STELLA Kunststofftechnik GmbH **- Translation -** **Article (6-4418-18-01)**

Designation: SECRO PP28, child-proof closure white, red ring, sealing disk TriSeal

Drawing: K64418h, (enclosure)

Changes in comparison to previous edition:

Statements on Compliance updated.
Section "Usability" added.

General Purpose:

The childproof closure is intended to form a package together with a container made of blow-moulded glass and a neck-finish with a screw-neck PP28 according to ISO 11418-2 or ISO 11418-3 in order to hold medicinal products. This may concern liquid preparations or solid administration forms for oral use.
If other than the above mentioned packaging materials are used together with this here described closure, its suitability is to be tested fully and on the own responsibility by the user.
At any rate, the suitability of this here specified packaging material for a particular content is to be tested fully and on the own responsibility by the user.

Production:

Production is made following "Recommendations, based on the Good Manufacturing Practice of the WHO (GMP Rules) for the production of injection-moulded components and blow-moulded plastic containers" published in:
Pharmazeutische Industrie 48, No 6 (1986)

The screw cap is injection-moulded from Eltex MED 100-MG12 (Ineos).

The outer cap is injection-moulded from Borealis RF 365 MO plus 4 % (m/m) Remafin-White CPK 059.

The tamper-evident ring is injection moulded from Purell PE 3020K plus 4 % (m/m) Remafin-Red PE 33001874-ZN.

The sealing disk made of Tri-Seal F217X5 (without EVA) is glued by the fusion adhesive Jowatherm 245.00 into the screw cap.

The top-plate of the outer cap is printed with a mixture of Norifin PPN black 948 and thinner Norifin PP 090.

Applying Silfar® 100 as lubricant reduces the friction between screw cap and outer cap.

The tamper-evident ring is assembled into the screw cap.

The screw cap is assembled into the outer cap.

According to plan, no other raw material, excipient and working material are added.

Statement on Compliance:

The statements on compliance presently available for the used materials are attached.

Note: According to the European Pharmacopoeia, there are no colourants generally approved for pharmaceutical use to colour plastic containers and plastic closures! Colourants to colour the natural coloured plastic materials may be used provided that 'they are approved in each case' by the competent authority responsible for the licensing for sale of the preparation in such a container.

Quality:

According to "Defect Evaluation List for Injection-moulded Parts Made of Plastic: Closures, Sealing Disks and Dosage Aids (Droppers, etc.)" Editio Cantor, expanded and revised edition 1997 with the restrictions regarding the following defect numbers:

22.01.01 Pallet and/or outer pack does not correspond to the specification
22.01.02 Securing of the pallet load does not comply with the specification
22.01.03 Labelling of the pallet must comply with the specification
22.01.04 Labelling of the containers must comply with the specification

For a faulty delivery there will be no general rejection. We have the opportunity for corrective actions unless the identity of the goods is incorrectly labelled on the boxes or the primary packaging is damaged.

22.02.01 Material must comply with the specification

We check the identity of the used colourless plastic raw material by IR-spectroscopy. If no deviations are found, the material complies with the specification.

The identity of the used colourant is documented by the respective supplier certificate. Any further tests regarding identity are not carried out by us.

The identity of the used sealing disks is documented by the respective delivery note and the test certificate issued by the supplier. Any further tests regarding identity are not carried out by us.

The identity of the used thinner, printing ink, hot-melt adhesive and lubricant Silfar ® 100 is documented by the respective delivery note issued by the supplier. Any further tests regarding identity are not carried out by us.

22.04.01 Contamination with foreign bodies or material residues or considerably soiled and/or dusty - gets into contents.

The defect class 2A is valid for visible contamination of material residues due to sprue runners.

22.04.02 Foreign bodies incorporated in the material

Burned plastic particles less than 0.5 mm are not considered as foreign bodies in the sense of this defect characteristic.

22.06.02.12 Connecting strip torn off - numerically more than half of the studs.

The defect class 2A is valid for this defect number.

22.07.03 Overprinting/embossed text missing, incorrect and/or incomplete.

The defect class 2A is valid for this defect number if the print is incomplete but still legible.

Packaging:

Approx. 1000 parts each are put scrambled packed in a foil bag made of PE-LD. The foil bag is marked with a STELLA test label and is closed dust-tight with a cable tie.
This so made and labelled inner package will be put in a corrugated cardboard folding box of size 2 that is closed with an adhesive tape.
This so made shipping package is marked with a STELLA shipping label on one front side.

Labelling:

The STELLA test label is a self-adhesive label printed with the trademark STELLA and our bar code packaging number (= STELLA test number).
The STELLA shipping label is a self-adhesive label printed with our company name, our article number, our article designation, our batch number, our bar code test number (= STELLA test number), quantity of items contained in that labelled package and the date of manufacture.

Transport:

Dry, protected from high and low temperatures and away from an atmosphere contaminated with gas, steam, aromatic substances and other smelling material.

Storage:
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in unopened original packaging, dry, at temperatures of +10°C up to +40°C and away from an atmosphere contaminated with gas, steam, aromatic substances and other smelling material.

Processing:

The product described herein should be processed with acclimatized parts at room temperature.
It has to be guaranteed during processing that the surface of the neck finish and the bottle neck thread is not contaminated with the filling content.
The closing torque should be applied in such a way that up to 10 minutes after closing, a torque of approx. 115 Ncm is necessary for opening the screw caps.

Stability:

This product has not yet been manufactured and stored for a longer period of time. Therefore, there are no other data available regarding stability of this product. However, due to the experience with other comparable products we assume that the product is stable for a minimum of two years when complying with our specification regarding storage and transport.

Usability of inventories that are manufactured and stored under the scope of previous editions:

Inventories that are manufactured and stored under the scope of previous editions can be used further on.

Validity:

This specification was issued per computer system and does not need a signature to become valid.

This specification is valid until the release of the following edition.

Regarding deliveries of this article already carried out or to be carried out in the future, this specification does not comprise any guarantee of quality or guarantee of durability. The consignee of the goods is not relieved from the obligation to carry out his own tests.

Benennung: SECRO PP28, KSV weiß, Ring rot, Einlage Triseal

Zeichnung: K64418h, (Anlage)

Änderung gegenüber Vorausgabe:

Unbedenklichkeitserklärungen aktualisiert.
Absatz Verwendbarkeit eingefügt.

Allgemeiner Verwendungszweck:

Der kindergesicherte Verschluss ist dafür vorgesehen, in Verbindung mit einem Behälter aus Hüttenglas und einer Mündung mit einem Schraubgewinde PP28 entsprechend ISO 11418-2 oder ISO 11418-3 eine Verpackung zur Aufnahme von Arzneimitteln zu bilden. Das Arzneimittel kann eine flüssige Zubereitung zum Einnehmen sein oder eine feste Darreichungsform zur oralen Anwendung haben. Werden in Verbindung mit dem hier beschriebenen Verschluss andere als die oben erwähnten Packmittel verwendet, ist deren Eignung vollumfänglich und in eigener Verantwortung durch den Verwender zu prüfen.
Die Eignung des hier beschriebenen Packmittels für ein bestimmtes Füllgut ist in jedem Fall vollumfänglich und in eigener Verantwortung durch den Verwender zu prüfen.

Fertigung:

Die Fertigung erfolgt in Anlehnung an die "Empfehlungen, orientiert an den Grundregeln der WHO (GMP-Regeln), für die Herstellung von Spritzgussteilen und Hohlblaskörpern aus Kunststoff", veröffentlicht in:
Pharmazeutische Industrie 48, Nr. 6 (1986).

Die Schraubkappe wird im Spritzgussverfahren aus Eltex MED 100-MG12 (Ineos) hergestellt.

Die Druck-Dreh-Kappe wird im Spritzgussverfahren aus Borealis RF 365 MO plus 4 % (m/m) Remafin-Weiß CPK 059 hergestellt.

Der Originalitätsring wird im Spritzgussverfahren aus Purell PE 3020K plus 4 % (m/m) Remafin-Rot PE33001874-ZN hergestellt.

Die Dichteinlage aus Tri-Seal F217X5 (ohne EVA) wird mit Schmelzkleber Jowatherm 245.00 in die Schraubkappe eingeklebt.

Die äußere Deckelfläche der Druck-Dreh-Kappe wird mit einer Mischung aus Norifin PPN schwarz 948 und Verdünner Norifin PP 090 bedruckt.

Die Reibung zwischen Schraubkappe und Druck-Dreh-Kappe wird durch die Aufbringung von Silfar (R) 100 als Gleitmittel verringert.

Der Originalitätsring wird in die Schraubkappe montiert.

Die Schraubkappe wird in die Druck-Dreh-Kappe montiert.

Es werden keine anderen Roh-, Hilfs- und Betriebsstoffe planmäßig zugesetzt.

Unbedenklichkeitserklärung:

Die uns derzeit vorliegenden Erklärungen zur Unbedenklichkeit der eingesetzten Materialien werden als Anlage beigefügt.

