



Declaration of Compliance

Business Operator	Vikan A/S Rævevej 1 DK-7800 Skive (+45) 96 14 26 00
商品名	テストキット, 55 mm, 青
製品名	11113
	
Plastic Material	金属とX線の検知できる添加剤を使用したポリプロピレン
EU 準拠	
Regulation (EC) No 1935/2004	In accordance with EU Commission Regulation no. 1935/2004 article 3, 11(5), 15 and 17 the product is intended for food contact. The product is marked with the "glass & fork" symbol on the packaging or on the product itself through moulding.
	
AP(89)1	All pigments in the masterbatch comply with resolution AP 89(1)
Regulation (EC) No 2023/2006	The product is produced according to EU Commission Regulation no. 2023/2006 of 22. December 2006 on good manufacturing practices for materials and articles intended to come into contact with food (GMP).
Regulation (EU) No 10/2011	本製品の製造に使用されるモノマー及び添加剤は、食品と接触するプラスチック材料及び製品に関する欧州議会及び理事会規則（EU）第10/2011号（2011年1月14日）の改正後の附属書IIに記載されています。 Monomers and/or additives with specific migration limit (SML) are used. The substances with a SML will not migrate in quantities that will exceed the SML, under the specified conditions of use. Upon request we will supply relevant information regarding these substances on a confidential basis. Vikan A/S does not use multi-layer materials or articles with a functional barrier.
Regulations (EC) No 1333/2008 and (EC) No 1334/2008	This material contains no "dual use" additives.



US FDA Compliance

All raw materials in this product are in compliance with FDA (Food and Drug Administration in the USA) 21 CFR parts 170 to 199.

The polymers and additives complies with FDA 21 CFR part 174, 175, 176, 177, 178, 181, 182, 184, or 186. Additives are cleared according to FDA 21 CFR Part 178 (Indirect food additives), are generally recognised as safe (GRAS), are prior-sanctioned food ingredients, or are cleared on basis of regulations for food additives of before 1958.

The polypropylene complies with FDA 21 CFR 177.1520 "olefin polymers".

The pigments in the masterbatch are listed under FDA 21 CFR 178.3297 „Colorants for Polymers“.

英国のコンプライアンス

この製品の材質はEUの食品に関する規制(2019 No. 704)に準拠しています。

Danish Compliance

The product complies with the Danish consolidation Act no. 681 of 25/05/2020.

溶出試験 樹脂

Samples of the product, or a similar product made from identical plastic material, have been tested for overall migration according to the test conditions specified in (EU) 10/2011 for repeated use, and the article comply with the overall migration limit of 10 mg/dm² or 60 mg/kg.

Test conditions for overall and specific migration were OM2 (10 days at 40 °C)

Compliance with specific migration limits, and other restrictions, has been documented through testing, calculation or simulation.

Food simulants used for overall migration were 10 % ethanol (simulant A), 3 % acetic acid (simulant B) and olive oil (simulant D2).

Max ratio of food contact surface area to volume

The ratio of food contact surface area to volume that has been used to determine the compliance of the product:

1.1 dm²/100 ml

食品接触 タイプ

The product is suitable for contact with the following types of food under the intended and foreseeable conditions of use:

- Aqueous
- Acidic
- Alcoholic
- Fatty
- Dry

Food contact usage time and temperature

Storage at room temperature or below up to 30 days, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.



Non-food contact usage temperature

Minimum temperature: -20 °C
Maximum temperature: 100 °C

General

クリーニングツールは、使用前に適切に洗浄、消毒、滅菌する必要があります。

また、適切な除染薬品を適切な濃度・時間・温度のもとで使用して、使用後にはクリーニングツールを適切に洗浄、消毒、滅菌することも重要です。

クリーニングツールの汚染除去を適切に行うことで、微生物の増殖と交差汚染のリスクを最小限に抑え、クリーニングツールの効率と耐久性を最大限にすることが可能です。

最大洗浄温度: 120°C

当社は、関係当局に向けて、関係者の要求に応じて、関連書類を提出いたします。

ヴァイカン本社（Vikan A/S）では、デンマーク獣医食品管理局（DVFA）へ登録しており、定められた自主管理システムについてDVFAによる監査を受けています。

本製品は、本適合宣言で指定された条件下での繰り返し使用に適しています。

再使用は、製品が無傷のままであり、損傷を受けておらず、使用と使用の間に適切な洗浄が行われていれば、適用される食品接触規制への製品の準拠に影響を及ぼしません。

Date

2025/09/30

Made By

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