that this substance is not intentionally used by ExxonMobil in this product does not exclude that trace levels of this substance may be present as a result of the specific characteristics of the raw materials and/or of the manufacturing process.

VALIDITY DATE: This document is valid for a maximum of one year as of the date of issue of the statement.

Reference Number: 0179749

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

We are pleased to provide the following information concerning the absence or presence of certain substances in the ExxonMobil Chemical product referenced above:

Melamine and/or cyanuric acid are not intentionally used by ExxonMobil in this product. Although this product is not routinely tested for their presence, based on product composition knowledge these substances are not expected to be present. However, the fact that these substances are not intentionally used by ExxonMobil in this product 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.

VALIDITY DATE: This document is valid for a maximum of one year as of the date of issue of the statement.

Reference Number: 0179749

STATEMENT

Issue Date: 04 AUG 2014
At request of: GERRESHEIMER PHARMASYSTEMS
Product Name(s): EXXONMOBIL LD653
Material Code(s): 5073282

We are pleased to provide the following information concerning the absence or presence of certain substances in the ExxonMobil Chemical product referenced above:

Substances of animal origin are not intentionally used by ExxonMobil in this product. Although this product is not routinely tested for their presence, based on product composition knowledge these substances are not expected to be present. However, the fact that these substances are not intentionally used by ExxonMobil in this product 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.

VALIDITY DATE: This document is valid for a maximum of one year as of the date of issue of the statement.

Reference Number: 0179749

Food contact declaration

Company

A. Schulman Plastics BVBA
Pedro Colomalaan 25
B-2880 Bornem - Belgium
T +32-3-890 42 11
ehs@eu.aschulman.com

General info

PRODUCT	**122001 PWI LD-48013 WHI**
PRODUCT CODE	21156601
VERSION	1.1
ISSUE DATE	20/04/2016
VALID TO	This document is valid until the next relevant legislative,regulatory and /or compositional change.
CONCLUSION EU	Based on the info received from our suppliers of the raw materials, we confirm that the composition complies with the EU legislation. It is up to the producer of the finished article to verify that migration limitation is not exceeded.
CONCLUSION USA	All components comply with FDA, CFR title 21; for the intended use.

European Union

1935/2004/EC	The product is produced in conformity to this Frame Regulation EC 1935/2004 and Commission Regulation EU 10/2011/EC amended up to EU 2015/174. All monomers and additives fulfill the requirements for food contact with following restriction:
Migration Limits	FCM No 403 - Ref No 96320 - FILLER - 25 mg/kg SML, expressed as Zinc Ref No Annex II - Barium - 1 mg/kg SML FCM No 433 - Ref No 68320 - ANTI-OXIDANT - 6 mg/kg SML
Dual use additives	FCM No 610 - Ref No 93440 - E171 - TIO2;PIGMENT FCM No 106 - Ref No 24550 & 89040 - E 470 - calcium salt - LUBRICANT FCM No 21 - Ref No 42500 - E170 FCM No 575 - Ref No 76721 - E 900 - LUBRICANT
AP(89)1	All pigments comply with resolution AP(89)1

USA

Polymers and additives	meet FDA 21 CFR §178.2010, FDA 21 CFR §177.1520(c)2.3, FDA 21 CFR §177.1520(c)3.1a, FDA 21 CFR §178.3297, FDA 21 CFR §175.105, FDA 21 CFR §175.300, FDA 21 CFR §177.1350, FDA 21 CFR §177.1520(c)2.1, FDA 21 CFR §177.1520(c)2.2, FDA GRAS
Pigments	are listed under FDA 21 CFR §178.3297

Responsibility

Appropriate overall and specific migration tests on the final material or article will determine the regulatory suitability for contact with different food types and various end-use conditions.However these are beyond the control of A. SCHULMAN and are a part of the responsibility of the user of this product.

Statement managed by A. SCHULMAN – Product Safety Department Date :22/04/2016

This document is created electronically and is valid without signature. Original text: English

To the best of our knowledge, the information contained in this statement is accurate and reliable as of the date of publication. The information relates only to the product specifically identified in this document when not used in combination with any other products or materials. A. Schulman makes no warranties, express or implied, and assumes no liability in connection with any use of this information.
Upon sale of A. Schulman products, A. Schulman warrants that the products conform to the applicable written specifications at the time the products are shipped from A. Schulman's facility. All other express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose, are disclaimed.
Purchaser acknowledges that it has sole control and responsibility to ensure, on a continuing basis, that the products and any method of use or application of the products are suitable for its purposes. Any assistance provided by A. Schulman to purchaser relative to the product, including without limitation, formulation, manufacturing and testing for the use or application of the products for purchaser's purposes, is made without any express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose.
A. Schulman will not be liable for consequential or indirect damages and purchaser's exclusive remedy for claims (including claims for breach of warranty, negligence and strict liability) is limited to the replacement of the non-conforming products or the refund of the purchase price of the non-conforming products or, with regard to services, to re-process purchaser's materials.

