ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR PART 25)

ENVIRONMENTAL ASSESSMENT FOR WOOD PALLETS WITH DODECYLBENENZE SULFONIC ACID USED IN HYDROCOOLING

1. **Date**: January 5, 2021

2. **Name of Applicant**: CHEP USA

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All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent in care of the authorized representative

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4. **Description of Proposed Action**

a) Requested action:

The action proposed in this notification is to permit use of the food contact substance (FCS) alkyl (C_{10}-C_{16}) benzene sulfonic acid, also referred to as dodecylbenenze sulfonic acid (DDBSA), in the treatment and assembly of wood pallets treated with the fungicide PQ-80. PQ-80 contains BIOSOFT S-101 as an ingredient. DDBSA is a component chemical in BIOSOFT S-101. DDBSA incorporated in the PQ-80 formulation is proposed for use as an indirect food additive through the pre-manufacture process utilizing FDA Form 3480 “Notification for New Use of a Food Contact Substance.”

Wood pallets treated with PQ-80, containing the FCS DDBSA, will be used in post-harvest hydrocooling and related processing of fruits and vegetables to prevent ripening or decay throughout distribution. PQ-80 contains the active ingredient copper quinolinolate, and will be applied at a rate of 40 micrograms of copper quinolinolate per cm^2.

In the PQ-80 formulation, DDBSA functions to solubilize the active ingredient and promote an even spread of PQ-80 on treated wood. BIOSOFT S-101, the chemical ingredient in PQ-80 containing the FCS DDBSA, also contains sulfuric acid and benzene, C_{10}-C_{13}-alkyl derivatives (collectively referred to as linear alkyl benzenes; LAB) as unreacted base material.

In hydrocooling water used to prevent pre-market ripening of fruits and vegetables, components of the BIOSOFT S-101 mixture containing the FCS are not anticipated to exceed 28.4 ppm DDBSA [see migration experiment description under Item 6(B) below].

CHEP USA is requesting approval to use wooden pallets treated with the fungicide PQ-80, containing the FCS DDBSA. The fungicide protects the wood from fungal damage and the wood pallets may be used in hydrocooling produce, which is an indirect food contact scenario.

Fresh produce continues to respire after harvest. To prevent produce breakdown (wilting, softening etc.) caused by natural respiration throughout the post-harvest distribution chain, the produce industry uses a variety of precooling techniques to slow the breakdown process. Precooling provides a non-chemical preservative method for fruit and vegetable processing, and keeps produce fresh through the distribution chain, maximizing the value of produce upon arrival at market.

Modern precooling techniques include vacuum cooling, pressure cooling, hydrocooling, HydroVac™ cooling and "icing." During precooling processes, commodities are stored on pallets and rotated through a hydrocooling container, typically by a conveyer belt[1].

In each precooling technique, raw produce is not in direct contact with pallets. Rather, produce is packaged in open storage containers, which are packed onto pallets. Open produce storage containers may be composed of wire mesh, plastic, or other materials.

b) **Need for action**:

CHEP USA is requesting approval to use wooden pallets treated with the fungicide PQ-80, containing the FCS DDBSA. Wood pallets may be used for the purpose of preventing produce decay during precooling of produce stored on treated pallets, preserving the market value of produce and ultimately providing safer foods for consumers.

The purpose of the DDBSA is to solubilize the active ingredient in PQ-80. DDBSA is also used to promote an even spread of PQ-80 on treated wood. The wood is produced by a third-party supplier at lumber yards where the PQ-80 will be applied. The PQ-80 supplier (ISK Biocides) buys BIOSOFT S-101 (DDBSA source) from Stepan.

[1] For examples of hydrocoolers, see: TRJ Refrigeration Inc. (2019). Hydrocoolers. Available at: http://www.trj-inc.com/hydroCooler.html.

c) **Locations of use/disposal**:

Use: As a component of finished pallets used in hydrocooling operations across the United States, the FCS is utilized in patterns corresponding to the needs and locations of produce hydrocooling operations throughout the country. Produce hydrocooling sites are typically located close to agricultural production, and are widely distributed across the United States. The FCS will be utilized in patterns corresponding to crop production, processing and demand.

Disposal: At the end of their service life, FCS-treated pallets may be disposed of in municipal solid waste (MSW) systems throughout the United States (either in a landfill or incinerated), or converted into mulch.

According to the U.S. Environmental Protection Agency (EPA)'s 2017 data[2] regarding MSW in the United States, a total of 267.8 million tons of MSW is generated annually, with approximately 52.1% disposed of in MSW landfills, 12.7% combusted with energy recovery, 25.1% recycled, and 10.1% composted.

Based upon a life cycle analysis further described in item 7(c) of this EA, provided as a confidential attachment to this EA (**Confidential Attachment O.4**), we anticipate that approximately 90% of pallet wood will be chipped for mulch and the remainder either landfill disposed (8%) or incinerated (2%).

