lamberti USA, Inc.

June 22, 2016

From: Kathy Dimataris
Environmental & Product Compliance Manager
Lamberti USA, Incorporated
P.O. Box 1000
Hungerford, TX 77448

To: Lisa Brines, Ph.D
National List Manager
USDA/AMS/NOP, Standards Division
1400 Independence Ave. SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268
Transmitted via email: nosb@am.usda.gov

Re: Lamberti USA, Incorporated Petition of Potassium Cellulose glycolate for Inclusion on the Nation List as a Synthetic Inert Ingredient Allowed for use in Organic Crop Production

Dear Ms Brines,

Lamberti USA, Incorporated hereby submits a Petition for the Inclusion of Potassium Cellulose glycolate (Potassium CMC) on the National List as a Synthetic Production Aid Allowed for Use in Organic Crop Production, under 7 C.F.R. 205.601(m).

Enclosed, you will find the following to support this petition:

1. Potassium Cellulose glycolate (Potassium CMC): Petition for Inclusion on the National List as a Synthetic Production Aid Allowed for Use in Organic Crop Production
2. Attachment 1: Safety Data Sheet – Lamfix K
3. Attachment 2: Label – Lamfix K

If you have any questions regarding the enclosed petition documentation or if additional information is needed, please let me know.

Sincerely,

Kathy Dimataris
Lamberti USA, Incorporated

Potassium Cellulose glycolate (Potassium CMC):

Petition for Inclusion on the National List as a Synthetic Substance Allowed for Use in Organic Crop Production

OVERVIEW

Carboxymethylcellulose is a polymer derived by chemical modification of the natural polymer cellulose that is obtained from renewable botanical sources.

Naturally occurring polymers fall under the definition of polymers contained in REACH (Article 3(5)), and being naturally occurring substances, they are considered to qualify for the exemption of registration as in the current version of Annex V paragraph 8. When natural cellulose is chemically modified, the resultant cellulose ether substance, in our case the Carboxymethylcellulose (CMC) still meets the definition of a polymer (Article 3(5)) and hence is exempted from the REACH registration requirements (Article 2(9)). The cellulose ethers manufactured by Lamberti S.p.A. all meet these criteria, and so are exempted from the REACH registration requirements.

Varying both the length of the polymeric backbone and the number of carboxymethyl group present, a wide range of CMC grades are manufactured, providing different levels of viscosity and tuning the several properties of the polymer.

In fact CMC acts as thickener, rheology modifier, water retention aid, filtration reducer, binder, dispersant, protective colloid, floating aid, crystallization inhibitor, ions exchanger, etc. This wide range of properties makes CMC virtually useful everywhere water is involved in a process and more typically in ceramics, coatings, detergency, drilling fluids, food, mining, paper, textiles (sizing and printing), amongst many.

Since 1973, the U.S. Food and Drug Administration has classified this chemical as GRAS (Generally Regarded as Safe). As such, the usage has grown in food and pharmaceuticals as a thickening or stabilizing agent.

While the potassium salt of carboxymethylcellulose has not been widely known, there is added benefits of performance with the potassium salt over the sodium.

ITEM A

1. Category Identification

Synthetic Production Aid allowed for use in organic crop production

ITEM B

Product Overview:

1. Substance Name

Potassium Cellulose glycolate (Potassium CMC)

2. Petitioner & Manufacturer Information

Petitioner Information

Lamberti USA, Incorporated
Attn: Kathy Dimataris
kathy.dimataris@lamberti.com
281-342-5675 x 125
P.O. Box 1000
Hungerford, TX 77448

Manufacturer Information

Lamberti SpA.
Via Piave 18
Albizzate, VA 21041
ITALY

3. Intended or Current Use

Current use is as a water management product (production aid) to use in combination with fertilizers and nutrients.

4. Intended Activities and Application Rate

Potassium CMC is part of several formulations where it works as water holding agent. Due to its "water like" behavior, Potassium CMC is able to hold water into the root zone providing benefit to the target crops. When present in the formulation, Potassium CMC is tank mixed @0.1% - 0.15%.

5. Manufacturing Process

The Carboxymethyl Cellulose (CMC) is produced by chemical modification of cellulose, the most abundant polymer in nature and a major component of wood and cotton. As a synthetically produced compound, potassium CMC is manufactured from naturally occurring cellulose and undergoes a chemical change not occurring in nature.

The following description of the Sodium CMC manufacturing process is publically available. The Potassium CMC follows a similar manufacturing process, except for the substitution of the Potassium Hydroxide in for the Sodium Hydroxide.

