

LABEL COPY COMING SOON.....

BioSpectra is implementing a new label design using qualified printers and validated software.

For additional information, please view the change notification attached.
Otherwise, reach out to Customer.Service@BioSpectra.us

Dear Valued Customer,

This letter serves as an update to a previous notification sent in Q1 of 2023 regarding BioSpectra's implementation of a new design for the finished goods labels as part of BioSpectra's continuing advancements in technology and electronic management systems. This implementation provides BioSpectra with enhancements to label printing. This change was approved in accordance with BioSpectra's change control program as a level 3 change and can be referenced as BCC23-13.

We are sending you this notification because our records indicate you have purchased one or more products from BioSpectra in the last 24 months. BioSpectra is in the beginning stages of implementation, which is considered the pilot stage. The new printed labels will be issued starting in September of 2024. Refer to page 3 for the new label design.

In addition to the change in labels, BioSpectra is updating the lot number structure of all finished good material. The new lot number format will now include a 3 alpha numeric digit identifying the location of the start of manufacturing or, as applicable, packaging and 4 numeric digits for batch number issued. Additionally, the historical product code is being removed from all labels and certificate of analyses. The updated lot number will be implemented with the new label printing. Refer to page 4 for the new lot number diagram.

Please note that this change will not impact the quality expectations or quality policies of BioSpectra's Quality Management System related to manufacturing processes, manufacturing procedures, or the quality characteristics of each product or its associated packaging.

Description of Change

BioSpectra is implementing a new label design using qualified printers and validated software. The new label design will not include synonyms for the product, historical product code and NFPA rating diamond.

The lot number diagram will now include the location of manufacturing and where applicable packaging. The diagrams detailed below will provide the lot number structure before the change and the lot number structure after the change.

What will not be Changing

This change is specific to the transition from the current finished goods label design to a newly designed label and lot number format. The product quality, compliance, manufacturing and packaging criteria will remain unchanged.

Classification of the Change

BioSpectra has classified this change as a Level 3 Significant Change based on BioSpectra's Level of Change Determination SOP which was created in accordance with the guidance listed below:

- The International Pharmaceutical Excipients Council of the Americas Significant Change Guide for Bulk Pharmaceutical Excipients.
- ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Guidance for Industry.

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The implementation of the Label and Lot number change will include the qualification of the label software and the approval of the label size and design for each packaging. BioSpectra will begin using the new label designs and lot number structure in September of 2024. Only the new label and lot number format will be issued after the implementation date, however, packages already labeled in inventory will continue to use the previous lot number configuration and label format until all inventory is consumed.

Previous Label Design

Bulk Package:

BIO SPECTRA

Intended Use Statement
Material in this package is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material in this package is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

BioSpectra
100 Majestic Way
Bangor, PA 18013
610.599.3400

Manufactured at: 1474 Rockdale Lane
Stroudsburg, PA 18360

Guanidine Hydrochloride
Guanidinium Hydrochloride
Grade: Bio Excipient Grade
Lot Number:
GHCL-XXXX-XXXX
Product Code (New/Historical):
GHCL-32XX-XX / GH32XX-K025
Size: 25kg
CAS Number: 50-01-1
EC Number: 200-002-3
M.W.: 95.53 g/mol
M.F.: NH₂C(NH)NH₂HCl

Bio Excipient Grade

Signal Word: Warning
Hazard Statements: H302 Harmful if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation. H332 Harmful if inhaled.
Precautionary Statements: P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P264 Wash hands thoroughly after handling. P270 Do not eat, drink, or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P332 IF SWALLOWED: Rinse Mouth. Call a POISON CENTER/physician if feeling unwell. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists, get medical advice/attention. P362 Take off contaminated clothing and wash before reuse. P501 Dispose of contents/containers to an approved waste disposal plant.

Emergency Contact in US & Canada:
800.424.9300
Emergency Contact Outside the US & Canada:
703.527.3887

www.biospectra.us

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New Label Design

Bulk Package

Excipient

Product Code: GHCL-3220-25

Guanidine Hydrochloride

NF, GMP, Excipient Grade

Lot Number: GHCL-S05-0224-0000
Retest Date: 02/28/26
CAS Number: 50-01-1
EC Number: 200-002-3
NET Weight: 25kg
Molecular Weight: 95.53 g/mol
Molecular Formula: $\text{NH}_2\text{C}(\text{NH})\text{NH}_2\text{-HCl}$

Bio Excipient Grade Level

Intended Use Statement: Material in this package is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material in this package is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Storage Conditions: Store below 30°C

Manufactured at: 1474 Rockdale Lane, Stroudsburg, PA 18360



Signal Word: Warning

Hazard Statements:

H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H332 - Harmful if inhaled.

