

FORMULANTS POLICY

- ▶ DEVELOPED WITHIN NAFTA WORKING GROUP
- ▶ BASED ON AND CONSISTENT WITH US APPROACH TO FORMULANTS (INERTS)
- ▶ ALL FORMULANTS WILL BE ASSIGNED TO LISTS RANKED ON LEVEL OF CONCERN AND SUBJECT TO CONDITIONS/REQUIREMENTS SPECIFIC TO THE LIST



FORMULANTS POLICY

Cont'd

- ▶ EXAMPLE:
- ▶ LIST 1 - FORMULANT OF TOXICOLOGICAL CONCERN
- ▶ REMOVAL/REPLACEMENT
 - ◆ FULL DATA PACKAGE TO FACILITATE RISK ASSESSMENT
 - ◆ INTERIM LABELLING UNTIL RISK ASSESSMENT COMPLETE



KEY FEATURES OF FORMULANTS POLICY

- ▶ REQUIRES SUBMISSION OF UPDATED SPECIFICATIONS FORMS ON ALL END-USE PRODUCTS AND ADJUVANTS
- ▶ ALL FORMULANTS WILL BE DESIGNATED TO LISTS SUBJECT TO CONDITIONS OF THE LIST
- ▶ REQUIRES DATA FOR NEW FORMULANTS AND FOR SIGNIFICANT NEW USES
- ▶ APPLIES DIRECTIVES OF TSMP AND MONTREAL PROTOCOL TO FORMULANTS



KEY FEATURES OF FORMULANTS POLICY Cont'd

- ▶ REQUIRES DATA ,LABELLING, REMOVAL /SUBSTITUTION OF FORMULANTS WITH POTENTIAL OR IDENTIFIED TOXICOLOGY CONCERNS
- ▶ REQUIRES DEVELOPMENT OF DATA PACKAGE FOR FORMULANTS THAT HAVE SUGGESTIVE BUT INCOMPLETE DATA ON TOXICITY OR WHERE SAR TO CHEMICAL WITH DEMONSTRATED TOXIC PROPERTIES
- ▶ SETS ACCEPTANCE CRITERIA FOR FORMULANTS THAT ARE DYES, FRAGRANCES OR OILS
- ▶ REQUIRES LABELLING FOR FORMULANTS THAT ARE COMMON ALLERGENS KNOWN TO BE ASSOCIATED WITH ANAPHYLACTIC REACTIONS



FORMULANTS POLICY - PMRA STATUS

- ▶ POLICY RELEASED AS PROPOSAL IN 2000
- ▶ NUMEROUS COMMENTS RECEIVED - CONSIDERED AND INCORPORATED AS APPROPRIATE
- ▶ ONGOING PREPARATION FOR IMPLEMENTATION
 - ◆ FORMULANTS TEAM BEING ESTABLISHED
 - ◆ PROCESS MAPPING ACTIVITIES - SOPS
 - ◆ DEFINING DATA BASE PARAMETERS
- ▶ APPROPRIATE LEAD TIME UPON IMPLEMENTATION
 - ◆ REGISTRANTS HAVE BEEN APPRISED POLICY IS COMING