Hinweis: Es gibt keine nach dem Europäischen Arzneibuch allgemein zugelassenen Farbmittel zur Einfärbung von Kunststoffbehältnissen und -verschlüssen für pharmazeutische Zwecke!
Bei Verwendung eines Farbmittels zum Einfärben des naturfarbenen Kunststoffmaterials muss daher "in jedem Einzelfall die Genehmigung erteilt werden", und zwar durch die Behörde, welche für das Inverkehrbringen der Zubereitung in einem solchen Behältnis zuständig ist.

Qualität:

Gemäß "Fehlerbewertungsliste für Spritzgussteile aus Kunststoff: Verschlüsse, Dichteinlagen und Dosierhilfen (Tropfer etc.)", Editio Cantor, Erw. und überarb. Auflage 1997, mit den Einschränkungen zu folgenden Fehler-Nummern:

22.01.01 Palette und / oder Außenverpackung entspricht nicht der Vorschrift
22.01.02 Sicherung der Palettenladung entspricht nicht der Vorschrift
22.01.03 Kennzeichnung der Palette muss der Vorschrift entsprechen
22.01.04 Kennzeichnung der Gebinde muss der Vorschrift entsprechen

Bei fehlerhafter Lieferung erfolgt keine generelle Zurückweisung. Wir erhalten Gelegenheit zur Nachbesserung, es sei denn, dass die Identität der Ware auf den Einzelgebinden falsch deklariert oder die Primärverpackung beschädigt ist.

22.02.01 Material muss der Vorschrift entsprechen

Die Identität der von uns eingesetzten farblosen Kunststoffrohmaterialien wird mittels IR-Spektroskopie geprüft. Wenn dabei keine Abweichungen festgestellt werden, entspricht das Material der Vorschrift.

Die Identität der von uns eingesetzten Farbmittel wird durch das jeweilige Lieferantenzertifikat belegt. Weitergehende Prüfungen der Identität führen wir nicht durch.

Die Identität der von uns eingesetzten Dichteinlagen wird durch den jeweiligen Lieferschein und das Werksprüfzeugnis des Lieferanten belegt. Weitergehende Prüfungen der Identität führen wir nicht durch.

Die Identität des von uns eingesetzten Verdünners, der Druckfarbe, des Heißklebers und des Gleitmittels Silfar (R) 100 wird durch den jeweiligen Lieferschein des Lieferanten belegt. Weitergehende Prüfungen der Identität führen wir nicht durch.

22.04.01 Verunreinigungen mit Fremdkörpern oder Materialresten oder erheblich verschmutzt und / oder verstaubt - gelangen ins Füllgut
Für Verunreinigungen mit Materialresten, die von Angussverteilern herrühren und mit bloßem Auge sichtbar sind, gilt die Fehlerklasse 2A.

22.04.02 Im Material eingeschlossene Fremdkörper

Verbrannte Kunststoffpartikel kleiner 0,5 mm werden nicht als Fremdkörper im Sinne dieses Fehlermerkmals angesehen.

22.06.02.12 Verbindungsstege abgerissen - anzahlmäßig mehr als die Hälfte der Stege

Für diese Fehler-Nummer gilt die Fehlerklasse 2A.

22.07.03 Druck / Prägung fehlt, falsch und / oder unvollständig

Für diese Fehler-Nummer gilt die Fehlerklasse 2A, wenn der Druck unvollständig aber noch lesbar ist.

Verpackung:

Jeweils ca. 1000 Teile werden in loser Schüttung in einen Folienbeutel aus PE-LD eingebracht. Der Folienbeutel wird mit einem STELLA-Prüfetikett gekennzeichnet und mit einem Kabelbinder staubdicht verschlossen.
Das so hergestellte und gekennzeichnete Innengebinde wird in eine Wellpappfaltkiste der Größe 2 eingelegt, die mit Selbstklebeband verschlossen wird.
Das so hergestellte Versandgebinde wird auf einer Stirnseite mit einem STELLA-Versandetikett
gekennzeichnet.

Kennzeichnung:

Das STELLA-Prüfetikett ist ein Selbstklebeetikett, das mit dem Warenzeichen STELLA und unserer barcodierten Packungsnummer (= STELLA Prüfungsnummer) bedruckt ist. Das STELLA-Versandetikett ist ein Selbstklebeetikett, das mit unserer Firma, unserer Artikelnummer, unserer Artikelbenennung, unserer Chargenbezeichnung, unserer barcodierten Prüfungsnummer (= STELLA Prüfungsnummer), der in dem gekennzeichneten Gebinde enthaltenen Stückzahl und dem Herstellungsdatum bedruckt ist.

Transport:

Trocken, geschützt vor hohen und tiefen Temperaturen und abseits von mit Gas, Dämpfen, aromatischen Substanzen und anderen riechenden Stoffen belasteter Atmosphäre.

Lagerung:

In ungeöffneter Originalverpackung, trocken, bei Temperaturen von +10 °C bis +40 °C und abseits von mit Gas, Dämpfen, aromatischen Substanzen und anderen riechenden Stoffen belasteter Atmosphäre.

Verarbeitung:

Das hier beschriebene Produkt ist auf Raumtemperatur angepasst zu verarbeiten.
Bei der Verarbeitung ist unbedingt sicher zu stellen, dass die Mündungsoberfläche und das Gewinde der Flasche nicht mit Füllgut benetzt sind.
Das Verschraubmoment sollte so bemessen werden, dass zum Öffnen der Schraubkappen bis zehn Minuten nach dem Verschließen ein Drehmoment von ca. 115 Ncm erforderlich ist.

Haltbarkeit:

Dieses Produkt wurde noch nicht hergestellt und für längere Zeit eingelagert. Es sind daher keine Daten zur Haltbarkeit des Produktes vorhanden. Aufgrund der Erfahrungen mit anderen, vergleichbaren Produkten gehen wir jedoch davon aus, dass das Produkt bei Einhaltung unserer Vorgaben zu Lagerung und Transport mindestens zwei Jahre haltbar ist.

Verwendbarkeit von Beständen, die unter Geltung der Vorausgaben hergestellt und gelagert wurden:

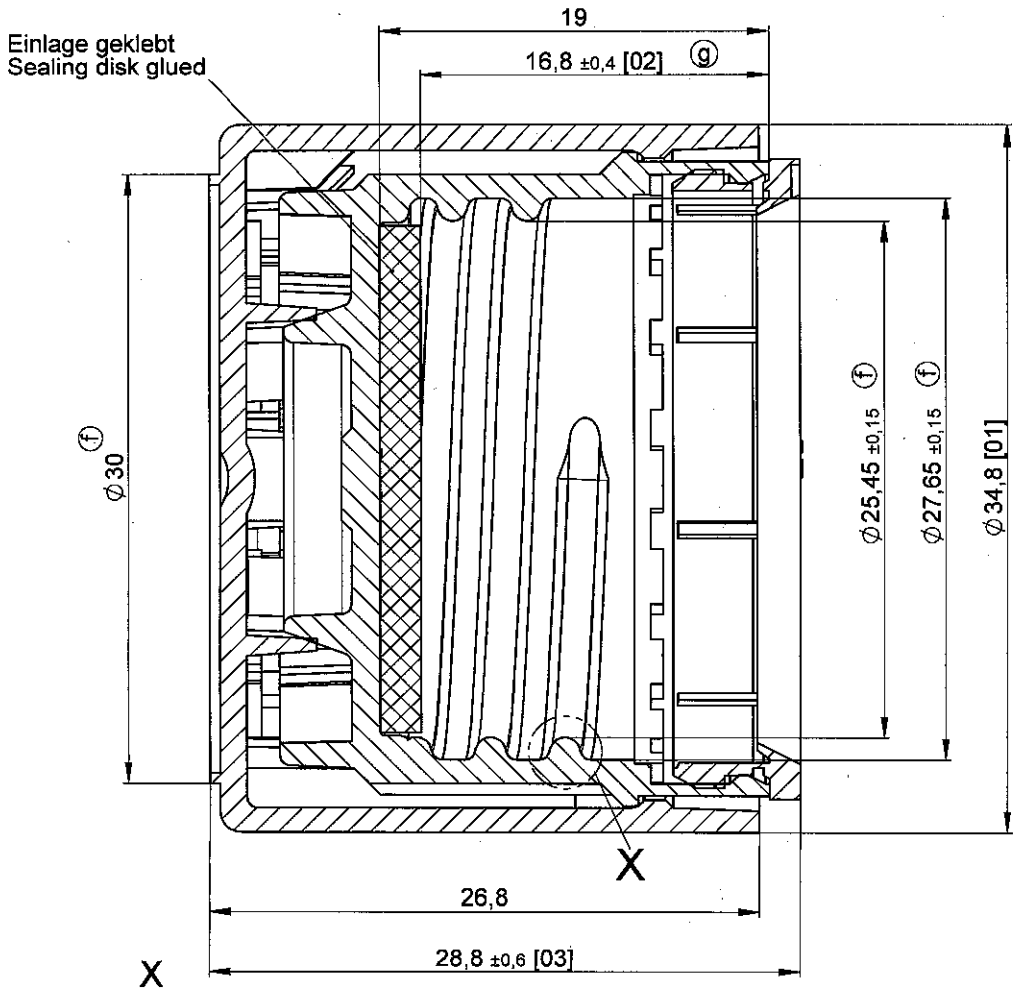
Lagerbestände, die unter Geltung der Vorausgabe hergestellt und gelagert wurden, sind weiterhin verwendbar.

