Environmental Assessment to:

ColorMatrix Group Inc. Food Contact Notification for sodium borohydride used in conjunction with palladium acetate (FCN 1160)

1.	**Date:**	**12th March 2012**
2.	**Name of Applicant/Notifier:**	ColorMatrix Group Inc.
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NON CONFIDENTIAL VERSION

4. Description of the proposed action

a) Requested action

The action requested in this notification is to establish clearance of the food contact substance (FCS) sodium borohydride, used in conjunction with palladium acetate (referred to by the trade name HyGuard™). The sodium borohydride is intended to be incorporated into a layer of polymer within a closure at a use level of up to 12%. This layer within the closure is overmoulded with a layer of inert polymer separating it from the foodstuff. The total weight of borohydride required in a closure is typically 20-60mg. The palladium acetate will be incorporated into a polyethylene terephthalate (PET) bottle (used in conjunction with the closure containing sodium borohydride) at a use level not to exceed 5 ppm (w/w). The finished food contact articles (bottles and closure system combined) are intended for use with food types: I, II, III, IVA, IVB, VIA, VIB, VIC, under conditions of use C through G as described in Tables 1 and 2 on FDA's website: http://www.cfsan.fda.gov/~rdb/opa-fcn3.html.

b) Need of action

The need for the requested notification of the food contact substance sodium borohydride used in conjunction with palladium acetate is for use as an oxygen scavenger. A detailed description of the intended technical effect was included in FCN1114 but is re-attached here for reference (see attachment 12). This FCN is intended to expand the use of FCN 1114 to allow for a thinner functional barrier to be used for the layer separating the sodium borohydride from the food stuff.

c) Locations of use and disposals

The notifier, ColorMatrix Group Inc does not intend to produce finished food packages using the food contact substance, but will supply the palladium acetate and sodium borohydride in a format appropriate for packaging manufacturers. Any additional components will already have food contact clearance for the intended use under either the code of federal regulations or a relevant food contact notification. Therefore it is anticipated that the use and disposal patterns of the PET bottles and closures produced with the FCS 'HyGuard™' will be the same as those for conventional PET bottles used in conjunction with olefin closures.

PET bottles/closure systems containing the HyGuard™ product will be utilized in patterns corresponding to the national population density and will be widely distributed across the United States. It is expected that the disposal of packaging systems containing HyGuard™ will occur nationwide with the material being land disposed, combusted, or recycled.

According to the U.S. Environmental Protection Agency's 2008 Facts and Figures Fact sheet regarding municipal solid waste in the United States (see Attachment 1), 54.2 %

of municipal waste generally was land disposed, 12.6 % was combusted, and 33.2 % was recovered for recycling and composting.

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of other food-contact materials in current use (including conventional PET and conventional polyolefin closures). Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of packaging systems containing HyGuard™.

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

The FCS that is subjected to this notification is

Sodium Borohydride ($Na^+[BH_4]^-$
CAS 16940-66-2
MW: 37.83

Used in conjunction with Acetic acid palladium 2+ salt
CAS 3375-31-5
MW: 224.49

The palladium acetate is reduced to palladium metal during moulding operations. These materials will be used as an oxygen scavenging system.

6. Introduction of the substance into the environment

6 a. Introduction of the FCS into the environment as a result of manufacture

The manufacture of palladium acetate and sodium borohydride is already well established as these chemicals are widely used in a range of other applications across the chemical industry. No additional environmental exposure is expected as a result of orders placed by ColorMatrix for these already readily available chemicals.

6 b. Introduction of the FCS into the environment as a result of use/disposal

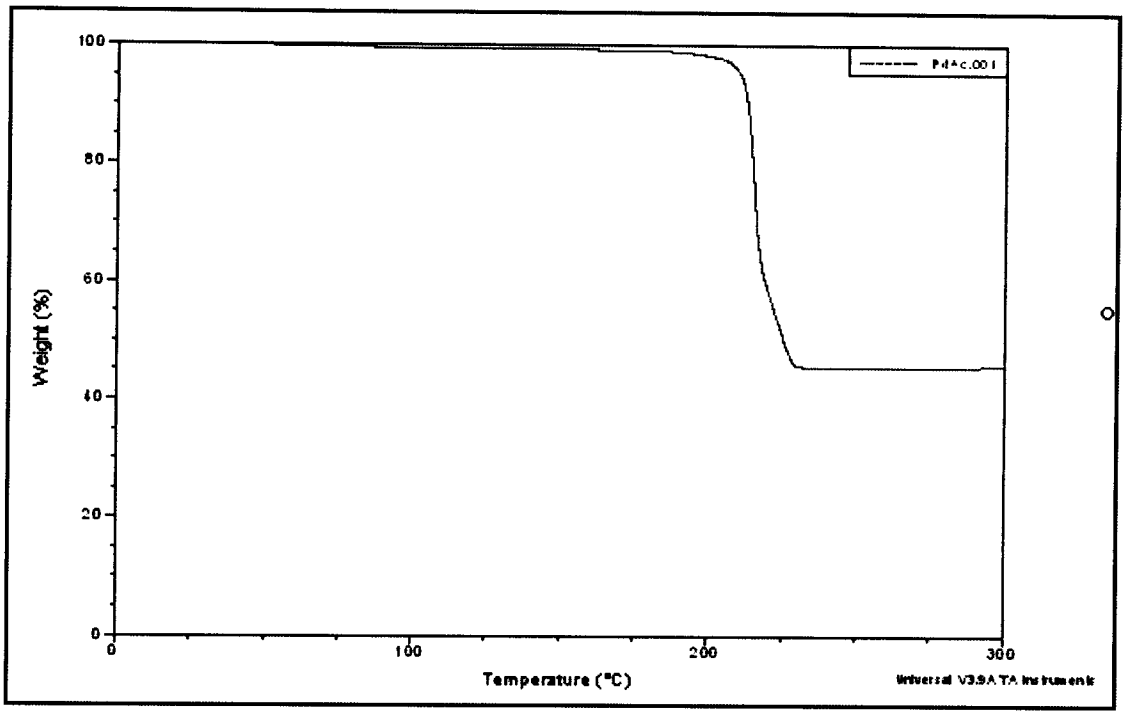
Palladium acetate

The palladium acetate will be added to PET in the same way as other PET additives. This process does not generate significant waste so is not expected to result in environmental exposure. Palladium acetate undergoes thermal decomposition to palladium metal at temperatures greater than 200° C. PET is typically processed at 280°C therefore will be incorporated into the PET as palladium metal. This is discussed further in attachment 47 to the FCN1114.

