



Declaration of Compliance



Contents Page

- **Section 1** – Introduction
- **Section 2** – Construction
 - **2.1** – Primary Raw Materials
 - **2.2 – 2.4** – Recycled content
 - **2.5** – Temperature range used at Beatson Clark
 - **2.6 – 2.15** – Annealing, Hot and Cold end coating application.
 - **2.16 – 2.17** – Sterile Statement
 - **2.18** – Recommendation on Inverting
 - **2.19 – 2.20** – Approved use for Glass Containers / GMP
 - **2.21 – 2.24** – Statement in reference to Pharmacopoeia.
 - **2.25** – Statement – Glass container components
 - **2.26 – 2.27** – Heavy metals declaration
 - **2.28** – TSE Statement
 - **2.29** – Prop 65 Statement
 - **2.30** – Reach Regulation
 - **2.31** – CLP Regulations
 - **2.32** – Phthalates/ Protamines
 - **2.33** - Change Control
 - **2.34 – CFR Regulations**
- **Section 3** – Performance
 - **3.1 – 3.4** – TEC References
 - **3.5** – Recommendation for customer new lines
 - **3.6 – 3.6.2** – Traceability details needed from customer
- **Section 4** – Suitability
 - **4.1** – Glass Suitability
 - **4.2** – Glass Temperature
- **Section 5** – Acceptable Quality Limits
 - **5.1 – 5.6** Glass acceptable quality limits
 - **5.7** Quality Assurance
- **Section 6** – Delivery
 - **6.1** – Storage of glass
 - **6.2 – 6.5** – Packaging of Beatson Clark Glass
 - **6.6 – 6.7** – Traceability of Beatson Clark finished stock pallets
 - **6.8 – 6.10** – Possible Issues on delivery
- **Section 7** – Nanomaterials
- **Section 8** – Elemental Impurities
- **Section 9** – Benefits of Glass
- **Section 10** – Allergen Policy

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Declaration of Compliance

1 Introduction

- 1.1 This declaration of compliance states the requirements for the supply of glass containers for the packing of food, drinks and pharmaceutical products, either for use in the UK or abroad.
- 1.2 This declaration of compliance applies to all glass containers manufactured and supplied by Beatson Clark, unless a customer specific specification has been received from the customer and agreed.

2. Construction

- 2.1 Glass containers are made from the primary raw materials, commonly known as soda-lime silica glass Type III, defined as white-flint or amber in colour.
- 2.2 Our glass containers do contain recycled content which is calculated in agreement with clause 7.8 Recycled Content and WRAP methodology, this recycled content figure includes Post consumer and post-industrial. The % is the following: -

Average recycled content of white flint containers is 50%.

Average recycled content of amber containers is 70%
- 2.3 This % includes Calumite (a waste material from steel production).
- 2.4 The above calculation is in agreement with **BS EN ISO 14021: 2016 Environmental labels and declaration- self declared environmental claims: Type II environmental labelling.**
- 2.5 The containers manufactured by Beatson Clark Limited are produced in a temperature range of 1200 – 1470 degrees Celsius.
- 2.6 Immediately after forming of the container the glass is passed through hot end coating tunnel which is in the form of a mist of Hot end coating which maintains the original strength to the outside of the container.



