# Environmental Assessment

## The Valspar Corporation

## Food Contact Substance: 1H-Azepine-1-carboxamide, hexahydro-2-oxo-N-[3,3,5-trimethyl-5-[[tetrahydro-3,5-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-2,4,6-trioxo-1,3,5-triazin-1(2H)-yl]methyl]cyclohexyl]-,

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| 1. | **Date:** | September 4, 2012 |
| 2. | **Name of Applicant/Notifier:** | The Valspar Corporation<br>2000 Georgetown Pike<br>Sewickley, PA 15143 |
| 3. | **Address:** | All communications should be sent to the Agent for the Notifier:<br>Ralph Simmons<br>1330 Connecticut Ave. NW,<br>Washington DC 20036<br>Telephone: (202) 429-6459<br>E-mail: rsimmons@steptoe.com |

### 4. Description of the Proposed Action

**a. Requested action**: The action requested in this Notification is to establish the clearance of the food-contact substance (FCS) 1H-Azepine-1-carboxamide, hexahydro-2-oxo-N-[3,3,5-trimethyl-5-[[tetrahydro-3,5-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-2,4,6-trioxo-1,3,5-triazin-1(2H)-yl]methyl]cyclohexyl]-, CAS Registry Number 1262431-48-0, as a component of coatings for use on metal substrates, at a maximum concentration of 13.9% (wt. solids).

The FCS is intended for use in contact with all food types as set forth in 21 C.F.R. § 176.170(c), Table 1, under Conditions of Use A through H, as set forth in § 176.170(c), Table 2.

**b. Need for action:** The FCS is essential as a component of coatings for metal food contact articles. The caprolactam-blocked IPDI trimer acts as a cross-linking agent in the polymerization of polyester/polyurethane coatings for metal substrates. This cross-linking agent allows for 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 with the following positive characteristics are produced:

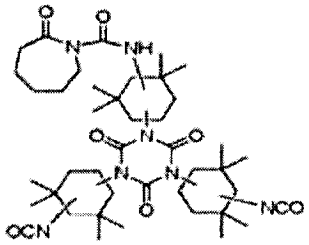
- Exceptional gloss retention and non-staining from foods, even after a two year exposure time;
- Excellent balance between hardness and flexibility. This property is especially important to achieve fabrication requirements and resistance to can damage. It is also necessary in applications where coated metal is embossed to obtain complex shapes;
- Outstanding chemical resistance, which is particularly important for 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 C.F.R. Section 175.300 or other applicable regulations or effective food contact notifications, it can be assured that polyester/polyurethane coatings meet the highest requirements in terms of chemical and technical performance.

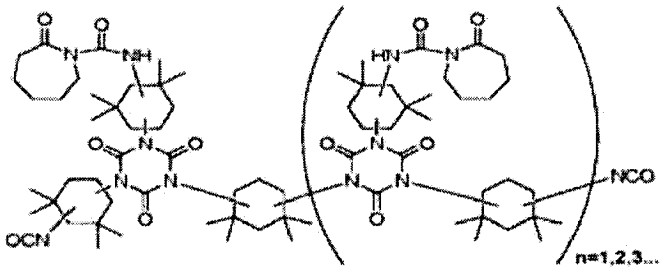
## 5. Identification of the Subject of the Proposed Action

The subject of the FCS of the proposed action is 1H-Azepine-1-carboxamide, hexahydro-2-oxo-N-[3,3,5-trimethyl-5-[[tetrahydro-3,5-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-2,4,6-trioxo-1,3,5-triazin-1(2H)-yl]methyl]cyclohexyl]-, CAS Registry Number 1262431-48-0.

The chemical structure of the substance is shown here:




CAPROLACTAM PARTIALLY BLOCKED IPDI TRIMER




PENTAMER, HEPTAMER, NONAMER...

## 6. Introduction of Substances into the Environment:

**a. As a result of manufacture:** Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on the relevant environmental issues relating to the use and disposal after use of the FCS. 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 regarding the manufacturing site and compliance with relevant emissions requirements is not provided.

**b. As a result of use/disposal:** During the use and disposal of the coating, the remaining portion of the FCS that is not released during the curing process does not change the existing environmental background. This is because the isocyanate and polyurethane that are produced are commonly used and not reasonably expected to pose an impact upon their disposal as a result of the use or on the anticipated recycling of the coated metal. Therefore, this EA focuses on 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 is nitrous oxide, particularly in the form of nitrogen dioxide ($NO_2$), based on the nitrogen component of caprolactam. The $NO_x$ formation during the oxidation (combustion) of nitrogen bound fumes is a function of many variables. $NO_x$ is the

generalized term used for NO, $NO_2$, and other oxygenated nitrogen compounds. During the combustion process, the majority of the $NO_x$ generated is NO. Once formed, NO can be converted to $NO_2$ in the atmosphere, and the emission estimates will be on the assumption that all of the $NO_x$ is generated as $NO_2$. This does not change the volumetric emission, but maximizes the weight emissions of the $NO_x$, allowing for the calculation of the maximum PTE.

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 are not triggered until there is an increase of 40 tons of NOx per year per project in an attainment area, 25 tons/year per project in a serious non-attainment area, and 10 tons/year per project in an extreme non-attainment area.

Based on sales projections of the formulated coatings containing the FCS (see confidential environmental assessment support information) the total production of $NO_2$ nationwide for the first year of production of the FCS will be well below levels that would trigger any of the above requirements. Therefore, we believe that the potential increases in $NO_2$ produced as a result of this FCN becoming effective for the use of the caprolactam-blocked IPDI trimer are insignificant.

Other components that are released during the curing process include organic solvents, which comprise a large percent of the caprolactam-blocked IPDI trimer formulation. The caprolactam-blocked IPDI trimer only accounts for a maximum of 13.9% of the total formulation and the remaining emissions can and will be handled by the existing controls. Additionally, existing formulations also contain organic solvents which are handled by existing controls.

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

Therefore, it can be concluded that there are no extraordinary circumstances that pertain to can coatings utilizing the FCS, as any introductions into the environment from the coatings made with the caprolactam-blocked IPDI trimer are minimal and adequately addressed by existing EPA guidelines and standards.

## 7. Fate of Emitted Subjects in the Environment

Because there will be no significant release of substances into the environment, we respectfully submit that it is not 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 address the environmental effects of the released substances.

## 9. Use of Resources and Energy

No significant increases are expected in the use of resources and energy consumption as a result of the manufacturing, use, or disposal of the FCS as compared to the manufacture, use, or disposal of alternative food contact can coating substances.

## 10. Mitigation Measures

As described above, 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

No potential adverse effects are identified which would require alternative actions to that proposed in this Notification. The alternative of not approving the proposed action in this FCN would simply result in the continued use of the materials that the subject FCS would replace. Therefore, the proposed use would have no environmental impact and can be considered safe.

## 12. List of Preparers

Ralph Simmons Partner, Steptoe & Johnson LLP

## 13. Certification

The undersigned official certifies that the information provided herein is true, accurate and complete to the best of his knowledge.

September 4, 2012

Ralph Simmons
Partner
Steptoe & Johnson LLP