Save the Children

Date of issue: 20th November 2017
Written by: Alice Burrell
Authorized by: Charlotte d'Elloy

PRODUCT SPECIFICATION SHEET

Oral Rehydration Salts for severely malnourished children

Oral Rehydration Salts for severely malnourished children	
1) General Description	ReSoMal (oral rehydration salts or ORS for severely malnourished children) is used in the treatment of children with severe acute malnutrition (SAM). ReSoMal contains a mixture of salts and minerals specially designed to correct deficiencies of potassium, magnesium, zinc and copper and to address high levels of sodium in children with SAM. One sachet of 42.1 grams is to be diluted in 1 litre of purified/boiled and cooled water which will give 1 litre of liquid ReSoMal. The reconstituted solution has to be consumed immediately or used within 24 hours if stored in a refrigerator.
2) Compositional requirements/ 42g sachet	**Sucrose:** 25 g **Glucose Anhydrous**: 10 g **Sodium Chloride:** 1.75 g **Trisodium citrate, dihydrate:** 1.45 g **Potassium Chloride**: 2.54 g **Tripotassium Citrate:** 0.65 g **Magnesium Chloride Anhydrous:** 0.61 g **Zinc Acetate:** 0.0656 g **Copper Sulphate Anhydrous**: 0.01129 g **Osmolality:** 300 mmol/l
3) Shelf life	The shelf life of ReSoMal is 36 months. Storage instructions are as defined by the manufacturer. The reconstituted solution must be consumed immediately or used within 24 hours, if stored in a refrigerator.
4) Raw material	All the ingredients must comply with one of the pharmacopeias: BP, Ph.Eur, Ph.Int, USP. Finished product must comply with the requirements stated under Oral Rehydration Salts Ph. Int. Oral Rehydration Salts BP or Oral Rehydration Salts USP. All ingredients, including optional ingredients, shall be clean, of good quality, safe and with excessive fibre removed where necessary. All ingredients and food

	additives shall be gluten free. Applicable standards reference: *-Codex Alimentarius guidelines for vitamin and mineral food supplements (CAC/gl 55 - 2005).*
5) Packaging and Labelling	• **Primary packaging** ○ 42g sachets The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. Packaging material must: • be of food-contact grade. • not transfer any element (particle, flavour, or odour) to the product • be able to withstand pressure changes associated with air transport • be free of damage, such as tears, cuts, holes, abrasions through one or more layers, leakage through seals etc. The closure seal must be free of wrinkles and occluded matter. An air and water tightness control must be implemented during the filling process. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply. - **Labelling** The labelling shall be at least bilingual. English is mandatory, the choice of other language(s) is as deemed appropriate. Labels will include: ○ Generic name: Rehydration salt for the rehydration of severely malnourished people ○ A clear statement: For the rehydration of ptients with Severe Acute Malnutrition ○ Any applicable warnings (such as handling product leftovers, how long at room temperature, how long in the fridge) ○ List of ingredients (raw material specified) in descending order quantity ○ Nutritional composition per 42 g sachet. ○ A detailed list of the active ingredients showing the amount of each present in a dosage unit, and a statement of the net contents of the container, e.g. number of dosage units, weight or volume should be provided in a leaflet and not on a product label ○ Name and address of the manufacturer, packer, distributor, importer, exporter or vendor and country of origin ○ Net weight ○ Batch number ○ Date of manufacture ○ Best before date ○ Storage conditions Applicable standards reference: *-Codex STAN 146-1985: General Standard for the Labelling of and Claims for Pre-packaged*

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	Foods for Special Dietary Uses. *-Codex STAN 1-1985: General Standard for the Labelling of Pre-packaged Foods* • **Secondary packaging** ○ 100 42g sachets per carton Packaging for nutrition products must be of a sturdy export quality, of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of 40C (tropical conditions). The packaging unit is strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing. The product is packed under inert gas (nitrogen or carbon dioxide) to prolong in shock resistant, strong export cartons. Each carton securely closed. The cartons are to be securely stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and stretch/shrink wrapped. The pallet load is to be strapped to the pallet by means of either steel or nylon straps (min. breaking strength 150 kg). - **Carton Label includes:** ○ Generic name: Rehydration salts for the rehydration of severely malnourished people ○ A clear statement: For the rehydration of Children with Severe Acute Malnutrition ○ Any applicable warnings ○ Name and address of the manufacturer, packer, distributor, importer, exporter or vendor and country of origin ○ Gross weight ○ Number of sachets per carton ○ Batch number ○ Date of manufacture ○ Best before date ○ Storage conditions ○ Purchase order number: optional for inner boxes ○ Cubic Measurement ○ IMCO classification (if applicable) No carton may contain items from more than one manufacturing batch. The packing list should indicate the manufacturing batch number (where applicable) and cross-reference to the carton numbers, pallets and containers. One copy of the packing list must be included with the shipment and another copy should accompany the shipping documents.
6) Safety	ReSoMal shall be free from objectionable matter. It shall not contain any substances originating from microorganisms, or any other poisonous or