Cellulose is a molecule consisting of between 2000 - 14000 residues of anhydroglucose, everyone carrying three reactive hydroxyl groups. These groups form many hydrogen bonds among adjacent

chains, regularly packing the chains together to form stable crystalline regions and giving a complete insolubility in water and in most of the organic solvents. By replacing one or more of cellulose's hydroxyls with carboxymethyl groups by etherification, water soluble CMC is obtained. The chemical modification runs through two steps: The first step is the treatment of the cellulose with caustic soda to break the crystalline clusters and obtain the alkali-cellulose complex, a substrate accessible to following reactions. The second step is the etherification reaction between the alkali-cellulose complex and Mono Chloroacetic Acid (MCA) with consequent formation of CMC and Sodium Chloride as by-product.

$$Cell - OH \ + \ NaOH \rightarrow Alkali - cellulose$$

$$Alkali - Cell \ + \ ClCH_2COOH \ \rightarrow Cell - O - CH_2COONa \ + \ NaCl \ + \ 2H_2O$$

An important side-reaction takes place, as Sodium Glycolate is formed by direct action of caustic soda on MCA.

$$ClCH_2COONa \ + \ NaOH \rightarrow HOCH_2 - COONa \ + \ NaCl$$

After the reaction NaCl, Sodium Glycolate and other impurities can be removed by treatment with an aqueous solvent to obtain pure grade CMC.

Varying both the length of the polymer backbone and the number of substitutive carboxylic derivative a wide range of CMC grades are manufactured, providing different levels of viscosity and tuning the several properties of the polymer.

Further details of Lamberti's manufacturing process is considered to be Confidential Business Information (CBI).

6. Ancillary Substances

As a manufacturing byproduct, the potassium CMC can contain less than 5% acetic acid, 2-hydroxy-, potassium salt, (1932-50-9) and less than 15% potassium chloride (7447-40-7).

7. Previous Review

Not applicable. Potassium CMC has not been reviewed by any state or private certification program. There is no requirement to have any state or private certification.

8. Regulatory Authority

Potassium CMC meets the definition of polymer under 40 CFR 723.250(e)(1). Accordingly, U.S. EPA, Office of Pollution Prevention & Toxic Substances has been petitioned in January of 2016. A lack of response is considered acceptance of this notification.

The European Registration, Evaluation, Authorization and Restriction of Chemicals Regulation, commonly referred to as REACH, places an obligation on European manufacturers and importers of substances to register the substances in order to continue production in or import into the European market.

Carboxymethylcellulose is a polymer derived by chemical modification of the natural polymer cellulose that is obtained from renewable botanical sources.

Naturally occurring polymers fall under the definition of polymers contained in REACH (Article 3(5)), and being naturally occurring substances, they are considered to qualify for the exemption of registration as in the current version of Annex V paragraph 8.

When natural cellulose is chemically modified, the resultant cellulose ether substance, in our case the Carboxymethylcellulose (CMC) still meets the definition of a polymer (Article 3(5)) and hence is exempted from the REACH registration requirements (Article 2(9)). The cellulose ethers manufactured by Lamberti S.p.A. all meet these criteria, and so are exempted from the REACH registration requirements.

This is a polymer which is exempted by registration under REACH regulation in Europe. No registration is required under Regulation EC 1107/2009 and Directive 91/414/EEC for inert ingredients in Plant Protection Products (PPPs).

9. Chemical Abstracts Service (CAS) Number and Product Labels

The CAS number for Potassium cellulose glycolate (Potassium CMC) is 54848-04-3. A copy of the commercialized product label containing Potassium CMC, Lamfix K, is attached.

10. Physical and Chemical Properties (a) Chemical Interactions with other substances, especially substances use in organic production; (b) Toxicity and environmental persistence; (c) Environmental impacts from its use and/or manufacture; (d) Effects on human health; (e) Effects on soil organisms, crops, or livestock;

Properties

- Appearance: Viscous, brown liquid
- pH: 7.5-9.5
- Relative density: 1.15-1.23 g/mL

Mode of Action

a. Chemical Interactions with other substances, especially substances use in organic production

No specific data is available for potassium CMC. However, this substance is very similar to carboxylmethylcellulose, sodium salt (CAS# 9004-32-4). The two structures are identical with the exception of the cation of the salt. As such, the risk evaluation can be based on a read across approach. There is relevant information available in open literature (Food and Agriculture Organization of the United Nations World Health Organization, 1967).

b. Toxicity and environmental persistence

No specific data is available for potassium CMC. However, this substance is very similar to carboxylmethylcellulose, sodium salt (CAS# 9004-32-4). The two structures are identical with the exception of the cation of the salt. As such, the risk evaluation can be based on a read across approach.

