

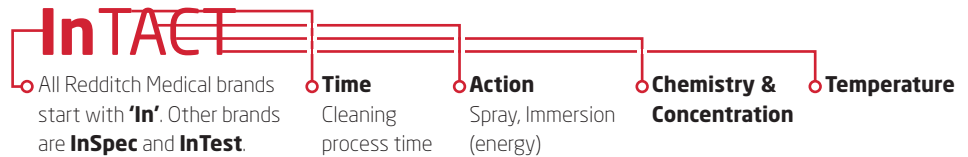
ALKALINE

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™ Alkaline is a unique low foaming, low residue, Clean-in-Place (CIP) and Clean-out of-Place (COP) concentrated alkaline detergent formulation based on Potassium hydroxide, biodegradable surfactants and chelants. InTact Alkaline is designed exclusively for use in GMP Pharmaceutical and Medical Device Industries where rapid processing and rinsing is required. Validation is further supported with:

- Pre-qualified analytical test methods - TOC and ICP-MS
- Toxicology and formulation profile – releasable to end-users under a non-disclosure agreement

Use and Application

InTact™ Alkaline is suitable for use in all Clean-in-Place & Clean-out of-Place component washers and ultrasonic bath systems and Clean-in-Place systems. Monitoring systems can also make use of the data held on **InTact™ Alkaline** viscosity and conductivity at frequently used dilution rates.

If additional surfactancy is required **InTact™ Acid** is full compatible with **InTact™ Neutral Booster** – refer to Technical Datasheet/InTact Neutral Booster Rev 001.

Manufacture

InTact™ Alkaline 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™ Alkaline 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 & 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
- ATP rapid detection (for protein based soils)

InTact™ Alkaline Products

Product	Pack Size	Number/case	Product Code	Gross Weight
InTact™ Alkaline 1,000 Litre IBC	1,000 Litre	N/A	CIP001GMP01K	1292 Kg
InTact™ Alkaline 200 Litre Drum	200 Litre	N/A	CIP001GMP200	254 Kg
InTact™ Alkaline 20 Litre IBC	20 Litre	N/A	CIP001GMP020	26 Kg
InTact™ Alkaline 5 Litre Can	5 Litre	2	CIP001GMP005	13 Kg
InTact™ Alkaline 1 Litre Bottle	1 Litr	12	CIP002GMP001	16 Kg