# Environmental Assessment
CAS number 61790-59-8

1. **Date:** March 29, 2019

2. **Notifier:** Akzo Nobel Industrial Chemicals B.V.

3. **Address:** Akzo Nobel Industrial Chemicals B.V.

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4. **Description of proposed action:**

Akzo Nobel Industrial Chemicals B.V. is submitting a Food Contact Notification (FCN) for the use of the food contact substance (FCS), Amines, hydrogenated tallow alkyl, acetates (CAS number 61790-59-8) as a production aid in the separation of potassium chloride from sodium chloride in mining operations in Europe.

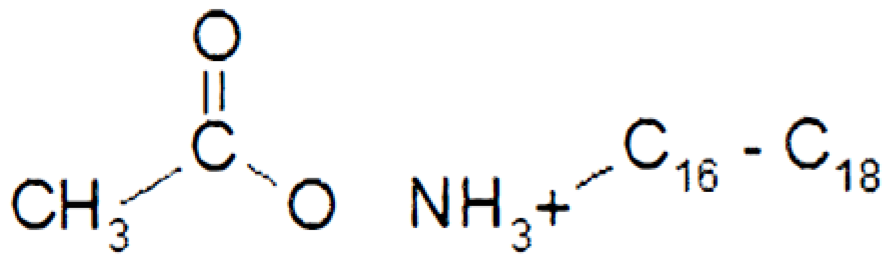
[Note: In Europe under the REACH legislation, the chemical name of the FCS is C16-18-(even numbered)-alkylamines acetates with CAS# 1273322-45-4 and European Commission (EC) number 800-526-8. Akzo Nobel is a member of the REACH consortium for this substance along with Clariant and supported the REACH dossier.]

The FCS is manufactured in Europe in accordance with local, national and European Union requirements. The FCS will be used by a customer as a processing aid only in Europe in the mining operation that separates potassium chloride from sodium chloride. The FCS is a flotation aid that binds to the potassium chloride. In Europe, the flotation layer containing the FCS and potassium chloride is then separated from the aqueous brine layer that contains sodium chloride. Greater than 99.99% of the FCS will remain with the potassium chloride phase however the aqueous brine layer will contain a maximum of 10 ppm of the FCS as an impurity. This process will take place in accordance with local, national and European Union requirements.

In a separate operation in Europe, the sodium chloride brine (dissolved sodium chloride in water) will be then processed into food-grade sodium chloride that will be used in Europe in various processed food applications (such as canned soups, canned vegetables, pre-packaged meals, etc.). Processed foods that contain sodium chloride may possibly be imported into the United States. The FCS impurity has no function in sodium chloride or in any food product. The FCS will only be present in food grade salt as an impurity (10 ppm maximum impurity level) from the sodium chloride mining operation. The food-grade salt containing low ppm levels of the FCS will not be used in baby formula or in baby food.

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

The FCS is chemically described as: Amines, hydrogenated tallow alkyl, acetates (CAS number 61790-59-8). The alkyl chains are derived from tallow (beef fat) fatty acids. The European EC number is 263-149-2. The structure of the FCS is as follows:




The FCS is a yellow solid at 25˚C. The melting point is 60 °C. and the pH (1% solution at 20 ˚C) of 5.7. The relative density is 0.990 at 20 ˚C. The n-octanol/water coefficient (log Kow) is 2.8. The FCS is not flammable and is not an oxidizing agent. The decomposition temperature is 168˚C.

## 6. **Introduction of substances into the environment:**

*Environmental Introductions Resulting from the Manufacture of the FCS*

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, the Notifier is not aware of information to suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact in the U.S. as a result of the manufacture of the FCS in Europe. Specifically, as set forth in FDA's guidance, extraordinary circumstances include situations where: 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); and 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. To the best of the Notifier's knowledge, no situations such as these apply to the use of the FCS in its intended use. Consequently, information on the European manufacturing site and compliance with relevant U.S. emissions requirements is not provided here.

Processed foods containing salt that contain trace levels of the FCS may be imported into the United States. Such processed foods may be present in sealed metal cans (cooked vegetables), sealed plastic containers (dried soup components) or in sealed paper containers (boxes of dried pasta). After shipment across the ocean and subsequent purchase in the U.S., the processed food packages will remain sealed and unopened before use. Therefore, during storage in the U.S. there would be no possible release to the environment.

When the containers of processed foods are opened as intended the food would be ingested by consumers. The estimated dietary exposure to the FCS is 47 ug/person/day (Annex 1, Concentration of FCS in the U.S. Diet; Annex 2, "You may be surprised by how much salt you're eating"; and Annex 3, "Sodium and Food Sources"). The expected exposure of 47 ug/person/day equates to an average of 16 ppb in the diet:

[47 ug/person/day] x [1 person/3 kg diet/day] = 15.67 ug/kg ~ 16 ppb in the diet

The FCS is expected to be efficiently metabolized within the body in a manner similar to dietary fatty acids (Tenne, 1985; Tominaga, 1987; Tynes, 1986). When ingested at a dietary level of 0.016 ppb, very little FCS should be excreted because trace dietary levels of the FCS would be expected to be metabolized in the body.