Good Manufacturing Practice (2023/2006 EC)

21167501 POLYBATCH GP-28061
21156601 POLYWHITE LD-48013
21154601 POLYBATCH GP-28056

In response to your request we confirm that our products are produced according to the COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

All product made by A. Schulman pass to the Quality Control. A. Schulman has a certified Quality Assurance System according to ISO 9001:2008. Detailed food contact statements /MSDS/Specifications are available on request.

This concerns only the composition of the above mentioned product(s) and does not guarantee the compliance of final articles made of that product.

This document is valid until the next relevant legislative and/or regulatory change.

Statement managed by A. SCHULMAN – Product Safety Department

Issue date: April 19, 2016

ABSENCE DECLARATION

21156601 POLYWHITE LD-48013

In response to your request we can confirm that the above mentioned product does not contain any intentional additives of the below referenced substance.

- heavy metals or heavy metal compounds.

EU packaging directive and CONEG regulation:

EU Packaging Directive 94/62/EC as amended by 2004/12/EC, is related to packaging waste and with permissible levels of heavy metals in packaging. Article 11 incorporates the limits of the American CONEG regulation (Coalition of North-eastern Governors).
The sum of the concentrations of Lead, mercury, cadmium & chromium(VI) must not exceed 100 ppm (total concentration in the colored or printed final product).

According to Directive 94/62/EC (as amended), Article 11 (on packaging and packaging waste), and CONEG Regulation, the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium does not exceed 100 ppm by weight.

This refers to 100 % Masterbatch; in practice, the used concentrations are reduced by factors 10 – 100. Any pollution with heavy metals in raw materials is, according to supplier's declarations, far below the limits of concentration as mentioned in these regulations.
We do not control our production with regard to these impurities and are not in a position to guarantee analytical limits.

The absence of such substances has not been verified by analysis or tests and is declared based on the information available to us from our raw material suppliers. It can therefore not be excluded that trace levels of these substances may be unintentionally present (amongst others because they may be ubiquitous in the environment) or may result from the specific characteristics of the raw materials or the manufacturing process. It is the responsibility of the recipient of our products to ensure that any local applicable rules and legislation are observed.

This document is valid until the next relevant legislative and/or regulatory change.

Statement managed by A. SCHULMAN – Product Safety Department

Issue date: May 18, 2016

ABSENCE DECLARATION

21167501 POLYBATCH GP-28061
21156601 POLYWHITE LD-48013
21154601 POLYBATCH GP-28056

In response to your request we can confirm that the above mentioned products do not contain any intentional additives of the below referenced substances.

- Restricted or prohibited phthalates as mentioned in Directive 2005/84/EC
- Natural rubber (latex or dry rubber) or rubber chemical compounds
- Rubber accelerators
- Synthetic latex
- Melamine (1,3,5-Triazine-2,4,6-triamine) - CAS N. 108-78-1
- Bisphenol A - CAS N. 80-05-7

The absence of such substances has not been verified by analysis or tests and is declared based on the information available to us from our raw material suppliers. It can therefore not be excluded that trace levels of these substances may be unintentionally present (amongst others because they may be ubiquitous in the environment) or may result from the specific characteristics of the raw materials or the manufacturing process. It is the responsibility of the recipient of our products to ensure that any local applicable rules and legislation are observed.

This document is valid until the next relevant legislative and/or regulatory change.

Statement managed by A. SCHULMAN – Product Safety Department

Issue date: April 19, 2016

assistance provided by A. Schulman to purchaser relative to the product, including without limitation, formulation, manufacturing and testing for the use or application of the products for purchaser's purposes, is made without any express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose. A. Schulman will not be liable for consequential or indirect damages and purchaser's exclusive remedy for claims (including claims for breach of warranty, negligence and strict liability) is limited to the replacement of the non-conforming products or the refund of the purchase price of the non-conforming products or, with regard to services, to re-process purchaser's materials.