The TGA in figure 1 (carried out in air at 10°C/minute heating rate) clearly shows that at approximately 200°C a major weight loss even occurs. This is believed to be the reduction of palladium acetate to palladium metal. This conclusion is supported by the fact that the percentage of material remaining on a weight basis is approximately 45%. The theoretical amount that would remain as palladium metal would be 47.4%.

No weight gain is observed on further heating to 300° C, corresponding to the maximum temperature expected in PET melts.

Figure 1: Thermogravimetric analysis of palladium acetate



When the Palladium acetate undergoes this thermal decomposition, there are 2 possible fates for the organic portion. (Gallagher and Gross, Journal of Thermal Analysis Vol 31 (1986) 1231-1241: The Thermal Decomposition of palladium Acetate) and (Jun-Ying Zhang, Hilmar Esrom, Ian W. Boyd, Applied Surface Science 96-98 (19%) 399-404 Decomposition mechanisms of thin palladium acetate film with excimer UV radiation)

1) Formation of acetic acid:. The boiling point of acetic acid is 118°C. It is therefore expected that some of this will volatalise during PET processing as the PET processing temperatures are significantly higher than this. However it is also well know that low boiling point substances (acetaldehyde for example) that are byproducts of PET processing, do remain with the PET, so it is expected that some will remain in the PET, it may also esterify with the PET. Metal catalysts have traditionally been added to PET as the acetate sales, therefore any reaction product formed by reaction of acetic acid with PET is no different to those present in standard PET.
2) Acetate released as the acetoxy radical, which then fragments to carbon dioxide and methane, both of which are widespread in the environment and part of the carbon cycle.

In the processing of palladium acetate the amount of acetic acid, carbon monoxide and methane produced is expected to be insignificant compared to the amounts already present in the environment.

Sodium Borohydride

The sodium borohydride will be incorporated into EVA or SEBS. There may be loss of sodium borohydride from material that is not emptied from bags, or residual material held up in a hopper or transfer line at the end of a run.
Empty packaging shall be disposed of as hazardous chemical waste, in the same manner that any other user of this industrial chemical would do so. The neat chemical sodium borohydride used at the polymer compounding plants is supplied with a material safety data sheet (see Attachment 3). All existing applicable procedures and regulations regarding disposal and transportation shall be followed, taking into account any state variations.

There will be 2 to 3% waste of compounded material resulting from compounding start-up and shut down operations when compounded material is lost and not suitable for packaging. This rate is likely to decrease as the market demand for HyGuard™ increases and machines are running for longer periods with less start up/shut down operations. The compounded material is also classified as a hazardous waste. It contains 8% of sodium borohydride so the hazard is significantly diluted. The hazard classification of polymeric material containing sodium borohydride is discussed in Appendix 1 to this EA.

The compounded sodium borohydride is then sold to closure manufacturers, who will incorporate this material into a central layer in a bottle closure. The amount of sodium borohydride that will result in an end closure will be 20-60mg.
There may also be scrap generated from this process. The scrap rate of closures in a compression moulding process is about 1 or 2%. Standard closure production is a 2 step process. Using HyGuard™ we anticipate the overall scrap rate to be 2 to 3% for HyGuard™ closures.

Due to the low (on a weight for weight basis) level the sodium borohydride is present in these closures, this scrap is no longer classified as hazardous waste (see Appendix 1).

Despite these scrap levels, these should not result in environmental exposure at this stage of the supply chains as such materials tend to be sold on within the plastics industry for use in further moulding operations for less sensitive (i.e. non food contact) applications. Hence end environmental exposure is still only relevant to disposal of any final resulting article.

Other commercially available oxygen scavenging products (for example Amosorb) produce around a 10% scrap rate (compared to the 2-3% expected from HyGuard™). In addition, as the alternative oxygen scavenging components are used in the PET, a larger quantity is usually required to achieve the same intended technical effect.

In addition to closure scrap during bottle production, we should also consider bottle scrap. Scrap generation when bottles are made is higher with oxygen scavenging systems added to PET than what we expect with HyGuard™. For example, scrap can be on the order of 3 to 5% for Amosorb, but should only be about 0.5% for HyGuard™. A comparison of HyGuard™ to alternatives is shown in Table 1.

Table 1: Comparison of use rates and scrap rates for HyGuard™ vs. alternatives

	HyGuard™	Amosorb™	No oxygen scavenger
Component	Sodium borohydride	Polymeric material	-
Location of active component	Layer within closure	PET bottle wall	-
Use rate	8% within closure layer	2% in PET bottle wall	-
Approx PET container weight (please note HyGuard™ allows light-weighting – see section 9 for further discussion)	26g	35g	35g
Typical Closure weight	4g	4g	4g
Scrap rate during PET compounding	n/a	10%	n/a
Scrap rate during polyolefin compounding	2-3%	n/a	n/a
Total package weight	30g	39g	39g
Total weight of active compound in package	0.3 -0.7g	0.7g	-
PET bottle scrap rate	0.5%	3-5%	0.5%
Olefin closure scrap rate (material is sold on for reuse)	2-3%	1-2%	1-2%
Max weight of scrap material from closure and bottle production expressed as g per container	(26g x 0.5%) + 4g x 3%) = 0.13g + 0.12g = **0.25g**	(35g x 5%) + (4g x 2%) = 1.75 + 0.08 = **1.83g**	(35g x 0.5%) + 4g x 2%) = 0.175g + 0.08 = **0.225g**

During the manufacture of closures, closure moulding facilities will handle compounded polymer containing 8% sodium borohydride. Scrap closures will be ground before being sold on. It is estimated that 99.5% of this material is sold on for reuse, only the floor sweepings will go to landfill. Such grinding operations may generate dust. At one of these facilities dust monitoring has been carried out to assess the level of exposure to workers from this operation. A table of the dust exposure limits obtained can be found in Attachment 4. Employee exposures were well under the permissible exposure limit of 15mg/m3. Hence employee exposures to total dust are well within the allowable OSHA limits.