- 2.7 The containers are then fed into an annealing lehr, reheated to approximately 540 degrees and cooled in a controlled manner to remove stress which would be created through rapid cooling.
- 2.8 The process of manufacturing glass requires high heat which in turn kills pathogens and destroys other impurities. The containers are then protected from such contamination through good manufacturing practices.
- No forms of Irradiation are used by Beatson Clark Ltd in the manufacturing process
- 2.9 Annealing time varies according to the individual container its weight, shape and size and will range from 40 minutes to 3 hours.
- 2.10 Glass leaves the annealing lehr at approximately 120 degrees as it leaves a cold end coating is applied to the external surface to create lubricity to allow the containers to pass down filling lines without damage caused by the abrasive nature of the glass.
- 2.11 The hot end coating acts as a catalyst for the cold end coating.
- 2.12 It is recognised that the coating of containers less than 50ml capacity are difficult to coat in both processes.
- 2.13 Hot End Treatment - Vaporised Tin Oxide, Chemical Name - Monobutyltin Trichloride.
- 2.14 Cold End Treatment – Vaporised Oleic Acid or Polyethylene solution.
- 2.15 After leaving the lehr the containers are fed down conveyors through inspection machines into packing machines.
- 2.16 Containers are generally considered sterile at the packaging stage due to the processing temperatures of the containers, the short time before packing and the low risk of becoming contaminated during inspection.
- 2.17 Containers are then packed in various formats for delivery to customers.
- 2.18 It is still recommend inverting the containers prior to filling in line with the MHRA Orange Guide.
- 2.19 All materials produced are for food, drink or pharmaceutical use.
- 2.20 All products are produced in accordance with the regulations under the **Materials and Articles in Contact with Food (England) Regulations 2005 and the Regulation (EC) No. 1935/2004 and compliance with GMP regulation 2023/2006. The MHRA GMP guide for pharmaceutical manufacturers and distributors 2022 (Orange guide) is followed where applicable. Our glass also complies to the Italian Ministerial Decree 21/03/73.**

- 2.21 The soda-lime-silica glass manufactured in both amber and white flint by Beatson Clark Ltd meets the requirements of the **British Pharmacopoeia and the European Pharmacopoeia (Issue 11.2) Section 3.2, Subsection 3.2.1, 'Glass Containers For Pharmaceutical Use', for hydrolytic resistance type III and the United States Pharmacopeia (USP-NF 2023, Issue 2) - Containers - Glass', Type III for hydrolytic resistance.**
- 2.22 Amber glass also meets the requirements for **light transmission in the U S and European Pharmacopoeia and the British Standard BS1679 - Containers for Pharmaceutical Dispensing.**
- 2.23 All glass testing is performed by Glass Technology Services, Sheffield, or SSDV.
- 2.24 Beatson Clark has U S Food and Drug Administration Drug Master Files (DMF) covering amber glass containers, with the following designations: -

Amber DMF No 10500

- 2.25 The glass produced by Beatson Clark is confirmed to be latex free **does not contain synthetic fungicides, fumigants, preservatives, & pesticides.**
The glass produced or its packaging is does not contain Acrylamides, Novolac Glycidyl Ethers (NOGE).

The thermal process of making glass requires the raw materials including cullet (recycled glass) to be melted at temperatures above 1500°C for over 24 hours. The molten glass exits the furnace after which the glass containers are then formed and annealed at temperatures between 1100°C and 550°C. These high temperatures mean that any non-intentionally added organic substances or foods which are contained in the cullet are destroyed in the furnace. As a result, the final glass **does not contain** any of the following:

- Allergens (14 allergens listed in Annex II of the EU Food Information for Consumers Regulation No.1169/2011)
- Bisphenol A (BPA) and other phthalates
- Polyfluoroalkyl substances (PFAS) including PFOS and PFOA.
- MOAH (Mineral Oil Aromatic Hydrocarbon)
- MOSH (Mineral Oil Saturated Hydrocarbon)
- Genetically modified organisms (GMOs)
- Melamine
- Nitrosamines (or nitrosating species compounds)

This also means that glass can be considered halal, kosher, vegan and gluten-free.

- 2.26 Beatson Clark glass conforms to the **REGULATION (EU) 2025/40 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

of 19 December 2024, on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC

2.27 The above legislation for glass allows a **100ppm** Heavy Metals content limit due to the usage of recycled materials. This is tested every 3 months, and an annual leach-ate test is undertaken for environmental purposes on a yearly basis. The current result for our Heavy Metal testing is as follows – (measured in ppm)

Date **August 2025**

Glass / Metal (ppm)	Flint	Amber
Lead	86	55
Cadmium	<2	<2
Chromium	<2	<2
Mercury	<1	<1

2.28 In compliance with the updated Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products **(EMA/410/01 Rev. 3)**. We herewith certify that these glass containers and the starting materials, additives, lubricants, processing aids and other materials used to manufacture these containers do not come from and/or are not in contact with animal derived-material at any stage of their manufacturing process.