Hydrocooling water is recycled through multiple hydrocooling cycles. Direct discharge to surface waters is not anticipated. However, such discharges would be regulated under National Pollutant Discharge Elimination System (NPDES) permitting. In accordance with an NPDES permit, wastewater would undergo pretreatment at the processing facility prior to direct discharge to surface waters or into a privately-owned treatment works system. More commonly, hydrocooling water would be directed through sanitary sewer systems into publicly-owned treatment works (POTWs) systems for standard wastewater treatment before movement into aquatic environments (i.e., surface water).

5. Identification of the Chemical Substance that is the Subject of the Proposed Action:

The fungicide PQ-80 contains BIOSOFT S-101 (60.8%) as an ingredient. The FCS in this notification is DDBSA. DDBSA is a component chemical in BIOSOFT S-101. BIOSOFT S-101 is a dark amber, viscous liquid containing DDBSA, sulfuric acid and unreacted LAB material. Chemical information for the BIOSOFT S-101 component of PQ-80 containing the FCS DDBSA is summarized in Table 1 below.

[2] U.S. EPA's Advancing Sustainable Materials Management: 2017 Fact Sheet available at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

Table 1. Chemical Components in BIOSOFT S-101.

Chemical name	CAS Reg. No.	%
Alkyl(C10-16)benzenesulfonic acid, also known as dodecylbenzene sulfonic acid (DDBSA) (Alt CAS 27176-87-0 85536-14-7)	68584-22-5	90 - 100
Alkyl Benzene-Ln. (C10-13) (LAB) (Alternate CAS: 67774-74-7)	129813-58-7	1 - < 3
Sulfuric acid	7664-93-9	1 - < 3
Other components below reportable levels		< 1

As noted in 4(b) above, the proposed use of DDBSA is to solubilize the active ingredient in PQ-80 and promote an even spread of PQ-80 on treated wood. Available information on the chemical identity of the FCS DDBSA is provided in Table 2 below.

Table 2. Chemical Identity of Dodecylbenenze Sulfonic Acid (DDBSA).

DDBSA	
Chemical Name	Dodecylbenzene sulfonic acid
Common or Trade Name	BIOSOFT S-101
CAS Registry Number	68584-22-5
Empirical Formula	$C_{12}H_{25}C_6H_4SO_3Na$
Structural Formula	N/A
Molecular Weight	326.5
Form	Liquid
Appearance	Brown viscous liquid
Odor	Sulfur dioxide smell
Solubility in Water	Soluble

DDBSA is part of a general class of chemicals called linear alkylbenzene sulfonates (LAS) which are C_{10}-C_{16} carbon chain (DDBSA is C_{12}, though commercially sold DDBSA is considered a mixture of carbon chain lengths). Authoritative agencies including the OECD prepared safety assessments of LASs which apply to DDBSA (OECD, 2005).

The below structure of a C_{12}-LAS is utilized as a representative structure for the full category (OECD, 2005).

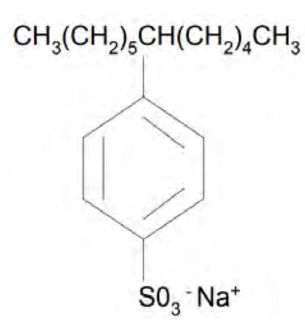

Figure 1. Dodecylbenzene sulfonic acid structure.

6. Environmental Assessment – Introduction of the Substance into the Environment

The following Environmental Assessment (EA) demonstrates that CHEP's use and disposal of DDBSA, as a component of the fungicide PQ-80 for use in hydrocooling, presents no significant environmental impact.

A. As a Result of Manufacture

Under 21 Code of Federal Regulations (CFR) §25.40(a), an EA should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. CHEP does not manufacture the wood, PQ-80, or the BIOSOFT S-101 utilized to treat wooden pallets for use in hydrocooling. Wood used to construct pallets to be treated with the FCS is generated by a third-party company outside the United States. CHEP purchases the wood from this third party seller, and assembles pallets at CHEP facilities in the United States. There is no reason to expect a significant release to the environment during assembly.

Manufacture of the FCS occurs only in plants that comply with all applicable federal, state, and local environmental regulations. Information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicating any significant adverse environmental impact as a result of the manufacture of treated pallets. Further, there are no extraordinary circumstances indicative of any significant adverse environmental impacts resulting from the manufacture of treated pallets. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

B. As a Result of Use/Disposal

Noting the specific use patterns for the FCS described above (i.e., to solubilize the active ingredient in PQ-80 and promote an even spread of PQ-80 on treated wood where treated wood is used to construct wooden pallets used in produce hydrocooling operations, preventing produce decay during precooling of produce stored on treated pallets), the primary pathway by which the FCS is anticipated to be introduced to the environment is through the treatment and disposal of hydrocooling process wastewater generated over the lifetime of a treated pallet [approximately 10 years; see Item 7(c) below].