In conclusion, no significant environmental release of either palladium acetate or sodium borohydride is expected during the manufacture of the FCS and during the production process of packaging articles containing the 2 materials. In addition, information available to the notifier does not suggest that there are any extraordinary circumstances in this case that indicate any adverse environmental impact as a result of the manufacture of the FCS and of its use in the production of PET bottles/polyolefin closure packaging systems.

Any scrap generated during the above mentioned manufacturing steps will be disposed of or reused as per usual industrial practices.

Therefore this environmental assessment of HyGuard™ packaging systems will focus on the relevant issues relating to the use and disposal of FDA-regulated articles as described under 21 CFR 25.40 (a).

It is believed that the introduction of HyGuard™ into the environment occurs in general as a result of the disposal of packaging systems that are formulated with this FCS. PET bottles/closures manufactured with the FCS are expected to be disposed of in patterns similar to conventional bottles/closures.

Palladium acetate resulting from HyGuard™ packaging

No environmental release is expected from the use of palladium acetate in polyethylene terephthalate (PET) bottles. In this application the palladium acetate is entirely homogenously incorporated in resin and furthermore is used at very low levels (5ppm). Therefore any waste material generated in the process of the polymerisation of PET and of the bottle blowing, e.g. plant scraps, are expected to be disposed as part of the bottle manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The palladium is immobilized in the polymer matrix and therefore it can not be released upon the use of food-contact articles manufactured with this FCS. Consequently the palladium acetate will remain with the food packaging throughout the use of the package by consumers. Given the PET bottle scrap rate shown in Table 1 of 0.5%, more than 99% of the Pd is expected to remain with the food contact packaging.

Containers containing up to 5ppm palladium acetate are expected to be disposed in patterns similar to the current disposal of conventional PET bottles systems. As PET bottles formulated with palladium acetate and conventional PET bottles are chemically identical with regard to the polymer resin, it is anticipated that PET bottles formulated with palladium acetate will bear the resin identification code used for PET and are expected to be disposed of similarly to conventional PET. Following established disposal patterns the disposal of PET bottles (either conventional or containing the additive palladium acetate) by the ultimate consumer will be by

conventional rubbish disposal including sanitary landfill and incineration. Containers will enter the recycling process as well.

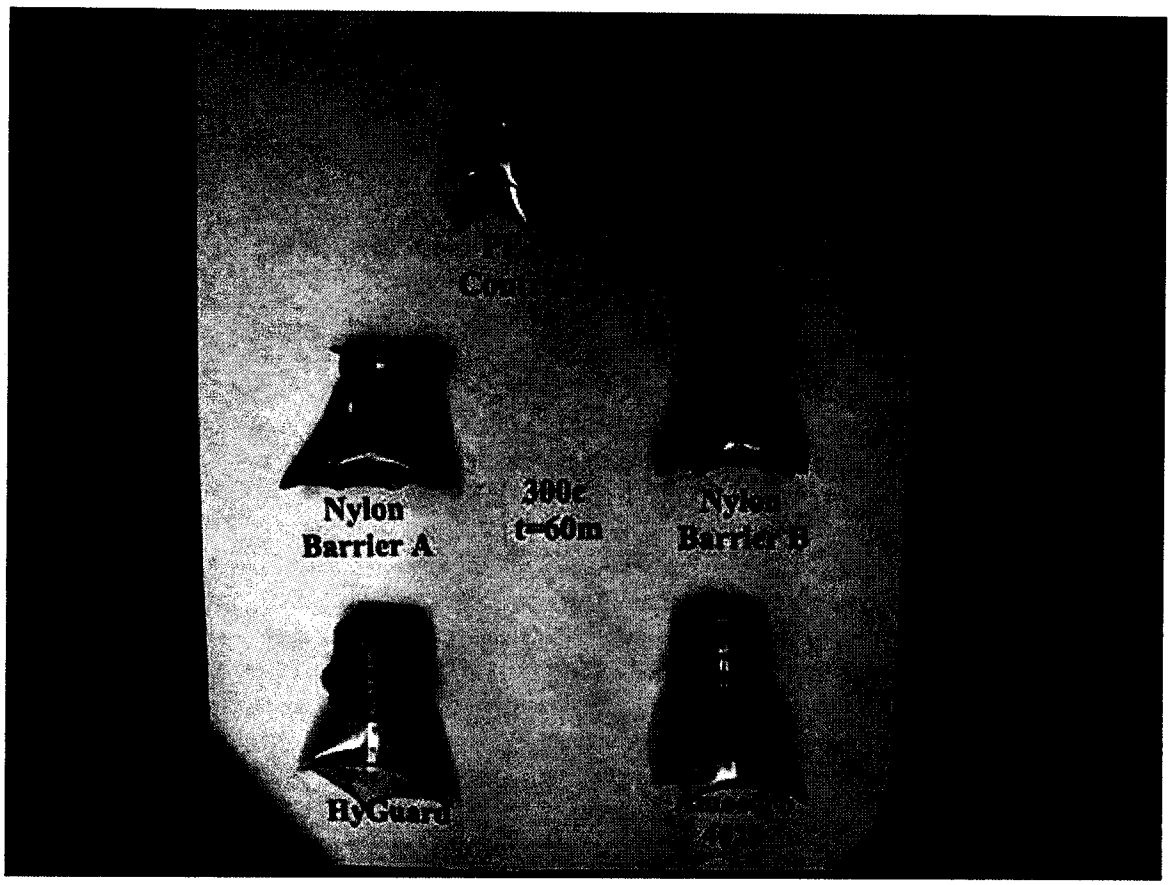
Based on data from the U.S. Environmental Protection Agency: Municipal Solid Waste Generation, Recycling, and Disposal in the United States Detailed Tables and Figures for 2008 (attachment 2), an overall amount of 2680 thousand tons of PET waste was generated from the use of bottles and jars in the year 2008. 730 thousand tons corresponding 27.2 % of these PET bottles disposed in the U.S. were subjected to recycling, while 1950 thousand tons of PET (72.8 %) was discarded.