Assuming a person ingests 47 ug of the FCS in the diet over the course of one day and the FCS is excreted in human waste, the human waste would be routed into the local sanitary sewer that directly connects to the local publicly owned treatment works (POTW). At a worst case, assuming all 47 ug of the FCS is routed to the POTW, the FCS would be further significantly diluted when the human waste is intermingled with other waste streams routed to the local POTW. According to the U.S. EPA the majority of POTWs fall in the 1 million gallon per day range (Annex 4). Therefore, 47 ug of the FCS would be significantly diluted going into the POTW resulting in much lower than parts per trillion FCS within the POTW:

47 ug FCS / (1 X $10^6$ gallons X 8 pounds/gallon X 1 kg/2.2 pounds) = 12.9 X $10^6$ ug/kg

Once within a POTW, the FCS would be subjected to primary and secondary treatment (EPA, 2004). In primary treatment the FCS would be expected to bind to sediment/sand in the waste water stream and the resultant suspended solids would be collected in the sedimentation tank in the mass termed primary sludge that is periodically removed and landfilled. Sediment binding is expected based on the results of an OECD 307 aerobic soil transformation study (3 soils) that was carried out with [1-14C]-Hexadecanamine (Annex 5, study summary from the ECHA REACH disseminated dossier for CAS# 1273322-45-4). Although this C16 alkyl amine is strongly sorbing to soil (median Kpsoil of 3875 L/kg at lowest measured concentration) half-lives between 8.1 and 9 days at 20°C. were determined_ The median half-life of 8.9 d at 20°C. corresponds to a median half-life of 16.9 days at an environmental temperature of 12° C.

After primary treatment, the wastewater, that may contain only minute amounts of the FCS, is routed to secondary (biological) treatment that is generally considered to remove up to 90% of the organic material in wastewater (EPA, 2004).

After final water treatment, the resultant treated water would be released to natural waterways in strict compliance with the conditions of the POTW's NPDES permit under the Clean Water Act. At this point, after human metabolism, significant dilution in the wastewater stream going to the POTW, removal by sorption to solid particles during primary treatment, and removal by biodegradation during secondary treatment, it is expected that the level of FCS remaining in the water released from the POTW would be so low as to have no environmental impact. There would be no release of significant amounts of the FCS to water.

Left-over foods would be disposed of in home or business trash containers that when filled would be taken to local municipal waste landfills. There would be no expected release of the FCS to natural waters or to the air. The FCS contains saturated, long carbon chains (16-18 carbons in length) that are not considered volatile and would not be released to air.

Regarding landfills, because of U.S. EPA regulations governing municipal solid waste landfills (40 CFR Part 258) little, if any, of the FCS would be expected to enter the environment as a result of the landfill disposal of the waste food containing the FCS. These regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water. Additionally, landfills are required to have groundwater monitoring systems. Although owners and operators of existing municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

## 7. Fate of Emitted Substances in the Environment

The FCS will only be manufactured and used in Europe during the production of food-grade salt and processed foods. When imported into the United States, the ingestion of these processed foods by U.S. consumers would not be expected to release the FCS into the environment because trace levels of the FCS and its impurity in processed foods imported into the U.S. will be metabolized within the human body: the resulting human waste will be diluted and sent to POTWs where any remaining trace amount of the FCS will be significantly diluted, removed and biodegraded within the POTW. Waste processed foods will be disposed of in municipal waste landfills that are constructed to prevent releases to groundwater. Therefore, no release to the environment is expected.

### (a) Air

Trace levels of the FCS in waste food will not be released to the air because both the FCS and its impurity primarily are composed of long carbon chains (16-18 carbons in length) that are not considered volatile.

The European REACH dossier for Amines, C16-18-alkyl, a close structural analog of the FCS, predicts that alkyl amines such as the FCS released into the atmosphere are likely to be degraded by reaction with hydroxyl radicals, with a half-life around 7.5 h (Annex 6 attached to this EA, study summary from the ECHA REACH disseminated dossier for CAS# 90640-32-7). The structure of the FCS is included in this REACH chemical category. However, because there are no expected significant releases into the atmosphere and volatilization is expected to be negligible, this removal mechanism is considered not to be relevant.

Greenhouse Gas (GHG) Analysis

To estimate the amount of greenhouse gas emissions (GHG) that may result from the incineration of food waste containing trace amounts of the FCS, information from the U.S. EPA was used (EPA, 2015a; EPA, 2015b).

