AKZO NOBEL

Environmental Assessment

1) Date: April 26, 2006

2) Submitter: Eka Chemicals Inc.,
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4) Description of Proposed Action

a. **Requested action:** To allow the use of the Food Contact Substance (FCS) hydrotalcite as a production aid in the manufacture of polymer coated paper board that will hold liquid foods (food types I, II and IV) at refrigerator temperatures.

The FCS will be added at the wet-end of the paper making process at a level of 1-2 kg FCS per active ton of dry paperboard based on the weight of the final paperboard, or up to 0.2% based on the dry weight of the paper board. Based on data provided in the Food Contact Notification (FCN), it is estimated that 68% of the added FCS will remain bound within the final (coated) paperboard after a single pass through the system. The remaining 32% of the FCS will be disposed of with the white liquor at the paper board mill.

b. **Need for Action:** The use of the FCS will enhance the paper making process by adsorbing to and precipitating out negatively charged components (anionic trash) in pulp suspensions that can have a detrimental effect on the paper making process. If not removed, these unwanted, negatively charged components can clog paper making machines, break the paper web, etc…

c. **Locations of use /disposal:** The FCS will be manufactured in Europe. The FCS will be imported into the United States by Eka. The European site is a chemical complex located within an urban setting. All wastes generated in the production of the FCS are collected and are treated in accordance with all local, national and EU requirements. Because there will be no manufacturing of the FCS in the United State, there will be no U.S. occupational exposure or environmental release as a result of production of the FCS.

The FCS will be sold to paper board mills for use in the paper board making process within the mills. Initial commercial interest in the FCS has developed in Europe. One customer has been identified in Sweden as having a significant interest, but as yet there are no such customers identified in the United States. A market projection for the U.S. has not been done.

With respect to customer use of the FCS at paper board mills, it is expected that occupational exposure to the FCS will be minimal. During the normal operation of the paper board machines there is little need for direct human involvement of mill workers. Potential Inhalation or dermal exposure to the FCS should be minimal when the recommendations for use of personal protective equipment are followed. The oral route of occupational exposure is generally not considered a major route of potential occupation exposure.

With respect to environmental release from customer mills, the primary route of disposal is expected to be through water discharge to wastewater treatment plants as a result of removal of the FCS-containing white water from the paper board making process.

With respect to disposal of FCS-containing coated paper board, it is expected that waste food packaging will be disposed of in landfills or through incineration. The FCS would be expected to be bound within the waste packaging especially because food packaging for liquid foods would be coated on both sides, further inhibiting migration of the FCS from the packaging in landfills. In any event, if released in low concentrations from landfills the FCS would be expected to act similarly to naturally occurring hydrotalcites already present in the environment.

5) Identification of the substance that is the subject of the proposed action: Hydrotalcite is a mineral clay that is naturally occurring in the environment. The subject of this Food Contact Notification (FCN) is the synthetic form of hydrotalcite that can be identified by CAS# 12304-65-3 (CAS# 12363-58-5 and CAS# 45465-31-7 are also suitable). Synthetic forms of hydrotalcite have been extensively and safely used for many years on a global basis in antacid products for direct human consumption. In addition, hydrotalcite is cleared by FDA for use up to 1000 ppm in food-contact polypropylene film and is also approved in the European Union for use as an additive in food-contact plastics under Directive 2002/72/EC.

Hydrotalcites have the general formula:

$$M(II)_{1-x}\,M(III)_x(OH)_2[A^{n-}]_{x/n}\,.\,mH_2O$$

with a structure that is made up of positively charged brucite-type metal hydroxide layers intercalated with anions $[A^{n-}]$ and water molecules (1).

The name hydrotalcite denotes the family of minerals having the same chemical structure, but that can differ in specific chemical make-up (Cavani, 1991; Trifiro, 1996). For example, instead of Al there may be Fe or Cr or Mn, etc., that are present in exactly the same structural positions occupied by Al in other forms of hydrotalcite. Mg can be replaced by Ni, Zn, Cu. etc… These other hydrotalcites are also found in nature and may have compound specific names. Members of the hydrotalcite family basically exhibit the property of being ion-exchangers.