ABSENCE DECLARATION

21167501 POLYBATCH GP-28061
21156601 POLYWHITE LD-48013
21154601 POLYBATCH GP-28056

In response to your request we can confirm that the above mentioned products do not contain any intentional additives of the below referenced substance.

• ALLERGENS as listed in Annex II of REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers

ALLERGEN	**PRODUCT CONTAINS THIS ALLERGEN (YES/NO)**	**PRODUCT IS PRODUCED ON SAME EQUIPMENT OR IN SAME FACILITY WHERE THESE ALLERGENS ARE USED/PRESENT (YES/NO)**
Cereals containing gluten (i.e. wheat, Corn, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	NO	NO to all
Crustaceans and products thereof	NO	
Eggs and products thereof	NO	
Fish and products thereof	NO	
Peanuts and products thereof	NO	
Soybeans and products thereof	NO	
Milk and products thereof (including lactose)	NO	
Nuts *(see below) and products thereof	NO	
Celery and products thereof	NO	
Mustard and products thereof	NO	
Sesame seeds and products thereof	NO	
Sulphur dioxide and sulphites (concentrations of more than 10 mg/kg or 10 mg/litre, as SO_2)	NO	
Lupines and products thereof	NO	
Moluscs and products thereof	NO	

* Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia).

The absence of such substances has not been verified by analysis or tests and is declared based on the information available to us from our raw material suppliers. It can therefore not be excluded that trace levels of these substances may be unintentionally present (amongst others because they may be ubiquitous in the environment) or may result from the specific characteristics of the raw materials or the manufacturing process. It is the responsibility of the recipient of our products to ensure that any local applicable rules and legislation are observed.

This document is valid until the next relevant legislative and/or regulatory change.

Statement managed by A. SCHULMAN – Product Safety Department

Issue date: April 19, 2016

To the best of our knowledge, the information contained in this statement is accurate and reliable as of the date of publication. The information relates only to the product specifically identified in this document when not used in combination with any other products or materials. A. Schulman makes no warranties, express or implied, and assumes no liability in connection with any use of this information.
Upon sale of A. Schulman products, A. Schulman warrants that the products confirm to the applicable written specifications at the time the products are shipped from A. Schulman's facility. All other express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose, are disclaimed. Purchaser acknowledges that it has sole control and responsibility to ensure, on a continuing basis, that the products and any method of use or application of the products are suitable for its purposes. Any assistance provided by A. Schulman to purchaser relative to the product, including without limitation, formulation, manufacturing and testing for the use or application of the products for purchaser's purposes, is made without any express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose. A. Schulman will not be liable for consequential or indirect damages and purchaser's exclusive remedy for claims (including claims for breach of warranty, negligence and strict liability) is limited to the replacement of the non-conforming products or the refund of the purchase price of the non-conforming products or, with regard to services, to re-process purchaser's materials.

Clariant Masterbatches

Gerresheimer Boleslawiec S.A

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

25554043 25.02.2015

Declaration

REMAFIN-WHITE/LUB PEZ121818X

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

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

- Zinc Stearate, Ref. No.: Salt of 89040 (Stearic acid), SML = 25 mg/kg (expressed as Zinc)
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate: SML = 6 mg/kg. Consider correction of specific migration in foods containing more than 20% fat by the fat reduction factor.
- 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)

610	Titanium dioxide	25 - 40 %

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.

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 colourants used meet the requirements listed in the section Plastic based materials intended to contact with foodstuffs of Turkish Food Codex Regulation issued in November 16th 1997 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.

Clariant Masterbatches

CLARIANT

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

27392831 07.06.2016

Declaration

REMAFIN-WHITE/LUB PEZ121818X

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.

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.

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.

Condition of Use and Restriction:
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)).

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

Country Product Stewardship

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

Katarzyna Jawor
Gerresheimer Boleslawiec S.A

PL -
Poland

27392822 07.06.2016

Declaration

REMAFIN-WHITE/LUB PEZ121818X

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.

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.

