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March 27, 2020

Via FedEx

Dr. Paulette Gaynor
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD 20740

Re: GRAS Notification for the use of Polyvinyl Alcohol (PVOH) in Plugs to Block Fecal Material During Meat Processing; Our File No. AD17486-1

Dear Dr. Gaynor:

We respectfully submit the enclosed (new) GRAS notification (in electronic format, *i.e.*, CD)[1] on behalf of our client, Adept Limited ("Adept"), for polyvinyl alcohol (PVOH) for use as a component of water-soluble, plugs for use in abattoirs to plug the anus of slaughtered sheep, lambs, and hogs for the purpose of blocking the exit of fecal material to prevent contamination of the carcass by intestinal contents during dressing. The enclosed GRAS notification provides detailed information related to the intended use, manufacturing, and safety of the PVOH.

FDA's written response to the enclosed GRAS notice is needed for prescribing the safe conditions of use of the PVOH component of Adept's plug devices in facilities that are under inspection by the United States Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS). As described in the enclosed GRAS notice, the PVOH and other components of the plug device are not reasonably expected to become a component of food under the conditions of intended use, although we have evaluated the safety of potential dietary exposure to PVOH under the conservative assumption that invisible trace amounts of PVOH remain on products that are used for human food. Again, in reality, however, PVOH is not expected to be absorbed upon contact of the plug device with animal tissue and the PVOH plugs are expected to be completely washed away during processing of animal material that contacts a plug.

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[1] All electronic files included in this submission have been checked and found to be virus free.

Please forward a copy of this GRAS notice to FSIS. We have provided the complete composition of Adept's plugs to FSIS under separate cover and requested an acceptability determination by FSIS regarding the use of Adept's plugs as a processing aid in FSIS regulated facilities once FDA has issued a letter indicating "no questions" concerning the GRAS status of the PVOH component for the intended use. As set forth in our request for an acceptability determination, when the plugs are used as intended, PVOH meets FDA's definition of "processing aid" in 21 C.F.R. § 101.100(a)(3)(ii)(a).

We look forward to FDA's review of this submission and would be happy to answer any questions. Thank you for your attention to this matter.

Sincerely,

Melvin S. Drozen

Enclosure

GRAS Notification for Polyvinyl Alcohol

Prepared for: U.S. Food and Drug Administration
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by: Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Date: March 27, 2020

Table of Contents

GRAS NOTICE FOR POLYVINYL ALCOHOL

SUBMITTED BY ADEPT LIMITED

Part 1 – Signed statements and certification

1.1 Applicability of 21 C.F.R. part 170, subpart E

We submit this GRAS notice in accordance with 21 C.F.R. part 170, subpart E.

1.2 Name and address of the notifier

Company: Adept Limited
Name: Yi Huang
Address: 2 McDonald Street
Morningside, Auckland
NEW ZEALAND
Phone: +64 9 815 2999
Email: yhuang@adept.co.nz

1.3 Name of the notified substance

Polyvinyl alcohol

1.4 Applicable conditions of use of the notified substance

Polyvinyl alcohol (PVOH) will be used as the primary component in water-soluble plugs that Adept has developed from a proprietary composition containing PVOH and other edible food grade ingredients. These plugs are intended for use in abattoirs to plug the anus of slaughtered sheep, lambs, and hogs. The plugs are inserted around 120mm deep into the rectum, pushing back and blocking the exit of fecal material to prevent contamination of the carcass by intestinal contents during dressing. Thus, the rectal plugs will contact the anal sphincter and rectum after the animals are slaughtered. The rectal plugs may also possibly contact the large intestine if inserted more deeply than recommended. The plugs are removed with the rectum/intestines during evisceration of the carcass. Adept's plugs are readily soluble and dispersible in either hot or cold aqueous media such as intestinal contents, blood, or water. As such, the plugs are expected to completely dissolve when meat from the anus, rectum, and intestines is washed and otherwise cleaned to remove fecal material prior to use of this meat as human food.

Although it is extremely unlikely than any PVOH will remain on meat that is washed to the degree necessary to remove fecal material and odor, we have assumed, as a worst-case, that trace levels of PVOH will remain with the meat (rectum and intestines).

1.5 Basis for the GRAS determination

The statutory basis for our conclusion of GRAS status is through scientific procedures in accordance with 21 C.F.R. §§ 170.30(a) and (b).

1.6 Exclusion from premarket approval

The notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) based on our conclusion that the notified substance is GRAS under the conditions of its intended use.

1.7 Availability of data and information

If the Food and Drug Administration (FDA) asks to see the data and information that are the bases for our conclusion of GRAS status, either during or after FDA's evaluation of our notice, we agree to make the data and information available to FDA. Further, upon FDA's request, we will allow the Agency to review and copy the data and information during customary business hours at the above address, and will provide FDA with a complete copy of the data and information, either in an electronic format that is accessible for the Agency's evaluation, or on paper.

1.8 Applicability of FOIA exemptions

This GRAS notice does not contain confidential business information (CBI) exempt from disclosure under the Freedom of Information Act per 5 U.S.C. § 552(b)(4).

1.9 Certification

We certify that, to the best of our knowledge, our GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

18/3/2020

Name: Yi Huang Date
Title: Quality and Regulatory Manager

Please address correspondence to Adept's counsel:

Melvin S. Drozen
Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001
Phone: (202) 434-4222
Email: drozen@khlaw.com

1.10 Applicability of 21 C.F.R. § 170.270

This GRAS notice does not contain any trade secrets such as would trigger an authorization statement under 21 C.F.R. § 170.270. We understand that FDA will send a complete copy of this GRAS notice to the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture.

Part 2 – Identity, method of manufacture, specifications, and physical or technical effect

2.1 Scientific data and information that identifies the notified substance

As described in the Food Chemicals Codex (FCC 11th Edition, Third Supplement), polyvinyl alcohol occurs as an odorless translucent, white or cream-colored granular powder. Commercially produced polyvinyl alcohol is a mixture of synthetic polymers produced by the polymerization of vinyl acetate and partial hydrolysis of the resulting esterified polymer. Polyvinyl alcohol is soluble in water and insoluble in aliphatic and aromatic hydrocarbons, esters, ketones, and oils (Handbook of Pharmaceutical Excipients, 1994). The PVOH used in Adept's plugs contains no additives.

