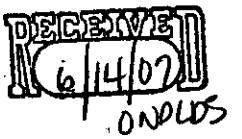
The Solae Company

June 12, 2007



Ms. Felicia Billingsley (HFS-820)
Director, Food Labeling and Standards Staff, Room 4D-045
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Petition for Allergen Labeling Exemption of Solae, LLC Solec™ Soy Lecithins When Used as Processing Aids

Dear Ms. Billingsley:

Pursuant to Section 403(i) 21 U.S.C. 343(i) of the Federal Food, Drug and Cosmetic Act ("Act"), as amended by Section 403(w) (6) of the Food Allergen Labeling and Consumer Protection Act [FALCPA (2004)], Solae, LLC (Solae) submits this Petition to exempt its proprietary SOLEC™ (SOLEC) soy lecithin products (examples that currently are used as processing aids include: SOLEC™E, SOLEC™F, SOLEC™152, SOLEC™HR, SOLEC™HR-4B, SOLEC™A, SOLEC™S, SOLEC™NVS , SOLEC™M , SOLEC™WD , SOLEC™GBR, SOLEC™CS, SOLEC™K-EML, SOLEC™100L, and SOLEC™8160), from declarative allergen labeling when used as processing aids.

Solae established that its SOLEC™ soy lecithin products, used as processing aids in a variety of food applications, provide significantly less ***potential soy protein/allergen*** than the standard soy lecithin reference used in the Food Chemicals Codex definition of soy lecithin. We conclude that our products would qualify for exemption from labeling beyond the 18-month interim term (wherein inspectors are instructed to use discretionary inspection authority for allergen labeling soy lecithin products), based on level of potential allergen in the product and use level of soy lecithins as processing aids.

The Petition contains background information covering the definition and characterization of SOLEC™ soy lecithin products, their potential for use as processing aids in a variety of food applications, and extrapolated potential exposure data from industry product use data documenting use as processing aids in food categories marketed in the United States.

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The information provided contains some proprietary data that is protected by law from disclosure. Solae believes disclosure of such information could potentially aid any competitors in making similar attestments; as such the information has been shared internally on a need-to-know basis, is marked as 'Company Confidential,' and should be held as confidential. In this Petition, Solae will provide scientific evidence to demonstrate that SOLEC™ soy lecithins, as characterized by the method(s) provided in this Petition, when used as processing aids, ***would not be expected to cause an allergic response that poses a risk to human health.***

Please feel free to contact me directly if you have any specific questions regarding the information provided in the Petition.

Sincerely,

Janet E. Collins, Ph.D., R.D.
Director, Global Regulatory Affairs
The Solae Company
P. O. Box 88940
St. Louis, MO 63188
Telephone: 202-728-3622
E-mail: jcollins@solae.com

Pursuant to Section 403(i) 21 U.S.C. 343(i) of the Food, Drug and Cosmetic Act, as amended by Section 403(w) (6) of the Food Allergen Labeling and Consumer Protection Act (FALCPA, 2004)[1] Solae, LLC (Solae) submits this Petition to exempt its proprietary SOLEC™ soy lecithin product line from declarative allergen labeling when used as processing aids. Based upon the Food Chemicals Codex[2] standard for composition of soy-based lecithin, and the FDA/CFSAN "Guidance for Industry,"[3] Solae established that SOLEC™ products provide significantly less potential soy protein/allergen than standard soy lecithin, as documented in the literature, and thereby would not be expected to pose a risk to consumer health when used as a processing aid at levels described below.

FALCPA 203(w)(6) provides that any person may petition the Secretary of the U.S. Department of Health and Human Services (Secretary) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements. The petitioner must demonstrate that such food ingredient, as derived by the method specified in the Petition, does not cause an allergic response that poses a risk to human health.[4] FALCPA establishes labeling requirements for the "eight major foods or food groups accounting for some 90% of food allergies," including milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans. Any non-commodity packaged food containing one of the eight major allergens must be labeled with the word, "contains," followed by the name of the food source from which the major food allergen is derived (such as, soy lecithin), or the common or usual name of the major food allergen (soy) must be provided in the list of ingredients.