Biodegradation

Type	Aerobic
Inoculum	Sludge and sewage
Result	71%
Method	Biodegradation – OECD 302
Year	1989
GLP	No
Test Substance	Carboxymethylcellulose Sodium
Remarks	-
Source	Lamberti SpA Ecotoxicological Laboratory – Internal Reports

Type	Aerobic
Inoculum	Sludge and sewage
Result	76%
Method	Biodegradation – OECD 302
Year	1998
GLP	No
Test Substance	Carboxymethylcellulose Sodium
Remarks	-
Source	Lamberti SpA Ecotoxicological Laboratory – Internal Reports

As such, the biodegradation (OECD 302) of sodium CMC has been tested under non-GLP conditions. Tests were repeated 9 years apart and found to have an average biodegradation of above 73% biodegradable (Lamberti SpA Ecotoxicological Laboratory – Internal Reports).

c. Environmental impacts from its use and/or manufacture

No specific data is available for potassium CMC. However, this substance is very similar to carboxylmethylcellulose, sodium salt (CAS# 9004-32-4). The two structures are identical with the exception of the cation of the salt. As such, the risk evaluation can be based on a read across approach.

EcoToxicological studies

<u>Fish Acute Toxicity</u>

Species:	Rainbow trout, Donaldson trout
Concentration:	no data
Exposure Time:	96 hours
Result:	LC 50 > 20000 mg/L
Methods:	Fish acute toxicity test
Year:	-
GLP:	No data
Test Substance:	Carboxylmethylcellulose Sodium
Remarks:	-
Source:	U.S. EPC-OPP Registration standard: 1p. (CBI Data) 1975

Species:	*Carassius carassius*
Concentration:	no data
Exposure Time:	96 hours
Result:	LC 50 > 20000 mg/L
Methods:	Fish acute toxicity test
Year:	-
GLP:	No data
Test Substance:	Carboxylmethylcellulose Sodium
Remarks:	-
Source:	U.S. EPC-OPP Registration standard: 1p. (CBI Data) 1975

<u>Crustaceans Toxicity</u>

Species:	*Crangon crangon*
Concentration:	no data
Exposure Time:	48 hours
Result:	LC 50 1000-3300 mg/L
Methods:	Algae acute toxicity test
Year:	-
GLP:	No data
Test Substance:	Carboxylmethylcellulose Sodium
Remarks:	-
Source:	Shellfish Information Leaflet No. 22 (2nd Ed.)

Species:	*Ceriodaphnia dubia*
Concentration:	no data
Exposure Time:	48 hours
Result:	EC 50 165 mg/L
Methods:	Algae acute toxicity test
Year:	-
GLP:	No data
Test Substance:	Carboxylmethylcellulose Sodium
Remarks:	No mortality detected, immobilization
Source:	Ecotoxicol Environ Saf. 44(2):196-206-1999

d. Effects on human health

No specific data is available for potassium CMC. However, this substance is very similar to carboxylmethylcellulose, sodium salt (CAS# 9004-32-4). The two structures are identical with the exception of the cation of the salt. As such, the risk evaluation can be based on a read across approach.

Toxicological Studies

Acute Toxicity

Species:	Rat
Route:	oral
LD_{50}(mg/kg/bw):	15,000-27,000
References:	Shelanski & Clark, 1948 CTFA, 1977 CTFA, 1978a,b CTFA, 1980

Species:	Gunea-pig
Route:	oral
LD_{50}(mg/kg/bw):	16,000
References:	Shelanski & Clark, 1948

Rats, guinea-pigs, and rabbits showed no symptoms after administration by stomach tube of 300 mg/kg bw in here divided doses (Rowe et al., 1944). Six rats given an intravenous injection of 1 mL of a 1.6% solution of CMC showed the presence of particles localized in cells of the reticulo-endothelial system 48 hours later (Jasmin & Bois, 1961). Four dogs given an i.v. injection of 4 0mL of 0.25% CMC in 1% sodium chloride solution reacted with a transitory leukopenia (Hueper, 1945).