Common or Usual Name: Polyvinyl alcohol; Vinyl alcohol polymer; PVOH

Chemical Name: Polyvinyl alcohol

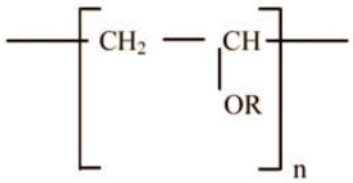
Chemical Abstracts Service Registry Number (CASRN): 9002-89-5

Nb., Adept follows the industry and regulatory practice of identifying the notified substance as "polyvinyl alcohol," with the associated CASRN 9002-89-5, although the substance commonly known as polyvinyl alcohol is not, in fact, fully hydrolyzed polyvinyl alcohol (*i.e.*, homopolymer, polyvinyl alcohol) as might be assumed under strict chemical naming conventions. Although the notified substance is not customarily called "partially-hydrolyzed polyvinyl alcohol" and the CASRN 25213-24-5 is not used in the food industry, this chemical name and CASRN match the degree of hydrolysis (*i.e.*, between 86.5% and 89.0%) of Adept's PVOH and that is specified for polyvinyl alcohol (CASRN 9002-89-5) in the FCC (first published in FCC 6th Edition) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Monographs 4 (2007), which supersedes the Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005). The degree of hydrolysis reflects the presence of 11% to 13.5% vinyl acetate repeating units in the polymer, as opposed to a 100%-hydrolyzed polymer that would consist solely of vinyl alcohol repeating units.

Chemical Formula: $(C_2H_3OR)_n$ where R=H and $COCH_3$ (randomly distributed)

Structural Formula: *See* Figure 1, below.

Figure 1. Structural formula of polyvinyl alcohol, where R=H and $COCH_3$ (randomly distributed).



Degree of Hydrolysis: 86.5% to 89%

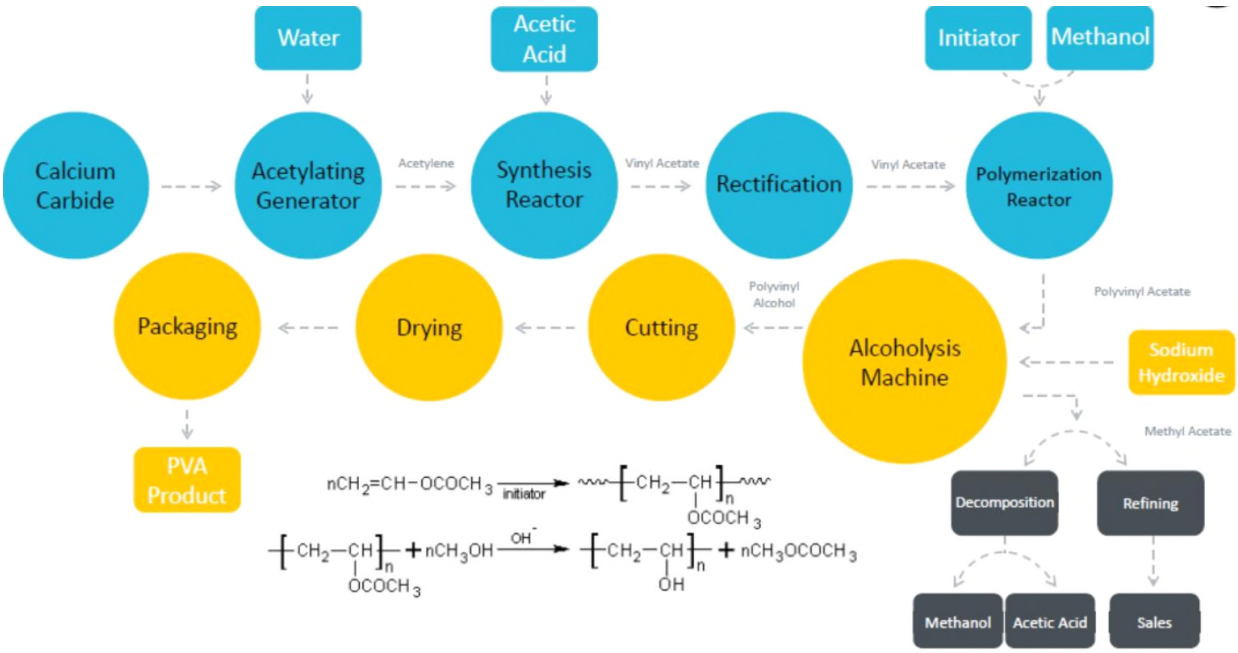
Molecular weight: 22,000 to 27,000 g/mol

2.2 Description of the method of manufacture of PVOH

Polyvinyl alcohol is manufactured from polyvinyl acetate dissolved in an alcohol (*i.e.*, methanol). Treatment with an alkaline catalyst causes a hydrolysis reaction that results in the partial replacement of ester groups in the vinyl acetate with hydroxyl groups. Following gradual addition of the aqueous saponification agent, polyvinyl alcohol is precipitated washed, and dried. The time point at which the saponification reaction component is stopped determines the degree of hydrolysis. The residual vinyl acetate in the PVOH is not detectable (limit of detection 1.0 ppm of vinyl acetate). Sodium acetate, methanol, and methyl acetate are the primary expected side products. As the resulting product is washed, most of the side products are expected to be removed in the aqueous solution. The sodium acetate is a reaction byproduct that is monitored by the residue-on-ignition test. The residual methanol and methyl acetate are monitored by process control, individual specifications and analytical methods. The final product is assayed for conformity with the specifications.

A flow diagram of the manufacturing process for polyvinyl alcohol is shown in Figure 2 below.

Figure 2. Manufacturing process for polyvinyl alcohol



2.3 Specifications for food-grade PVOH

Food grade specifications for the PVOH used in the preparation of post-slaughter rectal plugs have been established by Adept and are presented in Table 1. These specifications comply with those in the Food Chemicals Codex (FCC 11th Edition, Third Supplement). The chemical and physical characteristics of PVOH have also been reviewed in several other national and international official monographs, including the United States Pharmacopeia (USP, 2004) and the JECFA Monographs 4 (2007). Analytical results of multiple independently produced, representative batches (Appendix I) demonstrate that the PVOH consistently meets the specifications.

Table 1. Specifications for PVOH

Parameter	Characteristics	Reference/Test Methodology
Description	Translucent, white or cream-colored granular powder	Visual inspection
Identification		
Color reaction A	Blue color	FCC
Color reaction B	Dark red to blue color	FCC
Precipitation reaction	White turbid precipitate	FCC
Infrared absorption	Pass (*i.e.*, same maxima at the same wavelengths as reference standard)	FCC
Specific tests		
Acid value	NMT 3	FCC
Ester value	Between 125 and 153 mg KOH/g	FCC
Degree of hydrolysis	Between 86.5 and 89.0%	FCC
Loss on drying	NMT 5%	FCC
pH	5.0 - 6.5	FCC
Residue on ignition	NMT 1%	FCC
Viscosity	4.8–5.8 mPa·s (4% aqueous solution at 20°C)	FCC
Water insoluble substances	NMT 0.1%	FCC
Heavy metals		
Lead	NMT 2 ppm	ICP-MS
Organic impurities		
Methanol	NMT 1%	FCC
Methyl acetate	NMT 1%	FCC

NMT = Not more than;

ICP-MS = Inductively coupled plasma – mass spectrometry.

