ATTACHMENT #10

Part IV – B Environmental Assessment (EA)

Food Contact Substance: *Cyclohexane, 5-isocyanato-1(isocyanatomethyl)-1,3,3-trimethyl, homopolymer Me Et ketone oxime-blocked (solvent free)* (CAS Reg. No. 103170-26-9) also referred to as *"MEKO-blocked IPDI trimer."*

1. **Date: September 16, 2010**
2. **Name of submitter: Valspar**
3. **Business address of submitter: 2001 Tracy Street, Pittsburgh, PA 15233**
4. **Description of the proposed action:**

a. Requested action: A Food Contact Notification (FCN) for the Food Contact Substance (FCS) *Cyclohexane, 5-isocyanato-1(isocyanatomethyl)-1,3,3-trimethyl, homopolymer MeEt ketone oxime-blocked (solvent free)* (CAS Reg. No. 103170-26-9) as a component of coatings for use on metal substrates at a maximum concentration of 8.2% (wt. solids), in contact with all food types, and temperature conditions of use A through H

b. Need for action: The food contact substance (FCS) is essential as a component of coatings for metal food contact articles. The MEKO-blocked IPDI trimer acts as a cross-linking agent in the polymerization of polyester/polyurethane coatings for metal substrates. This cross-linking agent allows the use of polyester-based coatings as an alternative to epoxy-based coatings for metal food-contact articles. By utilizing the FCS as an alternative, coatings are produced which have the following positive characteristics:

- Exceptional gloss retention and non-staining from foods, even after a two-year exposure time;
- Excellent balance between hardness and flexibility; this property is especially important to achieve fabrication requirements and resistance to can damage; it also is necessary in applications where coated metal is embossed to obtain complex shapes;

- Outstanding chemical resistance, which is particularly important in coatings on packaging for very aggressive food media.

Therefore, with the addition of the FCS as an essential component of coatings on metal substrates in combination with food-contact substances cleared for the intended use by FDA under 21 CFR Section 175.300 or other applicable food additive regulations or effective food-contact notifications, one can ensure polyester/polyurethane coatings meet the highest requirements in terms of chemical and technical performance.

5. Identification of the substance that is the subject of the proposed action:

a) CAS name: Cyclohexane, 5-isocyanato-1(isocyanatomethyl)-1,3,3-trimethyl, homopolymer MeEt ketone oxime-blocked (solvent free)

b) CAS registration number: 103170-26-9

c) Molecular weight: minimum: 335 Daltons

d) Molecular formula: C48H81O9N9

e) Structural formula: Refer to Attachment #1 of FCN 000952

6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture: Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal after use. Consequently, because information available to the best knowledge of the notifier does not suggest that the manufacture of the notified substance poses any extraordinary circumstances in this case indicative of any adverse environmental impact, discussion about the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use/disposal:

During the use and disposal of the product coating the remaining portion of the FCS that is not released during curing does not change the existing environmental background because the isocyanate and polyurethane it makes are commonly used and not reasonably expected to pose an impact upon their disposal from the use or on the anticipated recycling of the coated metal. Therefore, this EA focuses upon the potential

for the environmental impact, if any, posed by those FCS components that can be released during the application and curing process.

One such component of the FCS with the possibility to be released during the curing of the can coatings forming nitrous oxide particularly in the form of nitrogen dioxide (NO2) is the nitrogen component MEKO. The NOx formation during the oxidization (combustion) of nitrogen bound fumes is a function of many variables. NOx is the generalized term used for NO, NO2 and other oxygenated nitrogen compounds. In the combustion process, the majority of the NOx is generated as NO and can be converted to NO2 in the atmosphere, the emission estimates will be based on the assumption that all of the NOx is generated as NO2. This does not change the volumetric emission but maximizes the weight emissions of the NOx allowing for the calculation of the maximum PTE.

Based on sales projections of the formulated FCS for the next three years 720,000, 420,000 and 420,000 gallons over 2011, 2012 and 2013 respectively, the total MEKO potential consumption for 2011 is 43,000 pounds with a total PTE for NO2 nationwide of 11.52 tons for 2011. The tons per year of NO2 generated are calculated as follows:

Weight per Gallon of formulation = 8.5 lbs/gal

720,000 Gal X 8.5 lbs/gal = 6,120,000 pounds

Percent of MEKO-blocked IPDI Trimer in Formulation = 2.6%

6,120,000 X 0.026 = 159,120 lbs MEKO-blocked IPDI trimer for 2011

Percent of MEKO in MEKO-blocked IPDI trimer = 27%

159,120 lbs X 0.27 = 42,962 lbs of MEKO

Percent of Nitrogen in MEKO = 16.1% Calculated as follows

MEKO = C4H9NO, Molecular weight (MW) = 87

Nitrogen Molecular weight = 14

Therefore 14/87 = 16.1%

Therefore 42,962 lbs MEKO X 0.161 = 6917 lbs of Nitrogen for 2011

Conversion to NO2

Nitrogen MW =14

NO2 MW = 46

N/NO2 = 14/46 = 0.30

Therefore 6917 lbs(N) /0.30 (N/NO2) = 23,056 lbs or 11.52 US tons NO2 for the peak year of 2011

If sales increased beyond projections the NO2 released would still be insignificant as maximum PTE using the maximum hours in a year of 365 days is still low at 1.75 tons per line per year and is calculated as follows:

MEKO-blocked IPDI will be applied at a rate of 50 gallons every 4 of coating/curing time operation per line.

