PRODUCT SAFETY DATA SHEET

1. Company/Undertaking Identification

Supplier: Health in Code, S.L.
Calle de la Travesía s/n, 15E Base 5, Valencia, 46024, España.
https://www.healthincode.com

Emergency Response: National Institute of Toxicology:
+34 91 562 04 20

2. Product information

Kit name	imegen® Quimera Screening Multiplex Plus II
Kit reference	IMG-116-25
Internal references	Without internal references
Reactions	8x10
Intended use	In vitro diagnosis use only

Components:

- **Specific Master-Mix:** Specific oligonucleotides and labelled probes for these markers:

Tube	INDELs
1	Q116-33I
	Q116-37I
2	Q116-38I
	Q116-44I
3	Q116-43I
	Q116-49I
4	Q116-39I
	Q116-50I
5	Q116-9I
	Q116-45I
6	Q116-20I
	Q116-41I
7	Q116-46I
	Q116-47I
8	RhD
	Q116-42I

Identification of hazards:

Health in Code S.L. declares that the following product, in accordance with the following declarations, complies with the applicable legislation:

- Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No. 1272/2088 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.
- Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Not regulated for transport by road (ADR), air (IATA) and sea (IMDG).

According to Regulation (EU) 2022/692 components containing no more than 1% of a component classified as hazardous and no more than 0.1% of a component classified as carcinogenic do not require a Material Safety Data Sheet (MSDS). Components marked with an asterisk "*" do, on the other hand, require an SDS.

*1 These reagents contain 1-10 % of a mixture of ingredients of unknown toxicity.

For these reasons, Health in Code S.L. shall not be liable for any damages, direct or indirect, resulting from harm caused using this product by the purchaser or user.

However, when working with products manufactured by Health in Code S.L., we always recommend following the warnings and precautions included in Section 4 of the product's Instructions for Use (IFUs).

Disclaimer

IMPORTANT: The information provided in this MSDS is based on our present knowledge as of the issue date (or subsequent revision date, if any), and is to be used only as a guidance for safe handling, use, processing, storage, transportation, disposal and release, and is not to be considered a guarantee (express or implied) for any specific product features and shall not establish a legally valid contractual relationship. This information relates only to the designated material as shipped and may not be valid for such material used in combination with any other materials or in any other procedures, unless specified in our instructions for use. It is the responsibility of the user to ensure that its activities comply with all applicable legislation and requirements.

If you have any questions, please contact: tech.support@healthincode.com

Edition history:

Edition	Date	Description of change
03	NOV 2022	Change of manufacturer's address: Health in Code S.L., Calle de la Travesía s/n, 15E Base 5, Valencia 46024, Spain. New contact for the toxicological information service.
02	SEP 2022	Change of the manufacturer's identification: from imegen S.L. to Health in Code S.L. Update of regulatory information.
01	JAN 2019	N/A