

James Walker	Cleandown Procedures for K2A Intermixer and Iddon Mill	Date: 17/02/2020 Reaffirmed 2021	Rev: 4	Page: Page 1 of 2	Document No: OPI 118 Approved by: J Banks
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REASON FOR UPDATE: Document Review

ASSOCIATED DOCUMENTS: n/a

1. PURPOSE

1.1 To provide a procedure for the cleandown of a K2A Mixer and an Iddon Mill.

2. SCOPE

2.1 This document applies to all those involved with the cleandown of a K2A mixer and an Iddon Mill.

3. RESPONSIBILITY

3.1 The Material Supply Chain Manager is responsible for updating and communicating the details within this procedure.

4. PROCEDURE

WHEN ARE CLEANERS REQUIRED?

- * WHEN CHANGING FROM ONE GENERIC TYPE OF RUBBER TO ANOTHER (e.g. NITRILE TO FLUOROCARBON) - NOTE: THE TYPE IS ON THE DJ
- * WHEN CHANGING FROM ONE CURE SYSTEM TO ANOTHER - PARTICULARLY WITH FLUOROCARBONS (e.g. BISPHENOL TO PEROXIDE CURE)
- * WHEN CHANGING FROM BLACK TO COLOURED, OR ONE COLOURED TO ANOTHER (e.g. BLACK TO GREEN, GREEN TO RED)
- * WHEN CHANGING FROM TYPE 1/TYPE 3 TO ANYTHING ELSE NOTE: THIS CLEANER MUST *NOT* BE RE-USED, DUE TO HIGH SULPHUR CONTENT

K2A CLEANER SEQUENCES

STANDARD	1. MASTICATED NR10 SMR-L RUBBER, WHICH CAN BE REUSED UNTIL IT IS TOO SOFT TO CLEAN EFFECTIVELY (UNLESS IT HAS BEEN USED AFTER TYPE 1 OR TYPE 3 - SEE ABOVE) NOTE: THIS MAY BE A 'USED' PHARMA CLEANER, SEE BELOW, OR ANY OTHER MATERIAL WHICH HAS BEEN APPROVED BY THE LAB FOR USE AS A CLEANER
PHARMA	1. STANDARD CLEANER AS ABOVE 2. VIRGIN MASTICATED NR10 SMR-L RUBBER. *RECORD LOT NUMBER USED ON CLEANER CONTROL SHEET* 3. REPEAT USING SAME CLEANER FROM STAGE 2 ABOVE THIS WILL BRING THE MIXER TO AN APPROPRIATE STANDARD OF CLEANLINESS FOR PHARMA COMPOUNDS.

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COLOURED

1. STANDARD CLEANER AS ABOVE
2. APPROPRIATE 'COLOURED' CLEANER, WHICH CAN BE REUSED UNTIL IT IS TOO SOFT TO CLEAN EFFECTIVELY (see below)
3. REPEAT USING SAME CLEANER FROM STAGE 2 ABOVE

NB. FOR A NEW COLOURED CLEANER, ADD 0.5-1KG OF THE PIGMENT & SOME WHITE FILLER TO A BATCH OF NR10 SMR-L

K2A CLEANER PROCEDURE - this applies to all the above cleaner types

1. SCRAPE, THEN SWEEP, TOP & SIDES OF RAM AND DROPDOOR, BEFORE BLOWING THROUGH WITH AIRLINE.
2. PUT CLEANER INTO MIXER (APPROX 36KG, SPEED 25), GIVE TWO RAM CYCLES AND DUMP AT 105C.
3. INSPECT MIXER FOR ANY CLEANER RESIDUE, REPEAT STEP 2 IF NECESSARY
4. RECORD DETAILS ON CLEANER RECORD SHEET FOR TRACEABILITY PURPOSES

MILL CLEANDOWN PROCEDURE

1. SWEEP BOTTOM OF MILL AND ROLLERS TO REMOVE ANY REMAINS OF LAST BATCH
2. FOR COLOURED COMPOUNDS - DUST THE BOTTOM OF THE MILL WITH WHITE FILLER AS PER THE RECIPE