2.29 Soda-lime-silica glass manufactured in both white flint and amber by Beatson Clark Ltd are free from any of the chemicals listed on the Prop 65 list (otherwise known as California's Proposition 65).

This is taken from **STATE OF CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENTS SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY**

2.30 Container glass as a UVCB substance is exempted from registration under **REACH Regulation** as amended by Regulation 987/2008 Annex II 11 as it does not contain “available dangerous constituents” as set out in the exemption, or SVHC. This is supported by peer-reviewed scientific experimental data.

Moreover, container glass fully conforms to the principles previously confirmed by the Commission for substances included in Annex V set out in Document CASG (annexes 11/2008)

and in particular 3.2.2.1 as an appropriate high level of health and environmental protection is properly controlled by other legislation (Food contact, Packaging and Packaging Waste, IPPC, worker protection.).

- 2.31 Also glass packaging is non-hazardous and does not require CLP or a safety data sheet.
- 2.32 **The soda-lime-silica glass manufactured in both white flint and amber by Beatson Clark Ltd does not contain phthalates or protamine's.**
- 2.33 Change control procedures exist should any change occur to the construction materials.
- 2.34 **CFR Compliance Summary for Glass Containers**
 Beatson Clark glass containers comply with applicable U.S. FDA regulations under Title 21 CFR, including:
- **Part 117** – CGMP for food packaging
 - **Part 170** – Food additives and food-contact substances (including GRAS and safety evaluations)
 - **Part 175** – Adhesives and coatings for packaging materials
- These regulations ensure that glass containers and any applied coatings are safe for food and beverage contact, with no harmful migration into the product.

3. Performance

- 3.1 The glass containers shall be strong enough to withstand traditional handling techniques as outlined in TEC 9 – General Guidelines for the Use of Glass Containers.
- 3.2 The glass containers where specified as carbonated beverage bottles shall meet the requirements of TEC 7 – Strength and Performance Standards for the Manufacture and Use of Carbonated Beverage Bottles.
- 3.3 Glass container quality shall be the responsibility of the glass manufacturer with particular respect to: -
- The clarity and distribution of the glass within the container
 - The weight and capacity of the container – in accordance with TEC 6
 - The overall dimensions of the container – in accordance with TEC 4
 - The verticality of the container – in accordance with TEC 4
 - The ovality of the container – in accordance with TEC 4
- 3.4 Tolerances will be as the agreed drawing, and are designed with an appropriate closure system.



- 3.5 Where new lines are being developed to fill containers, it is recommended that Beatson Clark be involved in the process to ensure the container in question is designed to withstand any new processes or handling it will be subjected to.
- 3.6 Customers should complete daily pallet usage logs to ensure traceability as required by current UK Law indicating the following information: -
- 3.6.1 Pallet number
- 3.6.2 Date and time of pallet being put to the line

4. Suitability

4.1 The soda-lime-silica glass manufactured in both white flint and amber by Beatson Clark Ltd is suitable for the following: -

- Low pH pastes (pH 2.8 – 4.2)
- Low aw pastes (>0.75)
- High fat content pastes (max. 25%)
- Paste products containing oleoresins
- Pastes containing Volatile oils
- Hot Pastes
- Hot Fill Products – Containers designated as pasturable are produced to withstand a 42oC downward thermal shock.

- 4.2 Beatson Clark glass can be heated up to temperatures in excess of 600 degrees without issue, however at this temperature the glass would need to be reannealed (cooled in the correctly controlled manner to remove stress).

Similarly, glass can be frozen, however the issue here is as the content of the glass freezes expansion of the content can result in failure of the container.

When glass is cooled it is put under tensile stress, when it is heated it is put under compressive stress.

The issue for glass is not an ability to withstand extremes of temperature, the issue is the rate of change. Sudden and/or rapid temperature change can result in thermal shock failure of the glass.

Thermal shock is caused as a result of changes in temperature, it does not require an instant increase or instant drop to occur, the speed of transfer results in the issue,

The failure is either as a result of the outside of the glass being cooled too quickly whilst the inside is still hot as a result of the product temperature, or the outside of the glass being heated too rapidly whilst the content is still cold. The differing opposing stresses overcome the strength of the glass resulting in failure.