24 hrs/ 4 hrs = 6, 6 X 50 gallons = 300 gallons a day applied

Weight per Gallon of formulation = 8.5 lbs/gal

300 Gal X 8.5 lbs/gal = 2550 pounds

Percent of MEKO-blocked IPDI trimer in Formulation = 2.6%

2550 X 0.026 = 66.3 lbs MEKO-blocked IPDI trimer per day per line

Percent of MEKO in MEKO-blocked IPDI trimer = 27%

66.3 lbs X 0.27 = 17.9 lbs of MEKO

Percent of Nitrogen in MEKO = 16.1% Calculated as follows

MEKO = C4H9NO, Molecular weight (MW) = 87

Nitrogen Molecular weight = 14

Therefore 14/87 = 16.1%

Therefore 17.9 lbs MEKO X 0.161 = 2.88 lbs of Nitrogen per line per day 2011

Conversion to NO2

Nitrogen MW =14

NO2 MW = 46

N/NO2 = 14/46 = 0.30

Therefore 2.88 lbs(N) /0.30 (N/NO2) = 9.61 lbs of NO2 per day, 3507 lbs per year or 1.75 US tons NO2 for the year 2011

In order to ensure proper due diligence, we contacted the Alabama Department of Environmental Management (ADEM) Air Division Chief Ron Gore and Environmental Engineer Expert for New Source Permitting Heather Abrams of EPA Region IV to discuss the PTE of 1.75 tons of NO2 per line per year. Upon discussion with Ron Gore and Heather Abrams they confirmed that this poses no issues with current National Ambient Air Quality Standards. Additionally, EPA guidelines and standards for the prevention of significant deterioration (PSD) review as part of the New Source Review program requiring further modeling and studies will not even be triggered until there is an increase of 40 tons of NOx per year per project in an attainment area and 25 to 10 tons/year per project in a serious to extreme non-attainment area[1].

Another such component released during curing is organic solvents of approximately 68% that are part of the MEKO-blocked IPDI trimer formulation. The MEKO blocked IPDI trimer only accounts for 2.6% of the total formulation and the remaining emissions other than the Nitrogen from the MEKO are typical organic emissions that can and will be handled by the existing controls. Additionally, existing formulations also contain approximately 68% organic solvents which are handled by existing controls.

The remaining high boiling and high molecular weight IPDI trimer is completely reacted and does not pose any significant impact on the environment during the curing process.

In conclusion there are no extraordinary circumstances that pertain to can coating utilizing the FCS, as any introductions into the environment from the coating with MEKO-blocked IPDI trimer are minimal and adequately addressed by existing EPA Standards and Guidelines.

7. Fate of substances released into the environment: Since there will be no significant release of substances into the environment, as discussed above, we respectfully submit that it should not be necessary to describe the fate of released substances.

8. Environmental effects of released substances: In accordance with Item 7, the absence of any potential significant release of substances into the environment eliminates the need to discuss the environmental effects of released substances.

9. Use of resources and energy: No significant increases are expected in resources and energy consumption as a result of the manufacturing, use or disposal of the FCS, as compared with the manufacture, use or disposal of other food-contact can coating substances.

[1] Electronic Code of Federal Regulations, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=5f2b25d1de7e11a0da1dbe1ebd0ce9a1&rgn=div8&view=text&node=40:2.0.1.1.2.6.8.6&idno=40>

10. Mitigation measures: Based upon a review of the data and information previously stated in the EA, no adverse environmental effects have been identified from the manufacture, use or disposal of the FCS that require mitigation measures

11. Alternatives to the proposed action: Again based upon a review of the data and information previously stated in the EA, no adverse environmental effects have been identified from the manufacture, use or disposal of the FCS that require alternatives to the proposed action plan.

12. List of preparers:

Shawn Blenis
Environmental Services Manager
Intertek Expert Services

Donald Corwin PE
Principle
Therm-a-Cor Consulting Inc

13. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best of my knowledge.

Date: September 16, 2010

Signature of responsible official:

[redacted]

Printed name and title of responsible official:

Naeem Mady
VP Regulatory Services
Intertek Expert Services