* For sales to customers located within the United States and Canada the following applies in addition:
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

DANISH
TECHNOLOGICAL
INSTITUTE

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Test Report

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 481192
Req. no: 3415 produkt 002813-2000
1347624
8 June 2012
MKK

Specifications

Closure

Type:	Dudek Handy Cap
Number:	002813-2000
Raw material:	LD 653 (PE)
Colour:	White, PE 1324184
Cavity:	B1-B12 (Mould B)

Container

Type:	Duma Special 30 ml
Number:	031030-0000
Raw material:	GF4760 (HDPE)
Colour:	White, PE 22305 (PE)
Cavity:	11

Date of receipt:	24 May 2012
Test period:	25 May – 8 June 2012

Water Vapour Permeation

10 specimens of containers and closures have been tested according to USP 35 <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	No 11	No 12
5.5	5.8	6.0	5.5	6.0	5.8	6.2	6.0	5.3	6.4	5.8	6.9

Average: 4.4 mg/d/l

Conclusion
The tested containers comply with the requirement of USP 35 <671> test for tight containers used for drugs being dispensed on prescription.

Centre: Packaging and Logistics

Maria Kisbæk
Consultant

Helle Allermann
Senior consultant

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Test Report

Client

Gerresheimer Vaerloese
Walgerholm 2-8
DK-3500 Vaerloese
Denmark

Report No 555374/5

23 May 2013
1347624
HEAN

Specifications

Closure

Type:	Duma Handy Cap 2813
Number:	002813-4000
Raw material:	LD 653 (LDPE)
Colour:	White, PE 1324184
Cavity:	4-5 (Mould A)

Date of receipt:	22 May 2013
Test period:	23 May 2013

Light Transmission

Closure has been tested according to USP 36 <671> - according to test requirements for containers.
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 closure.

Results

maximum % light transmission:

Sample No 1	Sample No 2
7.9	7.8

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

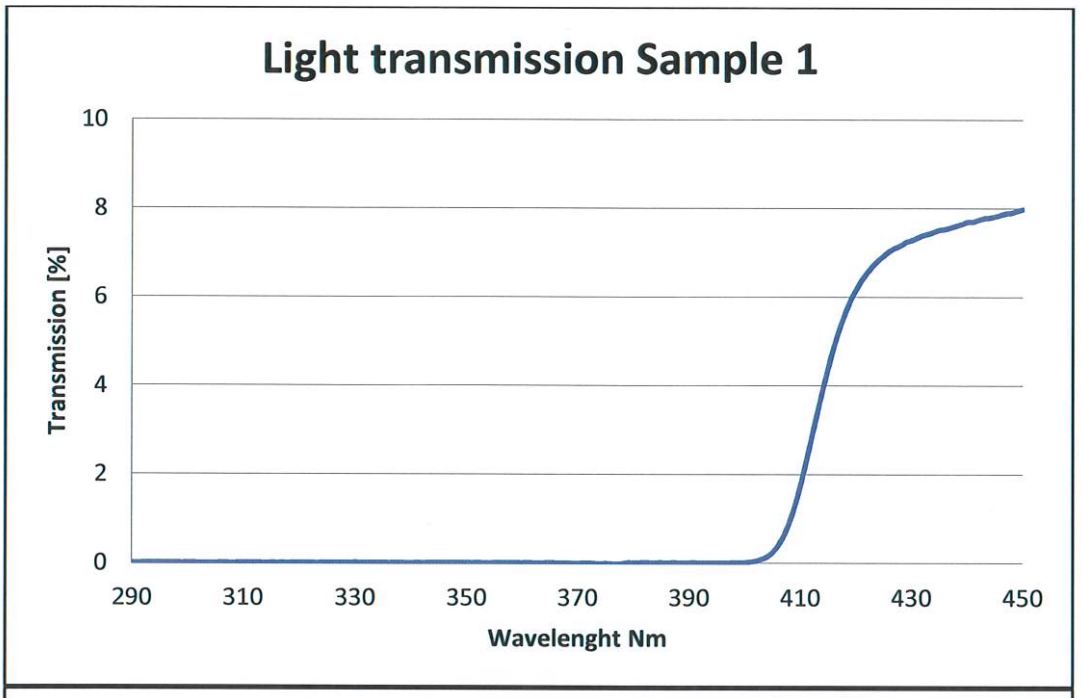
Centre: Packaging and Logistics

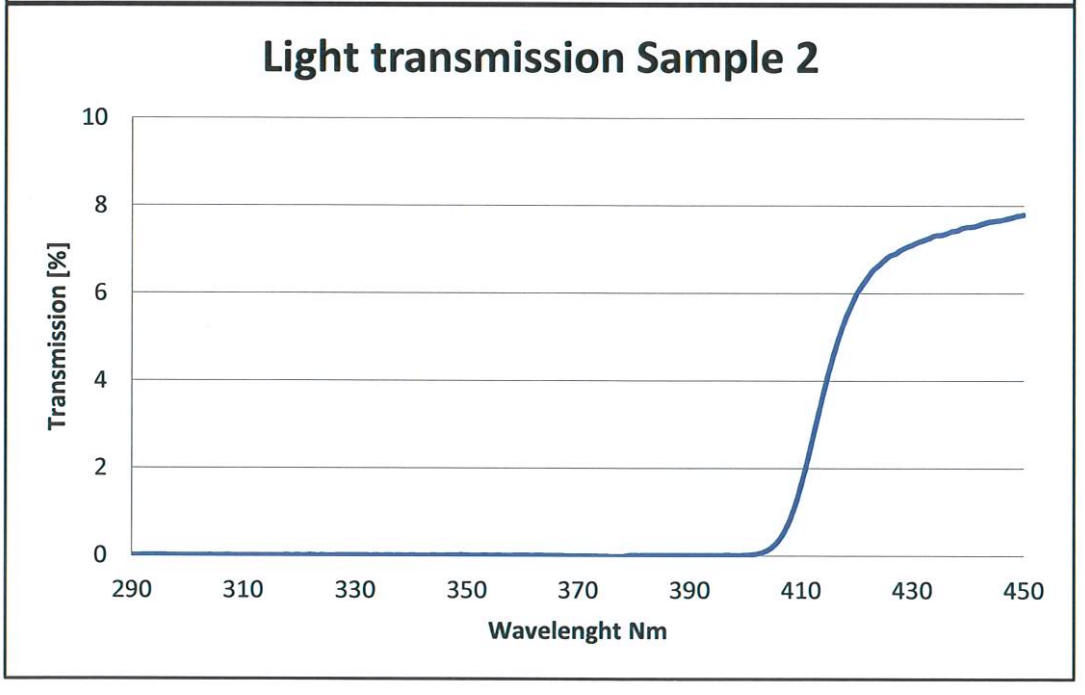
Helle Antvorskov
Senior consultant

Helle Allermann
Senior consultant

Gerresheimer Vaerloese

Type: Duma Handy Cap 2813
Number: 002813-4000





An error has happened on file: /d4doc/formularer/2013/07/004015-2000+006017-4000.pdf
Errortext: The remote server returned an error: (404) Not Found.

DANISH
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Gerresheimer
Att.: Rene Palmelund
Walgerholm 2-8
DK-3500 Værløse
Denmark

Test report no. 36901-3

Test required:	Duma Handy Cap. Migration tests and heavy metals according to USP 34 <661>
Sampling by:	Client
Sampling received:	11 June 2012
Test period:	11 – 27 June 2012
Remarks:	The results of the analysis and method summary are given on the next pages. The results relates only to the analysed subsamples. The results were forwarded by e-mail.

Laboratory for Chemistry and Microbiology, Taastrup

Nils Bernth
Lab. Manager, M.Sc.

Sesse Rasmussen
Technician

Introduction

According to agreement, migration tests were performed in accordance with USP 34 <661>.

Test Conditions

- Surface/volume ratio = 3 cm^2/cm^3
- Extraction with H_2O for 24 hours at 70°C
- Determination of non-volatile residue by evaporation at 105°C
- Determination of heavy metals e.g. antimony, arsenic, bismuth, cadmium, copper, lead, mercury, molybdenum, silver and tin by ICP-MS in extract.
- Determination of buffering capacity by titration
- Determination of non-volatile residue after extraction with ethanol for 24 hours at 70°C and with hexane for 24 hours at 50°C

Duplicate determinations were performed.

Results for: Duma Handy Cap

Non-volatile Residue, Buffer capacity and Heavy Metal after H_2O-Extraction

Lab. no.	Non-volatile Residue mg/50 ml Extract		Residue on Ignition of Non-volatile Residue		Heavy Metals Content in Extract determined by ICP-MS	
	Measured	Requirement	Measured	Requirement	Measured	Requirement
36901-3	1.9	< 12	*	< 5	< 0.1 ppm	< 1 ppm

Comments

*: If "Non-volatile Residue" is below 5 mg this test is not required.

Heavy metals are determined as the sum of the concentrations of Ag, As, Bi, Cd, Cu, Hg, Mo, Pb, Sb and Sn, if the measured concentration is below DL, then DL is used in the sum. The requirement is below 1 ppm (mg/kg) in the extract.

The measurements are based on independent double determinations.