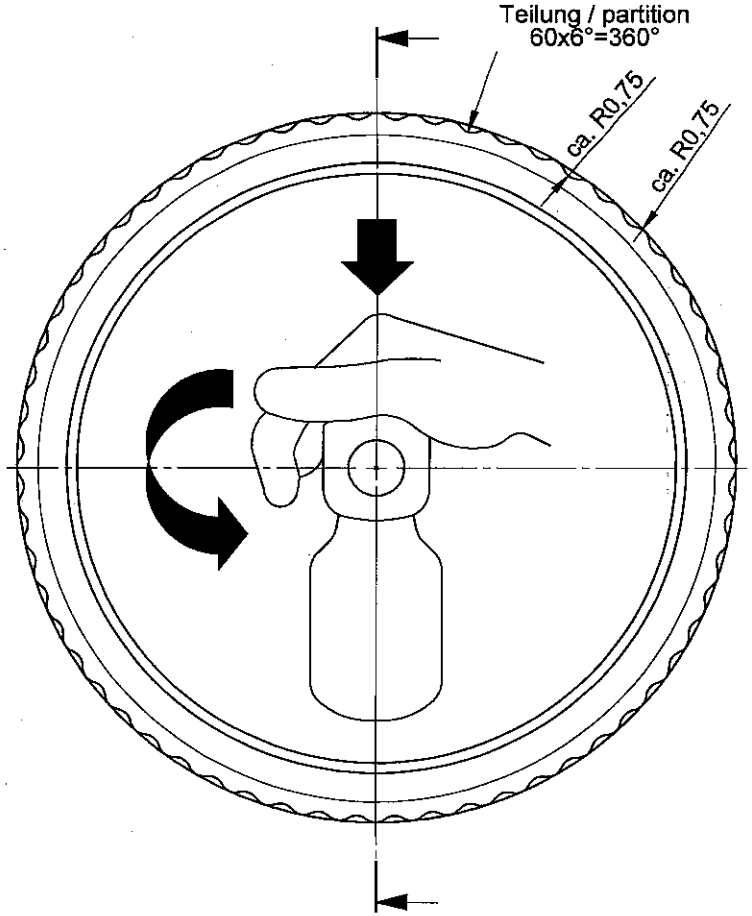
Gültigkeit:

Diese Spezifikation wurde per EDV erstellt und bedarf zu ihrer Gültigkeit keiner Unterschrift.

Diese Spezifikation ist gültig bis zur Freigabe einer Folgeversion.

Diese Spezifikation beinhaltet keine Übernahme einer Beschaffenheits- oder Haltbarkeitsgarantie in Bezug auf bereits erfolgte oder zukünftig erfolgende Lieferungen des hier spezifizierten Artikels. Sie entbindet den Empfänger der Ware nicht von der Obliegenheit, eigene Prüfungen durchzuführen.





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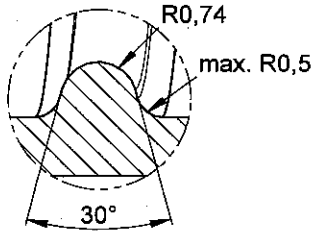

Gewindesteigung 7 Gang/Zoll
Thread pitch 7 threads/inch
P = 3,63 mm

Nummern für Prüfmaße in [ ] Klammern
Numbers for test dimensions in [ ] brackets

Freimaßtoleranz +/- 0,2 mm
General tolerance +/- 0,2 mm

Index	Number of Index	Revision	Date	Signature
h		Text "Anforderungen an die Genauigkeit der Messwerte" ergänzt.	04.05.2016	Röhrs
g		Maß 16,8 ergänzt.	05.11.2012	Röhrs
f		CAD-Format erneuert, Layout überarbeitet, Maßangabe entspr. Dok. 3.01-03-05 überarbeitet, Maß Ø 30,2 in Ø 30 geändert(an Produktionsware angepasst), Ø 31,7, Maß 0,5 und 1,5 entfernt, Zeichnungsnr. von K644183e in K64418f geändert.	09.05.2012	Röhrs

(h) Anforderungen an die Genauigkeit der Messwerte gemäß gleichnamigen STELLA-Dokument.
Requirements regarding accuracy of the measured values as per corresponding STELLA document.

Material:
Siehe Spezifikation
see specification

	2012	Datum/Date	Unterschr./ Signature
Gezeichn./ Drawn by		09.05.	Röhrs
Geprüft/ Approved by		09.05.	Röhrs

STELLA
KUNSTSTOFFTECHNIK GMBH

Maßstab/Scale: 4:1 (10:1)

Benennung/Designation:
SECRO PP28
kindergesicherter Verschluss mit Einlage

Zeichnungs Nr / Drawing No:
K64418h

INEOS

Olefins & Polymers Europe

INEOS Services Belgium NV/SA
Rue de Ransbeek, 310
B-1120 Brussels
Belgium

Eltex® MED 100-MG12

Regulatory & Product Stewardship Certificate

Polypropylene grade Eltex® Med 100-MG12

To whom it may concern:

Important note: whereas Ineos Olefins & Polymers Europe supplies to its customers the adequate information to allow them to fulfil their responsibilities, the downstream business operators do have to check and confirm that their product or final article meet the technical and regulatory requirements of the application, at their stage.

We are pleased to provide our customers with the attached Regulatory Certificate issued by INEOS Olefins & Polymers Product Stewardship.

Concerning the absence of specific substances in our grades, we understand the concerns that hazardous chemicals could be present in the products taken from INEOS. We have therefore already listed at the end of the Regulatory Certificate the most current chemicals whose presence in PP or PE is restricted by an EU Regulation / Directive or any other legislation or even related to health or environment concerns linked to a recent or particular issue.

Should there however be any specific topic or question unanswered for which there might be a particular reason to request a declaration, justified by legislation, the application or a specific market concern, it of course remains possible contacting us. We will then dedicate all our attention to give the appropriate answer.

Best regards,

Gerard Paulus
Product Steward

INEOS

Olefins & Polymers Europe

INEOS Services Belgium NV/SA
Rue de Ransbeek, 310
B-1120 Brussels
Belgium

Eltex® MED 100-MG12

Pharmaceutical and medical use

We confirm that the above mentioned grade, as dispatched from our plant, meets the compositional requirements of the European Pharmacopoeia Monographs:

3.1.3. Polyolefins (9th Edition)
3.1.6. Polypropylene for Containers and Closures for Parenteral Preparations and for Ophtalmic Preparations (9th Edition)

In regards to the testing set described in the European Pharmacopoeia, one production lot of this grade has been tested by an accredited laboratory against the Monograph 3.1.6. (6th Ed.) and the measurement results are within the specifications defined therein.

In regards to the testing sets described in the US Pharmacopoeia <88> Biological Reactivity Tests for Class VI Plastics, covering systemic injection test, intracutaneous test and implantation test, a production lot of the above mentioned grade has been analysed by an accredited laboratory. The analysed sample meets the requirements for USP Class VI.

This grade has been assigned the FDA Drug Master File # 20554.

The above mentioned grade is not intended for use as medical implant material or implantable medical devices. We do not support its use for such applications.

This certificate is valid two years after the issue date. It will be your responsibility to request a new certificate three months prior to expiration, should you wish a 2-years extension of validity.

INEOS
Olefins & Polymers Europe

INEOS Services Belgium NV/SA
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Eltex® MED 100-MG12

Food contact EU: Declaration of Compliance (DoC)

EU Declaration of Compliance, Annex IV, Regulation (EU) 10/2011

1. Identity and address of the operator issuing the DoC:

INEOS Services Belgium SA
Product Stewardship Department
Rue de Ransbeek 310
B-1120 Bruxelles
Belgium

2. Identity of the business operator which manufactures of imports the plastic:

INEOS O&P Europe
3, avenue des Uttins
CH-1180 Rolle
Switzerland

3. Identity of the material: see header of the page

4. Date of the declaration: January 13th, 2017

5. Confirmation that the plastic material meets the legal requirements

This grade complies with the relevant requirements of:

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended today
- 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 **(GMP)** as amended

The NIAS (Non Intentionally Added Substances) and the identified IAS (Intentionally Added Substances) present in this grade have been risk assessed in accordance with Art 19 of the Plastics Regulation (10/2011) and comply with the relevant requirements of the Framework Regulation (1935/2004).

More relevant information necessary for a risk assessment of the NIAS by the downstream operator will be communicated upon request. The conversion process can indeed affect the type and quantity of NIAS present in the articles and the converter must reassess them to guarantee their compliance. The compliance of the IAS present in this product will remain valid as no new IAS will be formed during the processing steps.

6. Adequate information on the substances used for which restrictions are set out

No monomers subject to Specific Migration Limit (SML) are used.