Hydrocooling water is recycled through multiple hydrocooling cycles after which it is discharged to a municipal sewer. The water will then be transported to a POTW where it will mix with other water sources and undergo water treatment. We note that direct discharge to surface waters under NPDES permitting is not anticipated. Due to the energy required to run hydrocooling equipment and the need to be in close proximity to a cold storage facility in order to maintain cold-chain integrity, hydrocooling does not occur, to our knowledge, near agricultural fields immediately after harvest.

Following use of the FCS at a hydrocooling or food processing facility, waste processing water generated and containing the diluted FCS material may be introduced to the environment via treatment and disposal of hydrocooling wastewater through the sewage system into waterways.

At the end of their service life, FCS-treated pallets may be disposed of in municipal solid waste (MSW) systems throughout the United States (either in a landfill or incinerated), or converted into mulch.

1) **Maximum market volume for proposed use**

The total amount of FCS utilized at a given food processing facility will depend on the volume of fruit and vegetable products processed via hydrocooling on pallets pre-treated with the FCS at that site. To adjust for variation in volume of fruit and vegetable products that may be processed at a given site, the expected introduction concentration (EIC) in surface water was calculated based on an intentionally conservative, worst-case assumption that all of the process water potentially containing diluted FCS is discharged to surface waters after water treatment on-site or at a POTW.

While hydrocooling machinery is mobile, hydrocooling typically is done in facilities with sufficient power supply to handle a large throughput. Therefore, in our experience, it is not done at individual farms where the water may be used for irrigation.

Migration experiments were conducted to measure DDBSA in hydrocooling process water after passing pallets treated with the fungicide PQ-80 through a simulated hydrocooling soak and estimate migration of residues to produce packed on pallets treated with the PQ-80.

Various conservative assumptions that would overestimate concentrations were made including:

- Assumption of worst-case conditions for hydrocooling, including a 12-hour cycle with 432 pallets, low water usage and no recycling, and low commodity volume (see below for details).
- Assumption that 100% of the chemical that migrated into the cooling water then migrates into the food commodity.
- Assumption that 100% of commodities that may employ hydrocooling with pallets were hydrocooled. In fact, for some portion of all commodities no cooling will be done and for some commodities other precooling methods are also used.
- Assumption that 100% of commodities that may employ hydrocooling with pallets use CHEP pallets.

- For repeat use pallets, assumption that there is a full dosage of PQ-80 available despite assuming that all of the chemical migrated in the first use.
- Assumption that the full top area of the pallet is available to contact water and potentially migrate chemical into the water despite the top area of the pallet being covered by the commodity container.

The laboratory method was designed to simulate the conditions in a water hydrocooler, in which recycled cold water contacts the pallets containing the commodities over the course of a day, and involved immersing wood pieces in a specific volume of water for time cycles that approximately corresponded to the residence times of pallets in the hydrocooler. The laboratory-scale approximation of the hydrocooling process is based on a 1,000-gallon capacity hydrocooler with a throughput of 36 pallets per hour, with a 40-minute residence time for each pallet. See EA Item 6(B)(4)(i) for a further description of this process. The temperature of the hydrocooling water is approximately 34°F. The maximum residue level of DDBSA is summarized in Table 3 below and is calculated by dividing the product of the measured DDBSA migration rate and the PQ-80 treated surface area of pallets hydrocooled in a 12-hr process by the total volume of hydrocooling water. The migration data and this calculation are provided in **Confidential Attachments O.1 and O.2** to this EA.

Table 3. Maximum concentration of constituents from migration test

Constituent	**Concentration (ppm)**
DDBSA	28.4

2) Percent of market volume that will enter the environment

Utilizing a worst-case assumption, an estimated 100% of the FCS is considered to be disposed of with waste processing waters after hydrocooling. Under this assumption, 100% of the FCS used at a given facility enters an on- or off-site wastewater treatment system and may be released into aquatic and/or terrestrial environments.

3) The mode of chemical introduction into the environment

The FCS will be directly applied to wood pallets prior to hydrocooling of fruits and vegetables packed on treated pallets. Assuming a worst-case scenario, all of the FCS that may migrate from pallets to hydrocooling process water will be discharged to surface waters after water treatment on-site or at a POTW.

4) Expected concentration of chemicals introduced into the environment

i. Estimated --- Concentration in the Aquatic Environment

As stated in Item 5 above, the FCS in this notification is DDBSA. DDBSA is a component chemical in BIOSOFT S-101. BIOSOFT S-101 is an ingredient in formulation for the fungicide PQ-80, and also contains sulfuric acid and unreacted LAB material.

Sulfuric acid dissociates readily to sulfate in the presence of water[3]. As such, this component is not anticipated to be introduced to the environment to any significant extent as a result of the use of BIOSOFT S-101 in PQ-80, or disposal of hydrocooling water. Due to the unique chemical properties of sulfuric acid and its rapid degradation, quantitative evaluations of the expected introduction or environmental concentrations and ecotoxicity for sulfuric acid is not necessary.