The FCC standard is a useful benchmark by which to characterize soy lecithin products in commerce in the US and internationally. In this case, a maximum level of 0.3% HI is acceptable for a product to fit the FCC standard for soy lecithin- and theoretically, this level of HI (if 100% soy protein), when present in a processing aid, would not pose a risk to human

[1] Food Allergen Labeling and Consumer Protection Act of 2004. 21 USC 301. Public Law 108-282, August 2, 2004.
[2] Food Chemicals Codex, 5th ed. FDA/CFSAN, Washington, DC., USA.
[3] FDA/CFSAN Guidance for Industry: Guidance on the labeling of certain uses of lecithin derived from soy under section 403(w) of the Federal Food, Drug, and Cosmetic Act. 2006. USDHHS, FDA/CFSAN, College Park, MD. USA.
[4] FALCPA Section 203(w) (6) (A, C).

health, and as such would not require labeling, when used at the levels typically associated with processing aids by the food industry.

In this Petition, the HI levels present in SOLEC™ lecithins, as reported markers for protein content in lecithin products, are documented to be substantially below the level referenced from the Food Chemicals Codex[5] and also well below that level documented in scientific literature as "allergenic" proteins to soy-allergic subjects.

The objective of the Petition is to gain exemption of SOLEC™ (Solae-brand) soy lecithin products, derived from soybean processing, from specific designation on the ingredient statement when used as processing aids, as described below.

Background

A. Soy Protein Allergy Prevalence

Prevalence of soy protein allergy in the general population is not known.[6] In diagnostic tests, including double blind placebo controlled food challenges (DBPCFC); a relatively low rate of soy allergy is reported. Giampietro et al. (1992)[7] reported that 3% of 317 children tested positive to soy allergy in DBPCFC; Magnolfi et al. (1996)[8] reported similarly, that of 704 generally allergic children, only 1.1% were found to be soy allergic in a DBPCFC.

Bruno et al. (1997)[9] reported from a multi-center study of 505 allergic children some 1.2% children were soy positive, while Burks et al. (1998)[10] reported that of 187 allergic children, only 1.8% were positive to soy challenge. Other studies that compiled food intolerance estimates report 0.3 to 4.4% soy "allergy" in adults and children (Bjornsson et al., 1996[11]; Young et al., 1994[12] ; and Sampson and McCaskill, 1985[13]). Definitive studies assessing the

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[5] Ibid.
[6] Taylor, S. 2006. Estimating prevalence of soy protein allergy. The Soy Connection. Chesterfield, MO.
[7] Giampietro et al. 1992. Ann. Allergy 69: 143.
[8] Magnolfi et al. 1996. Ann. Allergy Asthma Immunol. 77: 197.
[9] Bruno et al. 1997. Pediatr. Allergy Immunol. 8: 190.
[10] Burks et al. 1998. J. Pediatr.

prevalence of soy allergy are lacking, but it is currently estimated that 0.2% of children and adults in the US are allergic to soy. Based on this estimate, soy allergy appears to be less prevalent than allergies to other major food allergens. Taylor[14] surmises a similar prevalence (0.1-0.2% of the US population) based on calculations used to predict soy allergic response from various testing sources.