No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

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Indicative overall migration tests carried on this type of polymer on film or thin plaque, under the conditions 10 days / 40°C, in the food simulants A, B and D2 show that the Overall Migration Limit of 10 mg/dm² is not exceeded for this grade.

As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles to the OML.

7. Adequate information relative to the substances which are subject to a restriction in food.

Calcium Stearate (E470) (CAS nb 1592-23-0) is approved as direct food additive. It is present, as additive, in the above grade.

8. Specifications on the use of the material or article.

No other limitation or restriction than those listed in point 6 of this DoC applies to this grade.

9. When a functional barrier is used, confirmation that the the article complies with this legislation.

This information does not apply to the plastic manufacturer.

Switzerland

This product meets the requirements of the Swiss Ordinance 817.023.21 "Ordinance on Materials and Articles in Contact with Food" of 23/11/2005 in the frame of the Ordinance 817.02 "Foodstuffs and Utility Articles Ordinance" of 23/11/2005.

Food contact US

Under 21 CFR 177.1520 (c) Specifications 1.1a, this resin may be safely used in articles or components of articles used for packing or holding food during cooking.

All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN). No further restrictions apply to the finished polymer.

South America

This product meets the requirements of following regulations :

Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela):

- GMC Resolution No. 03/1992 of April 1st 1992, which "establishes the general criteria and classification of materials for packaging and equipment in contact with food"
- GMC Resolution No. 02/2012 of April 19th 2012 which provides a "positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food"
- GMC Resolution No. 32/2007 of December 11th 2007 which provides a "positive list of additives for plastic materials intended for packaging and equipment manufacturing for contact with foods"

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In order to guarantee the compliance with the Resolution, the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm².

Brazil

- RDC Resolution No. 91/2002 of Anvisa of May 11, 2001,which "establishes the general criteria and classification of materials for packaging and equipment in contact with food"
- RDC Resolution No. 56/2012 of Anvisa of November 16, 2012 that "provides for the Positive List of monomers and other starting substances authorized polymers for the production of plastic packaging and equipment in contact with food"
- RDC Resolution No. 17/2008 of Anvisa of March 17, 2008 that "provides for Technical Regulation on the Positive List of Additives for Plastic Materials for the purpose of packaging and equipment manufacturing in contact with food"

In order to guarantee the compliance with the Resolution, the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm².

Food contact China

This grade is in compliance with GB9685-2008 "Hygienic standards for uses of additives in food containers and packaging materials".

Toys

The above grade meets the relevant requirements of Directive 2009/48/EC (as amended in 2014/81/EU) and referred Community legal acts, and of the European Standard EN 71-3:2013+A1:2014.

Phthalates

It is well known that phthalates are used as minor component of the catalytic systems used for the production of polypropylene resins. INEOS Olefins & Polymers Europe also uses pre-catalysts containing phthalates for the production of most of its polypropylene grades.

These phthalates have been introduced in the REACH Authorisation process in 2009/2010 and have now passed their sunset date (21 February 2015).
This situation has retained our attention since the beginning. We have thus engaged discussions with all our catalytic systems suppliers and got the assurance that the use of the catalysts containing phthalates will not be negatively impacted and that we will be able to continue to use them for the production of our current polypropylene products, without any disruption and any change in their composition.

We have also gathered analytical evidence that the phthalate used in the catalytic system undergoes a complete chemical transformation during the polymerisation stage and is no longer present nor detectable as such in the final polypropylene with a detection limit well below 1 ppm.

We also confirm that all INEOS polypropylene grades manufactured from catalytic systems containing phthalate meet the relevant requirements of Commission Regulations EC 1907/2006, EU 10/2011 and those of Article 3 of Regulation EC 1935/2004.

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Eltex® MED 100-MG12

Bovine Spongiform Encephalopathy (BSE) Transmissible Spongiform Encephalopathy (TSE)

This grade contains an additive derived from animal tallow; we received from our suppliers the information that tallow derivatives such as glycerol and fatty acids manufactured from tallow undergo conditions described as rigorous by the "Note for Guidance on Minimising the Risk of transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Products " 2004/C 24/03, usually known as EMEA 410/01 rev.3, in such a way that the materials produced thereof are considered unlikely to be infectious irrespective of geographical origin and the nature of the tissues from which they are derived. Please note that, in the matter of description of the processes that are qualified as rigorous in regards to tallow derivatives, the two chapters § 6-4 in EMEA 410/01 rev.3 and § 6-4 in EUP 5.2.8 are identical.

Genetically Modified Organisms (GMO)

Among the large variety of polymer additives that we are using, only a few of them may be genetically modified. We would like to comment on the relevance of gene modification techniques to plastic materials.

The most significant fact is that the starting substances or additives possibly deriving from genetically modified organisms based materials are manufactured through multi-step conversion and/or purification processes, involving aggressive conditions like high temperature and pressure as well as action of chemically reactive substances. The final plastic materials themselves are produced under high temperature conditions and are further submitted during conversion processes (extrusion, moulding) to high temperature for a significant period of time.

On the basis of current scientific knowledge, it can be stated that no DNA and no proteins from a given organism (genetically modified or not) can resist to such a series of treatments. Therefore, their presence in our polymers and in plastic articles manufactured from them is unexpected.

In conclusion, we confirm that the above grade is safe to be manufactured, processed and used, even if it is manufactured from starting substances or contain additives which may be of genetically modified organism's origin.

Regulations: Hazardous Substances, RoHS, WEEE, Packaging Waste, EoL Vehicles, CONEG (Heavy Metals), Environment (France)

This grade meets the relevant requirements of the following Directives or Regulations:

- **Restriction of Hazardous Substances**: Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether), as amended
- **RoHS**: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic Equipment, as amended
- **WEEE**: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, as amended
- **EoL Vehicles**: Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, as amended

- **Packaging Waste**: European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, as amended
- **Coalition of Northeastern Governors (CONEG)**: USA CONEG Regulation, as amended
- **Environment Code (France)**: Décret n°2007-1467 du 12 octobre 2007 and Code de l'environnement, section 5-Emballages, sub-section 1, Articles R 543-42 to R 543-52, as amended

Cosmetic

This grade meets the relevant requirements of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended. In particular, none of substances listed in Annex II of the Regulation (EU) No 1223/2009 is used as additive or raw material.

Swiss VOC legislation

This product is in compliance with Swiss SR 814.018 "Ordonnance sur la taxe d'incitation sur les composés organiques volatils (OCOV) du 12 novembre 1997" as amended, about Volatile Organic Content (VOC).

Ozone layer-depleting agents

Chlorofluorocarbons (CFC's) and substances related to ozone depleting substances (as defined by the MONTREAL PROTOCOL and listed as class I & II substances by the US Clean Air Act) are not used as additives or raw materials in the manufacture of this grade.

None of the prohibited substances listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer (as amended), which repeals and replaces Regulation (EC) 2037/2000, is used as an additive or raw material in the manufacture of the above grade.

Nanomaterials and nanotechnology

Further to the publication of the EU Recommendation 2011/696/EU on the definition of nanomaterials, some substances used for decades as additives in the plastics industry suddenly became nanomaterials. The list includes among others, silica, carbon black and many organic pigments. When these substances are used as additives in polyethylene or polypropylene, they end up encapsulated into a polymeric matrix and are not intended to be released under normal and foreseeable conditions.

Based on these arguments, the PP or PE products containing such additive(s) are exempt from notification under the French Decree 2012-232 (cfr Q&A n° 20bis on the website of the Ministère de l'Ecologie, du Développement Durable et de l'Energie).

REACH / SVHC

All Polyolefins materials are compliant with REACH Regulation No. 1907/2006.

For further details: http://www.ineos.com/businesses/INEOS-Olefins-Polymers-Europe/SHE

- **REACH**: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended
- **CLP**: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended

Inventories

The above product is in compliance with following inventories:

- Australian Inventory of Chemical Substances: AICS
- Canadian Chemical Registration Regulations: NDSL/DSL
- Chinese List on New Chemical Substances: IECS (Inventory of Existing Chemical Substances in China)
- European Inventory of Existing Chemical Substances: EINECS/ELINCS
- Japanese Chemical Substances Control Law under METI: CSCL
- Korean Existing Chemicals List: (K)ECL
- Philippine Inventory of Chemicals and Chemical Substances: PICCS
- US EPA Toxic Substance Control Act: TSCA
- New Zealand HSNO - Hazardous Substances and New Organisms

Absence of substances

None of the following substances are used as additives or raw materials in the manufacture of this grade: however, since we do not systematically perform specific tests to verify the absence of these substances, we cannot guarantee that there is no trace amount of these substances, as impurity or otherwise, in this grade.

