

Technical Datasheet

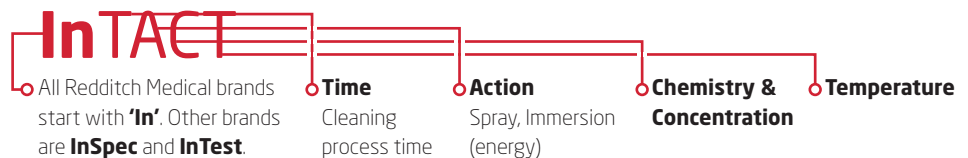
NEUTRAL BOOSTER

CIP & COP GMP Detergent System



Overview

Redditch Medical's InTact products are so named because TACT describes the key parameters involved in cleaning optimisation:



Description and Benefits

InTact™ Neutral Booster is a unique low foaming, low residue, Clean-in-Place (CIP) and Clean-out of-Place (COP) concentrated Neutral pH Booster detergent formulation based on non-ionic surfactants biodegradable surfactants and chelants. InTact Neutral Booster is designed exclusively for use in GMP Pharmaceutical and Medical Device Industries and validation is supported with:

- Pre-qualified analytical test method via TOC
- Toxicology & formulation profile – releasable to end-users under a non-disclosure agreement

Use and Application

InTact™ Neutral Booster is suitable for use in all Clean-in-Place & Clean-out of-Place component washers and ultrasonic bath systems and due to its neutral pH can also be used for manual cleaning.

InTact™ Neutral Booster may be used in conjunction with **InTact™ Acid** or **InTact™ Alkaline** products as they are fully miscible and compatible.

For monitoring and dosing systems, viscosity and conductivity at frequently used dilution rate are available in the specification section of the technical dossier.

Manufacture

InTact™ Neutral Booster is manufactured in an ISO 9001 and ISO 14001 registered facility with full batch traceability and complies with (EC) No. 648/2004 on detergent biodegradability.

InTact™ Neutral Booster is released with a certificate of analysis a two year expiration date for the date of manufacture. Safety data sheets (SDS) are available online or upon request.

Safe Handling

Always wear gloves and goggles or face protection, protective clothing. Always read the label and MSDS before use.

Conditions for Storage

Store in the tightly-closed, original container in a dry, cool and well-ventilated place. Keep upright to prevent leaking. Keep only in the original container. Corrosive storage. Additional test work supports that **InTact™ Alkaline** is unaffected by low temperatures – see freeze/thaw study – ref Freeze/thaw Study Rev 001.

Additional Supporting Services - InTact Optimisation Studies

Redditch Medical offer a laboratory-based service in which stainless steel or glass coupons representing an end-users actual drug and excipient soiling are tested in our laboratory to determine which cleaning agent should be used and at what concentration, time and temperature whilst mimicking cleaning process conditions.

The results from these studies provide both the rationale behind product selection and an optimised starting point to move to a pilot or pre-qualification trial with high assurance of success.

The service can also assist in reducing current cleaning times and rinsing volumes.

Processed coupons are reviewed and examined via several criteria to rapid establish how effective the cleaning and rinsing process has been under each set of TACT conditions. Criteria are:

- Visual
- Odour
- Water break free test ASTM Method F 22-65
- ATP rapid detection (for protein based soils)

InTact™ Alkaline Products

Product	Pack Size	Number/case	Product Code	Gross Weight
InTact™ Neutral Booster 1,000 Litre IBC	1,000 Litre	N/A	CIP003GMP01K	1073 Kg
InTact™ Neutral Booster 200 Litre Drum	200 Litre	N/A	CIP003GMP200	211 Kg
InTact™ Neutral Booster 20 Litre IBC	20 Litre	N/A	CIP003GMP020	21 Kg
InTact™ Neutral Booster 5 Litre Can	5 Litre	2	CIP003GMP005	11 Kg
InTact™ Neutral Booster 1 Litre Bottle	1 Litre	12	CIP003GMP001	13 Kg