

# Product safety data sheet

## 01 | Company / Undertaking Identification

<b>Supplier:</b>	Health in Code, S.L. Calle de la Travesía s/n, 15E Base 5, Valencia, 46024, Spain. <a href="https://www.healthincode.com">https://www.healthincode.com</a>
<b>Emergency Response:</b>	National Institute of Toxicology +34 91 562 04 20

## 02 | Product information

<b>Kit name</b>	TP53 OncoKitDx
<b>Kit reference</b>	IMG-317
<b>Internal references</b>	Without internal references
<b>Reactions</b>	48 rxn
<b>Intended use</b>	<i>In vitro</i> diagnosis use

### ➤ Components

- ◇ **General Master Mix III:** General PCR master mix with the quantities of enzyme with 7.5 mM MgCl<sub>2</sub>, nucleotides and buffer needed to perform the amplification reactions.
- ◇ **TP53 Buffer:** Contains MgCl<sub>2</sub> at the concentration needed to perform the PCR amplification reactions.
- ◇ **Water:** Nuclease free water.
- ◇ **Pool A PCR and Pool B PCR:** Contain the oligonucleotides needed to carry out the amplification of the kit's target regions.
- ◇ **TP53 Index (48):** Oligonucleotides used in the second PCR reaction with a unique sequence of 8 nucleotides, compatible with the Illumina adapters. These are necessary to mark the libraries of each sample with a unique combination that will allow its analysis and discrimination after sequencing.

### ➤ 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. 1272/2008 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).

Therefore, we confirm that:

- ◇ Hazardous labels should not be applied to internal or external packaging.
- ◇ It shall not be mandatory to provide the safety data sheet when substances which are dangerous according to Regulation (EC) No 1272/2008 or mixtures which are dangerous according to Directive 1999/45/EC, which are offered or sold to the general public, are accompanied by sufficient information to enable the user to take the necessary measures in relation to the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

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 the technical department: [tech.support@healthincode.com](mailto:tech.support@healthincode.com)

## ➤ Edition history

Edition	Date	Description of change
04	APR 2023	Revision of document content.
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.