From Table 1, Page 1 of the 2015 municipal solid waste (MSW) Tables and Figures, 262,430,000 short tons of MSW was generated in 2015 (EPA, 2015a). Of that amount, 15.1% was food waste. From Figure 3 of the MSW Fact Sheet, 12.8% of all MSW is combusted for energy recovery (EPA, 2015b).

According to FDA, about 15% of the U.S. food supply is imported, including nearly 50% of fresh fruit and 20% of fresh vegetables, and 80% of seafood (FDA, 2017). This FCN only addresses the presence of the FCS in processed foods imported from Europe. However, imported foods also include billions of dollars of fresh produce imported from Mexico each year (FDA, 2018). In addition, almost 4 billion pounds of agricultural products were imported from China in 2014 (AAM, 2014). According to the USDA, China also imports billions of dollars of seafood each year and Canada imports millions of head of cattle and pigs (Aurora, 2018).

For the GHG calculations in this FCN, the FDA data of 15% imported food in the U.S. food supply will be used even though it is assumed, as described above, that much of the food imported into the U.S. is not European processed food.

<u>These data yield</u>:

262,430,000 X 15% X 15.1% = 5,944,039 short tons of food waste generated in 2015 from imported food

5,944,039 X 12.8% = 760,837 short tons of food waste combusted for energy recovery in 2015

<u>Market volume combusted</u>:

760,837 X 10 ppm FCS residue level = 760,837 X 0.00001 = 7.61 short tons X 0.9 = 6.85 metric tons (mT)

<u>Chemistry of the FCS</u>:

6.85 mT X 82.19% carbon*= 5.63 mT C combusted (* Lenntech Molar Mass Calculator)

(6.85 X 4.79%) X 30%** = 0.098 mT N combusted
(** Morimoto, 1976: maximum 30% N converts to $N_2O$; 4.79% is N subtotal mass)

(0.098 mT N X 44***) / (2 X 14.01) = 0.15 mT $N_2O$ combusted (*** 44 = molar mass of $CO_2$; 14.01 = N subtotal mass in g/mol)

<u>GHG equivalents</u>:

5.63 mT C: enter in EPA GHG equivalents calculator (EPA, 2018)
0.15 mT $N_2O$: enter in EPA GHG equivalents calculator TOTAL $CO_2$-e = 65.3 mT

<u>Conclusion</u>:

65.3 mT of $CO_2$-equivalents ($CO_2$-e) result from combustion of the FCS. This amount is below the reporting threshold described in 40 CFR 98.2 for MSW combustion facilities that emit 25,000 mT $CO_2$-e or more per year.

**(b) Water**

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine or marine ecosystems are anticipated due to the proposed manufacture and use of the FCS in Europe. Following consumption of processed foods by consumers in the United States, any FCS in human waste will be effectively diluted, physically removed and biodegraded within POTWs.

The European REACH dossier for this chemical category states that based on the available studies on biodegradation, alkyl amines are estimated to be readily biodegradable, fulfilling the 10-days-window criterion. Long-chain alkyl amines (up to C18) have been shown to be biodegraded by bacteria isolated from soil and active sludge (Nguyen, 2008). Therefore, no significant amounts of the FCS are expected to be released to water.

**(c) Land**

Considering the factors discussed above, no effects on the concentrations of and exposures to any substances in terrestrial ecosystems in the United States are anticipated because of the proposed manufacture and use of the FCS in Europe, or the importation and consumption of processed food into the United States.

The FCS will not be present in waste packaging materials, and therefore there will be no leaching of the FCS or any harmful substance, and no exposure to terrestrial organisms in the United States. Processed food waste containing trace amounts of the FCS and its impurity will be disposed of in lined municipal waste sites to prevent release to the environment.

Considering the foregoing discussion, we respectfully submit that there is no reasonable expectation of significant environmental impact due to the proposed manufacture and use of the FCS in Europe, and the possible importation of processed foods from Europe into the U.S. that may contain trace levels of the FCS.

## 8. Environmental Effects of Released Substances

No significant quantities of the FCS will be released to the environment in the United States upon the manufacture and use and disposal of the FCS in Europe during the production of food-grade salt and processed foods in Europe. Trace levels of the FCS in processed foods imported into the U.S will be largely metabolized within the human body and are not expected to be released to the environment: treatment in POTWs are expected to effectively remove remaining trace levels of the FCS present in human waste that is sent to a POTW. Waste processed foods will be disposed of in lined municipal waste landfills to prevent release to groundwater. Trace levels of the FCS in waste food will not be released to the air because the FCS primarily is composed of long carbon chains (16-18 carbons in length) that are not considered volatile.