2.4 Information on the technical effect of PVOH

PVOH has multiple applications in food, food packaging, pharmaceuticals, medical products, and cosmetics (CIR, 1998; 21 C.F.R. §175.105, §175.300, §175.320, §176.170, §176.180, §177.1200, §177.1670, §177.2260, §177.2800, §178.3910, §181.30). The physical characteristics of PVOH, such as good film strength and adhesion qualities coupled with its water solubility are ideal for the purpose of Adept's post-slaughter anal

plugs – physically blocking fecal material that may otherwise leak from the rectum and contaminate the carcass, then subsequently dissolving when the anus, rectum, and intestines are removed from the carcass, emptied of feces, and thoroughly washed prior to use of this meat as human food. Adept's PVOH plugs (brand name: ADEPT Soluble Two-Flange Plug) are currently used to block fecal leakage in New Zealand.

Part 3 – Dietary exposure

Adept's plugs will contact the rectum and possibly the terminal straight end section of the large intestine (*i.e.*, "bung portions") of sheep, lambs, and hogs after post-slaughter insertion of the plugs into the rectum. The plugs have two flanges that are designed to block fecal contamination of primal cuts and other parts of the carcass by leakage from the rectum before the intestinal tract (including the bung portion of the carcass) is removed and diverted to a separate processing line.

3.1 No PVOH is expected to contact meat other than the intestinal tract

As the plug is expected to remain intact during the short interval between insertion of the plug and bung removal (and the plug remains with the bung portion), no transfer of polyvinyl alcohol (PVOH) from the plug to other parts of the carcass, including the pelvic cavity, is expected. Further, the bung portion (containing the plug) is diverted away from the carcass processing line immediately after bung removal. Therefore, no level of accidental transfer of PVOH to other parts of the carcass is expected, but if contamination by PVOH did occur, it is likely that fecal contamination would occur concurrently. Fecal contamination would be expected to be observed during inspection. Any necessary procedures for dealing with fecal contamination would simultaneously prevent the release of meat containing traces of PVOH. Therefore, accidental PVOH contamination of the carcass, if any, would be rare and would result in levels of PVOH on other cuts of meat at levels much lower than assumed, as discussed below, for bung meat portions that intentionally contact a plug.

3.2 Assumed worst-case concentration of PVOH on bung portions

3.2.1 Cleaning at the processing facility is expected to remove PVOH

Bung parts that contact plugs are cleaned after harvesting by a washing step. This washing step for bung meat, as well as intestines sold as food is necessarily extensive because fecal material and other undesirable elements that are naturally present must be completely removed. Because PVOH is water soluble, the plug is expected to be washed out along with the fecal matter during cleaning of the bung portions. In this regard, visual inspection of the meat (for ensuring feces are removed) would reveal if the washing step was inadequate for dissolving/removing the plug. Due to the high molecular weight of material, any dissolved PVOH from the plug making direct contact with the inner surface of the bung during slaughter will not penetrate the surface of the intestinal tissue to any significant extent and will be amenable to complete removal through the washing step. Likewise, the manufacturing of natural sausage casings from the intestines of the animal begins with vigorous cleaning of the runners (*i.e.*, ungraded casings).[1] In this case, cleaning includes a series of both hot and cold soaks and using rollers and large volumes of water to crush, break up and vigorously flush out the inner mucosa of the intestines. The cleaned runners are packed in saturated salt brine for

[1] http://www.insca.org/index.php/en/handling-casings.

preservation during storage and shipping.[2] Any PVOH from the plug that makes direct contact with the inner surface of the intestines during slaughter will be completely removed during cleaning. Thus, the water-soluble plugs are expected to dissolve and be completely washed away from the bung and sausage casings harvested from the animals such that no PVOH remains in portions that are ready for sale to be used as human food. We have assumed, however, that invisible trace amounts of PVOH could potentially remain on such products at the time it is packaged for sale.

3.2.2 Concentration of PVOH in sausage made with natural casing

Bung portions are expected to be consumed as meat or else used as edible or inedible natural casings for various types of sausages. Bung portions that are used as part of an entrée or snack are expected to be simmered in water as part of the cooking process (before serving the meat in chewy form or subsequently frying it to make a crispy victual). The preparation steps for bung meat used as an entrée or snack provide assurance that no PVOH would be present in the cooked meat. When used as natural casings, however, the bung portions would receive no additional washing (beyond the rinsing necessary to remove packing salt) before being stuffed with raw sausage ingredients. Thus, we have assumed that any trace amount of PVOH that may theoretically remain on the casing may not be completely removed before stuffing the casing with the raw sausage. Further, as is relevant to potential consumption of PVOH for sausages with edible casings, we have assumed that processing and preparation of the sausage would not necessarily remove any trace quantities of PVOH. With respect to the amount of such residual PVOH, we have conservatively assumed that 1% of the plug remains on each casing ("bung portion") and 99% is washed away. This assumption certainly overestimates the residual level of PVOH, if any, because the process of cleaning, flushing, and soaking the bung and runners is expected to result in the plug dissolving and its components being completely removed, even before an additional rinsing step to remove packing salt or brine (and any incidental traces of PVOH) when preparing these products for food use.

We assumed as a worst-case that 100% of each single retail unit of sausage consists of one edible, natural casing that contains 1% of a plug used post-slaughter for the lamb, sheep, or hog from which the casing was derived. A two-flange soluble plug weighs 6 grams and PVOH comprises 59% of the plug formulation. Thus, applying the exaggerative worst-case assumptions outlined above, the amount of PVOH that could remain on a casing is calculated to be 0.0354 g. [3]

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[2] National Provisioner with Joseph R. Escoubas, Ph.D., director and professor, Food and Agricultural Products Research and Technology Center, Oklahoma State University, Stillwater, OK, Casings 101 Report *available at* https://www.provisioneronline.com/articles/94392-casings-101-1.

[3] 6 grams Plug x 1% Residual x 59% PVOH = 0.0354 grams PVOH.