In accordance with usual solid waste disposal pattern about 80 % of the solid waste that is not recycled or composted will be disposed of by means of landfill and about 20 % will be incinerated. The use of HyGuard™ as an oxygen scavenging system is not expected to have an impact on this figure. In fact the use of HyGuard™ in PET can actually improve the recyclability of PET by reducing the number of containers utilizing conventional recycling-unfriendly oxygen scavengers.

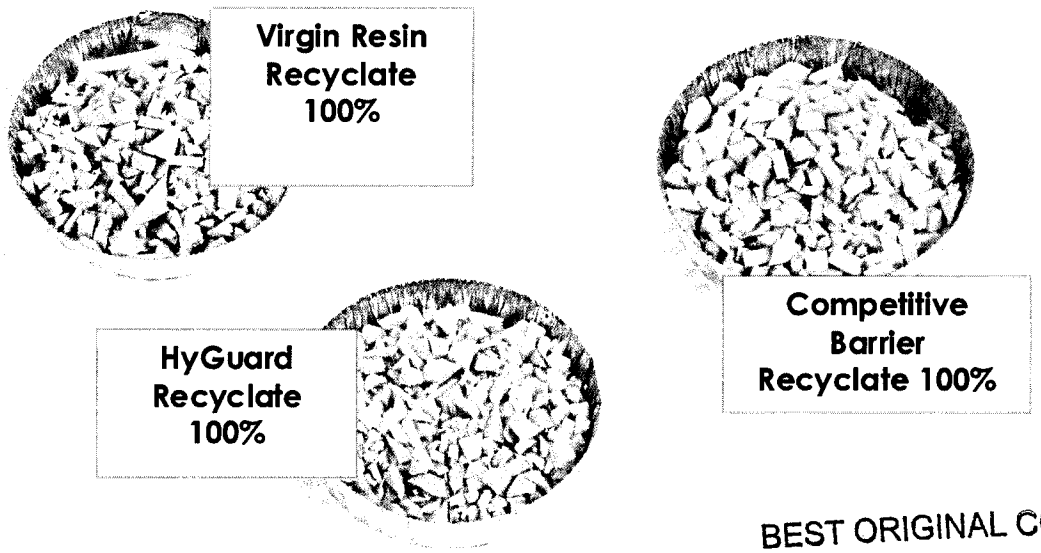
Alternative oxygen scavenging technologies require addition of oxidisable organic materials to the PET bottle wall. During recycling process, these organic species oxidise, resulting in yellow coloration. The mechanisms by which these oxygen scavengers work involve the generation of free radicals. These free radicals cause oxidation of the PET which leads to yellowing. In addition these alternative scavengers tend to increase the haze of PET.

Picture 1 shows PET bottles containing HyGuard™, three different conventional oxygen scavengers, and a PET control for comparison. All bottles were heated to 300 deg F for 60 minutes to represent typical drying conditions for recycled PET. Picture 2 shows crystallized PET flake containing a conventional oxygen scavenger, HyGuard™ or no scavenger (the control).

Picture 1: PET bottles containing HyGuard™, three different conventional oxygen scavengers, and a PET control for comparison



Picture 2: crystallized PET flake containing a conventional oxygen scavenger, HyGuard™ or no scavenger (the control)



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The impact of HyGuard™ on recycle performance of PET bottles has been evaluated according to APR protocols and not deemed to present any problems.

Once PET bottles or closures containing the additive palladium acetate are disposed of via sanitary landfills, no significant leaching of palladium into the environment is expected to take place. This assessment is based upon the fact that the additive palladium acetate is entirely homogenously incorporated in the polymer resin (as palladium). Due to its chemical inertness, insolubility in water, ethanol and acids and due to the diffusion characteristics of the polymer, the palladium is immobilized in the polymer matrix and therefore will not be released in significant quantities. This conclusion was confirmed by the results of the migration testing under exaggerated exposure conditions using 95 % ethanol as an extraction simulant. Leaching / migration of palladium from PET bottles was not observed at a detection limit of 0.5 ppb (0.5 µg/kg).

The organic portion of the palladium acetate may also remain in the PET (as acetic acid). To evaluate the presence of low volatility compounds with the potential to migrate, a screening exercise was carried out using headspace GC-MS (Attachment 13, Confidential). PET bottles manufactured with palladium acetate were analysed alongside PET bottles made with no palladium acetate. This screening exercise shows that acetic acid is a substance that is typically detected in PET. In addition, no additional peaks were seen in the bottle manufactured with Palladium acetate when compared to the bottle containing no palladium acetate. Furthermore the bottles were subject to an extraction in Dichloromethane, and again no additional peaks were detected that could be attributed to the organic portion of the palladium acetate. It is expected that some of the organic portion will volatilise during manufacture of the PET preforms and that some will remain in the PET. However, any material that does remain with the PET in the form of acetic acid will remain in the polymer matrix and is not expected to migrate. In addition the levels are insignificant compared to levels of acetic acid that may be present in the environment from other sources (for example disposal via landfill of other food packaging contaminated with acetic acid from the foodstuff).

Considering this lack of leaching of palladium or acetic acid from packaging even under conditions that exaggerate environmental conditions, it is concluded that there will be no environmental impact of palladium acetate due to leaching. Thus, it is expected that the FCS will not threaten a violation of EPA's regulations in 40 CFR Part 258 that pertain to landfills.