Precautionary Statements:

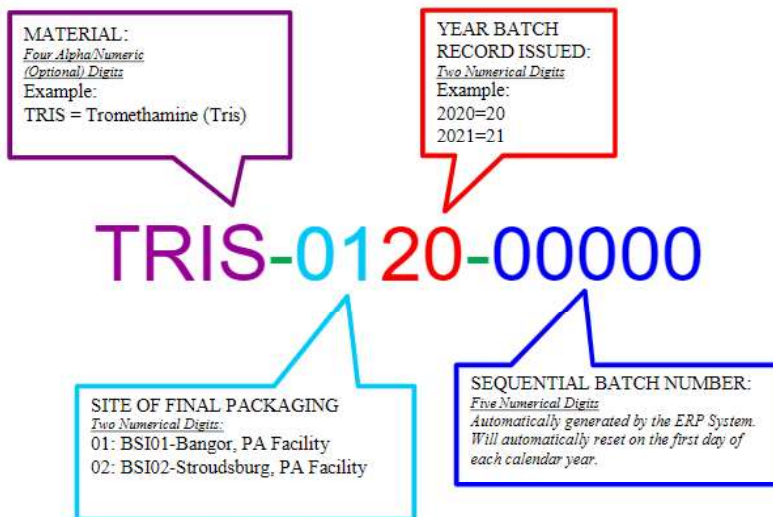
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink, or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331 - IF SWALLOWED: Rinse Mouth. Call a POISON CENTER/physician if feeling unwell. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists, get medical advice/attention. P362 - Take off contaminated clothing and wash before reuse. P501 - Dispose of contents/containers to an approved waste disposal plant.

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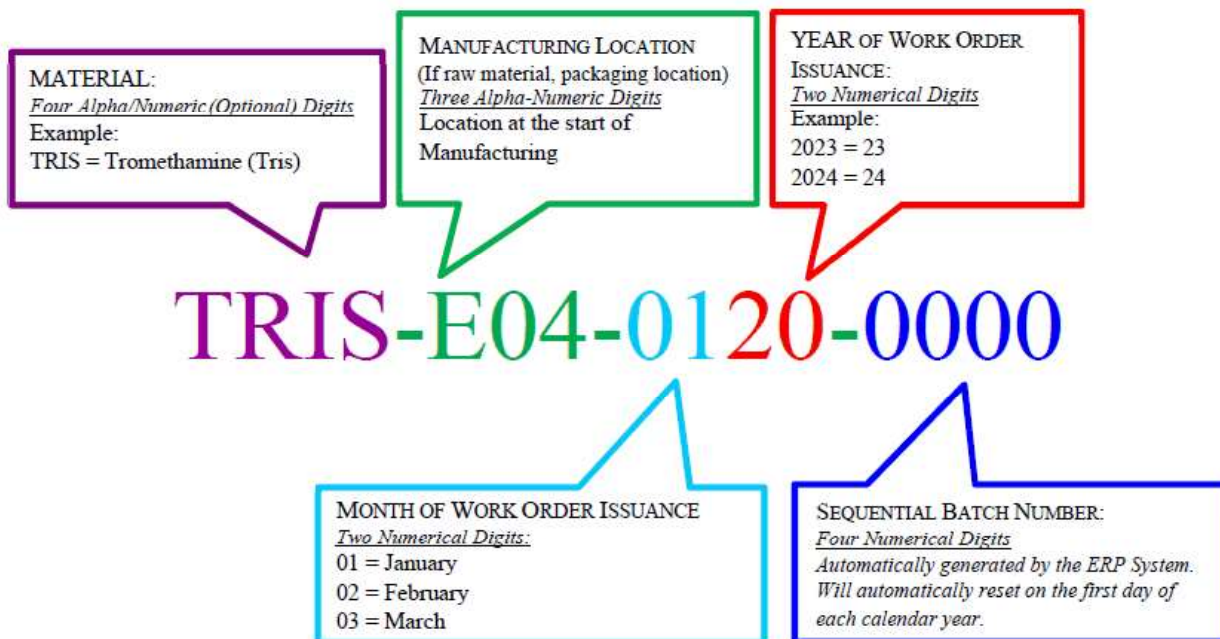
100 Majestic Way, Bangor, PA 18013
610.599.3400

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Emergency Contact Outside the USA & Canada: 703.527.3887

Previous Lot Number Structure



New Lot Number Structure



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Please direct any questions or concerns regarding this change to paul.dimarco@biospectra.us

Sincerely,

H. Kuchmas

Hannah Kuchmas | Senior Quality Manager, Rockdale & McConnell

100 Majestic Way | Bangor, PA 18013

+1.610.599.3479

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