Containers which are designed for thermal shock resistance are tested to a 42 degree drop in temperature, however the testing standard requires a delay in transfer from hot to cold to prevent false rejects from occurring detailing that the transfer should not be less than 16 seconds and should not exceed one minute.

With the above in mind we would recommend some simple activities which would reduce the risk of thermal shock.

For hot filled product we would recommend that the containers are not filled straight out of a cold warehouse, bringing the glass into the processing area, removing the shroud and allowing the temperature to settle to ambient would greatly reduce risk of thermal failure.

Heating or Freezing.

Heating and cooling should be gradual, slowly taking the glass up to the required temperature and slowly cooling back down.

Freezing should be slow ensuring sufficient headspace to allow the product to expand without unduly stressing the container. Thawing should be natural and not under assist from a heat source.

We would always recommend that in any doubt regarding the suitability of a container to perform under extreme conditions extensive testing under a controlled environment is undertaken on the container and the particular application before exposing a consumer to any risk.

5. Acceptable Quality Limits

- 5.1 Beatson Clark has well established Acceptable Quality Levels, in line with the glass industry for defects which may be produced outside of normal process variation as follows:

Critical 0.01%

Major 0.65%

Minor 4.00%

- 5.2 The lists for each category are not exhaustive, and dependent on the severity of the issue defects can range in classification from Critical to Minor.

5.3 Critical Defects – 0.01%

Defects which judgment and experience indicate could result in hazardous or unsafe conditions for individuals using the container. These faults have a zero AQL and, when found, invoke a special Intolerable Defect Procedure, overriding all other sampling and inspection procedures.

Major – 0.65%

A defect which could result in a container failing to pass successfully through the filling line, or to impair the quality of the finished pack.

Minor Defects – 4.0%

Defects of a minor nature only

- 5.4 On agreement by both companies, certain defects may be reclassified on individual containers. This will be specified on the individual container specification agreement.
- 5.5 Critical defects are classified in line with CETIE guidelines and these can be found in Work instruction QAWI04a.
- 5.6 Should glass fall outside these parameters a formal notification shall be made to the Quality Department of Beatson Clark, with the minimum following information:
 - Description of defect
 - Samples of the defect
 - Pallet number from where the defects occurred
 - Quantity filled during problematic period
 - The amount, if any, of filled stock on hold
 - The amount, if any, of unfilled stock from the same batch

5.7 **1. Physical Properties/Glass Quality**

The following tests are largely carried out on the glass itself, rather than on unique products:

Glass Density	- Monday - Friday
Seed Count	- Monday - Friday
Inhomogeneity	- Monday - Friday
Annealing	- twice per shift per line
Chemical Composition	- every month
Light Transmission (Amber)	- to European every month
Chemical Durability	- Pharmacopoeia } EP & USP monthly
Heavy Metal testing	- Every 3 months
Leachate / migration	- Annually

2. Hot End Inspection (immediately after forming)

Visual Inspection



Manual Gauging	- at least once per hour - 1 bottle from each mould
Container Weight	- recorded every 30 minutes - 1 bottle from each gob
Visual light screen check	- Every 60 minutes before swab

3. Cold End Inspection (Manual, after cooling)

Visual Inspection	- continuous,
Manual Gauging	- Three times per shift
Scratch test	-} once per hour
Checks on automatic inspection equipment operation – 3 times per shift	

6. Delivery

- 6.1 Pallets of glass are stored in ambient warehouses to reduce extremes of temperature which may have an effect on the stability of the pallet.
- 6.2 Glass containers are palletised with an over-shroud to assist in protecting the internal and external surfaces of the glass against: -
- Dirt and dust
 - Condensation
 - Insects and rodents
- 6.3 Glass containers are either palletised as bulk glass or as a polythene brick pack module on a standard 4-way entry 1200mm x 1000mm wooden heat-treated pallet.
- 6.4 Agreed packaging specifications for bespoke items are available and can be requested for general sale items. Where we will always try and adhere to this, should an incident arise where this cannot be achieved an alternative packaging specification will be used. This will be communicated to all concerned parties where reasonably practicable.
- 6.5 Layer pads are available in the form of corrugated board or sealed edge plastic layer pads.
- 6.6 Each pallet will be labelled as standard with the following: -
- Supplier Name
 - Product Code
 - Product Description
 - Date of Manufacture
 - Line of Manufacture