When incinerated, there are not expected to be any toxic combustion products originating from the palladium acetate. In the event of PET incineration, any palladium released will not vaporize (see Attachment 7). Palladium is in the same group in the periodic table as nickel so would be expected to behave in the same manner. Any palladium will most likely be trapped in the fly ash precipitators and/or scrubber system. To the extent palladium is released into the environment, the amount will orders of magnitude less than that released from automobiles in the form of emissions from catalytic converters (see attachment 9, WHO Environmental Health

Criteria 226 Palladium). With Regards to the organic portion, given that acetic acid is already detected in PET, incineration of bottles will not lead to any compounds not generated by incineration of standard PET or PET manufactured utilizing other acetate based catalysts.

Therefore we do not expect the palladium portion of the FCS to cause municipal waste combustors to threaten a violation of applicable emission laws and regulations, e.g. 40 CFR part 60 and/or relevant state and local laws.

Taking the fact into account that the palladium acetate does not leach significantly from the PET bottles, that no toxic thermal decomposition products are being formed during incineration and that only extremely small quantities of the material may enter the waste stream at the production site, it can be concluded that the use and disposal of palladium acetate used as additive for PET bottles closures does not adversely effect the environment.

Sodium borohydride resulting from HyGuard™ packaging

Limited environmental release is expected from the use of sodium borohydride at a level up to 55mg in polyolefin closures. The sodium borohydride is immobilized in the polymer matrix and held behind a functional barrier. Consequently the sodium borohydride will remain with the food packaging throughout the use of the package by consumers.

Closures containing the sodium borohydride portion of the HyGuard™ technology are expected to be disposed in patterns similar to the current disposal of conventional polyolefin closures. As closures formulated with HyGuard™ and conventional closures are chemically identical with regard to the polymer resin, it is anticipated that HyGuard™ closures will bear the same resin identification codes as the equivalent standard closures and are hence disposed of in the same manner by conventional rubbish disposal such as sanitary landfill, recycling and incineration. The impact on each of these processes is discussed further below.

Based on data from the U.S. Environmental Protection Agency: Municipal Solid Waste Generation, Recycling, and Disposal in the United States, Detailed Tables and Figures for 2008, an overall amount of 750 thousand tons of HDPE waste was generated from their use as containers. In 2008, 220 thousand tons corresponding 29.3 % of were subjected to the recycling process, while 530 thousand tons of HDPE (70.7%) was discarded.

In accordance with usual solid waste disposal pattern about 80 % of the solid waste that is not recycled or composted will be disposed of by means of landfill and about 20 % will be incinerated. The use of HyGuard™ as an oxygen scavenging system is not expected to have an impact on this figure.

Once closures containing the additive sodium borohydride are disposed of via sanitary landfills, no significant leaching of sodium borohydride into the environment is

expected to take place. This assessment is based on the fact that the additive is incorporated in the polymer resin within a central layer of a closure. Migration testing under exaggerated exposure conditions using 95 % ethanol as an extraction simulant show typical migration values in the range 10ppb (as boron). Considering this lack of leaching of boron from packaging even under conditions that exaggerate environmental conditions, it is concluded that there will be no environmental impact of boron due to leaching. Thus, it is expected that the FCS will not threaten a violation of EPA's regulations in 40 CFR Part 258 that pertain to landfills.

When incinerated, caps/closures containing sodium borohydride will result in the formation of borate compounds. Borates (such as borax) are commonly used as a flux for welding where it forms non-volatile metal borates. It is also a glass former, and as such would be expected to react with silicates and aluminates in the ash to form non-volatile borosilicate or boroaluminate ash. Hence no volatile materials are expected to be generated as a result of incineration.

Therefore we do not expect the sodium borohydride portion of the FCS to cause municipal waste combustors to threaten a violation of applicable emission laws and regulations, e.g. 40 CFR part 60 and/or relevant state and local laws.

During recycling, HyGuard™ caps/closures will remain with other caps as float material (in the sink/float process). Following this step the flaked closures that enter the caustic wash process will be exposed to hot alkaline water and detergents. Any exposed borohydride entering the caustic wash will be converted into soluble borate salts. Borates such as borax are already used as water softening chemicals for laundering applications, so no adverse effects are expected. The amount of boron entering the water stream from the sink/float or the caustic wash process is expected to be less than 1 ppm. Furthermore it is expected that the recycling plants have procedures in place for managing control of the caustic wash solution to ensure no negative environmental impact.

Taking the fact into account that the sodium borohydride does not leach significantly from olefin closures, that no volatile thermal decomposition products are being formed during incineration and that only small quantities of the material may enter the waste stream at the production site, it can be concluded that the use and disposal of sodium borohydride used as additive for polyolefin closures does not adversely effect the environment.

7. Fate of Emitted Substances in the Environment

As discussed above, considering the application, use and disposal of the FCS and the respective food-contact articles, the materials are not expected to be released into the environment in significant quantities. No environmental fate data is therefore included.

The Pd is present in its ionic form as Pd^{2+} in the palladium acetate which is reduced to Pd^0 during the melt processing operation. This is because palladium in a +2 oxidation state (such as in palladium acetate) is thermodynamically unstable with respect to reduction to Pd^0, with a ΔG_{298} of reaction of –43.86 kcal/mole. Kinetically, palladium acetate reduces rapidly at temperatures greater than about 80 deg C; therefore, melt processing of palladium acetate results in complete reduction to Pd^0.

Please consult Attachment 8 for detailed discussion of reaction chemistry including hydrolysis products.

Sodium borohydride is not considered hazardous to the environment. Please see Appendix 1 and 2 for details on hazard classification (including environmental hazard – if any, for both palladium acetate and sodium borohydride)

8. Environmental effects of released substance

No information need to be provided on the environmental effects of substances released into the environment as a result of the use and disposal of food-contact articles containing the FCS in landfills and by combustion, because, as discussed above, the FCS is not expected to be introduced into the environment. Therefore, the use and disposal of the food-contact articles in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR Parts 60 and 258.