Buffer capacity after H_2O-Extraction

Lab. no.	Buffer Capacity ml 0.010 N NaOH/20 ml Extract	
	Measured	Requirement
36901-3	< 1	< 10

Non-volatile Residue after Ethanol and Hexane Extraction

Lab. no.	Extraction media	Non-volatile Residue mg/50 ml Extract	
		Measured	Requirement
36901-3	Ethanol	11	< 75
36901-3	Hexane	91	< 350

Comments

Duplicate determinations were performed.

Conclusion

The results fulfil the requirements of USP 34 <661>.

Quality Control

Classification of defects

Effects of defects	Defect class	Individual permitted defect Containers / Caps		Total permitted defect Containers / Caps		Consequence
Critical defects are defects as defined in ISO 2859 which endanger human life and health or contravene legal requirements or lead to destruction or alterations of the filling material or seriously impair the reliability of production tools, filling and packaging equipment	1	0	0	0	0	Packaging material not usable
Major defects are defects as defined in ISO 2859 which lead to inefficient function and so to deficiency of the packaging material/pack or result in complaints from user or lead to reduced efficiency in production or impair the reliability of production, tools, filling and packaging equipment	2A	0.25	0.1	0.65	0.4	Usability of packaging material markedly impaired
	2B	1.0	0.4	2.5	1.0	Usability of packaging material moderately impaired
Minor defects are defects as defined in ISO 2859 which lead to a reduction of general quality	3	4.0	2.5	6.5	6.5	Usability of packaging material slightly impaired

AQL values for Duma Handy Cap - Vaerloese

Defects	Defect class
Incorrect use of raw materials, wrong identification, mix-up, foreign bodies, dust or oil inside, more than half of the tear band is torn off	1
Dimensions outside specifications	2A
Defects on sealing points, not fully cast, deformation, uneven surface, tear band not complete, black spots > 2 mm, inhomogeneous colour	2A
Flashes, black spots = < 2 mm, notches and clefts	2B

Quality control for Duma Handy Cap - Vaerloese

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. 1 sample of each cavity produced at the same time is visually controlled 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 second hour (one sample per cavity produced at the same time). New approval by production and QC is required after **machine stops**la sting more than 1 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 performs a **function test** on samples from two of the in-process controls by mounting, open and re-closing the system. The samples are from two different shifts. QC controls the pallets for mix-up and incorrect labeling, 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:

- **LD653 & White masterbatch**
- **LD653 & White masterbatch & Silica Gel/Molecular Sieve & Bottom Foil**
- **LD653 & White masterbatch & Silica gel & Bottom Foil**

Based upon product tests performed in accordance with the European Pharmacopoeia and our certified Quality system, Gerresheimer Vaerloese A/S hereby states compliance of above mentioned resin with the European Pharmacopoeia, paragraph 3.1.3 "Polyolefines".

Based upon certificates from our suppliers of masterbatches, Silica Gel, Molecular Sieve and Bottom Foil, Gerresheimer Vaerloese A/S hereby confirms that the above mentioned raw materials used during production of our products comply with the relevant regulations related to plastic materials intended to come into contact with food however the suppliers do not declare the materials 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

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

GERRESHEIMER

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
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 Handy Caps with or without desiccant – White coloured products**
- **Dudek Caps – 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: 1,0 dm^2 / 100 ml
  - Acetic Acid: 0,9 dm^2 / 100 ml – 1,0 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 the resin and the masterbatches, we state compliance of LD653 with relevant parts of FDA title 21 CFR § 177.1520 and of PE1324184 and Remafin-white/LUB PEZ121818X 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/bago r 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:	

1.1

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

An error has happened on file: /d4doc/formularer/Upload/2014/06/Labeling.docx
Errortext: Object reference not set to an instance of an object.

An error has happened on file: /d4doc/formularer/Upload/2014/06/Loose silica gel-loose desiccant- defect on desiccant.docx
Errortext: Object reference not set to an instance of an object.

An error has happened on file: /d4doc/formularer/Upload/2014/06/Mix-up.docx
Errortext: Object reference not set to an instance of an object.

An error has happened on file: /d4doc/formularer/Upload/2014/06/Partly- or disconnected TE-rings.docx
Errortext: Object reference not set to an instance of an object.

An error has happened on file: /d4doc/formularer/Upload/2014/06/Product defect.docx
Errortext: Object reference not set to an instance of an object.

An error has happened on file: /d4doc/formularer/Upload/2014/06/Transport.docx
Errortext: Object reference not set to an instance of an object.