Further, although the intestinal tract is divided into several different portions for separate natural casing applications, we have assumed as an additional conservatism that the entire amount of residual PVOH (*i.e.*, 0.0354 g) is not distributed evenly among all types of natural casings that may be derived from the intestinal tracts of animals processed using Adept's plugs. Instead, we have assumed as a worst-case that the total amount of PVOH is isolated to the single type of edible casing that has the smallest stuffing capacity (which would represent the highest ratio of casing-to-sausage).

Based on data available on the International Natural Sausage Casing Association (INSCA) website, the type of edible natural casing with the smallest stuffing capacity is the "fat end" or "hog bung," which is used for Braunschweiger and has a stuffing capacity of 600 grams per 50 cm casing.[4] Although the stuffing mixture is raw at filling, and the sausage is smoked and poached in water to produce the finished Braunschweiger (a sliceable or spreadable liver sausage), we assume that none of the PVOH potentially remaining in the casing would be lost during processing. Thus, based on the stuffing capacity of 600 grams, and assuming that the casing contains 0.0354 g of PVOH, we calculate that the Braunschweiger would contain PVOH at a level of 0.0059%.[5]

We have assumed that Braunschweiger may be consumed at the 90th percentile daily intake level of 114 g that is reported for the category "Frankfurters and Luncheon Meat" in the United States Department of Agriculture's (USDA) 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII 1994-1996) (Smiciklas-Wright et al., 2002) for quantities of foods consumed daily. The only category for sausages *per se* is "Pork Breakfast Sausage," which is a type of sausage that is not made using natural casings and for which the reported daily intake level (*e.g.*, 80 g at the 90th percentile) is lower than for Frankfurters and Luncheon Meat. The FDA commonly uses the estimated daily intake for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake. For Braunschweiger, an intake of 114 grams per day represents consuming a customary 2 ounce serving (57 grams) twice daily.[6]

Based on the above noted assumptions for Braunschweiger containing a worst-case level of PVOH (*i.e.*, 00.0059%) and consumption at the 90th percentile daily intake level (*i.e.*, 114 g), the estimated daily intake (EDI) of PVOH is calculated to be 5.8 mg/person/day.[7]

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[4] International Natural Sausage Casing Association (INSCA). *See* Natural Casings Hog, http://www.insca.org/index.php/en/natural-casings-hog. Because the typical hog bung used for casings is 1m in length, the bung will either be used for the manufacture of multiple casings, or trimmed to size. In either scenario, the total amount of PVOH remaining with the casing is expected to be reduced proportionally. Thus, the model described above is highly conservative.

[5] 0.0354 grams ÷ (600 grams + 0.0354 grams)] x 100 = 0.0059%.

[6] *See* Nutrition Facts panel, https://schallerweber.com/product/braunschweiger-liverwurst/.

[7] 114 grams/person/day Braunschweiger x 0.0059% PVOH = 0.0067 g/person/day PVOH, or 0.1 mg/kg bw/day.

Adopting FDA's assumption for body weight (*i.e.*, 60 kg), the EDI of PVOH from the intended use of Adept's plugs may be expressed as, roughly, 0.1 mg/kg bw/day.

The daily intake of PVOH from all other known food (including dietary supplements) and pharmaceutical applications was conservatively estimated to be 45.16 mg/kg bw/day. *See* GRN 767, Part 3, Table 3 at page 12. The possibility of additional consumption of PVOH as a result of its intended use in edible film would result in a new estimated daily intake of PVOH of 45.26 mg/kg/day.[8] Even if 10% of the PVOH from the plug is assumed to remain in the casing, rather than 1%, and all other assumptions remained the same, the total estimated daily intake of PVOH would be 46.13 mg/kg bw/day,[9] which is below the ADI of 50 mg/kg bw/day for PVOH.

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[8] 45.16 mg/kg/day + 0.1 mg/kg bw/day = 45.26 mg/kg bw/day.

[9] 6 grams Plug x 10% Residual x 51% PVOH = 0.306 grams PVOH.

0.306 grams PVOH ÷ (600 grams Braunschweiger + 0.306 grams PVOH)] x 100 = 0.051%.

114 grams/person/day Braunschweiger x 0.051% PVOH = 0.058 g/person/day PVOH, or 0.97 mg/kg bw/day.

45.16 mg/kg/day + 0.97 mg/kg bw/day = 46.13 mg/kg bw/day.

Part 4 – Self-limiting levels of use

The function of Adept's plugs (*i.e.*, blocking post-slaughter fecal leakage and then dissolving when meat harvested from the intestinal tract of the slaughtered animal is washed) limits the use of the plugs to one per animal. Performance considerations dictate the formulation (51% PVOH) and design (shape and size) of the plugs.

Part 5 – Experience based on common use in food before 1958

N/A

Part 6 – Narrative

In the published literature, several studies of polyvinyl alcohol are reported in different species following both oral and non-oral routes, such as rectal, intra-vaginal, subcutaneous, intravenous, intra-peritoneal and dermal. The findings from non-oral studies are considered not to be predictive of oral toxicity, because polyvinyl alcohol is very poorly absorbed following oral administration. Hence, in the following section, emphasis is placed on the oral studies. The safety assessment of polyvinyl alcohol is based on metabolic, mutagenicity, and toxicological data in general, and on the resulting exposure to polyvinyl alcohol from its proposed and existing uses. As indicated earlier, polyvinyl alcohol has been approved for use in coatings applied to pharmaceutical products. Polyvinyl alcohol has also been evaluated for safety-in-use by national and international regulatory and other agencies. In these comprehensive safety evaluations, polyvinyl alcohol has been extensively reviewed and demonstrated to be safe for use as a food or dietary supplement ingredient at the levels described in those assessments.

6.1 Regulatory Assessments

6.1.1 GRN 141 for use of PVOH in coating for dietary supplement capsules

In GRN 141, the notifier informed the FDA that polyvinyl alcohol is GRAS, through scientific procedures, for use in aqueous film coating formulations applied to dietary supplement products (*i.e.*, tablets or capsules), where the coating formulation is up to 4% (by weight) of the tablet or capsule, and polyvinyl alcohol is up to 45% (by weight) of the coating formulation. Assuming a person consumes a maximum of ten 1 g dietary supplement tablets or capsules and ten 1 g pharmaceutical tablets or capsules with polyvinyl alcohol film coating formulations per day, the maximum daily intake of polyvinyl alcohol was estimated as 180 mg/person/day from dietary supplements and 180 mg/person/day from its use in film coatings applied to pharmaceutical products. The total maximum daily intake of polyvinyl alcohol from its intended use in dietary supplements and from its use in pharmaceutical products was estimated as 360 mg/person/day, equivalent to 6 mg/kg bw/day for a 60-kg person.

