CRANE ChemPharma Flow Solutions

Saunders® the science inside

CRANE SAUNDERS COMPOUNDS WITH APPROVALS AND CERTIFICATION

Compound grade	Polymer type	Approvals								
		HC4					HC4 and IDV	IDV		
		EP3.1.9	USP Class I to VI	USP381 (EP 3.2.9)	EC1935-2004	ADCF	FDA	WRAS	Exp date	ATEX
300	Butyl		√		√	√	√	√	Oct-15	
425	EPM		√	√	√	√	√			
E3	Post cured EPM		√		√	√	√			
EE	EPDM		√		√	√	√			
EF	Post cured EPDM		√		√	√	√			
500	Silicone		√		√	√	√			
500 Post cured	Silicone	√	√		√	√	√			
EX	Silicone		√		√	√	√			
RB256	Nitrile									√
EL6 Lining	Semi-Ebonite				√	√	√	√	Aug-19	
BL Lining	Butyl				√	√		√	Feb-20	
Plastics										
PFA Lining	Fluoropolymer				√*	√	√			
PTFE Diaphragm	Fluoropolymer		√	√	√	√	√			
TFM Diaphragms	Fluoropolymer		√	√	√	√	√			
PP Lining	Polyolefin					√	√			
ETFE Lining	Fluoropolymer				√	√	√			
PVDF Lining	Fluoropolymer					√	√*			

* verified by supplier

FDA

Must meet extraction test criteria:

First 7hours: Not exceeding 175mg/in^2

Next 2hours: Not exceeding 4mg/in^2

The conditions used for the EC1935/2004 were as follows:

Elastomers

Nitrosamines

The overall migration limit will not exceed 0.1mg/Kg (teat products)	All Elastomers tested, passed

Plastic grades

List of simulants

A: 10% Ethanol	Passed for stimulants A, B, C and D1
B: 3% Acetic acid	
C:20% Ethanol	
D1: 50% Ethanol	
D2: Vegetable oil*	
E: DPPO 200nm	