Short-term studies

Rats

Ten rats received 300 to 500 mg of CMC daily for two months without any adverse effect (Werle, 1941). Ten male and 15 female rates were fed a diet containing 5% CMC for 201 to 250 days. Judged by growth rate, mortality, organ weights and the results of histopathological examination of the liver, kidney, spleen, pancreas, adrenal gland, testis and gastrointestinal tract, there were no significant differences between the treat and the control group (Rowe, et al., 1944). Another group of 10 rats received a diet containing 20% of CMC for 63 days. Slight growth retardation and laxative effect were observed. Organ weights and both gross and microscopic pathological examination revealed no abnormalities (Rowe et al., 1944). Two groups of 100 rats received 500 and 1000 mg/kg bw/day of CMC mixed in their diets for six months. No adverse effects were observed in any of the experimental animals as determined by growth rate, fertility and examination of the blood, urine and main tissues (Shelanski & Clark, 1948). Six rats were fed 14% of CMC in the diet for five weeks without demonstrable deleterious effect (Ziegelmayer et al., 1951).Ten rats given subcutaneous injections of CMC showed mast-

cell-like elements within the adrenal medulla. Changes in the adrenocortical cells and the presence of granules in the adrenal-vein were noted occasionally (Selye, 1955). Rodents (12 animals per group) were maintained for 21 days on a high-protein diet containing 0 or 15% sodium CMC of 10 viscosity grades (35-4500 cP) or 4 other vegetable gums. Animals were weighed on alternate days. Body weight gain for one sample of CMC exceeded that of controls and body weight gains for two CMC samples were less than that of controls. Average fecal water content (measured as percentage) was increased in all CMC-fed animals from 1.9-3.0 fold, and average filled cecal weight (g/kg bw) was increased 1.5-3.3 fold relative to controls. It was noted that there was a tendency for CMC samples of low molecular weight to produce high fecal wet weights. Measuring the viscosities of completely hydrated samples of CMC indicated that CMC can have a large or narrow molecular weight distributions. It was suggested that different molecular weight distributions in samples of CMC may product different physiologic or dietary responses to CMC (Anderson, 1986).

Guinea-pigs

Two groups of 100 guinea-pigs were fed CMC for six months t levels of 500 and 1000 mg/kg bw/day mixed in the diet. No signs of toxicity were observed (ref???). Two groups of 20 guinea-pigs received CMC in their diet at rates of 500 and 1000 mg/kg bw/day for one year. As judged by weight gain, gross and histopathological examination, no adverse effects were noted (Shelanski & Clark, 1948)

Rabbits

Three rabbits were fed CMC at levels of 4.8% and 9% in their diet for two periods of 15 days without any detectable toxic effects (Ziegelmayer et al., 1951).

Dogs

Two dogs were given daily doses of CMC (0.3-0.4 g/kg bw) in water by mouth for two months without adverse effects (Werle, 1941). Groups of 10 dogs were fed CMC in the diet at levels of 500 and 1000 mg/kg bw/day for six months. Growth rate was the same in all groups. Six animals from each group were examined post mortem. Histologically, the stomach, intestines, spleen kidney, heart, lung and pancreas in treated animals were no different from those of controls (Shelanski & Clark, 1948). Five dogs received intraveneous injections of0.25% CMC in 1% sodium chloride solution in doses increasing from 40 mL to 150 mL for a maximum of three months. There were no gross pathological changes. Histopathological studies revealed uptake of CMC in the reticuloendothelial cells in the aorta (Hueper, 1945).

Chickens

Groups of 20 one-day-old chicks were maintained on diets containing 0 or 2% sodium CMC for 20 days. Addition of sodium CMC to the diet resulted in decreased growth rate (Vohra & Kratzer, 1964).

Long-term studies

Mice

Groups of 50 male and 50 female mice were maintained for up to 100 weeks on *ad libitum* diets containing 0, 0.1 and 1% of sodium CMC. There was no apparent

difference in mortality and tumour incidence between the groups (Imperial Chemical Industries, 1966). Groups of 50 male and 50 female B6C3F1 mice were used as vehicle-controls in a carcinogenicity study of selenium sulfide, and received 50 mg/kg bw of CMC by gavage, 5 days per week for 103 weeks. Untreated mice served as controls. Test animals were observed twice daily and examined weekly for clinical signs and the presence of palpable lesions. Mean body weights were recorded every two weeks for the first 12 weeks, then monthly for the remaining 93 weeks. Animals that were moribund and those that survived to the end of the study were necropsied. Gross and microscopic examinations were performed on major organs and all gross lesions. CMC-gavaged animals had approximately the same or fewer neoplasm than untreated control animals (NCI, 1979).

