

**Ansell Healthcare Europe N.V.**Riverside Business Park
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EC Prohlášení o shodě výrobku

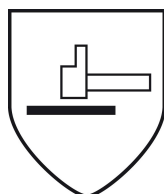
Category III

Výrobce se sídlem v Evropské unii

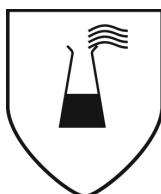
**ANSELL HEALTHCARE EUROPE N.V.
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BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS**

prohlašuje, že níže popsaná osobní pracovní ochranná pomůcka (POP):

Sol-Vex® 37-695



4101



AJL



odpovídá ustanovením Směrnice rady 89/686/EEC a Evropským sjednoceným standardům EN420:2003+A1:2009, EN388: 2003, EN374: 2003 a je identická s POP, která podléhá EU zkušebnímu testu s certifikátem číslo 3205079 vystaveným úředně stanoveným orgánem.

**CENTEXBEL (0493)
TECHNOLOGIEPARK 7
B-9052 ZWIJNAARDE**

podléhá postupu stanovenému v článku 11 bod A Směrnice 89/686/EEC pod dohledem úředně stanoveného orgánu

**CENTEXBEL (0493)
TECHNOLOGIEPARK 7
B-9052 ZWIJNAARDE****14. března 2015****Alison Arnot-Bradshaw
Senior Director – EMEA/APAC Regulatory Affairs
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PROHLÁŠENÍ O SHODĚ S POTRAVINAMI

Autorizovaný zástupce pro Evropskou unii:

**ANSELL HEALTHCARE EUROPE N.V.
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prohlašuje, že níže uvedené rukavice:

Solvex® 37-695

příslušející do kategorie "Elastomers and Rubber" (pro podrobnější informace o složení produktu, prosíme, nahlédněte do technického listu Ansell)

jsou v souladu s následujícími ustanoveními:

Nařízením 1935/2004 ES a Nařízením 2023/2006 ES vztahujícími se k Dobré výrobní praxi (GMP) pro materiály a předměty určené pro styk s potravinami (pro podrobnější informace, prosíme, nahlédněte také do Prohlášení o potravinách Ansell GMP).

Všechny složky, výchozí monomery a přísady použité při výrobě těchto rukavic jsou v souladu s:
- každým pozitivním seznamem
- každým relevantním SML (Specifický migrační limit) nebo nařízením jak je popsáno v související potravinářské legislativě EU 28.

France: Arrêté du 9 novembre 1994, relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires

Italy: D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale

Germany: BfR Empfehlung XXI (2011) Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk

Netherlands: Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen

Czech Republic: Vyhláška č. 38/2001 Sb. (Consolidated 2009-5-15) Annex 07: Elastomers and rubber products - list of materials

Slovakia: Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10

United Kingdom: FDA Code of Federal Regulations, Title 21, Part 177, section 2600 (21 CFR 177.2600) - Rubber articles intended for repeated use

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ISO 9002 Certificate
Number FM 40130

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Pro prohlášení o shodě v zemích mimo EU 28 nebo pro více informací, prosíme, kontaktujte společnost Ansell na: info@eu.ansell.com

Souhrnná data o migraci:

Type of foodstuffs - Testing conditions	Potraviny obsahující vodu	Potraviny obsahující alkohol	Kyselé potraviny	Potraviny obsahující tuk - korekční faktor 1	Potraviny obsahující tuk - korekční faktor 2	Potraviny obsahující tuk - korekční faktor 3	Potraviny obsahující tuk - korekční faktor 4	Potraviny obsahující tuk - korekční faktor 5
2 hodiny/teplota 40°C	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²
10 min/teplota 40°C	<10 mg/dm ²	<10 mg/dm ²	<50 mg/dm ²					

Analytická tolerance pro simulanty potravin obsahujících vodu, alkohol a kyselých potravin je 2 mg/dm² a pro simulant potravin obsahujících tuk je 3 mg/dm².

Závěry:

Žádná omezení používání pro žádnou z kategorií potravin v EU 28.

Alison Arnot-Bradshaw

Senior Director – EMEA/APAC Regulatory Affairs
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Date: 14-03-2015

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Date:14-03-2015

**Good Manufacturing Practices Declaration for Ansell's materials
and articles intended to come in contact with food**

Herewith, the undersigned declares that all Ansell gloves that are intended for contact with Food products are manufactured in accordance to the following requirements:

Regulation 1935/2004:

- Gloves are sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or deterioration in its organoleptic properties.
- Gloves are made with only legally acceptable Food-contact ingredients and do not exceed any legal migration levels based on the intended use of the product. Raw materials used in the production of the gloves are specified safe for food contact and are procured from an approved supplier.

Regulation 2023/2006:

- Gloves are made as per 'Good manufacturing practice (GMP)' meaning they are produced and controlled to ensure conformity with the applicable rules and applicable quality standards. This applies to all activities; from procurement through approved suppliers of materials and all aspects of manufacturing, processing, handling, storage, transport and distribution of the finished article.
- The manufacturing plant has a documented and effective quality assurance system in place with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
- The qualifications and training of personnel at manufacturing is documented. As well, the manufacturing facility and equipment is designed, cleaned, and maintained as necessary to ensure that in process materials and finished glove products comply with their specifications. Inherent in these requirements are personnel hygiene, pest

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control, contamination control, prevention of material damage from the environment, etc., etc.

- A formal risk analysis according to an established procedure has been conducted and each proposed change for its impact on risk to the user of the finished article is documented.
- The manufacturing plant has an effective quality control system and a documented system of tests, inspections, document reviews and formal dispositions on raw materials, in process materials and finished articles. This system includes clear decision-making criteria on materials and articles not meeting specifications.
- The manufacturing's quality control system monitors compliance with Good Manufacturing Practices and correct any failure to comply with GMP without delay. Ansell shall ensure adherence to the effective implementation of GMP through review of the supplier's internal audit system as described in the ISO 9001 Quality Management System.
- The manufacturing site maintains documentation on specifications, manufacturing formulae, and processing necessary to achieve regulatory compliance and product safety in electronic or paper (hard-copy) format.
- Finished articles are labelled with a unique control number, which relates to specific records held by the manufacturer.



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