Estimated environmental concentrations were not made for unreacted LAB for a few reasons. First, DDBSA contains levels of unreacted LAB so any ecotoxicity from LAB should be incorporated in ecotoxicity measurements for DDBSA. As shown in Table 1, LAB is present in much smaller quantities than DDBSA and it is much less soluble in water. The DDBSA solubility is 100 mg/L (see below) whereas the water solubility for LAB is only 0.041 mg/L (ECHA, 2020a). Therefore, LAB is not expected to migrate into the hydrocooling water nearly as much as DDBSA.

As outlined above, assumptions representing a worst-case scenario in which 100% of PQ-80 containing the FCS (DDBSA) would migrate to hydrocooling water and be discharged into surface water were utilized to calculate the Expected Introduction Concentration (EIC).

There is limited public documentation available on hydrocooling processes. Therefore, CHEP gathered information from its customers on how the pallets are used. Approximately 12-36 pallets are used in a hydrocooling batch, meaning the pallets holding the food commodities are placed on a conveyer which delivers them into and through the hydrocooling car. A high-end rate of 36 pallets/hour was assumed.

In hydrocooling, cold water is drained onto the pallets in a process that is completed in about 35-40 minutes. The quantity of food on a pallet ranges from 460 to 2000 lbs. Information provided by CHEP indicates that the amount of

[3] Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; available at https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb; see also Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006

water used varies according to unit size: a "1/2 Car Tube" holds approx. 500 gallons, and a "Full Car" can vary between approx. 1000 and 1500 gallons.

It is reasonable, however, to assume that the "1/2 Car Tube" variety will process a directly proportionally lower number of pallets than a full car, so the water-to-pallet surface ratio would be approximately the same. Therefore, for worst-case calculations, the following assumptions were made: 1000 gallons of water during a 12-hour hydrocooling cycle with 36 pallets/hour where each pallet has 460 lbs of food commodity.

A typical POTW has a daily flow of 2 million gallons[4]. Therefore, the hydrocooling flow represents 0.05%[5] of the typical daily flow through of a POTW. Conservatively assuming no removal from treatment, the estimated upper-bound aquatic introduction concentration ($EIC_{aquatic}$) for DDBSA is 14.2 ppb[6]. A summary of $EIC_{aquatic}$ values is shown in Table 4.

Table 4. Estimated aquatic introduction concentration for DDBSA

Constituent	$EIC_{aquatic}$ (ppm)	$EIC_{aquatic}$ (ppb)
DDBSA	0.0142	14.2

Chemical species present in the FCS are present in the aqueous phase. Because the FCS is anticipated for use as an indirect food additive through the pre-manufacture process (by application to wood pallets prior to hydrocooling of fruits and vegetables packed on treated pallets), chemical components surviving wastewater treatment may consequently be introduced to the aquatic environment (i.e., surface waters) via the disposal of process water processing plant wastewater. Surface water is anticipated to be the primary route of FCS environmental introduction.

The assessment conservatively assumes no removal of DDBSA from water treatment systems. However, the available evidence shows that DDBSA is substantially removed in water treatment systems. OECD (2005) reports that LASs are removed >99% in activated sludge systems and the average removal is trickling filter systems is 77% - 82%. There is no evidence that small quantities of DDBSA affect water treatment systems.

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[4] See EPA's 1996 Clean Water Needs survey, where the total POTW flow in the U.S. was 32,175 million gallons in 1996, and the total number of facilities was 16,024. Therefore, the average facility has approximately 2 million gallons per day of flow. https://nepis.epa.gov/Exe/ZyPDF.cgi/200044DI.PDF?Dockey=200044DI.PDF. More recent Needs surveys do not appear to include the total POTW flow.

[5] hydrocooling flow = 1000 gallons/day x 100 / 2,000,000 gallons POTW flow/day = 0.05%

[6] $EIC_{aquatic}$ (ppm) =0.05/100 x 28.4ppm = 0.0142 ppm. This is equivalent to 14.2 ppb

ii. Estimated --- Concentration in the Terrestrial Environment

Within the U.S., residual sludge from the wastewater treatment process is most commonly disposed of by land application, relocation to a surface disposal site or by incineration. Such disposal is regulated under the Clean Water Act (CWA). Thus, DDBSA entering sludge material following proper use of the PQ-80 fungicide may be landfilled or land applied. However, releases of DDBSA to the environment from such subsequent pathways are expected to be significantly controlled through relevant EPA regulations and state and local guidelines (see 40 CFR Part 503).

FDA states that substances with a K_{oc} > 1000 L/kg might absorb significantly to sewage sludge[7]. Substances that adsorb to sewage sludge might result in exposure in the terrestrial environment. OECD (OCED, 2005) has reported high K_{oc} values for LAS, including values of 10,471 L/kg (logK_{oc}=4.02) for C_{10} LAS, 67,608 L/kg (logK_{oc}=4.83) for C_{12} LAS, and 309,030 L/kg (logK_{oc}=5.49) for C_{14} LAS based on measurements by Traina et al. (1996). Given K_{oc}>1000 L/kg, a terrestrial assessment was conducted.

