

2/8/2006

NOTE TO THE JACKET

75174-U

Manufacturing process information not included.

Inert ingredient information not included.

2/8/06

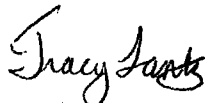
I received a chemistry review (D324179) on this product dated 2/1/06. Dennis and I discussed the deficiencies identified in the recommendations section of this review and the following conclusions were noted:

#3. After discussion with Juan we will revise this comment to read:

[redacted] should not be declared as impurities in the post reaction CSF. These components should be declared as unreached chemical or by their specific purpose in the formulation if it is known."

#4. Juan's comment #4 is inaccurate. The alternate solvent can not be used in an alternate formula for this product as this formula would not be in agreement with the poison/skull & crossbones language on the label. This comment should state: *"The formula with the alternate solvent [redacted] must be a separate registration as per the Agency letter for 75174-1 dated 10/22/03. Such a change in the formulation would result in a change in the toxicity statements associated with this product. Information regarding this alternate formulation should not be included in the chemistry data submitted for this product."*

#7. Juan's comment #7 is inaccurate. I will provide the following comment: *"It is not required that the studies represented in MRIDs 466829-01 and -03 meet GLP guidelines. These studies do not need to be revised in reference to GLP guidelines."*



Tracy Lantz
Team 31

75174-Un