The FCS has the same basic structure as naturally occurring hydrotalcite. One of the hydrotalcites that naturally occurs as a mineral clay has been described chemically as magnesium aluminum hydroxycarbonate hydrate with CAS# 12304-65-3 (National Chemical Inventories. American Chemical Society, 2004). This hydrotalcite is a mineral composed of magnesium, aluminum, hydrogen, carbon and oxygen with a molecular weight of approximately 604 and a chemical formula of (see http://webmineral.com):

$$Mg_6Al_2(CO3)(OH)_{16}.4(H2O)$$

The FCS is a synthetic form of hydrotalcite that can be described by the same chemical name as the naturally occurring form. Both forms of hydrotalcite are virtually insoluble minerals that have a brucite-like layer (or sheet) structure. The naturally occurring hydrotalcite described above has a molecular weight of ~ 604 and the FCS has a molecular weight > 550. Although having the same basic chemical formula as naturally occurring hydrotalcite, the FCS molecule can contain a somewhat different range of atoms and may not contain carbonate groups when manufactured. The general chemical formula for the FCS is described as:

$$Mg_xAl_y(OH)_z(ci).nH_2O$$

where, x/y can be 2-4, ci is the counter ion hydroxide (OH) or carbonate (CO_3) or a mixture of both counter ions, z is the number of hydroxide groups by formula 2x + 2y (typically z = 12-20) and n varies around 4.

When manufactured, the FCS does not contain any carbonate from the raw materials, however during storage and when in the environment, a chemical equilibrium with air transforms carbon dioxide into the slurry solution as carbonate that will anion exchange with hydroxyl groups. Therefore in practice all hydrotalcites contain some carbonate ions.

Typical examples of the FCS can include:

$Mg_6Al_2(CO3)(OH)_{16}$. $4H_20$ (i.e., the same formula as a naturally occurring hydrotalcite)

$Mg_4Al_2(OH)_{12}(OH).H20$

$Mg_8Al_2(OH)_{20}(OH)$. nH20

The FCS product is as an off-white, odorless slurry or powder. The density of the slurry is 1100-1200 kg/m^3. The pH range of the FCS product is 11.5–12.5.

6) Introduction of substances into the Environment

a. Introduction of substance into the environment as a result of manufacture: No extraordinary circumstances apply to the manufacture of this processing aid. The manufacturing site in Europe is compliant with all applicable emission and occupational safety requirements.

b. Introduction of substances into the environment as a result of use/disposal. The FCS will be used as a production aid in the production of paper board. The

FCS functions by binding to and removing unwanted negatively charged substances (anionic trash) in the pulp suspensions. The FCS is added at the wet-end of the paper board making process at an addition level of 1-2 kg per active ton of dry paper board.

Based on laboratory data it is estimated that 68% of the added FCS will remain bound within the finished paper board after the first pass through the process and therefore at a worst case that ~ 32% of the added FCS will remain in process white water after the first pass through the process. (Note: the laboratory paperboard making process did not include the use of retention aids. In paper board mills the normal use of retention aids will result in more of the hydrotalcite remaining in the paper board; therefore in actual use less than 32% of the FCS will remain in the process water at paper board mills.)

The FCS that remains in the process white water is expected to be bound at least in part to anionic trash. As a conservative estimate, it will be assumed that during use in a paper mill there will be only one pass of the white water (containing hydrotalcite not bound to the paper board) through the paper board making process. As a suspended particulate, any hydrotalcite not retained within paper board is expected to eventually sediment out due to its density. Based on this scenario it is expected that only a very little hydrotalcite will partition to the wastewater stream that leaves the paper board making process.

c. Mode of introduction into the Environment:

As previously discussed, it is expected that most of the added hydrotalcite will be retained in the finished paper board. A smaller amount may be present in process water that will eventually leave the paper board process area and be directed to the mill's wastewater treatment system.

Due to the large volumes of water used, virtually all U.S. paper mills have primary and secondary wastewater treatment systems installed to remove particulate and BOD produced in the manufacturing process (EPA, 2002). These systems also remove 30-70% of AOX and COD. Wastewater treatment sludge is the largest volume residual waste stream generated by the pulp and paper industry. A small number of pulp mills and a much larger proportion of paper making mills discharge effluents to POTWs.

Primary treatment removes suspended matter that leaves the system as sludge. Secondary treatment utilizes biological degradation to remove BOD, but also reducing the loading of COD and AOX. Effluent discharged from a well-run secondary treatment system and released to natural waterways should not be acutely toxic to aquatic organisms because the composition of the effluent is closely regulated by the U.S. EPA under the Clean Water Act. Secondary treatment also generates sludge. It is expected that sludge from the paper board mills will be land-filled, incinerated or land applied.