As stated above, sulfuric acid dissociates readily to sulfate in the presence of water. As such, this component is not anticipated to be introduced to the environment to any significant extent as a result of the use of BIOSOFT S-101 in PQ-80, or disposal of hydrocooling water, and was not further evaluated for the purposes of this assessment.

We estimated terrestrial concentrations as follows[8]:

EIC--Terrestrial (ppm) = A x B x C x D, where

A = kg/year production volume of the substance

B = 1/6.4 x 10^9 kg sewage sludge/year[9]

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[7] See Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix A. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan-6

[8] See Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix A. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan-6

[9] See Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment, Appendix A which states: "The volume of biosolids from POTWs was projected to be 7.1 million tons, or about 6.4 W 10^9 kg, for the year 2000 (*Biosolids Generation, Use, and Disposal in the United States*. EPA 530-R99-009; September 1999, p. 30)."

C = 0.555 (proportion of biosolids expected to be land applied[10])

D = 10^6 mg/kg (conversion factor)

The use volume of PQ-80 containing DDBSA was estimated by very conservatively calculating the amount of produce that may be hydrocooled each year. It would be inappropriate to include all DDBSA applied to pallets because the vast majority of pallets are never hydrocooled. The calculation of produce that may be hydrocooled was based on a consumption estimate of 57.8 gram/day of the diet of a typical person, which includes hydrocooled food items[11]. A consumption estimate of 57.8 grams/day of the diet of a typical person was developed by estimating U.S. food consumption for the 19 specific commodities that may be hydrocooled and was derived using the *What We Eat in America* dietary component of the National Health and Nutrition Examination Survey (NHANES) 2013-2016 (available at https:// wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2013) . The analysis includes raw, cooked, canned, frozen, and juice food forms and reflects the mean per user consumptions for the total U.S. population. This analysis is detailed in **Confidential Attachment O.3** to this EA.

Given the U.S. population of 330 million people, this results in a conservative estimate of 1.91×10^7 kg of hydrocooled food per day[12]. This calculation very conservatively assumes that all produce that could potentially be hydrocooled is indeed hydrocooled.

The mean food residue of DDBSA was 1.2 ppm (mg/kg) and is calculated by dividing the total mass of DDBSA in a full hydrocooling session by the total mass of food in a 12-hour hydrocooling session. This calculation is presented in Confidential Attachment O.2 to this EA and is based upon the DDBSA migration data given in Confidential Attachment O.1 to this EA. Thus, the total estimated DDBSA that could be in terrestrially applied sludge is 7658 kg/year[13] (again conservatively assuming 100% migration of DDBSA from hydrocooling water to food). We can conservatively use this value as estimate of the production volume, in this case, the DDBSA that is released during hydrocooling. It assumes that all

[10] See Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment, Appendix A which states: "The proportion of biosolids from POTWs projected to be land applied or composted was estimated to be 55.5% for the year 2000. (*Biosolids Generation, Use, and Disposal in the United States.* EPA 530-R99-009; September 1999, p. 35)."

[11] CHEP's experience with items that are hydrocooled is consistent with literature on commodity cooling methods compiled by UC Davis - UC Davis Biological & Agricultural Engineering Department. 2008. Status of energy use and conservation technologies used in fruit and vegetable cooling operation in California. Prepared for the Calif. Energy Commission. Report No. CEC-400-1999-005.

[12] 330×10^6 people * 57.8 gram/day * 0.001 kg/g = 1.9074×10^7 kg/day

[13] 1.9074×10^7 kg/day * 1.2 mg/kg * 365 day/year * 0.000001 kg/mg = 8354 kg/year

DDBSA that migrated into the hydrocooling water (conservatively estimated) either ends up in a wastewater treatment plant due to disposal of the hydrocooling water or is consumed in food and excreted. Given all of these assumptions and applying the formula above, the estimated EIC_{sludge} for DDBSA is 0.72 ppm[14].

The estimated EIC in sludge is highly conservative for numerous reasons, including the assumption that all vegetables or fruits that can be hydrocooled were hydrocooled using CHEP pallets treated with PQ-80 containing the FCS DDBSA. Additionally, DDBSA is substantially removed in water treatment systems. OECD (2005) reports that LASs are removed >99% in activated sludge systems and the average removal is trickling filter systems was between 77% and 82%.

Table 5. Estimated terrestrial introduction concentration for DDBSA

Constituent	EIC_{sludge} (ppm)	EIC_{sludge} (ppb)
DDBSA	0.72	720

Should DDBSA-containing sludge be disposed of in a MSW landfill, U.S. EPA regulations would enforce restricted movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, and groundwater monitoring requirements (40 CFR Part 258). DDBSA introduced to the environment via MSW landfills is anticipated to be at extremely low concentrations, if at all.