- Acrylamide
- Alkylphenol
- Alkylphenol Ethoxylates (APEOs)
- Allergens (as defined in Regulation (EU) No 1169/2011, as amended)
- Aromatic amines
- Asbestos
- Azodicarbonamide or semi-carbazide compounds
- Benzophenone, hydroxybenzophenone and 4-methyl benzophenone
- Biocides
- Bisphenol-A (BPA), Bisphenol-F (BPF) and Bisphenol-S (BPS)
- Brominated flame retardants
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated Paraffins
- Conflict minerals:
    - Columbite-tantalite (Coltan, Niobium, Tantalum)
    - Cassiterite (Tin)
    - Wolframite (Tungsten)
    - Gold
- Decabromodiphenylether (decaBDE)
- 2-Ethylhexanoic Acid (2-EHA)

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Belgium

- Di(ethylhexyl) adipate (DEHA) and di(ethylhexyl) maleate (DEHM)
- Dimethyl Fumarate (DMF)
- Dioxins and furans
- Endocrine Disruptors listed in the Japanese authority list "Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98) - Table-3: Chemicals Suspected of Having Endocrine Disrupting Effects"
- Epoxy derivatives:
  - BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether],
  - BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether],
  - NOGE [novolac glycidyl ether]

  as defined in Directive 2002/16/EC amended by 2004/13/EC, repealed by the Regulation 1895/2005/EC
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- (Heavy) metals: Antimony, Arsenic, Beryllium, Cadmium, Cobalt, Copper, Hexavalent Chromium, Lead, Mercury, Nickel, Selenium
- Isopropylthioxanthone (ITX)
- Latexes and elastomers
- Melamine and cyanuric acid
- Mercapto mix
- N-ethyl-o,p-toluolsulfonamide (NETSA) (CAS nb 1077-66-1)
- N-ethyl-p-toluenesulphonamide (NE-PTSA) (CAS nb 80-39-7)
- Nonylphenol and its derivatives including Tris(nonylphenyl) Phosphite (TNPP)
- Organo-tin compounds
- Pentabromodiphenyl ether, octabromodiphenyl ether
- Perfluorinated compounds (PFC), Perfluorinated tenside (PFT), Perfluorooctanoic acid (PFOA) & Perfluorooctane sulfonate (PFOS) listed in Directive 2006/122/EC
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), polybrominated terphenyls
- (PBTs)
- Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Recycled products as defined by Regulation (EC) 282/2008
- Short-chain chlorinated paraffins
- Silicone
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Thiuram mix
- Titanium Acetyl Acetone (TAA)
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS nb 3380-34-5)
- Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC, ...)
- Substances listed in:
  - California Proposition 65 State regulation as amended
  - GADSL, "Global Automotive Declarable Substance List", as amended
  - IKEA Specification, IOS-MAT-0010, chapter 3 & 6, as amended
  - IKEA Specification, IOS-MAT-0054, as amended

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Polypropylene
RF365MO

DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS

We confirm that this product fulfils the applicable requirements on substances used for the manufacturing of materials and articles or components of articles intended to come into contact with food as described in the below cited legislation and standards.

EU

The below listed regulations represent harmonised EU legislation and are applicable unchanged in all EU-member states. National legislation implementing such regulations is therefore not separately cited in this document.

We would like to stress that this product is an **intermediate plastic material** as defined in chapter 3.1. of Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain, from 28.11.2013. Therefore this confirmation is restricted to the requirements as applicable for intermediate plastic materials used for the manufacturing of materials and articles or components of articles intended to come into contact with food.

- Commission Regulation (EC) No 1935/2004. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 must be verified and tested by the producer of the final packaging material.
- Commission Regulation (EU) 10/2011 as amended. All used monomers and additives are listed in Annex I of this regulation. For any applicable restrictions see chapter "migration testing".
- Commission Regulation (EC) 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade.
- Commission Regulation (EC) 2023/2006. This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the Borealis statement "Food hygiene demands and standards".
- Commission regulation (EC) No 450/2009 on active and intelligent materials and articles is **not applicable** to polymer resins.

Additional national legislation in EU-member states

Polymerisation production aids, aids to polymerisation, colorants and solvents, if not already listed in Annex I of Regulation (EU) 10/2011 can be used based on their national approval and are subject to mutual recognition. The process chemicals used for the manufacturing of this grade are permitted by at least one of the following national regulations/recommendations, or were rated as safe in a risk assessment acc. article 19 of Regulation (EU) 10/2011

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Polypropylene
RF365MO

France	Brochure N°1227 (2002), et Arrêté du 02.01.2003 tel que modifié incl. Arrêté du 19.12.2013
Germany	BfR-Empfehlung VII Polypropylen, Stand 01.07.2016
The Netherlands	Verpakkingen- en Gebruiksartikelenbesluit, 1979 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amendmended (last update from 27.03.2014)

Europe (Non-EU-countries)

Norway	Sosial- og helsedepartementets forskrift 1993-12-21-1381 (referring to Regulation EU 10/2011)
Switzerland	Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21) ; Stand 01.05.2017, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff

World

China	GB9685-2016 - National standard on the use of additives in food containers and packaging materials GB 4806.1-2016 - National standard on general safety requirements for materials and articles in food contact - so far applicable to polymer resins. GB 4806.6-2016 - National standard on plastic resins for food contact use - Appendix A - 29 Propylene-copolymer - no co-monomers with SML used
USA	FDA, CFR, Title 21, 177.1520 (a)(3)(i)(c)(1), (b) and (c)3.1a Olefin polymers

Limits of use (FDA)

Test samples made from this product fulfilled the extraction requirements according to FDA CFR 21 §177.1520 (c), as defined for the type of polymer described above. Therefore this product may be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use C through G as described in table 2 of CFR 21 §176.170(c). **The product is not intended for use in packing or articles holding food during cooking. It is the responsibility of the converter or food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.**

Migration limits and testing

Migration limits

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Article 6.3.a and Annex II) and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid;

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Polypropylene
RF365MO

4h/100°C) did not show any migration above 0,04 mg/kg.

The product may contain a residual component from the catalyst system which is regulated with a specific migration limit in EU. Migration tests in 95% Ethanol for 10 days at 60°C showed a migration level significantly below the SML, so when applying a standard surface volume ratio of 6, this SML cannot be exceeded under any forseeable conditions of use. For more details pls. ask your Borealis sales contact.

Other used monomers and additives are not regulated with specific migration limits.

Substances also authorised as direct food additives ("Dual use additives") are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of the limits as set in the applicable food legislation.

Migration testing

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21 and article 2.12 of Chinese standard GB4806.1 the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg)

A representative sample from this or a comparable material, tested for 2d at 20°C in isooctane (1 mm plate / total immersion) did not exceed the limit of 10 mg/dm² for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.

Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 10/2011; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8-2016. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

Non-intentionally added substances - NIAS

Commission Regulation (EU) 10/2011 notes that not all contaminants and reaction products of authorised monomers and additives can be listed in its Annex I. The identification of non-listed migrants may therefore not be an exclusion criterion in itself. However, a toxicological evaluation of these migrants needs to be performed.

The major fractions of NIAS in Polyolefins are the oligomers, which are unavoidably formed during polymerisation and cannot be removed. A recent joint study of polyolefin producers demonstrated that oligomers migrating from all

Polypropylene
RF365MO

types of polyolefins only consist of linear and branched alkanes (POSH) and alkenes (POMH), no cyclic or aromatic compounds were found. The toxicological assessment of such migrants concluded that they are sufficiently characterised by the existing overall migration limit.

Further a variety of representative Borealis products, covering the whole Borealis product spectrum, was assessed in relation to migrating NIAS by renowned test institutes. Beside oligomers the typical NIAS are reaction- and decomposition products from antioxidants, many of them known as "Arvin-substances". Another joint industry study confirmed that none of these Arvin-substances are genotoxic and can therefore be rated at least as "Cramer-class III", allowing a daily consumption of 90 µg/person/day.

However, we wish to stress that a NIAS-assessment is subject to the finished food contact article and the formation of NIAS is influenced by thermal and mechanical treatment during conversion, mixture with other substances and the applied test conditions. A raw material screening therefore can never monitor all potential criteria, so Borealis cannot provide a final answer in this regard.

Prepared by Borealis, Group Product Stewardship / Jürgen Emig

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication.

The legislation cited above applies to the final packaging which is intended to come or is brought into contact with foodstuff. This statement however is restricted to the Borealis product as it leaves production. It is the customers responsibility to verify compliance with applicable legislation of the final packaging under actual and foreseeable conditions of use.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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Polypropylene
RF365MO

STATEMENT ON ORIGIN OF RAW MATERIALS

Animal based materials and BSE/TSE
We certify that manufacturing this product, we do not use or intentionally add into it any substances of animal origin. We therefore state that our product is to be considered safe with respect to BSE and TSE transmissions.

Halal certification
This product does not have an official Halal certification.
We certify that manufacturing this product, we do not use or intentionally add into it any substances of animal origin or drinkable alcohol (ethanol).

Kosher certification
This product does not have an official Kosher certification.
We certify that manufacturing this product, we do not use or intentionally add into it any substances of animal origin, wine, dairy products, marine products or their derivates.

Palm oil, palm kernel oil and their derivates
In this product we incorporate small amounts of stearates or other materials derived from fatty acids. These are derived from vegetable oils that can be of palm oil or palm kernel oil origin.

Prepared by Borealis, Group Product Stewardship / Aino Haritonova

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however we do not assume any liability whatsoever for the accuracy and completeness of such information.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

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STATEMENT ON CHEMICALS, REGULATIONS AND STANDARDS

We certify that during manufacturing of this product we do not use or intentionally add any of the chemicals restricted by the following regulations and standards and their subsequent amendments in amounts which exceed the applicable limits.