	deleterious substances like heavy metals or pesticide residues, in amounts which may represent a hazard to health The level of pesticides residues and heavy metals should be checked in the finished product once a year and must be in accordance with the levels allowable by Codex Alimentarius. The product should not contain detectable levels of antibiotics or other drugs used in animal husbandry.
7) Quality Assurance	All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content. The production process shall be in accordance with the Recommended International Code of Hygienic Practice for Foods for Infants of the Codex Alimentarius (Volume 4, Second Edition, FAO Rome 1994) and Good Manufacturing Practice (GMPs) and other Codex Alimentarius applicable references. Except when otherwise specified, the product shall comply with the Standards and Guidelines on Foods for Infants and Children of the Codex Alimentarius (Volume 4, Second Edition, FAO Rome 1994). All producers must have a food safety policy in place and a complete quality management system based on a Hazard Analysis and Critical Control Points (HACCP) approach to food safety. Pre-requisite programs including environmental monitoring programs must be implemented. The variation of the final product with respect to contents of moisture, protein, fat and micronutrients shall not exceed plus or minus 5% of the original value using standard analytical techniques. Products not meeting this requirement are liable for rejection. The manufacturer is responsible to elaborate an analytical plan of finished product. All analytical test procedures must be described in sufficient details, including microbiological methods. ISO 17025 certified laboratories shall be preferably used. Applicable standards reference: · *Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003* · *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. CAC/RCP 66 - 2008* · *ISO 22000:2005 - Food safety management systems – Requirements for any organization in the food chain.* The supplier must have registered the products in its intended countries of supply, in order to facilitate import and use of product. Suppliers must ensure that the use of the goods sold under this contract does not infringe any patent, design, trade name or trademark.

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	- **Validation of the process and coefficient of variation** The coefficient of variation, calculated using the method proposed by WFP[1], shall be as low as possible, and always <10. - **Traceability** A complete traceability system must be in place. For every batch number, the manufacturer must be able to find all the history of the finished products (composition, raw materials used, processing parameters, analytical results, quantity produced and dispatched, customers sites delivered, etc).
8) Documents to provide	• **Complete analysis** The manufacturer must conduct a complete analysis of the finished product in order to verify that the finished product is manufactured in a homogeneous and consistent content. All parameters included in this specification sheet shall be tested at least once a year. • **Certificate of analysis** Suppliers will be required to submit a Certificate of Analysis from the manufacturer's own quality control laboratory covering each batch delivered along with shipping documents. A confirmatory certificate of analysis from the supplier should be available at least for the duration of the shelf life of all batches of finished products in which the ingredients and excipients are used. Customer should be notified and approve of any changes in ingredients, excipient sources and finished product specifications. Customer should be notified and approve of any changes in sources, routes of synthesis and/or specifications. The Certificate of Analysis should include: ○ Order number ○ Generic name of product together with pharmaceutical formulation and strength per dosage unit ○ Composition of the product using International Non-proprietary Names (INN) ○ Pharmacopoeia reference (if applicable) ○ Batch number ○ Batch quantity ○ Date of manufacture ○ Expiry date (dd/mm/yyyy) ○ Date of test (dd/mm/yyyy) ○ Contents of dosage form per unit package ○ Description (clarity, colour, etc.) ○ All attributes necessary for the quality control of the type of product, including identity, content (assay), dissolution, sterility, pyrogen and if applicable all other test required by the specified pharmacopoeia. Both the actual results and the limits for the individual tests should be given. ○ The Certificate of Analysis for one batch of product should be submitted for the following microbiological tests every 6 months (Save the Children can require more frequent testing): The batch cannot be released if there is a failure to meet the specified criteria. • **Other certificates required (on demand only)**

[1] *http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator*

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	○ Certificate of Origin ○ Certificate of Conformity ○ Health Certificate (issued by independent regulatory authority) ○ Certificate of non-radioactivity ○ GMO Free Certificate (when applicable) ○ Halal certificate (when applicable) ○ Dioxin free certificate

REFERENCES

(1) UNICEF Technical Specs: https://www.unicef.org/supply/files/ReSoMal_technical_specs.pdf
(2)