Land applications are regulated under U.S. EPA 40 CFR 503 Standards, which establish pollutant limits, general requirements, operational standards for pathogen and vector attraction reduction, management practices, monitoring frequency, and recordkeeping and reporting requirements for land appliers and facilities generating sludge for use in land application (U.S. EPA, 1994).

We do not expect waste and/or sludge generated from wastewater at food processing facilities to be incinerated. However, should sewage sludge generated as a byproduct of processing plant wastewater treatment be incinerated, incinerators and incineration practices are sufficiently regulated under 40 CFR Part 60. If and/or when DDBSA is combusted, there is nothing to suggest that DDBSA incineration would threaten a violation of 40 CFR 60, the regulations governing sewage sludge incinerators, as carbon, hydrogen, phosphorus and oxygen are typical elements in MSW and in sludge.

i. Estimated --- Concentration in the Atmospheric Environment

DDBSA is not volatile. Therefore, it is not expected to be present in the atmosphere in any meaningful quantities.

[14] EIC_{sludge} = 8354 kg/year * (1/6.4x10^9) * 0.555 * 10^6 = 0.72 ppm

7. Fate of Substances Released into the Environment

As outlined above, negligible amounts of the FCS may be released into the environment as the result of use and hydrocooling water disposal. Sulfuric acid dissociates readily to sulfate in the presence of water and is not anticipated to be introduced to the environment to any significant extent as a result of the use of BIOSOFT S-101 in PQ-80, or disposal of hydrocooling water.

As discussed in Item 6, we do not expect any significant release to the environment as a result of the use or migration of the FCS to hydrocooling process water. However, in full disclosure, a detailed discussion of the potential fate of the FCS that may be released into the environment is included below.

Basic physicochemical and environmental fate properties of the FCS are included in Table 6 and were obtained from the ECHA dossier for the sulfonate[15], which describes DDBSA in solution, except that the K_{oc} is from the OECD report because the ECHA value is based on a quantitative structure activity relationship (QSAR) as opposed to a measurement. DDBSA is water soluble with a very low vapor pressure. It is considered readily biodegradable and the estimated K_{oc} > 10,000 L/kg. The soil-half life in sludge was 23.1 days. DDBSA is stable to hydrolysis. It has a low potential for bioaccumulation.

Table 6. Physicochemical and environmental fate properties of DDBSA

Property	DDBSA
Water solubility	100 mg/L[16]
Vapor pressure	3.05×10^{-13} Pa (not volatile)
Partition coefficient	$logP_{ow} = 3.0$
K_{oc}	>10,000 L/kg (see above)
Aerobic soil half-life (sludge)	23.1 days
Anaerobic soil degradation	52% mineralization to CO_2 in 42 days
Hydrolysis	>1 year
Photolysis in air	7.9 hours
Readily biodegradable	Yes

a. Water

DDBSA is water soluble and readily biodegradable. The OECD SIDS review concluded that it has limited potential for bioaccumulation (OECD, 2005). The

[15] https://echa.europa.eu/registration-dossier/-/registered-dossier/11639/1

[16] This value refers to the sulfonate. Other values of 134 mg/L and 800 mg/L are also cited in the ECHA dossier. The OECD (2005) document cites a much higher value of 250 g/L for the acid.

estimated environmental concentration (EEC) is estimated by assuming a 10-fold dilution of the POTW effluent (see Table 7).

Expected Environmental Concentration (EEC) in Surface Water: Applying a 10-fold dilution factor to the aquatic $EIC_{aquatic}$ for DDBSA ($EIC_{aquatic}$ = 14.2 ppb), the $EEC_{aquatic}$ for DDBSA from the proposed use on wooden pallets in hydrocooling of fruits and vegetables is estimated to be **1.42 ppb in surface waters** directly receiving the treated effluent (see Table 7).

Table 7. Estimated aquatic introduction concentrations for DDBSA

Constituent	$EIC_{aquatic}$ (ppb)	$EEC_{aquatic}$ (ppb)
DDBSA	14.2	1.42

b. Land

There is no anticipated, statistically meaningful exposure of terrestrial organisms to the FCS as a result of its use in the treatment of wooden pallets to be used in fruit and vegetable hydrocooling.

Expected Environmental Concentration (EEC) in Wastewater Sludge: Assuming disposal of sludge in accordance with EPA regulations, sludge may be considered the "terminal" fate for DDBSA introduced to sludge material. Therefore, the EEC for DDBSA in wastewater sludge does not incorporate degradation. No additional dilution factor or removal mechanism is applied. Thus, the EIC is assumed to equal to the EEC in this scenario (**EEC = EIC = 0.72 ppm for DDBSA**).

Table 8. Estimated terrestrial introduction concentrations for DDBSA

Constituent	$EIC_{terrestrial}$ (ppm)	$EEC_{terrestrial}$ (ppm)
DDBSA	0.72	0.72

Sludge resulting from wastewater treatment may end up landfilled or land applied. Incineration of sludge generated from food processing facilities is not likely. Should sludge containing DDBSA be land-applied, DDBSA is expected to biodegrade (ECHA, 2020b). Thus, final concentrations of DDBSA in soil are expected to fall below 0.72 ppb over time.