Thus, no significant adverse effect on organisms in the environment in the United States is expected, and the intended use of the FCS will not threaten a violation of applicable
U.S. laws and regulations, such as the EPA's regulations in 40 CFR Parts 60 and 98.2.

## 9. Use of Resources and Energy

The FCS is not produced in the United States and therefore the production will not involve the use of natural resources such as water, petroleum products and coal in the United States. The use of the FCS only in Europe is not expected to result in any increase in the use of energy and resources currently used in the United States. The imported processed foods (that contain trace levels of the FCS) are the same foods already being imported into the United States and therefore no additional amounts of waste left-over foods will be disposed of. Therefore, the approval of this notification is not expected to have any adverse impact on the use of natural resources and energy in the United States.

## 10. Mitigation Measures

No significant environmental impacts in the United States resulting from the proposed use of the FCS have been identified. Therefore, no mitigation measures are required.

## 11. Alternatives to the proposed action

If this FCN should not be approved then the use of already-approved FCS and processes would continue, which is not expected to have a significant impact.

## 12. Preparer

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Dr. Bisinger is currently the Senior Science Advisor in the Toxicology and Environmental Expertise Team for Nouryon Chemicals LLC. He has held technical and managerial positions not only in private industry, but also in the not-for profit sector (Corporate Toxicologist with Underwriters Laboratory) and is a former member of the U.S. Environmental Protection Agency (Environmental Scientist).

He received his PhD in occupational and environmental toxicology from the University of Illinois, School of Public Health with a focus in chemical risk assessment. He is a member of the Society of Toxicology and is a Diplomate of the American Board of Toxicology (DABT). Dr. Bisinger has more than 25 years of experience in chemical risk assessment, toxicology study design and interpretation, and in new substance notifications. He has successfully filed several Food Contact Notifications with the U.S. FDA over the past 15 years

## 13. Certification

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

DATE: March 29, 2019

[redacted]

# Cited references in Environmental Assessment


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# Annex 1

## Concentration of the FCS in the U.S. diet

The U.S. FDA states the average American diet contains 3.4 g sodium, and therefore 3.4 g Na is contained in 8.5 g NaCl, i.e., 3.4/0.4 = 8.5 (Annex 2).

About 71% of sodium in the average American salt intake comes from processed food/restaurants and of this percentage, 65% is derived from processed foods bought in retail stores and 25% comes from restaurant food (Annex 3). Therefore, as a worst case, assuming all processed food purchased in retail stores and about half of the sodium used in restaurant food comes from processed foods, 0.71 x (0.65 + 0.13) = 55% of sodium is derived from processed foods bought in retail stores.

Assuming a worst case of 10 ppm FCS in salt (maximum) = 0.001% FCS in salt

Then 0.00001 X 8.5 g X 0.55 = 0.000047 g = 0.047 mg FCS in the daily U.S. diet

EDI = 0.047 FCS mg/ person/ day

There are no other dietary sources of the FCS in the U.S., therefore,

CEDI = 0.047 FCS mg/person/day

DC = 0.049 mg/3 kg = 0.016 mg/kg = 16 ppb FCS

Where:

EDI= estimated dietary intake DC = dietary concentration

3 kg = average amount of daily dietary intake

# Annex 2

The attached article, "You may be surprised by how much salt you're eating", appeared on the U.S. FDA Consumer Update website (updated July 19, 2016). The website address is https://www.fda.gov/ForConsumers/Consumer/ucm327369.htm.

*[See website to view this information]*

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# Annex 3

The attached article, "Sodium and food sources", appeared on the U.S. Centers for Disease Control (CDC) website (updated March 28, 2017). The article can be accessed online at: https://www.cdc.gov/salt/food.htm

*[See website to view this information]*

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# Annex 4

The attached Table 1-2, CWNS 2008 number of treatment facilities by flow range, is from the U.S. EPA report (page 129) titled, 2008 Clean Watershed Needs Survey, Report to Congress. EPA Report EPA-832-R-10-002. The EPA report is available online at: https://www.epa.gov/sites/production/files/2015-06/documents/cwns2008rtc.pdf. Table 1-2 is on page 129 of this report.
The attached biodegradation in soil study summary for [1-14C]-Hexadecanamine is from the ECHA REACH disseminated dossier for CAS# 1273322-

*[See website to view this information]*

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# Annex 5

45-4. The study summary report can be accessed online at https://echa.europa.eu/registration-dossier/-/registered-dossier/13168/5/3/4

*[See website to view this information]*

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# Annex 6

The attached photo transformation in air study summary is from the ECHA REACH disseminated dossier for GAS# 90640-32-7. The study summary report can be accessed online at: https://echa.europa.eu/registration-dossier/-/registered-dossier/13168/5/3/4.

*[See website to view this information]*

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