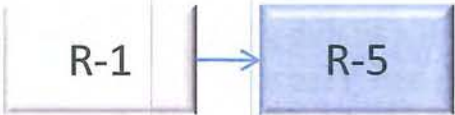
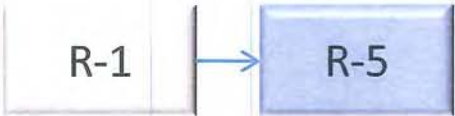

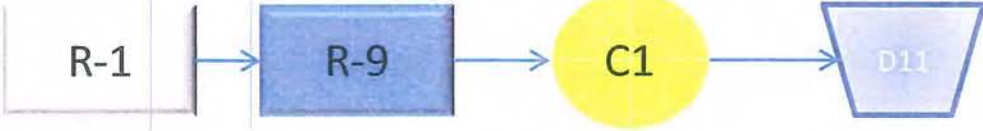
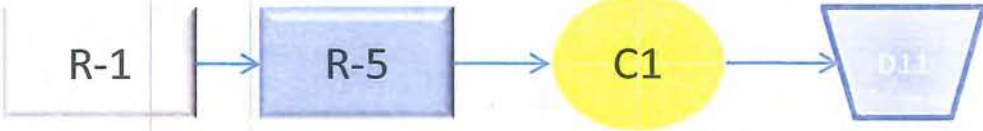
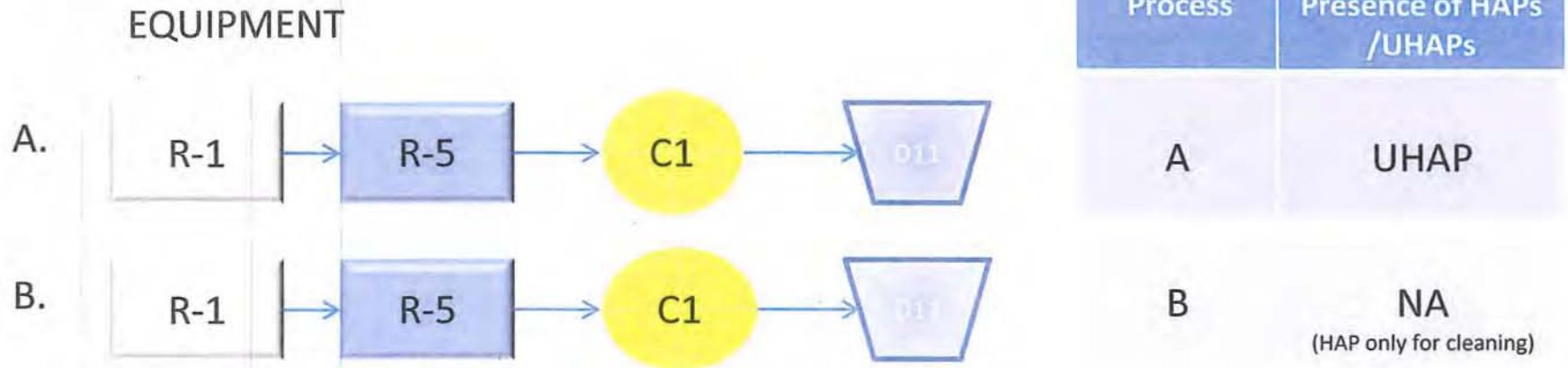


FAMILY OF MATERIALS API 5 STEP PROCESS

EQUIPMENT		Chemistry Step	Presence of HAPs /UHAPs
A.		A	UHAP
B.		B	NA
C.		C	HAP
C _{RC1}		C _{RC1}	HAP
C _{RC2}		C _{RC2}	HAP

FAMILY OF MATERIALS



Process A, Process B and Process C use the same CMPU

Process A uses raw material X and raw material Y and a solvent (water) to make product Z

Process B uses raw material X and raw material Y and a solvent (IPA) to make product W