The aerobic soil half-life (sludge) for DDBSA is estimated to be 23.1 days (ECHA, 2020b; Table 6). If DDBSA-containing sludge is disposed of in a landfill, DDBSA would be expected to be controlled by the relevant EPA regulations and state or local guidelines.

c. Air

A report from CHEP USA's parent company, Brambles, provides a life-cycle analysis for treated and untreated CHEP pallets (assessment for whole pallet fleet; **this report is provided as a confidential attachment to this EA, Attachment O.4**). A Life Cycle Assessment (LCA) is an accounting of the energy, waste, and emissions associated with the creation of a new product, through use and reuse/disposal. LCA quantifies resource use, energy consumption, and environmental emissions to the air, water, and land for a given product system based upon the study boundaries established. The unique feature of this type of analysis is its focus on the entire life cycle of a product, from raw material acquisition to final disposition, rather than on a single manufacturing step or environmental emission. The "life-cycle" impacts evaluated as part of the CHEP assessment included:

- Extraction and processing of raw materials;
- Platform processing and manufacturing;
- Transportation of the platform to the customer;
- Use of the platform by the customer (including transportation cycles);
- Recovery, reuse, recycling or disposal of each platform at the end of its useful life.

It should be noted that the scope of LCA is significantly different and wider than typical corporate emissions tracking and reporting.

<u>Also, it is important to consider that hydrocooling should not meaningfully increase emissions because it does not result in meaningful increased pallet usage.</u> Fruit or vegetables that were palletized for hydrocooling would normally have been shipped on pallets regardless of whether the commodities were hydrocooled. It is possible that hydrocooling could have a very small impact on pallet useful life, but that would be difficult to estimate. On the other hand, the use of the fungicide should help increase pallet lifetime and thus reduce new pallet construction.

As a part of the LCA, Brambles estimated the total potential emissions resulting from the construction, processing and use of CHEP pallets over the full pallet life cycle. Specifically, estimated emissions of all six EPA criteria air pollutants (ozone, carbon monoxide, nitrogen dioxide, sulfur dioxide, particulate matter and lead) and greenhouse gases (GHGs; methane, carbon dioxide and nitrous oxide) were calculated per 100,000 anticipated pallet trips.

Because ozone is not emitted directly but is formed via chemical interactions between volatile organics and nitrogen oxides (NO_x) in the presence of sunlight, emissions of volatile organics and non-methane hydrocarbons were calculated as a proxy for ozone. Again, both pallets treated with PQ-80 containing the FCS, and untreated pallets were included for the purposes of this assessment. The large majority of pallets in the CHEP fleet are untreated. Thus, estimates of potential emissions from the production and use of CHEP pallets presented in this report largely overestimate emissions anticipated from the fraction of pallets treated with PQ-80 containing the FCS.

Results of CHEP's LCA indicate that emissions associated with CHEP pallets are a very small contributor to total U.S. air pollutant and GHG emissions even after making conservative assumptions.

Further, GHG emissions resulting from incineration of articles containing the FCS in MSW combustion facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting. The above total carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis.

Additionally, we have concluded that the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

As noted above, these values were obtained using conservative estimates, but clearly indicate a negligible contribution to total air pollutant and GHG annual U.S. emissions. As only a fraction of the CHEP pallet fleet is anticipated to be treated, emissions from treated pallets would represent a fraction of the above emissions estimates.

Considering all above information, we respectfully submit that there is no expectation of significant environmental introductions of substances relating to the FCS from the proposed use of DDBSA in PQ-80 used to treat wooden pallets manufactured from non-domestic wood materials and internally distributed. As noted above, hydrocooling does not meaningfully increase pallet usage because the pallet would have been used to ship the commodity even if it was not palletized for hydrocooling.

8. Environmental Effects of Released Substances

The ECHA dossier summarizes the available ecotoxicity data[17]. The most sensitive values for each species class for freshwater are summarized in Table 10.

[17] https://echa.europa.eu/registration-dossier/-/registered-dossier/11639/6/2/1

Table 10. Most sensitive aquatic ecotoxicity levels for DDBSA

Class	Species	EC_{50}/LC_{50}/NOEC (ppm)	Test Duration
Short-term toxicity to fish	*Salmo gairdneri*	LC_{50} = 3.2-5.6	96 hours
Long-term toxicity to fish	*Pimephales promelas*	NOEC=0.9	28 day
Short-term toxicity to aquatic invertebrates	*Daphnia magna*	LC_{50} = 3.5	48 hours
Long-term toxicity to aquatic invertebrates	*Daphnia magna*	NOEC=1.18	21 days
Algae	*Selenastrum capricornutum*	EC_{50} =29.0	96 hours
Aquatic plants	*Lemna minor*	EC_{50}=2.7 NOEC=0.9	7 days
Toxicity to microorganisms	*Soil microorganisms (activated sludge)*	EC_{50}=500-723	3 hours

The aquatic EEC is more than 1000-fold lower than the lowest effect value in the table above. Therefore, we conclude that this use does not present any risk to aquatic environmental organisms.