- Annex XVII of the REACH Regulation 1907/2006/EC (superseding Directive 76/769/EEC) - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
- CONEG "Toxics in Packaging" Model Legislation, rev. 2008
  Directive 94/62/EC (Packaging and packaging waste - PPW) and related EN13428 and CR13695
  - Sum of Cd, Cr, Hg and Pb < 100 ppm
- Directive 2000/53/EC (End of life vehicles - ELV) - Cr(VI), Hg and Pb < 0.1 wt%, Cd < 0.01 wt%)
- Directive 2011/65/EU (Restriction of the use of certain Hazardous Substances in electrical and electronic equipment - ROHS) - Cr(VI), Hg, Pb, PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 wt%, Cd < 0.01 wt%
- Directive 2012/19/EU (Waste Electrical & Electronic Equipment - WEEE, repealing 2002/96/EC) - Annex VII - No ingredients used which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated FR)
- Chemicals List of Proposition 65 of the State of California and subsequent amendments, as known to the State of California to cause cancer or reproductive toxicity
- Regulation 1005/2009/EC (Substances that deplete the ozone layer)
  - Prohibition of CFC's, HCFC's, Halons, CCl4, Trichloroethane, HBFC's
- US Clean Air Act, Title VI, Classes I and II (EPA Final Rule; Federal Register 8136, 11.2.1993) on substances that deplete the ozone layer
- Regulation 850/2004/EC on persistent organic pollutants (POPs)
- Regulation 1169/2011/EU - Annex II (allergens) repealing Annex IIIa of Directives 2003/89/EC, 2006/142/EC, 2007/68/EC
- Global Automotive Declarable Substance List (GADSL) and VDA232-101
  - No use of prohibited or declarable substances above threshold limits
- Swiss SR 814.018 (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen - VOCV) - VOC's according to Annexes 1 & 2 < 3 wt%
- Regulation 1223/2009/EC "on cosmetic products" - prohibited and restricted substances
- Directive 2009/48/EC (safety of toys)
- European Standard EN 71-3:2013+A1:2014 "Safety of Toys", Part 3: "Migration of certain elements" - Migration below limits for toy material category III in Table 2, and EN 71-9:2005+A1:2007 "Organic chemical compounds - Requirements" (Tables 2 A-I).
- Japanese CSCL; Class I and II Specified Chemical Substances
- Japanese PRTR law; Class I or Class II Designated Chemical Substances

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Polypropylene
RF365MO

Regarding classification of the above product according to REGULATION (EC) No 1272/2008 and its subsequent amendments, reference is made in the SDS/PSIS for the above product.

We also certify that during the manufacturing of the above product we do not use or intentionally incorporate into it any of the following materials:

Acrylamide
Antimony, Arsenic, Beryllium, Bismuth
Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII)
Artificial Musks
Asbestos
Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)
Azodicarbonamide, semicarbazide
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2´-Dimethoxy-2-phenylacetophenone)
BHA or BHT
Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)
Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)
Cadmium, Chromium (VI), Lead, Mercury
CFC, HCFC
CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC *
Colophony (rosin)
4,4'- Diaminodiphenylmethane (MDA)
Di-2-ethyl-hexyl maleate (DEHM)
Dimethylfumarate (DMF), Dibutylfumarate
1,4-Dioxane
Endocrine disruptors: Category 1 substances in the European Commission EDS database *
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams
Flame retardants (halogenated or phosphorus based)
Formaldehyde
Fragrances
Furfural
Glycol ethers (EGME, EGMEA, EGEE, EGEEA)
Glyoxal
Gold, Indium, Nickel, Palladium
Halogenated organic compounds
Melamine, Cyanuric acid
MOAH (mineral oil aromatic hydrocarbons)
Nanomaterials (>50% of particles <100 nm)
Natural rubbers, Latex
Nitrosamines, Nitrates, Nitrites
Octyl- and Nonylphenols and Octyl- or Nonylphenolethoxylates; TNPP
Organotin compounds
Parabens
PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
PFOA, PFOS
Plasticisers (e.g. Adipates, ESBO, Phthalates*)
Polychlorinated Bi-, Terphenyls and Naphthalenes
Polychlorinated dibenzodioxins and dibenzofurans
Polycyclic aromatic hydrocarbons (PAH)
Radioactive substances
Recycled materials
Selenium, Silver, Tellurium, Thorium
Styrene, Polystyrene
SVHC on "Candidate List of Substances of Very High Concern for Authorisation"*
Thiuram mix
Tin, Gold, Tantalum, Tungsten
UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
Vinylchloride, Vinylidenechloride, PVC or PVDC

*) DEP, DEHP or DIBP may be used in the catalyst system, which may result in traces of these phthalates in the product, typically in concentrations below 1 ppm.

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Polypropylene
RF365MO

The substances used in the manufacturing of the above product, and if applicable the basic polymer(s), are listed in the following chemical inventories:

Australia/AICS
Canada/DSL
China/IECSC
Europe/EINECS or ELINCS or NLP
Japan/ENCS
Korea/KECL
New Zealand/NZIoC
Philippines/PICCS
Taiwan/TCSI
USA/TSCA

Prepared by Borealis, Group Product Stewardship / Barbara Lindorfer

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however we do not assume any liability whatsoever for the accuracy and completeness of such information.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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D-65343 Eltville

***Purell* PE 3020K**

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

Dear Thilo Stern:

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

lyondellbasell

Purell PE 3020K

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.

Specific Migration Limits

This product does not contain monomers, additives or other components which have SMLs or QMAs as specified by Regulation 10/2011/EC.

Dual use additives, as defined in Regulation 10/2011/EC, are not intentionally used in the manufacture or formulation of this product.

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)(2)(i) and (c)2.2.

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

Allergen - Food Allergen European Regulation 1169/2011

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)

Components derived from animal sources are not used in the manufacture or formulation of this product.

Tallow

Tallow derived components are not used in the manufacture or formulation of this product.

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 - European Pharmacopoeia Edition 9.0

This product is in compliance with monograph 3.1.4 (Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations) - European Pharmacopoeia Edition 9.0

ISO 10993

Biological reactivity evaluations have been performed on representative samples of this product according with the requirements of USP 661.1; specifically the Chapter 88 - USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test) and Chapter 87 - Biological Reactivity Tests, in Vitro for polymeric materials (Elution Test). These USP tests may fit the requirements of certain sections of ISO 10993-5 (tests for in vitro cytotoxicity), 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 meet the requirements of USP Chapter 661.1 (Edition USP 39).

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. 29978. Contact LyondellBasell for a DMF authorization letter to be sent to FDA.

ICH Harmonized Guideline Q3D (Elemental Impurities)

The elemental impurities of Class 1, 2, 3 listed in the ICH Harmonized Guideline Q3D of 16 December 2014 are not intentionally used in the manufacture or formulation of this product. However this product has not been tested for these substances.

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 intentionally used in the manufacture or the formulation of this product. 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;

Alkylphenols

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.

Phthalate Free

Phthalates are not used in the manufacture 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 July 7, 2017) 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.
(iv) tobacco related products and applications, electronic cigarettes and similar devices;
(v) safety components in automotive applications, for example: air bags, air bag unit housings and covers, seat belt mechanisms, brake systems, pedals and pedal supports, steering systems.

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

Stella Kunststofftechnik GmbH

H.J.-Mueller-Strasse 4
D - 65343 Eltville
Germany

0000126135 29845300 24.01.2018

Declaration

Remafin White CPK 059

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
No component is subjected to further specific limitations.
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	20 - 25 %
106	Stearic acid & derivatives	< 0,1 %

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 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 Plastics & Coatings (Deutschland) GmbH

Country Product Stewardship

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

Stella Kunststofftechnik GmbH

H.J.-Mueller-Strasse 4
D - 65343 Eltville
Germany

0000126135 30105297 15.03.2018

Declaration

REMAFIN-RED PE33001874-ZN

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

- Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8 - C22) alcohols, SML = 1,8 mg/kg. In compliance with the specification laid down in Annex I / Table I.

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	3 - 5 %

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.

Additional information
The previous statement means the colorant product fulfills the purity criteria with regard to heavy metal trace impurities and the content of primary aromatic amines according to Koninklijk Besluit/Arrêté royal dated May 11, 1992, Belgisch Staatsblad/Moniteur Belge dated July 24, 1992, page 16719.

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).

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)	Specific migration limit
HDPE	No limitation.	
LLDPE	No limitation.	
LDPE	No limitation.	
PP	No limitation.	

If your application polymer is not listed, please contact us.

Italy: Decreto Ministeriale

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

Additional information
The previous statement means the colorant product fulfills the purity criteria with regard to heavy metal trace impurities and the content of primary aromatic amines according to Decreto Ministeriale of March 21, 1973 and subsequent amendments.

The Netherlands: Warenwet

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

Additional information
The previous statement means the colorant product fulfills the purity criteria in regard to heavy metal trace impurities according to "Warenwetregeling verpakkingen en gebruiksartikelen" (Warenwet), Regulation dated 14.03.2014 (the determination of primary aromatic amines is performed according to AP(89)1).

