

Product Specification

Product	Cough Mixture Aroma Concentrate 15266	
Description	A homogenous non-toxic liquid of aromatic pure synthetic substances in a USP grade solvent, with a clear or slightly tinged appearance.	
Specification Status	Confirmed	
Specification Date	16/02/2023 revision 3	
Shipping Description	Liquid mixture of non-hazardous solvent >80% and pure substances <20%	
CLP Category	Flash point is >60°C. (Regulation EC1272/2008 and United Nations GHS). Refer to SDS for details.	
International Tariff Code	38249992	
Origin	Manufactured in the United Kingdom.	
Suitable For	Indirect consumption when diluted to manufacturer's recommendations. Not for direct (undiluted) consumption.	
Recommended Use	Normal use (unless otherwise agreed), 5-10% in an appropriate pharmaceutical grade solvent, packed for consumer sales in units that meet local regulatory requirements.	
Storage Conditions	Cool, dry, ambient storage away from direct sunlight, 5-20°C. Do not chill or freeze.	
Product Life	Best Before End (BBE) 12 months from date of manufacture (DOM) when stored unopened under recommended storage conditions.	
	Tinge might develop over product life (is expected); the flavour will be unaffected within the BBE date.	
Density (@ 20°C)	1.040g/ml ±0.010 (range of acceptable tolerance)	
Refractive Index (@ 20°C)	1.435g/ml ±0.010 (range of acceptable tolerance)	
Flash Point (Closed Cup)	>60°C	
Sensory Standard	Appearance, Odour, Taste (AOT) meet a previously accepted Standard (assessed independently by a minimum of two Qualified Flavour Technicians).	
	Contact the Manufacturer for sensory evaluation methodology.	
Microbiological Standard	Total Viable Count	<10,000/g
	Yeasts & Moulds	<1,000/g
	Coliforms	<10/g
	Salmonella spp	Not Detected/25g
	E. coli	Not Detected/g
	Coagulase +ve staph	Not Detected/g
	This mixture will not support microbiological growth. Testing is not a part of routine QC release, please contact a sales advisor, if required.	

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Particle Size	100% passes through a 560 micron mesh filter.
Allergen Status	Free from allergens required for labelling as listed under Regulation (EU) 1169/2011 Annex II. For manufacturing site allergen status and cleaning standard see Regulatory and Quality Compliance Summary (below).
Free From	Alcohol, Animal Origin, Tobacco.
Suitability for Special Diets	Coeliac, Vegan, Halal, Kosher. 'Suitability' does not imply 'Certified' – consult manufacturer for further information.
Ingredients List	Solvent (USP), flavouring substances (defined by EC1334/2008). A full ingredient listing in descending order by weight is provided on purchase.
Hazard Assessment	A detailed quantitative report (by % or weight, to 6 d.p.) including CLP hazard status of each substance, is available subject to cost.
Ingredient Policy	Based on Available Data referenced on the ECHA website, and comprehensive toxicological screening, subject to continuous review. This mixture DOES NOT CONTAIN: 1. Substances with known carcinogenic, mutagenic, or reproductive toxicity (CMR) 2. Substances with known cardio-pulmonary toxicity 3. Substances classified as Respiratory Irritants 4. Substances known to have respiratory sensitizing properties. 5. Substances with STOT1 toxicity 6. Substances prohibited by Dir. 2014/40/EU Art. 20, and the United Kingdom Statutory Instrument 2016 no. 507 7. Substances excluded by the UK PAS 54115 8. Chemically complex Natural Flavouring Preparations (unless by customer specification) 9. Natural materials that have a testing verification requirement for levels of pesticide, herbicide, or heavy metal residues (EU Regulation 396/2005) 10. Substances known to elute with nicotine (GCMS analysis) 11. Substances known to generate respiratory sensitization under conditions of use, or in combination with each other. 12. Levels of substances likely to cause respiratory sensitisation with chronic exposure. 13. Water This mixture is sold B2B as a manufacturing ingredient. The manufacturer using this mixture in a finished product for consumer sales is responsible for the consumer safety risk assessment (including TRA) of the product as placed on the market for consumption.
Packaging	UN-certified HDPE containers with tamper-evident closures. All contact plastics are food grade with appropriate specifications and migration data available.

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Pack Net Contents

1KG and multiples for order quantity 1-4KGs
5KG and multiples for order quantity 5-20KGs
25KG and multiples for order quantity 25KGs and over

By Special Order:

Cardboard case of 22x1KG units
Cardboard case of 4x5KG units (for quantity 25KGs+)
Intermediate Bulk Containers (IBC) 550KG/1100KG (approx. tbc)

Label Information

- 5-digit product code
- Unique production batch number
- Net contents (min)
- Date of manufacture (DOM)
- Best before End (BBE) date
- Customer order reference (if supplied)
- Customer part-code (if supplied)
- Customer product description
- Contact details (manufacturers, or resellers by agreement)
- CLP statements and pictograms (if relevant)

Traceability System

Electronic, by Microsoft Dynamics 365 database with daily off-site back-up, maintaining the following searchable elements (forward or backward): invoice - dispatch record - customer order number - manufacturing batch code - QC release record - batch manufacturing record - individual raw material GRN record - QC received record (including suppliers' own traceability coding) - raw material purchase order - supplier record

Regulatory and Quality Compliance Summary

- The manufacturing site is certified to ISO9001:2015, HACCP (2003/13A) & GMP food safety management system, and GFSI standard.
- The Quality System meets the requirements of the EU guidelines (2015/C 95/02) on the formalised risk assessment of appropriate GMP for excipients of medicinal products.
- No high-risk allergens are permitted on site. The site handles the following low-risk allergens (as listed in Regulation EU1169/2011 Annex II) from time to time: Cereals containing gluten and products thereof (pure processed oat fibre); Fish and products thereof (anchovy paste, and refined cod liver oil); Soybeans and products thereof (soy sauce and refined soya bean oil); Milk and dairy products (cheese powders, lactose); Nuts and products thereof (refined bitter almond oil); Celery and products thereof (refined celery seed oil); Mustard and products thereof (refined mustard seed oil). Inter-batch clean down is verified to <25ppb. A full risk-assessment is available to purchasing customers.
- Solvents used are USP (United States Pharmacopeia) grade; flavouring substances are listed in EC1334/2008 Appendix I (Union List of Flavourings and Source Materials).
- Contact packaging meets the requirements of Regulations (EC)1935/2004, (EC)2023/2006, (EU)10/2011, and the United Kingdom Materials and Articles in Contact with Food Regulations (2012).
- The traceability of all finished product batches, and each unit of raw material and contact packaging complies with the General Food Law Regulation (EC) 178/2002. The system is challenged by a full scenario-based test conducted without warning at least twice a year, both forwards and backwards through the supply-chain
- The supply-chain is subject to a formal Vulnerability Risk Assessment complying with the BSI PAS96:2014; suppliers are certified to appropriate standards by third-party audits (GFSI and ISO); each raw material is subject to a detailed HACCP risk-assessment

Contacts for Incident Management and Reporting

During UK Office hours Monday-Friday 0830-1700 +44 (0)1442 822621 #1

Out of UK office hours (weekends and public holidays)

- +44 (0)79823 462037 (Emergency Site Contact)

Out of Office Hours contacts for incident management are also available by recorded message if our main number is called when the factory is closed +44 (0)1442 822621 – the message will also confirm the factory opening times.

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Revision Record

Revision Date: 16/02/2023

Revision Note: Updated specification layout and references

Authorised By:

QST