Regarding safety, the notifier reported that acute and subchronic oral toxicity studies conducted in animals including rats, mice, and dogs as well as a two-generation reproductive toxicity study conducted in rats fed polyvinyl alcohol showed no adverse toxicological or reproductive effects. *In vitro* and *in vivo* genotoxicity studies with polyvinyl alcohol also did not reveal any evidence of mutagenic or clastogenic effects. These studies suggest that polyvinyl alcohol is not mutagenic, genotoxic, or carcinogenic by the oral route. The notifier concluded that animal toxicology data (subchronic toxicity and reproductive toxicity study) support a no-observed-adverse-effect-level (NOAEL) for polyvinyl alcohol of 5,000 mg/kg body weight/day, the highest dose tested. In an April 28, 2004 response letter to the notifier, FDA did not question the conclusion that the ingredient polyvinyl alcohol is GRAS under the intended conditions of use.

6.1.2 GRN 767 for use of PVOH in edible film

In GRN 767, the notifier informed the FDA that polyvinyl alcohol is GRAS, through scientific procedures, for use as a component of water-soluble, edible film that may be used to form pouches containing pre-portioned aliquots of (1) certain dry ingredients (*i.e.*, instant tea, instant coffee, hot chocolate mix, flavored drink powder, and whey protein supplement powder) to be used by the consumer in preparing ready-to-serve foods and beverages at a level up to 0.734 g PVOH/serving, (2) approved color additives to be used in manufacturing flavored beverages (non-dairy and non-alcohol) at a level up to 0.0006 g PVOH/serving, and (3) dry ingredients to be used by commercial establishments in making pizza dough at a level up to 0.0075 g PVOH/serving. The total maximum daily intake of polyvinyl alcohol from its intended use in edible film was estimated for the total users only U.S. population as 45.16 mg/kg bw/day at the 90th percentile. The notifier discussed the safety of PVOH using the same published studies that were discussed in GRN 141. The notifier reported that a literature search was conducted through January 2018 and did not report any new data or information that would contradict their GRAS conclusion. In a September 19, 2018 response letter to the notifier, FDA did not question the conclusion that the ingredient polyvinyl alcohol is GRAS under the intended conditions of use.

6.1.2 JECFA review

In 2004, the Joint FAO/WHO Expert Committee on **Food Additives** (**JECFA**) evaluated a large database of studies regarding the toxicity of polyvinyl alcohol after administration by various routes to several species. The Committee concluded that polyvinyl alcohol was very poorly absorbed following oral administration, that the acute oral toxicity was generally very low, and that the overall results were consistent with very low toxicity and showed no evidence for carcinogenicity. No adverse effects were noted in a two-generation reproductive toxicity study and a subchronic toxicity study in rats. There was no evidence for genotoxicity in a battery of tests undertaken with preparations of polyvinyl alcohol. The Committee identified a No-Observed-Effect-Level (NOEL) of 5000 mg/kg bw/day for polyvinyl alcohol based on the maximum dose tested in both the 90-day and the two-generation studies in rats. The Committee established an acceptable daily intake (ADI) for polyvinyl alcohol of 50 mg/kg bw/day, based on the NOEL of 5000 mg/kg bw/day from the subchronic toxicity and two-generation studies in rats, with a safety factor of 100.

6.1.3 European Commission Evaluation

The Scientific Panel of the European Food Safety Authority (EFSA) reviewed the safety of polyvinyl alcohol as a food additive when used as film coating agent for food supplements. Following a critical review of the relevant polyvinyl alcohol data, including physical/chemical properties, specifications, manufacturing process, proposed use levels, exposure, safety-related studies, etc., the EFSA Panel concluded that the consumption of polyvinyl alcohol, through its use as a coating agent for food supplement tablets and/or capsules at its intended use level and resulting in a total (cumulative) intake of 4.8 mg/kg bw/day from the proposed and existing food uses is not of safety concern.

The Panel noted that the NOAEL of 5,000 mg/kg bw/day (the highest dose tested) derived from the 90-day (subchronic) and two-generation reproductive dietary toxicity studies with polyvinyl alcohol indicates a low order of toxicity. Polyvinyl alcohol is only minimally absorbed following oral administration. The maximum assumed combined intakes of 4.8 mg/kg bw/day from the proposed uses plus existing uses from pharmaceutical products was over 1000-fold below the established NOAEL.

6.2. Toxicological Studies

6.2.1. ADME

Following oral administration, polyvinyl alcohol was found to be poorly absorbed from the gastrointestinal tract (EFSA, 2005; Sanders and Matthews, 1990). In an experiment in the rat, over 98% of the radioactivity associated with a single oral dose (0.01 mg/kg ^{14}C-labeled) of polyvinyl alcohol was excreted in the feces within 48 hours of administration (Sanders and Matthews, 1990). In this study, < 0.2% of the total radioactivity was detected in the urine. To further characterize absorption and subsequent bioaccumulation, Sanders and Matthews (1990) administered 0.10 mg/kg ^{14}C-labeled polyvinyl alcohol to rats via gavage for 10 consecutive days. The majority (~ 100%) of the radioactivity was found in fecal matter, suggesting that polyvinyl alcohol is very poorly absorbed by the oral route (Sanders and Matthews, 1990). The EFSA Expert Panel concluded that polyvinyl alcohol is very poorly absorbed, from the gastrointestinal tract and is, thus, unavailable for distribution through the bloodstream to the internal tissues and organs of the body (EFSA, 2005). Adept agrees with the Panel's conclusion that the data reported by Sanders and Matthews (1990) show that only trace amounts of polyvinyl alcohol can be absorbed in the digestive tract. Adept notes that a substance or its breakdown products must be absorbed from the gastrointestinal tract and reach the internal organs and tissues in sufficient amounts to have the potential to exert systemic effects in the body. Adept concurs with the determinations of Sanders and Matthews (2009) and the EFSA Panel (EFSA, 2005) that polyvinyl alcohol is not broken down or absorbed systemically to any significant extent in the gastrointestinal tract and that it passes through and is excreted from the gastrointestinal tract essentially intact and unabsorbed. Adept determines that these observations support Adept's conclusion that polyvinyl alcohol is GRAS when used as intended as the primary component in water-soluble plugs that Adept has developed for use in abattoirs to plug the anus of slaughtered sheep, lambs, and hogs.