However some relevant information is given for the 2 compounds:

Palladium

The information in this section has been extracted from attachment 9: WHO (2002) Environmental Health Criteria 226: Palladium. World Health Organization, Geneva, 222 pp

For palladium compounds from environmental toxicity endpoints are tabulated below:

Table 3: Some Pd environmental toxicity values

Tetraammine palladium hydrogen carbonate	72-h EC50 value of 0.066 mg/litre (corresponding to 0.02 mg palladium/litre)	cell multiplication inhibition test with *Scenedesmus subspicatus*
	48-h EC50 of 0.22 mg/litre (0.08 mg palladium/litre	immobilization of *Daphnia magna*
	96-h LC50 of 0.53 mg/litre (0.19 mg palladium/litre	acute toxicity to rainbow trout *Oncorhynchus mykiss*

	0.04 mg/litre (0.014 mg palladium/litre) (algae),	No-observed-effect concentrations (NOECs) for algae
	0.10 mg/litre (0.05 mg palladium/litre)	The no-observed-effect concentrations (NOECs) for *Daphnia magna*
	and 0.32 mg/litre (0.11 mg palladium/litre)	The no-observed-effect concentrations (NOECs) for fish
Palladium(II) chloride	3 mg/litre (1.8 mg palladium/litre)	Phytotoxic effects observed in terrestrial plants
	0.22 mg palladium (II) chloride/litre (0.132 mg palladium/litre).	growth retardation and stunting of the roots occurred in several crop plants, the most sensitive being oats

The lowest of these values is 0.014mgPd/L. Palladium acetate is classified as hazardous for the environment. The lowest EC50 value given on the supplier MSDS is 0.02mg/L. Given that no detectable migration was detected from HyGuard™ systems with a LOD of 0.5ppb, there will be no exposure at any level that will present any environmental concern. In addition the palladium acetate is used in ColorMatrix formulations (i.e. palladium acetate dispersed in carrier oil) at less than 1%, and furthermore the amount of palladium acetate, in the form of insoluble palladium metal, in the HyGuard™ packaging system will be less 5ppm maximum. Hence the products offered for sale will not be classified as hazardous for the environment (please see Attachment 5 for supplier MSDS and Appendix 2 to this document for discussion of palladium acetate hazards as relevant in HyGuard™ products)

Palladium is already present in the environment, and the use of HyGuard™ will not have a significant impact on these levels. For example, palladium is present as dust near heavy traffic areas from catalytic converter at levels between 50-290 µg/kg). It is also found in soil near heavy traffic areas at levels of up to 47µg/kg. The use of HyGuard™ will not significantly increase the amount of palladium already present in the environment.

With regard to the organic portion; acetic acid is not highly toxic to aquatic plant and animal species and does not present an environmental concern (U.S. HIGH PRODUCTION VOLUME (HPV) CHEMICAL CHALLENGE PROGRAM ASSESSMENT PLAN For ACETIC ACID AND SALTS CATEGORY (June 28 2001)

Boron (from sodium borohydride):

The information in this section has been extracted from attachment 11: EPA Health Effects support document, January 2008, 136 pp

Borax (hydrous or anhydrous) and boric acid are widely used for a wide range of industrial purposes:

- manufacture of porcelain enamel,
- ceramic glazes,
- glass,
- fiberglass
- metal alloys/soldering metals,
- fire retardants,
- laundry additives,
- herbicides,
- fungicides,
- fertilizers,
- antiseptics,
- detergents,
- astringents,
- antifreeze,
- industrial water algaecide,
- corrosion inhibitor, emulsifying agent in cosmetics,
- printing, dyeing, painting, leather making,
- soap manufacture,
- paper products for food packaging,
- adhesives, and
- coatings e.g. constituent of insect baits, repellants, and poisons.

The principal uses for boron compounds in the United States in 2001 were estimated as follows: 78% glass and ceramics; 6% soaps and detergents; 3% agriculture; 4% flame retardants; and 9% as other boron compounds.

In addition, boron is also already present in the environment. Natural weathering of boron-containing rocks is thought to be the primary source of boron compounds in water and soil. Releases to air from oceans, volcanoes, and geothermal steam are other natural sources of boron in the environment. Global releases of elemental boron through weathering, volcanic, and geothermal processes are estimated at approximately 360,000 metric tons annually.

Human causes of boron contamination include releases to air from power plants, chemical plants, and manufacturing facilities. Fertilizers, herbicides, and industrial wastes are among the sources of soil contamination. Contamination of water can come directly from industrial wastewater and municipal sewage, as well as indirectly from air deposition and soil runoff. Borates in detergents, soaps, and personal care products can also contribute to the presence of boron in water.

Boric acid and its sodium salts are registered for use as pesticides. Data from the U.S. Bureau of Mines, cited in the U.S. EPA's 1994 re-registration eligibility document for boron pesticides, suggests that approximately 293,000 pounds of boron minerals were used annually for "agricultural purposes" during a period around 1990.

Anthropogenic (man made) sources of boron are considered to contribute a lesser amount to the environment than natural processes. Borax may be persistent for one or more years, depending on soil type and rainfall. Borax is less persistent in acidic soils and in high rainfall areas, with it leaching rapidly under high rainfall conditions. Boron is thought to accumulate in plants. Boron content of lentil and barley plants from soil treated with 8 ppm boron was approximately 7- and 8-fold that of control plants, respectively.

The use of HyGuard™ is not expected to result in an increase in the amount of boron present in the environment due to lack of release via the disposal mechanisms discussed. Any small quantities of environmental release that may result are deemed insignificant in the context of all the other routes of boron in the environment detailed above.

9. Use of resources and energy

HyGuard™ technology will compete with other available oxygen scavenging technologies. It will also allow oxygen scavenging technology to be developed for new applications where use of existing commercially available oxygen scavenging materials was not previously possible.