- Unique bar code
- Unique Pallet Number
- Quantity

6.7 On bespoke items the customer name and customer reference number can be added to the pallet label on request.

6.8 Any issues on delivery should be recorded on the Proof of Delivery and be signed by both the recipient of the glass and the delivery driver. These could include the following issues: -

- Dirty pallets
- Broken Glass visible on pallets
- Broken wooden pallets
- Loose / Poor shrouding
- Wet packaging

6.9 Any issues found after delivery should be reported within 3 days of that delivery as per the standard Terms & Conditions of sale.

6.10 Any such issues should be supported with clear photographic evidence to ensure a thorough investigation can take place.

7. Nanomaterials

7.1 Nanomaterials: substances which have been consciously and deliberately designed, technically manufactures or produced by human inducement (anthropogenic) with the intention to obtain very specific characteristics (e.g. shape, surface properties or chemical properties) at the nanoscale (approx. 1-300nm in at least one dimension) such as only possible at the nanoscale. Particles with larger diameters may come under this definition in cases where there is evidence of effects specific to the nanoscale at this size.

Particles accidentally generated at the nanoscale, which can occur in the course of traditional processing methods (such as, for example homogenisation, grinding, foaming, freezing) and particles at the nanoscale that occur as natural environmental elements (e.g. volcanic or airborne particles) or in foodstuffs (e.g. monosaccharides, amino acids or fatty acids) are excluded from this definition.

Concerning the packaging material that Beatson Clark supply / produce, Beatson Clark can hereby confirm that no anthropogenic nanomaterials according to the above definition are used, neither as raw material nor in the manufacturing process.



8. Elemental Impurities

8.1 Below are 3 tables which lists the elemental impurities for glass containers manufactured by Beatson Clark Ltd in both Amber and Flint in accordance with the elemental impurity regulations for ICH Q3D.

Class 1 and 2A

Elemental impurity	Cadmium	Lead	Arsenic	Mercury	Cobalt	Vanadium	Nickel
El Symbol	Cd	Pb	As	Hg	Co	V	Ni
Class	1	1	1	1	2A	2A	2A
Intentionally added	No	No	No	No	No	No	No
Known to be present from other sources	No	Yes	No	No	No	No	No
If added or known to be present record the max concentration observed.	<2ppm	Amber 55 ppm Flint 96 ppm	Not known	1ppm	0.8 ppm	Not known	Not known
Recorded value obtained by validated test procedure	Yes	Yes	Not known	Yes	Not known	Not known	Not known
Specification limit	* 200 ppm See below	* 200 ppm See below	None	* 200 ppm See below	None	None	None
Method & LOD if known (ppm)	AAS 1mg/kg	AAS 3mg/kg	None	ICPMS 1mg/kg	ICP OES 0.5ppm	None	None
Any controls implemented to reduce metal content	No	Yes	No	No	No	No	No
Is the metal content tested routinely	Yes	Yes	No	Yes	No	No	No
Is the metal content listed on the COA	No	No	No	No	No	No	No
Comments	* Please refer to The Packaging (Essential Requirements) Regulations 2015 Schedule 3 Regulation 5(3)(b) Requirements for Exemption for Glass Packaging from Heavy Metal Concentration Levels Specified in Regulation 5(1)						

Class 2 B

Elemental impurity	Silver	Gold	Iridium	Osmium	Palladium	Platinum	Rhodium	Thallium	Rubidium	Selenium
El Symbol	Ag	Au	Ir	Os	Pa	Pt	Rh	Tl	Ru	Se
Class	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B
Intentionally added	No	No	No	No	No	No	No	No	No	Yes, in Flint
Known to be present from other sources	No	No	No	No	No	No	No	No	No	No
If added or known to be present record the max concentration observed.	Not known	Not known	Not known	Not known	Not known	Not known	Not known	Not known	Not known	1 ppm
Recorded value obtained by validated test procedure	Not known	Not known	Not known	Not known	Not known	Not known	Not known	Not known	Not known	Not known
Specification limit	None	None	None	None	None	None	None	None	None	None
Method & LOD if known (ppm)	None	None	None	None	None	None	None	None	None	ICP-OES 0.5ppm
Any controls implemented to reduce metal content	No	Yes	No	No	No	No	No	No	No	No
Is the metal content tested routinely	Yes	Yes	No	Yes	No	No	No	No	No	No
Is the metal content listed on the COA	No	No	No	No	No	No	No	No	No	No
Comments	None									