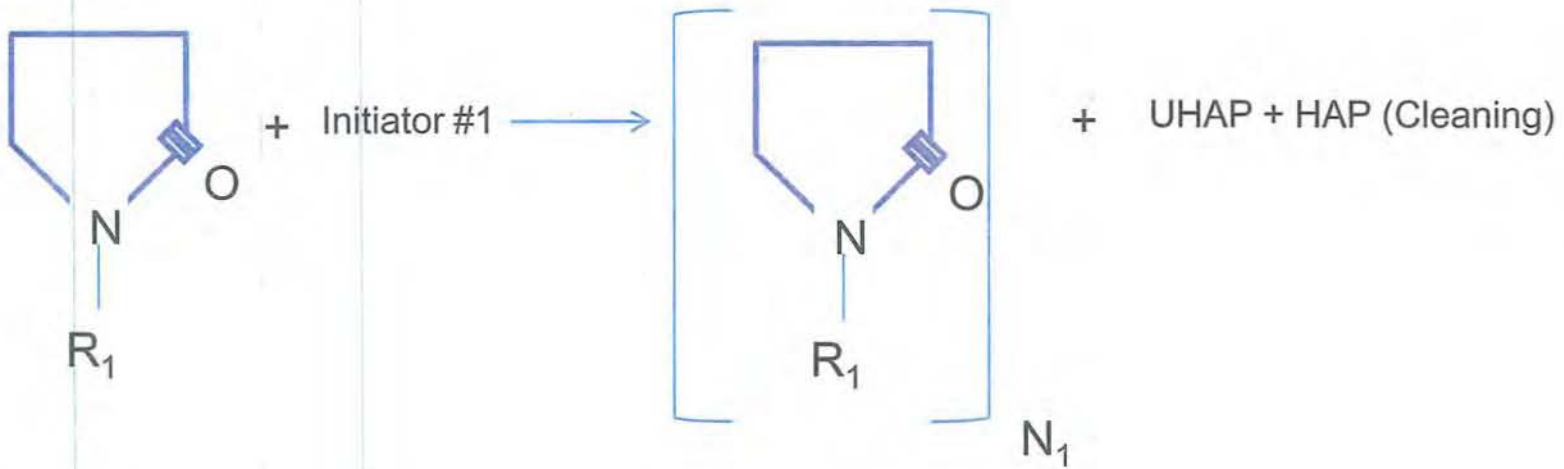
Product A generates an UHAP as by product

Product B does not generate an UHAP, but uses a HAP for equipment cleaning

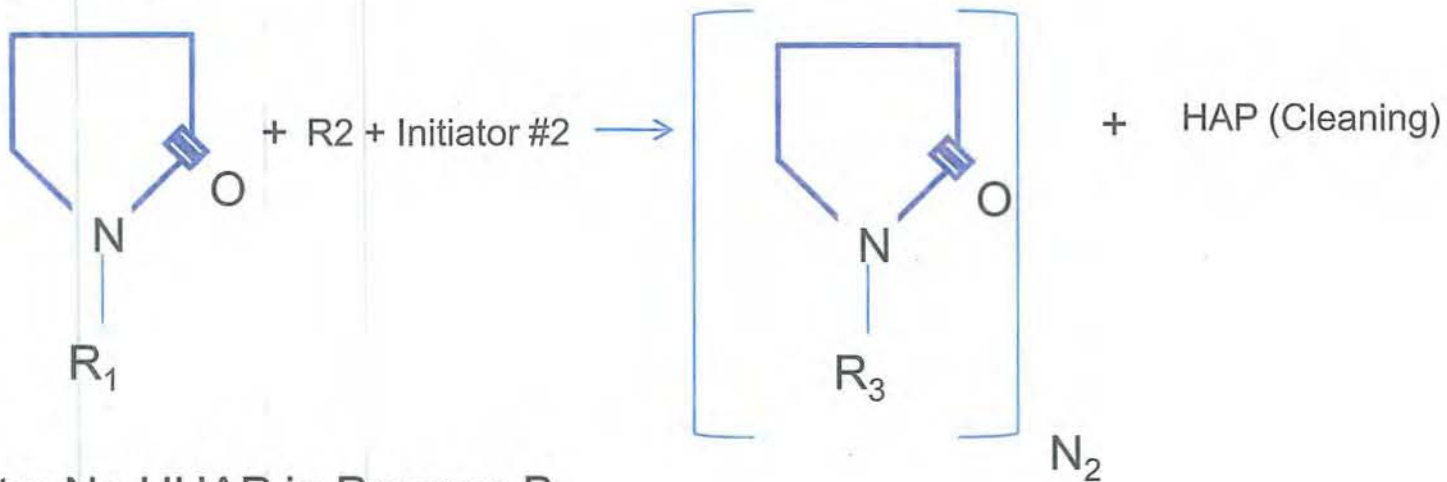
These products have similar end use, but different application.