Rats

Groups of 25 rats, divided about equally by sex, were placed for two years on diets containing CMC in concentrations providing 100, 500, and 1000 mg/kg bw daily. Three generations of litters produced and kept on the same diet as their parents. According to growth rates, monthly urine and blood examinations, fertility, and histopathological examination of the main organs there were no differences between the test rats and the controls. No neoplasms were found in any of the experimental animals (Shelanski & Clark, 1948). Groups of 50 male and 50 female rates were maintained for up to two years on ad libitum diets containing 0, 0.1, and 1% of sodium CMC. No difference in mortality and tumour incidence was apparent between the groups (McElligot & Hurst, 1968). Thirty rats were given weekly injections of 1 mL of a 2 % aqueous solution of CMC subcutaneously. After 73 weeks, 43% of the animals showed tumours at the site of injection, characterized as fibrosarcomas of moderate malignancy (Lusky & Nelson, 1957). Twenty rats were given subcutaneous injections once a week of 2% aqueous solution of CMC. In 4 animals, tumours developed at the site of injection within 13 to 16 months. Two of the neoplasms were fibromas and two fibrosarcomas (Jasmin, 1961). Fifty F344 fats of each sex served as the vehicle control for a carcinogenicity study of selenium sulfide and received 5 mg/kg bw of CMC by gavage five days per week for 103 weeks. Untreated rats served as controls. Test animals were observed twice daily and examined weekly for clinical signs and the presence of palpable lesions. Mean body weights were recorded every two weeks for the first 12 weeks, then monthly for the remaining 93 weeks. Animals that were moribund and those that survived to the end of the study were necropsied. Gross and microscopic examinations were performed on major organs and all gross lesions. Eighty percent of CMC-fed male rates and 76% of CMC-fed females rates survived until the end of the study. These percentages were similar to those for untreated rates. CMC-gavaged animals has approximately the same or fewer neoplasms than untreated control animals (NCI, 1979).

Reproductive Studies

No data

Genotoxicity

Results of Genotoxicity assays on CMC are summarized in the following Table.

Test System	Test Object	Concentration of CMC	Results	Reference
Ames test (1, 3)	S. typhimurium – TA1535, TA1537, TA1538	5.0% Na CMC	Negative	Litton Bionetics, 1975
Ames test (1, 4)	S. typhimurium – TA1535, TA1537, TA1538	2.5, 5.0 & 10.0% Na CMC	Negative	Litton Bionetics, 1975
Ames test (2, 3)	S. typhimurium – TA98, TA100, TA1535, TA1537, TA1538	0.5, 1, 10, 100, 1000, 2500 & 5000 µg NA CMC/plate	Negative	Litton Bionetics, 1980
Ames test (2, 3)	S. typhimurium – TA92, TA94, TA98, TA1535, TA1537, TA100	≤ 2.5 mg Na CMC	Negative	Ishidate Jr. et al., 1984
Recombinogenicity	S. cerevisiae - D4-ade, D4-try	0.25, 0.50, 1.00%	Negative	Litton Bionetics, 1975
Chromosome Aberration	Chinese Hamster fibroblasts	≤ 2.8 mg Na CMC/mL	Negative	Ishidate Jr. et al., 1984

(1) Both with and without rate, mouse or monkey liver, lung or testes S-9 fraction
(2) Both with and without rat liver S-9 fraction
(3) Plate incorporation assay
(4) Suspension assay

Teratogenicity

Mice

Sodium CMC (0, 16, 74, 345, 1600 mg/kg bw/day) was administered as a corn oil solution by gavage to groups of 19-24 pregnant mice (Albino CD-1 outbred females) from days 6-15 of gestation. A positive control group of 24 pregnant mice received 150 mg aspirin/kg bw/day. All pregnant females survived until the end of the study. No effects were observed on nidation or on maternal or fetal survival. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring spontaneously in sham-treated controls (Food and Drug Research Laboratories, 1975).

Rats

Sodium CMC (0, 16, 74, 345 1600 mg/kg bw/day) was administered as a corn oil solution by gavage to groups of 19-22 pregnant rats (Wistar-derived) from days 6-15 of gestation. Nineteen pregnant rats (positive control group) were dosed with 250 mg aspirin/kg bw/day. All pregnant females survived until the end of the study. No effects were observed on nidation or on maternal or fetal survival. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring spontaneously in sham-treated controls (Food and Drug Research Laboratories, 1975). Twenty male rats (albino, Sprague-Dawley-derived) were treated at least 60 days and 40 female rats were treated at least 14 days before mating and during a 6-day mating period with 200 mg/kg bw/day by gavage; 20 male and 40 female