The vast majority of existing commercially available oxygen scavengers for PET packaging systems utilise an organic oxidisable species in the PET bottle wall, which oxidises via a free radical mechanism. There are limitations to this technology.

For these conventional scavengers, reaction with oxygen begins as soon as the packages are formed. Therefore, the additive is consumed while the bottles are in warehouse storage before filling. If manufactured packages are not used within a specified time they will have to be disposed of. HyGuard™ technology requires the 2 components to be together in order for the oxygen scavenging mechanism to start (i.e. the palladium in the PET bottle wall alongside the sodium borohydride in the closure). Therefore the preforms and closures do not have a finite shelf life before they must be used. They can be stored in a wide range of warehouse conditions with no loss of efficacy.

In addition, a major attraction of HyGuard™ is the ability to light-weight. Specifically, with other scavenging technologies the scavenger source is in the bottle sidewall. Consequently, light-weighting not only increases the oxygen ingress rate, but also decreases the amount of scavenger available. It is not usually possible to simply increase the amount of oxygen scavenger in the bottle wall as this has a detrimental effect on the bottle aesthetics. Hence for existing commercially available oxygen scavengers light-weighting opportunities are limited. In contrast, with HyGuard™ the main active component is in the closure and not in the bottle wall and so light-weighting the bottle does not reduce the oxygen scavenging potential. In addition, since we are only putting ppm levels of Pd in the bottle sidewall (vs. wt% levels with other scavengers) there is no impact of HyGuard™ on recycling (see previous

discussion on recyclability) thus, as PET packaging users switch to HyGuard™ the quality of the recycle stream will improve.

As indicated in table 1 the typical weight of a standard PET bottle (or bottle containing a competing scavenging technology) is 35g. With HyGuard™ technology it is possible to reduce this to 26g (a 25% reduction in weight). Obviously such light-weighting has a positive impact on resources used as less raw materials are required. Light-weighting will also help to lower carbon footprint by reducing resources associated with manufacture and transportation.

HyGuard™ offers improved barrier performance over existing technologies and as a result it can also be used to replace glass and metal in some applications. Typically glass and metal offer better oxygen barrier than PET and there are some applications where the oxygen scavenging that is achievable in PET is simply not adequate in comparison to the barrier offered by glass. For example the maximum shelf life that is targeted with PET packaging is 6-9 months. However as HyGuard™ offers improved oxygen scavenging capabilities, it can be used in even the most sensitive applications and by selecting an appropriate level of sodium borohydride, it offers a shelf life of up to 2 years.

Again this helps to significantly reduce resources, for example in a wine application, 75 cL glass bottle weighs around 400 g; the same size in PET weighs 54 g, one-eighth of the weight. This weight reduction makes transport more efficient and helps to reduce the carbon footprint.

Glass bottles are made, and shipped (as the bottle) to the filling plant. PET bottles are made into preforms, and the preforms are transported to the bottling plant for filling. Preforms are significantly smaller than bottles, reducing resources required for transportation as many more PET preforms can be transferred to a filling plant in one single trip that glass bottles in the equivalent transport unit. In addition, losses due to breakage are non-existent for PET.

Existing barrier technology is limited by aesthetics. It is not possible to simply add more oxygen scavenger to achieve the desired shelf life as this can have a significant effect on bottle aesthetics (i.e. reduced clarity and increased yellowing). However as the active component in HyGuard™ is used in the closure of a PET bottle, it is possible to increase the active content to target a particular shelf life without detrimental effects on the bottle aesthetics. This can result in longer shelf life products and hence less potential for spoilage/waste.

The resources/energy to produce a package utilizing HyGuard™ will at most be the same as a conventional package, and in many cases will be substantially less because of the light-weighting opportunities offered by HyGuard™.

There is an extra step in putting the HyGuard™ layer in the closure (see section 6) however, the energy/resources required for these steps are minimal compared to the resources required to make caps or bottles.

Therefore the replacement of other additives or other packaging types by HyGuard™ technology is not expected to have any adverse effect on the use of natural resources and energy in the production of packaging systems, and most likely will offer significant improvements.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use of HyGuard™ packaging and from the disposal of such systems. This is primarily due to the non-leaching properties of the components with respect to landfill, the formation of no toxic combustion products and the non-adverse impact on the use of resources and energy compared to conventional PET. Thus, the use of HyGuard™ as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measurements of any kind.

11. Alternatives to the proposed action

No potential adverse effects have been identified that would require any alternative actions to those proposed in this notification. Non-approval of the proposed action would result in the continued use of alternative oxygen scavenging additives in PET for achieving the intended technical effect or PET bottles would continue to be produced without the benefit of such an additive, respectively. Alternatively glass or metal packaging will be used.

Considering the fact that the substances palladium acetate or sodium borohydride are not expected to enter the environment in significant quantities upon the use and disposal of PET bottles and/or closures and the absence of any significant environmental impact which would result from their use, the establishment of an effective Food Contact Notification to permit the use of "HyGuard™" as additive in packaging systems is safe from an environmental perspective.

12. List of preparers

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13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of her knowledge.

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Victoria Sayer

Regulatory Manager

ColorMatrix Group Inc

Date: 12th March 2012

14. References

Sekine et al, Release behaviour of trace elements from coal during high temperature processing; Powder technology, 180 (2008) 210-215

WHO (2002) Environmental Health Criteria 226: Palladium. World Health Organization, Geneva, 222 pp

EPA Health Effects support document, January 2008, 136 pp (Attachment 11)

EPA Drinking water health advisory for boron, May 2008, 65pp (Attachment 10)

U.S. Environmental Protection Agency's 2008 Facts and Figures Fact sheet regarding municipal solid waste in the United States (attachment 1)

U.S. Environmental Protection Agency: Municipal Solid Waste Generation, Recycling, and Disposal in the United States, Detailed Tables and Figures for 2008 (attachment 2)

Gallagher and Gross, Journal of Thermal Analysis Vol 31 (1986) 1231-1241: The Thermal Decomposition of palladium Acetate