6.2.2. Acute Toxicity

Acute oral toxicity of polyvinyl alcohol has been evaluated in rats, mice and dogs. The LD_{50} values of polyvinyl alcohol for mice, rats and dogs following oral administration have been reported to range from > 1.5 to approximately 22 g/kg bw (JECFA, 2003; EFSA, 2005).[10] The oral LD_{50} of polyvinyl alcohol in mouse, rat and dog studies were

[10] JECFA and EFSA cited unpublished studies, *i.e.*, Burford and Chappel (1968) and Hazleton Laboratories (1959), and one published study, *i.e.*, Zaitsev, N.A., Skachkova, I.N., Sechenov, I.M. Substantiation of hygienic norms in water media of some polymer compounds

reported as > 4000, >21500 and > 20000 mg/kg bw, respectively. Adept notes that the acute oral LD_{50} of polyvinyl alcohol exceeds the greatest of the very high doses tested in acute toxicity studies, which is consistent with the very poor absorption of this ingredient in the gastrointestinal tract. Adept determines that polyvinyl alcohol is practically nontoxic following acute oral administration, which supports Adept's GRAS conclusion for the intended use of this ingredient.

6.2.3. Subchronic Toxicity

Kelly et al. (2003) investigated the potential systemic and neurotoxic effects of polyvinyl alcohol in a GLP-compliant rat study. In this study, male and female Sprague-Dawley rats (20/sex/group) were fed a diet providing dose levels of 0, 2,000, 3,500 and 5,000 mg/kg/day for 90 days. Control rats (20/sex) were given untreated standard laboratory diet. Assessments included clinical observations, ophthalmology, body weight and food consumption, hematology, coagulation, clinical chemistry, urinalyses, motor activity and functional observational battery evaluations and gross and microscopic pathology. The only overt polyvinyl alcohol treatment-related finding observed during the study was unformed stool with brown/black anogenital staining in male rats fed 3,500 and 5,000 mg/kg bw/day. This finding was attributed to the consumption and excretion of high levels of polyvinyl alcohol. It was not accompanied by macroscopic or microscopic changes in these rats. Adept agrees with Kelly et al. (2003) that unformed stool and anogenital staining observed in the males exposed to the two highest doses of polyvinyl alcohol in this study was caused by the large amount of unabsorbed polyvinyl alcohol in the stool of these animals. Adept notes, in agreement with the authors of this study, that the unabsorbed polyvinyl alcohol in the colon of these animals is conducive to water retention in the stool, resulting in soft stools and staining of the anogenital area from the excretion of softened, potentially watery stools. Adept concurs with the authors that this is a physiological process, not a toxic effect. (This laxative effect is not expected in consumers at the ADI derived for polyvinyl alcohol (*i.e.*, 50 mg/kg bw/day), which is much lower (*i.e.*, 40 times lower) than the dose that did not produce the effect in the male or female rats in this study (*i.e.*, 2000 mg/kg bw/day). No treatment-related changes were noted in mortality, ophthalmology, body weight and food consumption data, hematology, clinical chemistry, urinalysis data, functional observational assessments, motor activity, organ weight data and macroscopic and microscopic examinations. The investigators concluded that administration of polyvinyl alcohol as a dietary admixture to rats at doses of 2,000, 3,500 and 5,000 mg/kg/day for up to 90 days did not result in any adverse, toxicological effects. The results of this study suggest a NOAEL of 5,000 mg/kg/day. The polyvinyl alcohol used in the Kelly et al. (2003) study was 85-89% hydrolyzed, like the polyvinyl alcohol that is the subject of the present GRAS assessment. Adept concurs with the findings and interpretation of the results of the study Kelly et al. (2003) study, as reported by the authors of this study, and determines that the data support Adept's GRAS conclusion for the intended use of polyvinyl alcohol.

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using "stage-by-stage" principle = [Substantiation of hygienic standards for some polymeric compounds in water with the use of gradual standardization]. Gig Sanit 10, 75-76, 1986.

6.2.4. Genotoxicity

In a series of experiments, Kelly et al. (2003) also investigated the genotoxic potential of polyvinyl alcohol: (1) in a bacterial reverse mutation assay in *Salmonella typhimurium* and *Escherichia coli* (Ames assay); (2) in an *in vitro* forward mutation assay in a sub-line of mouse lymphoma L5178Y cells; and (3) in an *in vivo* mouse micronucleus assay. In the Ames assay, polyvinyl alcohol at concentrations of up to 5,000 μg/plate, both in the presence and absence of liver preparations from Aroclor 1254-induced rats (S9 mix), was not mutagenic to *S. typhimurium* strains TA1535, TA1537, TA98 and TA100, or to a tryptophan-dependent mutant of *E. coli* strain WP2*uvr*A/pKM101 (CM 891) (Kelly et al., 2003). Similarly, in the mouse lymphoma assay, in the presence and absence of metabolic activation (S9 mix), polyvinyl alcohol at concentrations up to 5,000 μg/mL did not increase the incidence of forward mutations at the thymidine kinase locus (TK+/-). In the *in vivo* mouse micronucleus assay, administration of single doses of polyvinyl alcohol via oral gavage to male and female Swiss mice at doses of up to 2,000 mg/kg bw did not show any evidence of causing chromosome damage or bone marrow cell toxicity at 24 to 48 hours following administration. These observations are further supported by the studies described in the JECFA evaluation of polyvinyl alcohol (JECFA, 2003). As described in the JECFA report, negative results were noted in several strains of *S. typhimurium* in both the presence and absence of metabolic activation, as well as in an *in vitro* Chinese hamster V79 chromosomal aberration assay and *in vivo* in a female mouse bone marrow micronucleus test.

Adept concludes from the publicly available data that polyvinyl alcohol is not genotoxic, which supports Adept's GRAS conclusion.

6.2.5. Chronic Toxicity and Carcinogenicity

In the published literature, no chronic toxicity or carcinogenicity studies were found following oral administration of polyvinyl alcohol. In a well-designed 2-year National Toxicology Program (NTP) study, intra-vaginal administration of polyvinyl alcohol to female B6C3F1 mice did not reveal compound-related neoplastic or non-neoplastic lesions. The only clinical finding observed in this study was vaginal irritation (NTP, 1998). The NTP concluded that "under the conditions of this 2-year study, there was no evidence of carcinogenic activity...." Adept concludes that the absence of carcinogenic activity reported in a lifetime bioassay conducted by the NTP in exposed intra-vaginally to polyvinyl alcohol indicates that polyvinyl alcohol is not carcinogenic, does not pose a carcinogenic risk from dietary exposures to this ingredient and, thus, supports Adept's GRAS conclusion.