Table 11. Most sensitive terrestrial ecotoxicity levels for DDBSA

Class	Species	EC_{50}/LC_{50}/NOEC (ppm)	Test Duration
Earthworms	*Eisenia foetida*	NOEC=250 mg/kg	14 days
Arthropods	*Folsomia fimetaria*	EC10 (reproduction) = 147 mg/kg	21 days
	Folsomia fimetaria	EC10=85-93 mg/kg	21 days
Terrestrial plants	*Phalaenopis*	EC50=100 mg/kg	Field study
	Phalaenopis	NOEC=10 mg/kg	Field study
	B. rapa,	EC10=86 mg/kg	14 days
	A. sativa	EC10=80 mg/kg	14 days
	S. alba	EC10=200 mg/kg	14 days
Birds	*Chicken (Leghorn hens)*	NOEC=200 mg/kg diet	45 days

The very conservatively estimated EEC is more than 10-fold lower than the lowest effect level in Table 11. The EEC is conservative for numerous reasons outlined above, including that the DDBSA production volume was calculated by assuming that all food in the U.S. that could be hydrocooled were hydrocooled using PQ-80 treated pallets. Furthermore, it is expected that there will be significant removal in wastewater treatment plants, other than in primary sludge. The OECD report concludes the following:

> "US monitoring data indicated that LAS is largely removed in wastewater treatment plants, averaging over 99% removal in activated sludge, 98% for lagoons/oxidation ditches, 96% for rotating biological contactors and 77-82% for trickling filters (McAvoy et al. 1993, Trehy et al. 1996). Monitoring data from five European countries showed LAS removal in activated sludge treatment ranged from 98.5-99.9% (DiCorcia et al. 1994, Waters and Feijtel 1995) and averaged 92.9% in four trickling filter plants in the U.K. (Holt et al. 2000). Results of a mass balance study of an activated sludge treatment plant indicate that removal is primarily due to biodegradation with only about 20% of the influent LAS removed with the sludge (DiCorcia et al. 1994)."

While some DDBSA may be in the primary sludge (as distinct from activated sludge from secondary treatment), DDBSA is removed in various treatment processes through primarily biodegradation.

Therefore, we conclude that this use does not present any risk to terrestrial environmental organisms.

According to the ECHA dossier for DDBSA (ECHA, 2020b), the FCS shows low potential for bioaccumulation. Therefore, we do not expect any significant adverse effect on the terrestrial environment.

9. Use of Resources and Energy

CHEP currently does not use a fungicide on its pallets and hydrocooling will occur whether or not DDBSA is approved for food contact. It is not known if other FCSs are used on the pallets of other manufacturers used in hydrocooling. Different types of wood pallets (without PQ-80 treatment) are already used in hydrocooling, including wood and plastic pallets. If this FCN is approved, we do not expect any change in the demand for the use of wood pallets in hydrocooling or any change in the overall demand for wood pallets.

As is the case with other food contact materials, the production, use and disposal of the FCS will involve the use of energy and natural resources such as petroleum products, coal, etc. However, the use of this FCS is not anticipated to result in a net increase in the use of energy or resources within the United States, as the FCS is intended for use in wooden pallets which will be used in place of similar articles already in use.

The use and subsequent disposal of wood pallets treated with the FCS is not expected to result in a net increase in the energy and resources required to transport and/or dispose of wastes, as the amount of FCS disposed of annually in the United States is estimated to comprise a negligible component of total POTW streams [see Item 6(B)(4)].
We believe that granting the FCN will not result in any appreciable change in the demand for wood resources or energy use. Granting the FCN will simply allow wood pallets designed

for other purposes to also be used in hydrocooling and remove the possible impact of separating pallets with the FCN from other pallets when providing pallets for hydrocooling.

10. Mitigation Measures

No significant adverse environmental effects have been identified in this environmental assessment. Therefore, mitigation measures are not necessary.

11. Alternatives to the Proposed Action

Because the current action has minimal to no known environmental effects, it is unnecessary to propose alternatives to the proposed action. The alternative of not approving the action proposed herein would simply be the continued use of pallets on the market without pretreatment with PQ-80 fungicide. As such, the action would have no significant environmental impact. The proposed use of the FCS is not anticipated to enter terrestrial or aquatic environments to any significant extent, and no significant environmental impact is anticipated from its use.

12. List of Preparers

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13. Certification

I, Richard Reiss, certify that the information presented is true, accurate, and complete to the best of my knowledge.

January 5, 2020______________________________
Date

[redacted]

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Richard Reiss, Authorized Representative for CHEP

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