



PRODUCT SPECIFICATION SHEET

Salt test kit, salt fortification with Iodide

Material No: S0003005
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(replacing 1.1)
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1.0 General Information

1.1 Product Description

The finished product is an iodised salt rapid test kit for qualitative detection of iodine in salt fortified with potassium iodide (KI). The kit contains test and recheck solutions, a salt holder, colour reference chart, instructions for use and an opening device.

The kit is intended to determine the presence or absence of iodine only. It is not intended for quantitative determination of iodine concentration in salt.

1.2 Intended Use

To support rapid field screening and programme monitoring of salt iodisation in salt fortified with potassium iodide (KI).

1.3 Target Users

Personnel conducting salt iodisation monitoring, including programme staff, inspectors and survey teams.

1.4 Product Classification

Food fortification monitoring product; qualitative rapid test kit.

2.0 Product Composition

2.1 Kit Components

Each kit must contain the components listed in Table 1, in the indicated quantity and configuration.

One kit should provide sufficient reagent to test approximately 60-75 salt samples.

Table 1: Salt test kit components and minimum requirements

Component	Minimum Specification	Quantity per Kit
Test solution	For qualitative detection of iodine in salt fortified with potassium Iodide (KI); white cap	2 x 10 mL
Recheck solution	For identifying false-negative reactions in salt samples; red ampoule or vial	1 x 10 mL
Salt holder	Standardized plastic measuring sample holder	1
Instruction leaflet(s)	Instructions for use for fine and coarse salt; available in English, French, Spanish and Arabic	1 set

Component	Minimum Specification	Quantity per Kit
Colour reference chart	White = no reaction; any shade in the purple range = iodine present	1
Opening device	Safety pin or equivalent device for opening/piercing the ampoules or vials	1

2.2 Reagents and Test Principle

The test solution must be suitable specifically for salt fortified with potassium Iodide (KI). When the test solution is applied to an iodised salt sample, a coloured reaction indicates the presence of iodine. The reaction should be visible within one minute and compared with the colour reference chart.

If no colour develops, the recheck solution is used to identify false-negative reactions that may occur with salt samples.

The test is qualitative. No reaction (white) indicates iodine is not detected; colour as per the colour chart indicates iodine is present. Colour intensity must not be used to assign or confirm iodine concentration.

2.3 Instructions and Reference Materials

The colour reference chart and instructions for use must be provided with each kit.

Instructions must cover use for fine and coarse salt, interpretation of the qualitative result, use of the recheck solution, and safe opening of the ampoules/vials.

3.0 Manufacturing Requirements and Quality Standards

3.1 Finished Product Manufacturing Requirements

The finished kit should preferably be produced according to a documented quality management system such as ISO 9001:2015 or equivalent. The quality system should cover, at minimum, reagent preparation and filling, control of incoming materials, kit assembly, batch traceability, release testing, control of labels and instructions for use, complaint handling and change control.

4.0 Packaging

Packaging materials must be suitable for the intended contents and protect the kit components during storage, handling and transport.

4.1 Primary Packaging - Reagent Container Closure System

Test and recheck solutions must be filled into 10 mL ampoules or vials with closures that prevent leakage, contamination and deterioration of the reagents.

4.2 Secondary Packaging - Kit Container

All kit components must be packed together in a high-quality resealable plastic container, preferably opaque, with a tight screw cap or equivalent closure to prevent loss of components and leakage during transport. The kit should be further packed for shipment in a manner suitable for humanitarian logistics.

5.0 Labeling and Artwork

5.1 Minimum Information

The product label should include, at minimum, the following information:

- Name/description of the product prominently displayed as "Iodised salt test kit for salt fortified with potassium Iodide (KI)"
- Qualitative Iodisation levels indicated: 0 ppm, < 15 ppm, > 15 ppm
- Kit contents list
- Name and address of the manufacturer
- Batch number
- Manufacturing date and Expiry/Use by date
- Storage conditions
- Applicable safety instructions

5.2 Secondary Container Labeling

Secondary container labelling should follow applicable UNICEF packing, packaging and labelling requirements for supplies and any additional requirements stated in the Purchase Order.

6.0 Shelf Life

The shelf life should be, at minimum, 18 months for unopened kits.

6.1 Useful References

- WHO/UNICEF/ICCIDD. Assessment of iodine deficiency disorders and monitoring their elimination: A guide for programme managers, 3rd edition (2007)
- WHO. Guideline: Fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders (2014)
- UNICEF specification on packing, packaging and labelling (secondary packaging), latest version

FOR MORE INFORMATION

Contact CPHHQ-SD-Nutrition Supplies: sd.nutritionsupplies@unicef.org

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