In order to calculate the concentration of the FCS that may potentially leave a paper board mill in its water effluent, a number of assumptions have been made. These include the following:

(1) The maximum level of 2 kg Hydrotalcite will be used per ton of dry paper board;
(2) A conservative estimate of 32% Hydrotalcite remaining in the white water will be used to represent a first-pass scenario, based on laboratory data;
(3) Hydrotalcite will undergo only one pass in the process white water;
(4) the paper mill will have on-site primary and secondary treatment of its waste water that will conservatively remove 50% of Hydrotalcite as a particulate;
(5) Residual Hydrotalcite in white water will preferentially partition to sludge during primary and secondary treatment operations.
(6) A paper board mill will have a capacity to produce 1000 tons of paper board per day (Eka estimate);
(7) The total daily wastewater effluent from a mill producing 1000 tons of paper and paperboard per day is estimated to be up to 26 million gallons of water, or, $99X10^6$ L (World Bank Group, 1998);
(8) The paper board mill does not send wastewater effluent to a Publicly Owned Treatment Works (POTW);
(9) A 10-fold dilution of the wastewater containing the FCS occurs when the FCS enters a river or other receiving water body.

Based on these generally conservative assumptions, calculation of the environmental introduction concentration (EIC) and the expected environmental concentration (EEC) of hydrotalcite leaving a paper board mill in its wastewater effluent can be estimated as follows:

$$EIC\ (kg/L) = ((FCS\ (kg/ton) \times \text{metric tons paper/d} \times 0.32) \times 0.5) / 99\times10^6\ L$$

$$EIC = ((1000\ t \times 2\ kg/ton \times 0.32) \times 0.50) / (99\times10^6\ L) = 3.23 \times 10^{-6}\ kg/L = 3.23\ ppm$$

$$EEC = EIC / \text{dilution factor}$$

$$EEC = 3.23\ ppm / 10 = 0.323\ ppm$$

In addition to the wastewater effluent from the mill, the hydrotalcite removed within the wastewater treatment systems will be located in sludge. This sludge from the paper board mills will be either land filled, incinerated or land applied. Land filled or land applied hydrotalcite will be bound to anionic trash or other substances encountered during the primary and secondary waste treatment operations. This hydrotalcite can be considered as inert solids/clay that will be similar to substances already naturally present in natural soils. Therefore it is expected that very little in any FCS will leach from the wastewater treatment plant sludge in landfills.

Land application of FCS-containing sludge is not expected to have a significant adverse impact on the environment. Only very small amounts of the FCS could theoretically be introduced into the environment through land application because only a very small percentage of paper mills in the U.S. land apply their sludge. Further, based on its close structural similarity to naturally occurring hydrotalcite, very small amounts of the FCS bound in mill sludge are not expected to have any material adverse impact on the soil following land application.

Even if very small quantities of the FCS migrate from sludge it is concluded that only extremely low quantities will actually enter the environment. This conclusion is based on the existing solid waste regulations administered by the U.S. Environmental Protection Agency as well as on individual state requirements that regulate the landfilling of sludge from paper board mills.

It is not known what percentage of sludge containing the FCS would be incinerated versus being sent to a landfill. However, the incineration of sludge containing the FCS would be expected to represent only an extremely small fraction of the total solid waste that would be incinerated in the U.S. and therefore would not result in a notable increase in air emissions from all other sources; hydrotalcite compounds are naturally occurring and prevalent in the environment.

d. Material Safety Data Sheet

The European Safety Data Sheet (SDS) is included as ATTACHMENT A.

7) Fate of Substances released in the Environment:

The primary means by which the FCS substance is expected to be released into the environment is as a component of waste water effluent from the wastewater treatment operations at the mill. A conservative estimate of the concentration in this effluent is estimated to be 3.23 ppm. This concentration will be greatly diluted once the effluent reaches the receiving water. Based on a conservative river dilution factor of 10 the environmental concentration would be less than 0.323 ppm in natural waterways as suspended solids. This low level of suspended solids, similar in structure to naturally occurring hydrotalcites in the environment, is not expected to have a significant adverse impact on the environment.

Wastewater discharges from paper board mills are strictly regulated under the Clean Water Act and each paper board mill discharging to a natural waterway would have to meet the specific requirements of its National Pollution Discharge Elimination System (NPDES) permit. The discussion in the previous paragraph is a conservative approach that does not take into account the fact that paper board mills may route wastewater effluent directly to a POTW. Treatment within a POTW would be expected to remove the majority of FCS prior to discharge into a natural waterway. In addition, the paper board mill would have pre-treatment requirements of its wastewater effluent that must be met prior to acceptance by the POTW. The POTW would then have to meet its own NPDES permit requirements before its effluent stream could be discharged to a natural waterway.

