

## Product Specification

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|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <b>Product</b>                   | Tobacco Menthol Medium Aroma Concentrate 14643                                                                                                                          |                  |
| <b>Description</b>               | A homogenous non-toxic liquid of aromatic pure synthetic substances in a USP grade solvent, with a clear or slightly tinged appearance.                                 |                  |
| <b>Specification Status</b>      | Confirmed                                                                                                                                                               |                  |
| <b>Specification Date</b>        | 16/02/2023 revision 3                                                                                                                                                   |                  |
| <b>Shipping Description</b>      | Liquid mixture of non-hazardous solvent >80% and pure substances <20%                                                                                                   |                  |
| <b>CLP Category</b>              | Flash point is >60°C. (Regulation EC1272/2008 and United Nations GHS). Refer to SDS for details.                                                                        |                  |
| <b>International Tariff Code</b> | 38249992                                                                                                                                                                |                  |
| <b>Origin</b>                    | Manufactured in the United Kingdom.                                                                                                                                     |                  |
| <b>Suitable For</b>              | Indirect consumption when diluted to manufacturer's recommendations. Not for direct (undiluted) consumption.                                                            |                  |
| <b>Recommended Use</b>           | Normal use (unless otherwise agreed), 5-10% in an appropriate pharmaceutical grade solvent, packed for consumer sales in units that meet local regulatory requirements. |                  |
| <b>Storage Conditions</b>        | Cool, dry, ambient storage away from direct sunlight, 5-20°C. Do not chill or freeze.                                                                                   |                  |
| <b>Product Life</b>              | 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.                                                                |                  |
| <b>Density (@ 20°C)</b>          | 1.030g/ml $\pm$ 0.010 (range of acceptable tolerance)                                                                                                                   |                  |
| <b>Refractive Index (@ 20°C)</b> | 1.435g/ml $\pm$ 0.010 (range of acceptable tolerance)                                                                                                                   |                  |
| <b>Flash Point (Closed Cup)</b>  | >60°C                                                                                                                                                                   |                  |
| <b>Sensory Standard</b>          | 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.                                                                                                            |                  |
| <b>Microbiological Standard</b>  | 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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| <b>Particle Size</b>                 | 100% passes through a 560 micron mesh filter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Allergen Status</b>               | Free from allergens required for labelling as listed under Regulation (EU) 1169/2011 Annex II.<br><br>For manufacturing site allergen status and cleaning standard see Regulatory and Quality Compliance Summary (below).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Free From</b>                     | Alcohol, Animal Origin, Tobacco.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Suitability for Special Diets</b> | Coeliac, Vegan, Halal, Kosher.<br><br>'Suitability' does not imply 'Certified' – consult manufacturer for further information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Ingredients List</b>              | Solvent (USP), flavouring substances (defined by EC1334/2008).<br><br>A full ingredient listing in descending order by weight is provided on purchase.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Hazard Assessment</b>             | A detailed quantitative report (by % or weight, to 6 d.p.) including CLP hazard status of each substance, is available subject to cost.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Ingredient Policy</b>             | Based on Available Data referenced on the ECHA website, and comprehensive toxicological screening, subject to continuous review.<br>This mixture DOES NOT CONTAIN: <ol style="list-style-type: none"> <li>1. Substances with known carcinogenic, mutagenic, or reproductive toxicity (CMR)</li> <li>2. Substances with known cardio-pulmonary toxicity</li> <li>3. Substances classified as Respiratory Irritants</li> <li>4. Substances known to have respiratory sensitizing properties.</li> <li>5. Substances with STOT1 toxicity</li> <li>6. Substances prohibited by Dir. 2014/40/EU Art. 20, and the United Kingdom Statutory Instrument 2016 no. 507</li> <li>7. Substances excluded by the UK PAS 54115</li> <li>8. Chemically complex Natural Flavouring Preparations (unless by customer specification)</li> <li>9. Natural materials that have a testing verification requirement for levels of pesticide, herbicide, or heavy metal residues (EU Regulation 396/2005)</li> <li>10. Substances known to elute with nicotine (GCMS analysis)</li> <li>11. Substances known to generate respiratory sensitization under conditions of use, or in combination with each other.</li> <li>12. Levels of substances likely to cause respiratory sensitisation with chronic exposure.</li> <li>13. Water</li> </ol><br>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. |
| <b>Packaging</b>                     | UN-certified HDPE containers with tamper-evident closures. All contact plastics are food grade with appropriate specifications and migration data available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## Product Specification

### 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.

## Product Specification

### Revision Record

Revision Date: 16/02/2023

Revision Note: Updated specification layout and references

Authorised By:

QST