rates were maintained under identical conditions but were not dosed with CMC (controls). For one half of the females, treatment was continued until sacrifice on day 14 of gestation; for the remaining half of the females, treatment was continued until weaning of the progeny (day 28 after birth). No reactions to treatment with CMC were noted in the parents. Average body weights were comparable throughout the experiment (however, the body weight gain for males treated with CMC was less than the body weight gain for control males at 7 of the 10 weighings). No difference was observed in mating efficiency or pregnancy rate. The mean numbers of corpora lutea and implantation sites, as well as the ratios of corpora lutea to implantation sites, were comparable in both the CMC-treated and control groups. The rate of resorptions was not significantly increased in the CMC-treated group. In both groups of rats, the normal pregnancy duration was maintained (21-22 days) and no disturbances of parturition were noted. No significant difference was noted in litter size and sec ratio between the CMC-treat and control groups. The body weight gain of the pups was comparable for both groups. No abnormal nesting behavior (nursing, suckling, and creeping) was noted, and eye opening and pinna detachment followed the normal course in both groups. Results of behavioral tests (which included righting reflex, photophobotaxis, cliff avoidance, palmar grasp ability, negative geotaxis, and exploratory locomotion pattern in a cylindrical cage, direct pupillary reflex, and hearing ability by startle response), were comparable in test and control offspring (Fritz & Becker, 1981).

e. Effects on soil organisms, crops, or livestock

No specific data is available for potassium CMC. However, this substance is very similar to carboxylmethylcellulose, sodium salt (CAS# 9004-32-4). The two structures are identical with the exception of the cation of the salt. As such, the risk evaluation can be based on a read across approach.

Terrestrial Toxicity

A study of 56 day(s) duration using natural soil media was conducted in a Lab site location on *Phaseolus vulgaris* (bean). The seed(s) were exposed for a duration of 56 days to a 1 dose x time per study period application of Cellulose, carboxymethyl ether, sodium salt (CAS# 9004-32-4) in not reported carrier. The reported chemical concentrations are the result of unmeasured analysis of chemical solutions. The concentrations are based on undefined soil weight and are the result of unmeasured analysis of the chemical concentration in soil. No effects or data are reported (Miller et al., 1980).

A study of 56 days duration using natural soil media was conducted in a Lab site location on *Zea mays* (corn). The seeds were exposed for a duration of 56 days to a 1 does x time per study period application of Cellulose, carboxymethyl ether, sodium salt (CAS# 9004-32-4) in not reported carrier. The reported chemical concentrations are the result of unmeasured analysis of chemical solutions. The concentrations are based on undefined soil weight and are the result of unmeasured analysis of the chemical concentration in soil. No effect or data are reported (Miller et al., 1980).

11. Safety Information

No specific safety information is available. This product is not classified as a hazardous chemical according to Safety Data Sheet is available in the attachments

12. Research Information

No Data available

13. Petition Justification Statement

- Inclusion of a Synthetic on the National List
    - **Explain why the synthetic substance is necessary for the production or handling of an organic product.**

      Water management is the capacity to move water wherever is needed in order to improve plant health. The water-like natural base polymer, potassium CMC, is able to hold water in two the root zone balancing the behavior of most of soil surfactants that move water into the soil. The potassium salt is preferred to the sodium salt as it provided better performance at the same concentration and is not increasing the sodium balance into the soil.

    - **Describe any non-synthetic substances, synthetic substances on the National List, or alternative cultural method that could be used in place of the petition synthetic substance.**

      So far the only way found to obtain the same results, we achieved using potassium CMC as water holding agent, was to increase from 30-40% the amount of dripped water. To the best of our knowledge there are no non-synthetic substance/s able to provide the same benefit at the same concentration.

    - **Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that supports its use instead of the use of a non-synthetic substance or alternative cultural method.**

      Using potassium CMC, we were able to save 30-40% of dripped water in several different crops or to increase yield using the same amount of dripped water. This can results in huge water saving in areas where water has become a very limited resource.

14. References

Anderson, 1986

CTFA, 1977

CTFA, 1978a,b

CTFA, 1980

Ecotoxicol Environ Saf. 44(2):196-206-1999

EPA “Cellulose Carboxymethyl Ether, Potassium Salt; Tolerance Exemption,” Vol. 80, No. 196, Fed. Reg. (October 9, 2015) (to be codified at 40 C. F. R. Part 180), 61122-61125

Food and Agriculture Organization of the United Nations World Health Organization, 1967. Meeting for Sodium Carboxymethylcellulose. Retrieved from http://www.inchem.org/documents/jecfa/jecmono/40abcj20.htm , on 29 April 2016.