8) Environmental effects of released substances:

There are no specific test data available on the environmental or ecological effects of the FCS. Use of the U.S. EPA modeling software (ECOSAR) did not retrieve any estimates of toxicity or environmental fate. However, low concentrations of the FCS would be expected to behave similarly as naturally occurring hydrotalcites and there are no known data that indicate naturally occurring hydrotalcites have had a negative impact on the environment or in environmental organisms. Therefore, it can be concluded that low levels of the FCS, a mineral clay very similar to naturally occurring mineral clays, would not be expected to result in significant adverse environmental impacts.

In actuality hydrotalcites that occur naturally in the environment have been described as important sinks for environmental contaminants and may be important in controlling concentrations of metal contaminants in natural waters (Allada, 2002). Uncalcined and calcined Hydrotalcite has been shown to remove chromium (VI) from wastewater (Alvarez-Ayuso, 2005). Phosphorous removal from wastewater has been reported using hydrotalcite-like compounds (Shin, 1996). Synthetic hydrotalcite clays were found to be very effective in binding undesirable humic substances in surface water (Amin, 1996). Boron was preferentially adsorbed onto Mg-Al hydrotalcites from aqueous solutions in laboratory studies (Ferreira, 2005). Hydrotalcites have been shown to bind organic pesticides in aqueous media (Villa, 1999). Hydrotalcites have also been shown to adsorb radioactive molecules from low-level waste (Balsley, 1998). Finally, inorganic arsenic (a potential contaminant in ground water) has been shown to be adsorbed and removed by synthetic hydrotalcite compounds (Kiso, 2005).

9) Use of resources and energy:
The proposed use of the FCS is intended to make the paper board process run more efficiently by adsorbing and removing negatively charged components (anionic trash) in pulp suspensions that can have a detrimental effect on the paper board making process. If not removed, these unwanted, negatively charged components can clog paper making machines, break the paper web, etc…, resulting in loss of paper board, increased maintenance costs, increased downtime of the machines, and increased use of other additives used in the paperboard process whose effectiveness is decreased when they bind with anionic trash. Therefore the use of the FCS is expected to result in a decreased amount of waste paper board, decreased amounts of water needed due to less frequent clean-up of clogged machines, and decreased amounts of resources needed especially in the area of human labor and paper board making additives. Energy usage is not expected to be significantly affected.

10) Mitigation Measures:
No adverse environmental effects have been identified therefore there is no need to discuss mitigation measures.

11) Alternatives to the proposed action:
No adverse environmental effects have been identified therefore there is no need to discuss alternatives to the proposed action.

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13) Certification:
"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Akzo Nobel Inc."

4/27/06

(Date)

(signature of responsible official)
Edwin C. Bisinger Jr., PhD, DABT
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14) References:

Allada, R., Navrotsky, A., Berbeco, H., Casey, W.: Thermochemistry and aqueous solubilites of hydrotalcite-like solids. Science 296: 721-723; 2002.

Alvarez-Ayuso, E., Nugteren, H.: Purification of chromium (VI) finishing wastewaters using calcined and uncalcined Mg-Al-CO3-hydrotalcite. Water Res. 39(12): 2535-2542; 2005.

Amin, S., Jayson, G.: Humac substance uptake by hydrotalcites and PILCS. Water Res. 30(2): 299-306; 1996.

Balsley, S., Bardy, P. Krumhansl. J., Anderson, H.: Anion scavengers for low -level radioactive waste repository backfills. J. Soil Contam. 7(2): 125-141; 1998.

Cavani, F., Trifiro, F., Vaccari, A.:Hydrotalcite-type anionic clays: preparation, properties and applications. Catalysis Today 11(2). 1991.

EPA: Profile of the pulp and paper industry 2nd edition. U.S. Environmental Protection Agency EPA/310-R-02-002. Washington, D.C. 2002.

Kiso, Y., Jung, Y., Yamada, T., Nagai, M., Min, K.: Removal properties of arsenic compounds with synthetic hydrotalcite compounds. Water Supply 5(5); 75-81: 2005.

Shin, H., Kim, M., Nam, S., Moon, H.: Phosphorous removal by hydrotalcite-like compounds HTLCS. Water Sci.Tech. 34(1-2): 161-168; 1996.

Trifiro, F., Vaccari, A.: Hydrotalcite-like anionic clays (layer double hydroxides). In, Comprehensive Supramolecular Chemistry. Volume 7. Eds. Alberto, G., Bein, T. Pergamon Press, 1996.

Villa, M., Sanchez-Martin, M., Sanchez-Camazano, M.: Hydrotalcite and organic hydrotalcite as sorbents for removing pesticides from water. J. Env. Sci. Health (Part B) 34(3): 509-525; 1999.

15) Attachment

ATTACHMENT A Safety Data Sheet for FCS