Jun-Ying Zhang, Hilmar Esrom, Ian W. Boyd, Applied Surface Science 96-98 (19%) 399-404 Decomposition mechanisms of thin palladium acetate film with excimer UV radiation

U.S. HIGH PRODUCTION VOLUME (HPV) CHEMICAL CHALLENGE PROGRAM ASSESSMENT PLAN For ACETIC ACID AND SALTS CATEGORY (June 28 2001)

15. Attachments

Attachment 1: U.S. Environmental Protection Agency's 2008 Facts and Figures Fact sheet regarding municipal solid waste in the United States

Attachment 2: U.S. Environmental Protection Agency: Municipal Solid Waste Generation, Recycling, and Disposal in the United States, Detailed Tables and Figures for 2008

Attachment 3: Sodium borohydride Material Safety Data Sheet (MSDS)

Attachment 5: Palladium acetate Material Safety Data Sheet (MSDS)

Attachment 7: Sekine et al, Release behaviour of trace elements from coal during high temperature processing; Powder technology, 180 (2008) 210-215

Attachment 8: Sodium borohydride chemical properties

Attachment 9:, WHO Environmental Health Criteria 226 Palladium).

Attachment 10: EPA Drinking water health advisory for boron, May 2008, 65pp

Attachment 11: EPA Health Effects support document, January 2008, 136 pp,

16. Confidential Attachments

Attachment 4: Dust monitoring results

Attachment 6: PCI recycle report

Attachment 12: Intended Technical Effect

Attachment 13: Screening of bottles containing Palladium acetate (Fraunhofer report)

Attachment 14: Confidential version of Environmental assessment

Appendix 1: Hazard Classification of sodium borohydride in HyGuard™ products

Sodium borohydride: Physical hazards

In its neat form sodium borohydride generates hydrogen gas when it comes into contact with water. Sodium borohydride is therefore classified as highly flammable and is hazardous for transportation.

However, for HyGuard™ applications the sodium borohydride is encapsulated within a polymer matrix and the bulk of the sodium borohydride is not readily accessible to reactive species such as moisture. On a weight for weight basis, the sodium borohydride content is significantly diluted therefore; the rate of gas generation is considerably reduced with respect to the neat form.

Once the compound has been moulded into a finished article (for example a closure or liner) the change in available surface area results in a much slower rate of hydrogen gas generation. The rate of gas generation from moulded constructions is very slow and not at any level that would trigger classifications in either Europe or the US. Hence, for final articles containing HyGuard™ compounds, no specialist packaging or shipping is required.

	Rate of Gas Evolution	**Hazard rating**
Sodium borohydride	> 10 L per kg per minute	Transport hazard - packing group 1
HyGuard™ polymer (8% NaBH4)	1-10 L per kg per hour	Transport hazard - packing group 3
HyGuard™ formed article	< 1L per kg per hour	Not classified as hazardous for transport

Sodium borohydride: Human Health Hazards

Sodium borohydride in its neat form is classified as:

- Toxic in contact with skin and if swallowed.
- Corrosive; causes burns.

The classification of HyGuard™ products is indicated in the table below:

	Corrosivity	**Toxicity***
Sodium borohydride	Corrosive – causes burns	Toxic in contact with skin and if swallowed. LD50: 50 mg/kg (oral), 230mg/kg (skin)
HyGuard ™ polymer (8% NaBH4)	Irritant (contains 5-10% corrosive material). *(However, when compound submerged in water, solution*	By dilution calculation: LD50: 625 mg/kg (oral), 2875 mg/kg (skin) Therefore classified as harmful if

	does not reach a pH exceeding 11.5 as required for corrosivity classification according to EU legislation)	swallowed.
HyGuard™ formed article (e.g. multilayer film containing 8% active in an PE layer)	NOT CLASSIFIED. Will contain <1% sodium borohydride by weight.	By dilution calculation: LD50: 6250 mg/kg (oral), 23000mg/kg (skin) Therefore NOT CLASSIFIED.

- Cut off LD 50 value for non-classification is 2000 mg/kg. Dilution calculations carried out to standard industry practice.

In the United States, moulded articles containing HyGuard™ are considered non-hazardous. The materials are not listed wastes (on F, K, U or P lists) and do not meet the criteria for ignitability, corrosivity, reactivity or toxicity.

HyGuard™ compound and process waste should be treated as hazardous waste (due to corrosivity and reactivity). ColorMatrix customers are provided with an appropriate Material Safety Data Sheet and advised to contact a specialist waste contractor to ensure proper disposal.

Appendix 2: Hazard Classification of palladium acetate in HyGuard™ products

In its neat form palladium acetate is classified as:

- Harmful if swallowed.
- May cause sensitisation by skin contact.
- Risk of serious damage to eyes.
- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Under the new Globally Harmonised System of Classification and labeling (GHS) this translates to:

- Acute toxicity: Cat. 4 (oral)
- Serious eye damage/eye irritation: Cat. 1
- Skin sensitizer: Cat. 1
- Acute hazards to the aquatic environment: Cat. 1
- Chronic hazards to the aquatic environment: Cat. 1

Palladium acetate is also classified as hazardous for transport under UN number 3077 (Environmental Hazard).

The resulting ColorMatrix products are ***NOT*** classified as hazardous, due to dilution effects.

This classification is based on the cut off of 1% in the US OSHA regulations for substances in mixtures (29 CFR 1910.1200), and the percentage limits for each risk phrase given in the European Dangerous Preparations directive. (1999/45/EC) as indicated in the table below:

Hazard classification	**European dangerous preparations directive, cut off for classification**	**Status in ColorMatrix products**
Harmful if swallowed	25%	**< 1% NOT CLASSIFIED**
May cause sensitisation by skin contact	1%	**< 1% NOT CLASSIFIED**
Risk of serious damage to eyes	5%	**< 1% NOT CLASSIFIED**
Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	2.5% (for a toxic classification). At 0.25% – 2.5% classified as harmful but no labelling or specialist shipping requirements	In final article **<1% NOT CLASSIFIED.**