FAMILY OF MATERIALS

Process A



Process B

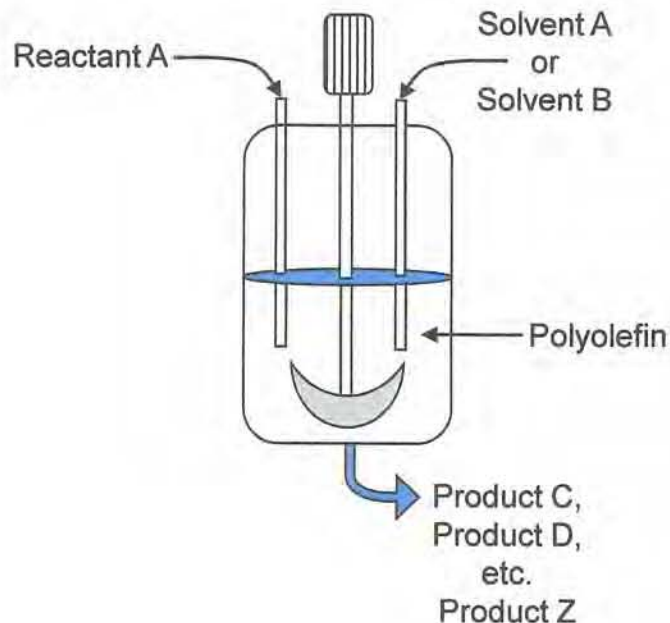


Note: No UHAP in Process B

FAMILY OF MATERIALS

Circumvention of Vent Standards

The final rule requires management practices and 85 percent control (90 percent for new sources) if the total organic uncontrolled HAP emissions from batch process vents within a CMPU are 10,000 lbs/yr or greater.



- The company packages and sells a variety of specialty polyolefins. A large number of customers buy the polyolefins, many wanting a slightly different molecular weight, degree of saturation, solvent, etc.
- Emission profiles differ somewhat because Reactant A (HAP) addition times control molecular weight, Solvent A may produce UHAP emissions while Solvent B does not....

63.2550 (MON) **Family of materials** means a grouping of materials with the same basic composition or the same basic end use or functionality produced using the same basic feedstocks with essentially identical HAP emission profiles (primary constituent and relative magnitude on a pound per product basis) and manufacturing equipment configuration. Examples of families of materials include multiple grades of the same product or different variations of a product (e.g., blue, black, and red resins).

Pharmaceutical Product and FOM Definition



Questions:

1. Are the Pharmaceutical products PhRMA A and PhRMA B in the same family of Materials?
2. What criteria should be used to answer the above question?
3. Suppose PhRMA A and PhRMA B are somewhat different compounds (including for example the case where they are isomers) but have clearly different pharmacological properties and/ or treat different medical conditions or diseases, would they belong to the same Family of Materials?

Note:

1. The same CMPU is used to make PhRMA A and PhRMA B
2. Pharmaceutical products PhRMA A and PhRMA B have different pharmacological properties and/or treat different medical conditions or diseases. They are both regulated as 2 distinct products and processes under FDA regulations.
3. It appears that EPA excluded the concept of Family of Materials from the PhRMA MACT because the Family of Materials concept would not work in the pharmaceutical manufacturing category as subsequently intended under the MON MACT.