

Gözmer'de üretilen tüm gözlüklerimizde sağlığa zararlı olmayan İsviçre Grilamid TR 90 natural hammaddesi kullanılmaktadır.

In all glasses, that are produced in Gözmer Eyewear, Switzerland Grilamid TR 90 natural raw material is used.
This material is totally in peace with human health and nature.



Global Registration and Strategic Consulting 

CERTIFICATE

Issued by Harlan Laboratories Ltd, Global Registration and Strategic Consulting, Iltingen / Switzerland - accredited as Certification Body in accordance with EN 45011 - following the Council Directive 93/42/EEC concerning Medical Devices in respect to the requirement biocompatibility.

It is hereby declared, that on the basis of our examination adequate confidence has been provided that

Grilamid TR 90 natural
intended for the manufacture of spectacle frames

manufactured by
EMS-CHEMIE AG
Business Unit EMS-GRIVORY Europe
CH – 7013 Domat/Ems / Switzerland

and which may be used for the manufacture of surface devices in (a) permanent contact with skin, (b) prolonged contact with mucosal membranes and breached or comprised surfaces is with respect to its biocompatibility in compliance with ISO 10993.

Appropriate tests for the following biological effects were performed:

biological effect	test / guideline / project	result
• Cytotoxicity	XTT-Test / ISO 10993-5 / RCC-CCR 602601	not cytotoxic
• Sensitization	Butler Test / OECD 406 / RCC 680242	not sensitizing
• Irritation	* As Grilamid TR 90 natur possesses no cytotoxic potential in XTT-test; it caused no skin effect in Butler test and is considered to be non-sensitizing. Therefore, no further skin irritation study has been performed.	*


Limitations
This certificate is based on the information provided to Harlan Laboratories Ltd., Global Registration and Strategic Consulting and on the present legislation as mentioned above. The validity expires in case of any modification of the formulation or any change of the legislation.


Dr. S. Niven
Head Regulatory Affairs


Dr. W. Nef
Regulatory Affairs Manager

Iltingen, October 7th, 2014
Expiration date: October 7th, 2017
Harlan Laboratories Project D09668 / NEW

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EMS-GRIVORY

Domat/Ems, 27. Juli 2016

Bisphenol A


Sehr geehrte Damen und Herren
Dear Sir, dear Madam,


Wir bestätigen, dass unsere Produkte Grilamid TR in allen Farben gemäss Rezeptur kein Bisphenol A oder andere Bisphenolverbindungen enthalten.

We can confirm that our products Grilamid TR, in all colours, do not contain any bisphenol A or other bisphenol compounds as part of their formulation.

Mit freundlichen Grüßen
Kind regards

EMS-GRIVORY
Quality Assurance / Material Testing


Dr. Jürgen Müller

Regulatory Affairs

Dr. Thomas Emerschitz

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