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.

Additional information
The previous statement means the colorant product fulfills the purity criteria with regard to heavy metal trace impurities and the content of primary aromatic amines according to Real Decreto 847/2011, dated 17th of June 2011.

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 Masterbatches

CLARIANT

Clariant Plastics & Coatings (Deutschland) GmbH

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

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Regulatory Data Sheet

Gasket & Lining Material

F 217X SERIES

PLASTIC FORMULATION

uncolored and white

FOOD CONTACT [1]

US:

Is in compliance with F.D.A.: 21 CFR

- 177.1520 Olefin Polymers (c)3.2a
- 178.3297 Colorants for polymers

EU:

Is in compliance with Regulation (EC) No. 1935/2004 of the European parliament and of the Council on materials and articles intended to come into contact with food.

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

Is in compliance with Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, effectively replacing Commission Directive 2002/72/EC and amendments.

All composing ingredients are listed in Annex I of Commission Regulation (EU) No. 10/2011, or otherwise authorized in accordance with the requirements laid down in this regulation.

Does not contain monomers which are regulated with a specific migration limit.

Contains one or more intentionally incorporated additives which are regulated with a specific migration limit:

Tris(nonylphenyl) phosphate	
EC Ref. No. 74400	SML=30mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	
EC Ref. No. 68320	SML=6mg/kg
Zinc Oxide	
EC Ref. No. 96240	SML=25mg/kg

...*

Contains one or more intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex IV of Commission Regulation (EU) No. 10/2011:

...*

(1) Declaration based on certificates received from our suppliers

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Gasket & Lining Material

F 217X SERIES

PLASTIC FORMULATION

uncolored and white

Overall (OML) migration testing was performed on a representative sample under the following conditions:

- Sample specification: F 217-5
- Sample thickness: 1,5mm
- Food simulants: A, B, D2 (representing contact with all food types)
- Test conditions: 10 days at 40°C

The overall migration limit (OML) of 10mg/dm^2 was not exceeded.
The results of this test do not exclude the possibility that this material will still comply under other test conditions.

SML values have been calculated for the above compound, based on the following conditions:

- 100% migration of substances with SML
- Specification: F 217X5
- Thickness: 1,5mm

According to calculations, based on the information received form our suppliers regarding SML substance content in the raw materials, all SML's can be safely respected as long as the contact surface to food product volume does not exceed 0,2m^2/kg.
No specific (SML) migration testing was performed on this material.

Please note that it is the responsibility of every actor within the supply chain to ensure compliance to the existing Regulations for every step under his responsibility. It remains the responsibility of the food packager to ensure the suitability of our product for a specific use with a specific type of food through testing.

* The identity of any additional substances can be disclosed for testing purposes

PHARMACEUTICAL USE

EU:
The contact layers are in compliance with the following monographs of the European Pharmacopoeia 9th edition:

- Monography 3.1.3 "Polyolefines"
- Monography 3.1.5 "Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations"

The final responsibility for the decision wheter a material is fit for a certain application lies with the responsible pharmacist of the pharmaceutical firm.

HEAVY METALS (1)

Complies with CONEG Regulations on heavy metal content (the cumulative content of Pb, Cd, Hg and Cr(VI) does not exceed 100 ppm).

Complies with Commission Directive (EU) No. 94/62/EC including amendments 2004/12/EC & 2005/20/EC (the cumulative content of Pb, Cd, Hg and Cr(VI) does not exceed 100 ppm per weight).

(1) Declaration based on certificates received from our suppliers

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Gasket & Lining Material

F 217X SERIES

PLASTIC FORMULATION
uncolored and white

REACH [1]

Does not contain any substances as part of the formulation which are classified carcinogenic, mutagenic, toxic to reproduction or dangerous for the environment, according to Directive 67/548/EEC as amended and/or Regulation (EC) No. 1272/2008 as amended and/or Regulation (EC) No. 1907/2006 as amended.

Does not contain SVHC substances as published on the ECHA candidate list dd. 07/07/2017 in concentrations exceeding the legal threshold of 0,1% w/w.
Since the presence of these substances are not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

Tekni-plex Europe nv will actively inform its customer base in case ingredients that are part of the formulation become listed.

BSE/TSE [1]

All ingredients are manufactured in accordance with the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 Rev. 3 – July 2011) adopted by the Committee for Proprietary Medicinal Products (CPMP)and by the Committee for Veterinary Medicinal products (CVMP).

We therefore state that these materials are to be considered safe to use in food applications with respect to BSE and TSE transmissions.

COSMETIC APPLICATIONS [1]

Does not intentionally contain any substances which are restricted according to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products.

EPOXY DERIVATIVES [1]

Does not contain any of the epoxy derivates mentioned in the Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (BADGE, BFDGE, NOGE).

TOYS DIRECTIVE [1]

The chemical composition complies with EN 71-3: Safety of Toys.

ROHS [1]

The chemical composition complies with Directive 2011/65/EU of the European Parliament and of the council on the restriction of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS), repealing Directive 2002/95/EC of the European Parliament and of the Council.

(1) Declaration based on certificates received from our suppliers

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Gasket & Lining Material

F 217X SERIES

PLASTIC FORMULATION
uncolored and white

CALIFORNIA PROPOSITION 65 (1)

None of the ingredients are expected to cause any contravention of the regulation of Safe Drinking Water and Toxic Enforcement Act of 1986, or the California Proposition 65.

ABSENCE OF SUBSTANCES AND CHEMICALS (1)

Based on our suppliers' certifications on the materials used for the above compound, we can safely state that the following substances are either not intentionally used, no longer present in the finished product or not present above applicable legal thresholds :

- Azodicarbonamide
- Benzophenone compounds
- Bisphenol A
- BTHC
- Chlorinated compounds
- DEHP
- DEHTP
- Dimethyl fumarate
- Dioxin
- DOA
- Galaxolide
- Gluten
- Glycerides
- GMO
- Hexamol DINCH
- Hydrazines
- ITX
- Lactose
- Latex
- Nitrite
- N-Nitrosamines, N-Nitrosatables
- N-substances
- PAH
- Parabens
- Phthalates
- TAA
- Tonalide
- TOTM

Since the presence of these substances are not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

For Tekni-Plex Europe NV
Industrielaan 37
9320 Erembodegem
Belgium

Also belong to the TEKNIPLEX Global strength. Superior solutions. group of companies::

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Tel: +49 (0) 5182 90 88 80
E-mail: info@top-seals.de

(1) Declaration based on certificates received from our suppliers

Food Contact

Declaration on food contact status according to the EC Directive 1935/2004 in combination with the Directive EC 10/2011

The Jowat SE, Ernst-Hilker-Str. 10 - 14, D - 32758 Detmold, as supplier of the product

Jowatherm 245.00,

declares as follows concerning regulations and recommendations listed below applicable for food contact.

A. Regulations of the European Community

In its components, this product does not meet the requirements of the **EC Directive 10/2011** with its revisions, Annex I "Substances" and Annex II "Restrictions on materials and articles".

B. Regulations of the USA

The product in its composition meets the **FDA recommendation 175.105**.
This means that the adhesive is suitable for use in the packaging of food with indirect food contact.

C. Migration data

We are not in a position to make statements concerning the migration of various substances, because this depends on the type of processing, the quantities used, and the quality of the other materials employed in the bonding process.

This information is based on our knowledge. The distributor of the product getting in contact with food is responsible for the compliance of the product regarding migration values, local laws and intended use.

This certificate is valid for one year as of date of signature, and we would be pleased to renew it upon request.

Detmold, October 16, 2017
i.V. Jan-Peter Bölcke
Environmental Management

Jowat SE · Ernst-Hilker-Straße 10-14 · 32758 Detmold · Deutschland · Telefon: +49 (0)5231 749-0 · Telefax: +49 (0)5231 749-105 · info@jowat.de · www.jowat.de

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65343 Eltville

Pröll
Treuchtlinger Straße 29
D-91781 Weißenburg i. Bay.
Telefon (0 91 41) 9 06 - 0
Telefax (0 91 41) 9 06 - 49
E-mail: info@proell.de
Internet: www.proell.de

Declaration

In the European Directives

- 2000/53/EC (ELV = End of Life Vehicles),
- 2011/65/EC (RoHS = Restriction of the use of certain Hazardous Substances in electrical and electronic equipment)

the following substances are restricted:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent chromium (Cr VI)
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Pentabromodiphenyl ether (PentaBDE)
- Octabromodiphenyl ether (OctaBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP).

We herewith declare that our products do intentionally not contain any of the above-mentioned substances as well as animal compounds (incl. BSE/TSE).

None of the raw materials appearing on the General Exclusion List of the European Associations of the Manufacturers of Paint, Printing Ink and Artists' Colours EuPIA and CEPE (see www.eupia.org => General Info About Printing Inks => Exclusion Lists) are used to manufacture our products. The raw materials which are used, however, are produced under industrial conditions and may therefore contain inevitable traces of contamination. The requirements stipulated for the manufacturing, market distribution and use of certain dangerous substances, preparations and products comply with the European Regulation 1907/2006/EC (REACH), Title VIII and Annex XVII, or the German law on Prohibited Chemicals (Chemikalien-Verbotsverordnung). This also applies to any contaminants which may be contained.