Class 3

Elemental impurity	Barium	Chromium	Copper	Lithium	Nickel	Antimony	Tin
El Symbol	Ba	Cr	Cu	Li	Ni	Sb	Sn
Class							



	3	3	3	3	3	3	3
Intentionally added	No	No	No	No	No	No	No*
Known to be present from other sources	No	Yes	No	No	No	No	Yes*
If added or known to be present record the max concentration observed. (Wgt %)	Not known	0.038	Not known	Not known	Not known	Not known	Not known
Recorded value obtained by validated test procedure	Not known	Yes	Not known	Not known	Not known	Not known	Not known
Specification limit	None	None	None	None	None	None	None
Method & LOD if known (ppm)	None	XRF	None	None	None	None	None
Any controls implemented to reduce metal content	No	Yes	No	No	No	No	No
Is the metal content tested routinely	Yes	Yes	No	Yes	No	No	No
Is the metal content listed on the COA	No	No	No	No	No	No	No
Comments	* An Organo Tin solution is applied to the external surface of the container as part of the bottle coating process. This is a mono molecular layer and does not enter the container.						

9. Benefits of Glass

9.1 Sustainable

- 100% Infinitely recyclable & never degenerates
Glass is one of the few materials that can be recycled infinitely, over and over again, without any loss of quality unlike most plastics. Glass is therefore 100% recyclable and genuinely recycled.
- Raw Materials are plentiful and sourced locally
Contrary to plastics, glass is made from local raw materials (sand, soda ash and limestone). It is produced locally.
- Contains recycled materials



Healthy

- Totally inert, keeps product safe from contamination
Inertness is linked with absence of (chemical) reactivity. This means that inert packaging will not leach any element in and will not react with the content.
- Does not contain harmful chemicals
Because it doesn't leach, because it doesn't react chemically with the content and because it offers an excellent barrier to gases, glass is the only packaging material that fully preserves the original taste of food and beverages.
- Exempt from REACH registration
- Protects against Ultra Violet light
- Received GRAS certification from American FDA
Glass is recognised as being Generally Regarded as Safe.

Glass packaging preserves the taste of its contents; it is considered healthy, safe, and is environmentally friendly.

Section 10. Allergen Policy

An allergen is a known component which causes physiological reactions due to an immunological response.

Beatson Clark are aware that Allergies have a potential to be life threatening therefore Allergens are considered in the annual HACCP risk assessment review.

According to the food standards agency there are 14 Allergens and Beatson Clark has identified nuts as being an allergen of interest due to the severity of the possible reaction and customer interest.

Beatson Clark operate a quality management system in line with BRC global standard for packaging and packaging materials, this includes hygiene practices such as handwashing before entering production and resort areas and prohibition of eating in the production, resort and storage areas.

In addition to good manufacturing practices Beatson Clark have taken the following management steps and precautions to reduce the risk of Allergen cross contamination to our packaging: -

No Allergens are used as an ingredient in our products



The Site is covered by a site wide Nut Free policy QSP 72, this includes Spencer Park warehouses no nuts, nut derived products or products containing nuts as an ingredient will be allowed on site, failure to follow this may result in disciplinary action.

All visitors / contractors as part of induction to site will read the visitor policy which states our control of food in the production / resort and storage areas and what hygiene requirements are expected.

At induction all staff are given hygiene training which includes Allergen awareness training.

Hygiene refresher training is given to all staff periodically and includes Allergen awareness training.

All maintenance materials such as lubricants, grease and chemicals etc are nut free, this is controlled at purchasing through COSHH information provided and monitored through internal/ GMP audits.

Dave Binney

Quality and Sustainability Director