6.2.6. Reproduction and Developmental Toxicity

In a GLP-compliant study, Rodwell et al. (2003) investigated the effects of polyvinyl alcohol on fertility, early embryonic development, growth and subsequent development in rats. In this 2-generation study, groups of P_0 and F_1 parental Sprague-Dawley rats (26/sex/group) were fed diets containing polyvinyl alcohol at dose levels providing dose levels of 2,000, 3,500, or 5,000 mg/kg bw/day for at least 70 consecutive days prior to

mating. The treatment of male rats was continued during the 14-day mating period and throughout the post-mating period until euthanized. Female rats continued their respective treatments during the 14-day mating period, gestation, and lactation. Females were generally euthanized on lactation day 21. As evaluated by mating and fertility indices and sperm counts, polyvinyl alcohol did not induce any treatment-related effects on P_0 or F_1 male reproductive performance. Similarly, as assessed by mating, fertility, and pregnancy indices, and estrous cycling data, there were no biologically significant effects attributable to polyvinyl alcohol treatment on P_0 or F_1 female reproductive performance. No polyvinyl alcohol related effects on litter parameters (litter size, pup sex distribution, pup survival, clinical observations, and body weights) in either the F_1 or F_2 generation were noted. Absolute organ weights, or organ to body weights and organ to brain weight ratios were unaltered by polyvinyl alcohol treatment in both F_1 and F_2 generations. Macroscopic and microscopic observations performed on the P_0 and F_1 parental animals and of the F_1 and F_2 pups did not reveal any adverse effects from polyvinyl alcohol exposure. The results of this study suggest a NOAEL 5,000 mg/kg bw/day for both parental and offspring in this reproductive study, the highest dose tested (Rodwell et al., 2003). Adept concurs that 5,000 mg/kg bw/day is an appropriate NOAEL for parental rats and offspring based on the data published by Rodwell et al. (2003).

In addition, Adept concurs with the ADI of 50 mg/kg bw/day established by JECFA for polyvinyl alcohol, which was calculated by applying a safety factor of 100 (*i.e.*, 10 for interspecies difference and 10 for intraspecies variability) to the NOAEL of 5000 mg/kg bw/day obtained from the two-generation study in rats as well as the subchronic toxicity study discussed in Section 6.2.3. above.

6.3. Basis for GRAS Conclusion for Intended Use of PVOH

The safety of polyvinyl alcohol is supported by toxicity studies, including several GLP-compliant studies (*i.e.*, a 90-day oral toxicity study, a 2-generation reproductive toxicity study, and *in vitro* and *in vivo* genotoxicity assays). Following oral administration, PVOH is only minimally absorbed. The acute oral toxicity studies in rats, mice and dogs suggest that PVOH is of a low order of acute toxicity. In the subchronic toxicity study, there was no evidence of systemic toxicity following dietary administration of PVOH. The highest dose level of PVOH tested was 5,000 mg/kg bw/day. The only notable finding in this study consisted of loose stools that appear to be related to the high content of non-absorbed PVOH in the dietary admixture. Similarly, in a 2-generation reproductive toxicity study in the rat, no adverse effects of PVOH administration occurred in parental (p-generation), or first or second-generation animals. In this study, the highest dose level of polyvinyl alcohol tested was also 5000 mg/kg bw/day. The results of a series of *in vitro* and *in vivo* mutagenicity and genotoxicity assays performed with prokaryotic and mammalian test systems suggest that polyvinyl alcohol is neither mutagenic nor genotoxic. No oral long-term toxicity and carcinogenicity studies were available. In a topical carcinogenicity study, intravaginal administration of polyvinyl alcohol to female mice did not indicate any carcinogenic activity.

Adept's GRAS conclusion is based on the conservative EDI of PVOH under the intended conditions of use (*i.e.*, 0.1 mg/kg bw/day) and the cumulative EDI for PVOH from all known food (including dietary supplements) and pharmaceutical uses (*i.e.*, 45.26 mg/kg bw/day) being below the ADI of 50 mg/kg bw/day that was determined by JECFA.

6.4. Safety of Constituents

As noted in the product specifications (Table 1), polyvinyl alcohol contains methanol and methyl acetate at levels up to 1%. As described in Part 2.2, these are the side products and their levels are monitored by process control, individual specifications and analytical methods. The resulting estimated daily intake of these manufacturing by-products (methanol as well as for methyl acetate) from the intended uses of polyvinyl alcohol as a food ingredient will be below 0.5 mg/kg bw/day (*i.e.*, less than 30 mg per day for an individual weighing 60 kg).

Per 21 C.F.R. § 173.250, methanol residues are permitted from its use as a solvent in the following foods under the conditions specified: (a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million. (b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; Provided, that: (1) The hops extract is added to the wort before or during cooking in the manufacture of beer. (2) The label of the hops extract specifies the presence of methyl alcohol and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section. Additionally, other clearance permit methanol residues with limits in parenthesis as follows: 21 C.F.R. §§ 175.105 ("Adhesives"); 172.859 ("Sucrose fatty acid esters") (10 ppm); 172.560 ("Modified hop extract") (250 ppm, 100 ppm, or 50 ppm, depending upon the extraction method); 172.867 ("Olestra") (300 ppm, per FCC monograph); and 73.615 ("Turmeric oleoresin") (50 ppm).

It is also important to recognize that dietary methanol can arise from fresh fruits and vegetables, where it occurs as free alcohol, methyl esters of fatty acids or methoxy group on polysaccharides such as pectin. Orange juice is also a good example of fruit juice that contains methanol. A typical serving of orange juice (6 ounces or 200 ml) with the reported methanol level of 500 mg/liter in orange juice results in consuming 100 mg of methanol. Based on this example for orange juice alone, it would be appropriate to assume that the resulting intake of methanol (< 30 mg/day) from the proposed uses of polyvinyl alcohol is safe.

The other processing by-product, methyl acetate is among the listed synthetic flavoring substances and adjuvants permitted under 21 C.F.R. § 172.515 for use in accordance with the following conditions: a) they are used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practice, and 2) they consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, prior-sanctioned for such use, or regulated by an appropriate section in this part. The Flavor and Extract Manufacturer's Association has also approved food uses of methyl acetate as a flavoring agent (FEMA No. 2676) in beverages, ice cream, candy and baked goods at levels ranging from 11 to 29 ppm.

Part 7 – List of supporting data and information

7.1 References

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7.2 Tables

Table 1. Specifications for PVOH.

7.3 Figures

Figure 1 Structural formula for of polyvinyl alcohol, where R=H and $COCH_3$ (randomly distributed).

7.4 Appendices

Appendix 1 Product specifications test results from three non-consecutive lots.