Food and Drug Research Laboratories, 1975

Fritz & Becker, 1981

Hueper, 1945

Imperial Chemical Industries, 1966

Ishidate Jr. et al., 1984

Jasmin, 1961

Jasmin & Bois, 1961

Lamberti SpA. – Ecotoxicological Laboratory – Internal Reports

Litton Bionetics, 1975

Litton Bionetics, 1980

Lusky & Nelson, 1957

McElligot & Hurst, 1968

Miller, R.W., Honarvar, S., and Hunsaker, B., 1980, Test number 46406, Reference 44338

NCI, 1979

Rowe et al., 1944

Selye, 1955

Shelanski & Clark, 1948

Shellfish Information Leaflet No. 22 (2nd Ed.), Ministry of Agriculture Fishe Food, Fish Lab Furnham-on-Crouch, Essex, and Fishe Exp. Station Conway, north Wales: 12p. -1971

U.S. EPC-OPP Registration standard: 1p. (CBI Data) 1975

U.S. Food and Drug Administration, “Select Committee on GRAS Substances (SCOGS) Opinion: Carboxymethyl cellulose (Packaging) and Sodium carboxymethyl cellulose” Retrieved from http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm261244.htm , on 29 April 2016

Vohra & Kratzer, 1964

Werle, 1941

Ziegelmayer et al., 1951

Attachment 1: Safety Data Sheet – Lamfix K

Safety Data Sheet dated 25/11/2015, version 1

Printing date:6/5/2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name:	LAMFIX K
MSDS code:	F007899
Chemical description:	Carboxymethyl cellulose, potassium salt

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use:

Industrial uses.

1.3. Details of the supplier of the safety data sheet

Supplier:

LAMBERTI S.p.A. - Via Piave 18 - 21041 Albizzate (VA)

Tel.: +39 0331 715 111 - Fax.: +39 0331 775 577 - e-mail: hse@lamberti.com

Competent person responsible for the safety data sheet:

hse@lamberti.com

1.4. Emergency telephone number

LAMBERTI S.p.A. - Tel. : +39 0331 715 111 - 24h

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Symbols:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH208 May produce an allergic reaction.

Contents

1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one: May produce an allergic reaction.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

None

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. Seek immediately medical advice.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

4.2. Most important symptoms and effects, both acute and delayed

Not known.

4.3. Indication of any immediate medical attention and special treatment needed

Treatment:

Not known.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

Not known.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove all sources of ignition.

Remove persons to safety.

See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3. Methods and material for containment and cleaning up

Suitable material for taking up: absorbing material, organic, sand

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.
Do not eat or drink while working.
See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.
Incompatible materials:
None.
Instructions as regards storage premises:
Adequate ventilation in working area.
Packaging suggested:
Plastic drums.

7.3. Specific end use(s)

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No occupational exposure limit available
DNEL Exposure Limit Values
N.D.
PNEC Exposure Limit Values
N.D.

8.2. Exposure controls

Eye protection:

Use close fitting safety goggles. (ref. EN 166, EN 140, EN175).

Protection for skin:

Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or viton. (ref. EN 340).

Protection for hands:

Chemical protective gloves should not be needed when handling this material. Consistent with general hygienic practice for any material, skin contact should be minimized. In case of prolonged contact, the use of protective gloves is recommended , providing comprehensive protection to chemicals (refer to EN 374).

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged, e.g. (ref. EN 136, EN 140, EN 141, EN 143, EN 149, EN 405).

Thermal Hazards:

None

Environmental exposure controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance and colour: Liquid
Odour: No
Odour threshold: N.D.
pH: 6.5 - 9@20°C
Melting point / freezing point: N.D.
Initial boiling point and boiling range: 103°C
Solid/gas flammability: N.D.
Upper/lower flammability or explosive limits: N.D.
Vapour density: N.D.

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Flash point: N.D.
Evaporation rate: N.D.
Vapour pressure: N.D.
Relative density: 1.15 kg/l
Solubility in water: Soluble
Solubility in oil: N.D.
Partition coefficient (n-octanol/water): N.D.
Auto-ignition temperature: N.D.
Decomposition temperature: N.D.
Viscosity: 2500 cP
Explosive properties: N.D.
Oxidizing properties: N.D.

9.2. Other information

Miscibility: N.D.
Fat Solubility: N.D.
Conductivity: N.D.
Substance Groups relevant properties N.D.

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Stable under normal conditions

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the mixture:

a) acute toxicity:

LD50 Oral Rat > 2000 mg/kg Calculated data.

b) skin corrosion/irritation:

Irritation Skin : repeated and prolonged contacts may cause slight irritation.

c) serious eye damage/irritation:

Irritation Eye : repeated and prolonged contacts may cause slight irritation.