Weissenburg, 21 January 2016

Pröll KG

ppa. Dr. Silke Kupfer

i. A. Marco Auer

Treuchtlinger Straße 29
D-91781 Weißenburg i. Bay.
Telefon (0 91 41) 9 06 - 0
Telefax (0 91 41) 9 06 - 49
E-mail: info@proell.de
Internet: www.proell.de

Declaration

According to Regulation (EC) No. 1907/2006 (REACH) our company, as manufacturer of mixtures, is only a downstream user given that we do not produce or import substances as defined by the above-stated regulation and most of our raw materials are mixtures themselves.

The data on the composition of these raw materials is based on the Material Safety Data Sheets we have received from our suppliers. The Material Safety Data Sheets are compiled by our suppliers according to the applicable regulations which do not require listing all substances contained.

Furthermore, the raw materials used are produced under industrial conditions and may, therefore, contain inevitable traces of contamination.

Based on the information provided by our suppliers, all raw material or their ingredients have been pre-registered and will be registered by the corresponding deadline applicable to production or import volume.

The substances which are mentioned on the "Candidate List of Substances of Very High Concern" for inclusion in Annex XIV of the REACH regulation, released in January 2017, are not contained as constituent ingredients of our products.

It should be noted, however, that substances of very high concern (SVHC) might not only be contained in the ink film, but also in the substrate or other components of your product, so that both concentrations of the corresponding SVHC might have to be added to determine the total amount.

We would like to point out that a duty of disclosure, in accordance with Article 33 of the REACH Regulation for manufacturers of preparations, does not exist on principle. Article 33 governs the duty of disclosure for manufacturers of articles containing a substance of very high concern in a concentration exceeding 0.1 % (w/w). If the concentration of an SVHC in an article is less than 0.1 % (w/w), there is no obligation for the producer to relay the information within the supply chain.

Within the supply chain, manufacturers of mixtures are required to forward or communicate safety- related information concerning their products in their Material Safety Data Sheets. This applies, in particular, to any materials classified as "substances of very high concern".

In case an authorization procedure is required for any ingredients of our products, we will proceed to inform our customers immediately.

Weissenburg, January 2017

Pröll KG

Reinhard Port
General Manager

i. A.

Marco Auer
Quality Manager

WACKER

Regulatory Product Information

SILFAR® 100 DIMETHICONE

RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2011/65/EU (RoHS 2) are intentionally introduced during manufacture. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

WEEE (Waste of Electrical and Electronic Equipment)

None of the substances mentioned in Directive 2012/19/EU (WEEE) are intentionally introduced during manufacture. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

Heavy Metals

- Directive 94/62/EC (Packaging and packaging waste)
- CONEG (Coalition of Northeastern Governors)
- Directive 2000/53/EC (End-of life vehicles)

None of the substances concerned (lead, chromium VI, cadmium, mercury) are intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

REACH SVHC (Substances of Very High Concern)

Product does not contain SVHC in amounts > 0.1 %.

ODS (Ozone Depleting Substances)

Substances mentioned in "The Montreal Protocol on Substances that Deplete the Ozone Layer" are not contained as intentionally added ingredients.

Allergens

- Regulation (EU) No 1169/2011, substances listed in Annex II
- Substances listed in the Food Allergen Labeling and Consumer Protection Act (FALCPA)

- Latex
- Fragrances

The substance(s) mentioned above are not used in the manufacture or the formulation of this product.

GMO (Genetically Modified Organisms)

Product is not derived from genetically modified organisms and for its manufacture no intermediates and/or auxiliary agents which are genetically modified are used.

BSE/TSE

Product is not derived from human or animal origin and for its manufacture no intermediates and/or auxiliary agents which are of human or animal origin are used.

HACCP (Hazard Analysis and Critical Control Point)

The product is not produced under HACCP principles.

Food Contact Regulations

European Regulations

- Regulation (EU) No 10/2011

The product is listed under its chemical name Polydimethylsiloxane (ref.-No. 76721) and complies with the specifications under column (4) and (10). It is not subject to a specific migration limit (SML). Dimethylpolysiloxane is approved as food additive under E 900, therefore the product formally meets the definition of a dual use substance. However, the product is not recommended for this use and should not be used as food additive. In addition, Dimethylpolysiloxane is mainly used as a processing aid and does not have a technological effect in food. NIAS are not contained at levels which could endanger human health.

- Regulation (EC) No 1935/2004

Provided appropriate processing, the product is suitable for the manufacture of food contact materials and articles according to this Regulation. Compliance with the requirements of Regulation (EC) No 1935/2004, especially the suitability of the material or article for the intended use, the observance of any given limitations, the effect on taste and smell of the food has to be ensured by the producer of the finished food contact material or article as it is placed on the market.

- Regulation (EC) No 2023/2006

Not applicable. This product is considered as a starting material and therefore out of the scope of this Regulation.

Germany

The product complies with the positive lists of the following Recommendation(s) of the BfR:

- XV. Silicones
- XIV. Plastic Dispersions
- XXXVI. Paper and Board
- XXXVI/2. Paper and Board for baking purposes

Switzerland

- Swiss Ordinance SR 817.023.21

The product is listed under its chemical name in annexes 1, 5 and 6 as a fully evaluated substance.

USA

The product is suitable for use under the following section(s) of Title 21 of the Code of Federal Regulations and those which refer to these:

- §175.105 ADHESIVES; Functional barrier or additional use limitations a.s described in 175.105(a)(2).
- §175.300 RESINOUS AND POLYMERIC COATINGS; limited for use on metal substrates only; Extractive limits under (c) - (e) on finished article
- §176.170 COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS; Extractive limits under (c) - (d)on finished article.
- §176.180 COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH DRY FOOD
- §176.200 DEFOAMING AGENTS USED IN COATINGS
- §176.210 DEFOAMING AGENTS USED IN THE MANUFACTURE OF PAPER AND PAPERBOARD
- §177.1200 CELLOPHANE
- §177.1210 CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS; Extractive limits under (c) on finished article
- §177.2260 FILTERS, RESIN-BONDED; special restrictions for use conditions and extractives to be observed
- §177.2800 TEXTILES AND TEXTILE FIBERS
- §178.3120 ANIMAL GLUE; use conditions to be observed

China

- Standard GB 9685-2008

Paper	Dosage as necessary		
Rubber	Dosage as necessary		
Coatings	Dosage as necessary		
Adhesives	Maximum level	0.02 %	
Inks	Maximum level	1.0 %	
Plastics	Dosage as necessary:		PE, PP, PS, AS, ABS, PC, PVC, PVDC
PA, POM	Maximum level	2.0 %	
PET	Maximum level	0.3 %	

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe for contact with food by regulatory bodies. The responsibility for compliance of the finished article and any testing requirements relating to migration, extraction or volatile limits resides with the manufacturer of the finished product.

WACKER

Drinking Water Regulations

Germany
The product is listed as polydimethylsiloxane in the positive list (Annex 1) of the Guideline for Hygienic Assessment of Lubricants in Contact with Drinking Water of the German Federal Environment Agency.

Pharmaceutical Regulations

European Regulations
- European Pharmacopoeia monographs

The product meets the purity requirements of the monograph „Dimeticone" under the current version of the European Pharmacopoeia. Solvents as mentioned in Guideline for residual solvents (CPMP/ICH/283/95) of the current edition of European Pharmacopoeia are not intentionally introduced.

US Regulations
- US Pharmacopeia monographs

The product meets the purity requirements of the monograph „Dimethicone" under the current version of the US Pharmacopoeia. Solvents as listed under Section 467 of the US Pharmacopoeia are not intentionally introduced.

GMP (Good Manufacturing Practice)

This product is manufactured under ISO 9001

Toy Regulations

- DIN EN 71-3

Substances mentioned in DIN EN 71-3:2013, table 2 are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

- DIN EN 71-9

Substances mentioned in DIN EN 71-9:2007, tables 2A – 2I are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

- CPSIA (Consumer Product Safety Improvement Act) of 2008

None of the substances concerned (lead, phthalates) are intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

Substances

- PAH (Polycyclic aromatic hydrocarbons)

- DMF (Dimethylfumarate)
- APEO (Alkylphenol ethoxylates)
- Phthalates
- Azo compounds
- PCDD/PCDF (Polychlorinated dibenzodioxins and dibenzofurans)
- Asbestos
- Melamine
- BPA (Bisphenol A), BPS (Bisphenol S)
- Radioactive substances

The substances mentioned above are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

Irradiation

Product does not undergo any form of radiation treatment.

Chemical Inventory Status

See Safety Data Sheet.

Certificates

Available ISO Certificates can be downloaded via
http://www.wacker.com/cms/en/wacker_group/wacker_facts/ims/certificates/certificates.jsp

This document was created electronically and does not require a signature.

For questions relating to this data sheet, please contact:
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