



Nr. 11/18 – 1 din 18.11.2020

Agenția Națională pentru Siguranța Alimentelor
mun. Chișinău, str. Mihail Kogălniceanu, 63
Tel.: 022-264648

Clarificarea ofertei

"Ecochimie" SRL a recepționat decizia ANSC nr. 03D-859-20 din 16.11.2020 privind soluționarea contestației "ARCTUS IMPEX" SRL împotriva Agenției Naționale pentru Siguranța Alimentelor (nr. intrare ANSC 02/1046/20 din 26.10.2020), prin care a contestat rezultatul evaluării ofertelor, inclusiv adjudecarea lotului 58 către Ecochimie SRL.

În pct. 3 a deciziei, Agenția Națională pentru Siguranța Alimentelor a fost obligată să reevalueze oferta "Ecochimie" SRL în partea ce ține de lotul 58 "Cuțite din plastic sterile" cu luarea în considerare a constatărilor din partea motivată a deciziei.

Comunicăm că specificația tehnică a bunului corespunde cu specificația tehnică solicitată de autoritatea contractantă, fiind oferit cuțit din plastic (PS – polisteren, este plastic alimentar rezistent la temperaturi înalte), lungime 175 mm, sterilizat cu radiații GAMMA, ambalat individual. Întru confirmarea specificației tehnice a bunului oferit prezentăm broșura furnizorului în care este specificată descrierea bunului:

- compoziția corpului fiind din "WHITE PS" ceea ce în traducere înseamnă "Polystyrene alb"
- Materia primă din care este confecționat cuțitul corespunde cerințelor EU pentru bunurile care intră în contact cu produse alimentare: 1935/2010/EC și 10/2011/EC.
- Polisterenul are temperatura de topire aprox. 240 grade Celsius, astfel putem conchide că este rezistent la temperaturi înalte.

Sperăm ca clarificarea prezentată să elucideze toate neclaritățile asupra bunului oferit.

Cu profund respect,
Director "Ecochimie" SRL
Nicolae Iurcu _____

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Corning Incorporated
Life Sciences

Registered ISO 9001

Product description

Catalog Number COUT-02
PDS reference PDS_Cbor_2200 Version _ 1
Product description Corning® Gosselin™ Knife, White PS, Sterile, 1/Bag, 1000/Case

Sanitary Assurance Level

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10⁻³

Expiration Statement

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level.

Primary body composition

White PS

Secondary body composition

N/a

Closure

N/a

Special feature

N/a

Packaging

1/Bag, 1000/Case

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Regulation Statement

We hereby confirm that we do not intentionally use the following substances in the manufacturing of the product :

- LATEX
- BISPHENOL A (CAS No 80-05-7)
- PHTHALATES as per Regulation 1907/2006/EC (SVHC) .

Raw material suppliers also guarantee the following requirements through certificates of compliance :

- EU Food Contact 1935/2010/EC and 10/2011/EC.

We hereby confirm that we do not intentionally use the following substances in the manufacturing of the product :
pongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

- Compliance to REACH SVHC candidate list (Regulation 1907/2006/EC). They certify that the here above mentioned products do not contain more than 0.1% (w/w) of any substance of very high concern listed in the ECHA candidate list in accordance with Article 33 of the Reach regulation, as updated on January 12, 2017.
- Heavy Metals Free as per directive 94/62/EC. The chemical composition of this product meets the relevant requirements of Directive 92/62/EC as amended) on packaging and packaging waste. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm

Raw material suppliers also confirm through certificates of compliance that they do not intentionally use the following substances :

- LATEX
- BISPHENOL A (CAS No 80-05-7)
- PHTHALATES as per Regulation 1907/2006/EC (SVHC) .



Cedric Maes
Plant Quality Manager, Borre & Chorges
maesc@coming.com

CORNING

Corning Life Sciences
836 North Street
Building 300, Suite 3401
Tewksbury, MA 01876

11 February 2019

To Whom It May Concern:

Safety Data Sheets (SDS) are not required for Corning-Gosselin Laboratory testing consumables/glassware such as Petri Dishes, bottles, dippers, containers, inoculating loops and allied products as these products are classified as articles in accordance with the following regulations:

U.S.A.

2012 HCS, The OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(6)(v) and (c).

European Union

EU-CLP or 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 (CLP), amending and repealing Directives 67/548/EEC (Dangerous Substance Directive) and 1999/45/EC, and amending Regulation (EC) No 1907/2006 concerning Registration, Evaluation, Authorization and Restriction of Chemicals (REACH as amended).

Regards,

Kafe Dido

Regulatory Affairs Product Stewardship Lead

Corning Incorporated | Life Sciences

836 North Street, Building 300, Suite 3401

Tewksbury, MA 01876

didok@corning.com

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Corning Restricted

CORNING

Certificate of compliance

CORNING GOSSELIN SAS
123 Rue de Caëstre - CS40019
59529 HAZEBROUCK CEDEX
BORRE - FRANCE

Date of certificate : 2020 - 11 - 06

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Product description

Knife PS wh L175, 1/bagSTERILE SAL 10-3

Catalogue number

COUT-02

Manufacturing date

2020/08/19

Lot number

751026

Lots : 751026

Sterility Assurance Level

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10-3

Expiration date

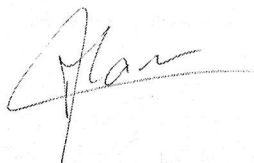
2023/05/01

Expiration statement

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level.



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