Toxicological information of the main substances found in the mixture:

Other : N.D.

If not differently specified, the information required in Regulation 453/2010/EC listed below must be considered as N.D.:

a) acute toxicity;
b) skin corrosion/irritation;
c) serious eye damage/irritation;
d) respiratory or skin sensitisation;
e) germ cell mutagenicity;
f) carcinogenicity;
g) reproductive toxicity;
h) STOT-single exposure;

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i) STOT-repeated exposure;
j) aspiration hazard.

SECTION 12: Ecological information

12.1. Toxicity

Ecological information of the mixture:

a) Aquatic acute toxicity:

Notes: LC50 > 100 mg/l - aquatic species (according to the criteria of the CLP Regulation).

12.2. Persistence and degradability

Ecological information of the mixture:

N.D.

12.3. Bioaccumulative potential

Ecological information of the mixture:

N.D.

12.4. Mobility in soil

Ecological information of the mixture:

N.D.

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Other adverse effects

None

Use according to criteria of good industrial practice, avoiding product dispersion in the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

If possible recover the product in accordance with local regulation.

SECTION 14: Transport information

14.1. UN number

N.A.

14.2. UN proper shipping name

Proper Shipping Name: N.A.

14.3. Transport hazard class(es)

Road (ADR): N.A.
Air (ICAO/IATA): N.A.
Sea (IMO/IMDG): N.A.

14.4. Packing group

ADR-Packing Group: N.A.

14.5. Environmental hazards

Environmental Pollutant: No

14.6. Special precautions for user

N.A.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

N.D.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Dir. 2000/39/EC (Occupational exposure limit values); Dir. 2006/8/CE. Regulation (CE) n. 1907/2006 (REACH).

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For non-EU Countries, the Material Safety Data Sheet it is prepared following the main principles of Globally Harmonized System of Classification and Labelling of Chemicals (GHS) which are adopted worldwide.

15.2. Chemical safety assessment

No

SECTION 16: Other information

N.A. = Not Applicable
N.D. = No Data available

This safety data sheet has been completely updated in compliance to Regulation 453/2010.

This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources:

TOXNET - Databases on toxicology, hazardous chemicals, environmental health, and toxic releases;
NIOSH - Registry of toxic effects of chemical substances (1983) - Occupational Health Guidelines for Chemical Hazards (1995) - Pocket Guide to Chemical Hazards (on line)
European Chemical Bureau - ESIS: European chemical Substances Information System;
CESIO - Classification and labelling of anionic, nonionic surfactants (January 2000).
M.Sittig-Handbook of toxic and Hazardous Chemicals and Carcinogens- III Ed.
E.R. Plunkett - Handbook of Industrial Toxicology - III Ed. 1991.
Samson Chem. Pub.-Chemical Safety Sheet working safely with hazardous chemical.
SAX'S Dangerous Properties of Industrial Materials. VIII (1993)
ACGIH "2013 TLVs and BEIs".
ILV "1998/24/EC Directive and subsequent addition".

The product must be stored, handled and used according to criteria of good industrial practice and to regulations in force. This leaflet is offered for your consideration and guidance only. This leaflet complements the Technical Data Sheet but does not replace it. The information herein contained is given to the best of our knowledge at the time of issue.
Due to the several ways in which the product may be used and the possible interaction with variables not depending on or unknown to the supplier, we also cannot accept any liability whatsoever for any loss or damage however arising from the handling and use of our products.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization"

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	(ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
LTE:	Long-term exposure.
PNEC:	Predicted No Effect Concentration.
REACH:	Registration Evaluation and Authorization of Chemicals.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STE:	Short-term exposure.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
SVHC:	Candidate List of Substances of Very High Concerns.
TLV:	Threshold Limiting Value.
TWATLV:	Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
WGK:	German Water Hazard Class.

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Attachment 2: Label – Lamfix K

Lamberti S.p.A.

chemical specialties

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CST PPC Exxon Rd
14622 Exxon Road
Conroe TX 77302 (US)

USA

F007899-601600 **LAMFIX K**

batch: 2014030002

delivery: 0081235383
purch.order : 4500422989

net weight: 120,00 Kg tare: 5,50 Kg gross weight: 125,50 Kg

NON SUPERARE LA TEMPERATURA DI 60°C **NON SUPERARE LA TEMPERATURA DI 60°C**

Country of origin Italy

Shipping Agent: FORNI RIVA-SPED.TRASP. S.A.S. CARDANO AL CAMPO-VA VIA CAMPO DEI F