APPENDIX I. Product specifications test results from three non-consecutive lots.

(1) Lot No. 090401

(2) Lot No. 090401

(3) Lot No. 090917

Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7091632 Version 1

Lot No: 090401 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
Assay Lead 2019-08-12 ICP-MS	NMT 2.0 mg/Kg	< 0.1 mg/Kg
Acid Value 2019-08-12 FCC	NMT 3.0	0.6
Color Reaction A 2019-08-14 FCC	Blue	Blue
Color Reaction B 2019-07-30 FCC	Dark Red to Blue	Dark Red
Degree of Hydrolysis 2019-08-21 FCC	86.5-89.0 %	87.4%
Ester Value 2019-08-14 FCC	125-153 mg KOH/g	139 mgKOH/ g
Infrared Absorption 2019-08-14 FCC	Spectrum matches USP Polyvinyl Alcohol RS	Conforms
Limit of Methanol (Methyl Acetate) 2019-08-21 FCC	NMT 1.0 %	Passes
Limit of Methanol (Methyl Alcohol) 2019-08-21 FCC	NMT 1.0 %	Passes
Loss on Drying 2019-08-12 FCC	NMT 5.0 %	3.1%
Particle Size 2019-08-21 FCC	NLT 99.0% passes through 100-mesh sieve	99.6% pass through 100 mesh sieve

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Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7091632 Version 1

Lot No: 090401 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
pH 2019-07-31 FCC	5.0-6.5	5.87
Precipitation Reaction 2019-07-30 FCC	White, turbid, or flocculent precipitate	White turbid precipitate
Residue on ignition 2019-08-14 FCC	NMT 1.0 %	0.5%
Viscosity 2019-08-21 FCC	4.8-5.8 mPas (4% solution at 20 degrees)	5.0 mPas (4% solution at 20 degrees)
Water Insoluble Substances 2019-08-21 FCC	NMT 0.1 %	Passes

Issuance Date: 2019-08-27

Approved By:
N. Abochama, M. Sc.
QA Director

Requisition: 1089R3489 **Received On** 2019-07-30 **Code No:** BP-05 **For** Adept Ltd., 6 McDonald St. Morningside, Auckland, 10075, Tel: +6421476403 Fax:.

11575 Sorrento Valley Rd, San Diego, San Diego County 92121,USA, www.american-testing.com, Tel: (858)-230-2155

Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7093215 Version 1

Lot No: 090914 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
Assay Lead 2019-10-10 ICP-MS	NMT 2.0 mg/Kg	< 0.1 ppm
Acid Value 2019-10-18 FCC	NMT 3.0	1.7
Color Reaction A 2019-10-18 FCC	Blue	Blue
Color Reaction B 2019-10-18 FCC	Dark Red to Blue	Dark red to Blue
Degree of Hydrolysis 2019-10-18 FCC	86.5-89.0 %	87.9%
Ester Value 2019-10-18 FCC	125-153 mg KOH/g	142 mgKOH/g
Infrared Absorption 2019-10-18 FCC	Spectrum matches USP Polyvinyl Alcohol RS	Matches
Limit of Methanol (Methyl Acetate) 2019-10-10 FCC	NMT 1.0 %	Passes
Limit of Methanol (Methyl Alcohol) 2019-10-10 FCC	NMT 1.0 %	Passes
Loss on Drying 2019-10-10 FCC	NMT 5.0 %	0.85%
Particle Size 2019-10-18 FCC	NLT 99.0% passes through 100-mesh sieve	99.5% pass throught 100 mesh

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Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7093215 Version 1

Lot No: 090914 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
pH 2019-10-18 FCC	5.0-6.5	6.0
Precipitation Reaction 2019-10-18 FCC	White, turbid, or flocculent precipitate	White and Turbid
Residue on ignition 2019-10-18 FCC	NMT 1.0 %	0.8%
Viscosity 2019-10-10 FCC	4.8-5.8 mPas (4% solution at 20 degrees)	5.0 mPas
Water Insoluble Substances 2019-10-18 FCC	NMT 0.1 %	0.08%

Issuance Date: 2019-10-23

Approved By:
Mo Lababidi
Senior Analyst

Requisition: 1092R4111 **Received On** 2019-10-09 **Code No:** BP05 **For** Adept Ltd., 6 McDonald St. Morningside, Auckland, 10075, Tel: +6421476403 Fax:.

11575 Sorrento Valley Rd, San Diego, San Diego County 92121,USA, www.american-testing.com, Tel: (858)-230-2155

Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7093216 Version 1

Lot No: 090917 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
Assay Lead 2019-10-10 ICP-MS	NMT 2.0 mg/Kg	< 0.1 ppm
Acid Value 2019-10-18 FCC	NMT 3.0	0.6
Color Reaction A 2019-10-18 FCC	Blue	Blue
Color Reaction B 2019-10-18 FCC	Dark Red to Blue	Dark red to Blue
Degree of Hydrolysis 2019-10-18 FCC	86.5-89.0 %	87.5%
Ester Value 2019-10-18 FCC	125-153 mg KOH/g	140 mgKOH/g
Infrared Absorption 2019-10-18 FCC	Spectrum matches USP Polyvinyl Alcohol RS	Matches
Limit of Methanol (Methyl Acetate) 2019-10-10 FCC	NMT 1.0 %	Passes
Limit of Methanol (Methyl Alcohol) 2019-10-10 FCC	NMT 1.0 %	Passes
Loss on Drying 2019-10-10 FCC	NMT 5.0 %	0.47%
Particle Size 2019-10-18 FCC	NLT 99.0% passes through 100-mesh sieve	99.6% pass through 100 mesh

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Certificate of Analysis

Product: Polyvinyl Alcohol (PVOH) Certificate No.: P7093216 Version 1

Lot No: 090917 **Issued for:** Adept Ltd.

Test / Date / Method	Specification	Results
pH 2019-10-18 FCC	5.0-6.5	6.1
Precipitation Reaction 2019-10-18 FCC	White, turbid, or flocculent precipitate	White and Turbid
Residue on ignition 2019-10-18 FCC	NMT 1.0 %	0.5%
Viscosity 2019-10-10 FCC	4.8-5.8 mPas (4% solution at 20 degrees)	5.1 mPas
Water Insoluble Substances 2019-10-18 FCC	NMT 0.1 %	0.05%

Issuance Date: 2019-10-23

Approved By:
Mo Lababidi
Senior Analyst

Requisition: 1092R4111 **Received On** 2019-10-09 **Code No:** BP05 **For** Adept Ltd., 6 McDonald St. Morningside, Auckland, 10075, Tel: +6421476403 Fax:.

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