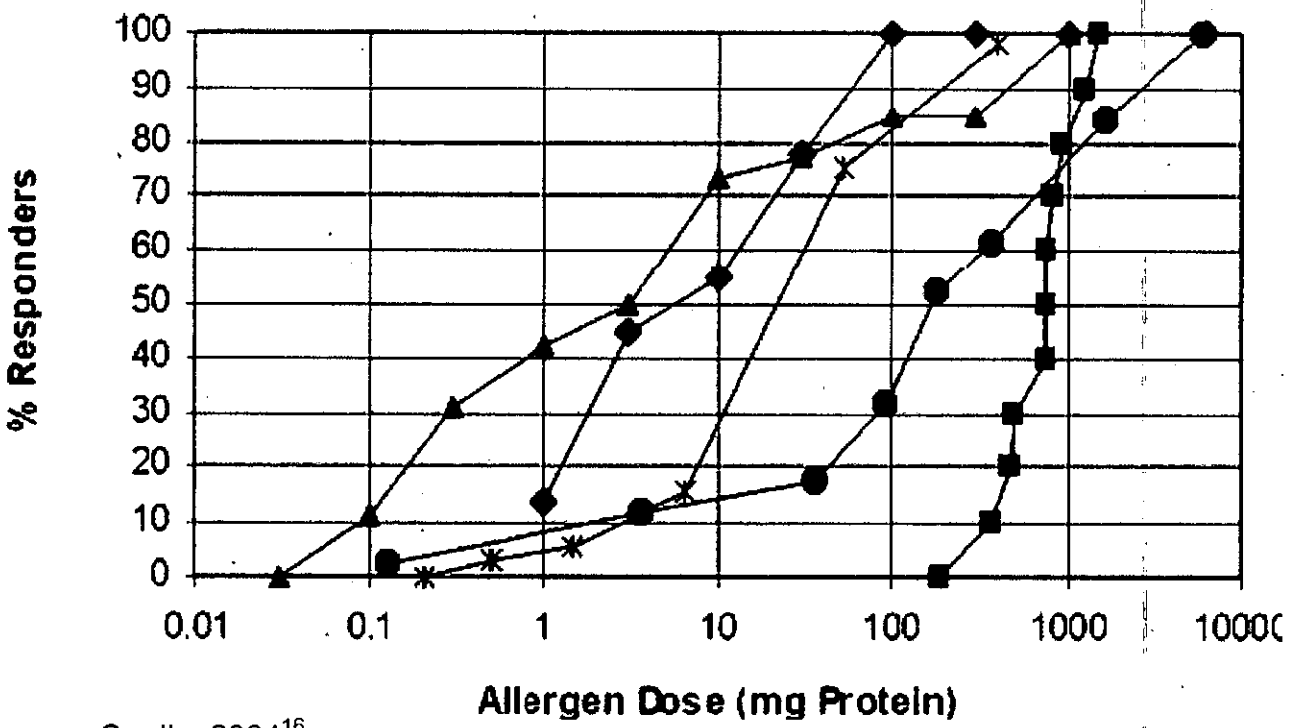
B. Allergenicity of Soy Protein

There is no consensus on the minimal dose of soy protein that will elicit an adverse effect (LOAEL). Further complicating the assessment is that soy protein does not appear to elicit the level of observed response as that from other food allergens, as reported in a review article by Cordle (2004)[15] Specifically, as can be seen from Figure 1, 'safe protein doses,' (those doses which would not elicit an allergic response in 90% of other-wise allergic subjects), demonstrates that the level is about 0.1mg for peanut; 1mg for hazelnut and for soy, approximately 400mg was required before an allergic response was noted. As Cordle states, the over 100 fold difference between soy protein safe level and other food allergens is striking.

Clinical studies reported in the literature are confounded by initial doses that may elicit a response in one or more subjects- but the subjects often are previously diagnosed as allergic to some allergen and thus do not appropriately represent the general population; therefore, no "No Observed Adverse Effect Level" (NOAEL) has been reported for soy protein.

[11] Bjornsson et al. 1996. Ann. Allergy Asthma Immunol. 77: 327.
[12] Young et al. – KENT- what is the reference for this citation.
[13] Sampson, H.A. and McCaskill, C.C. 1985. J. Pediatri. 107: 669.
[14] Ibid.
[15] Cordle, C. 2004. J. Nutri. 134: 1213S.

Figure 1: Food Allergen Reaction Thresholds*



Cordle, 2004[16]
Ingested allergen dose (mg protein) vs. % allergic responses in challenged patients. Allergens across the x- axis; (number) patients: ▲peanut (31), ◆hazelnut (32), ✳egg (33), ●milk (27), ■soy (27).

Soy is more similar in its allergenic profile to milk and eggs than to the severe allergens such as peanuts, tree nuts and shellfish.

- Allergic reactions to soy occur predominately in children ≤ 3 years of age (Bock, 1987)[17]
- Most children in the US who have reactions to soy outgrow the allergy by age four.[18]
- The most common symptoms of soy allergy are similar to those of egg or milk allergies: stomach upset, rashes and hives (Sicherer et al., 2000).[19]
- Bindslev-Jensen et al. (2002)[20] predicted a 12-175 fold higher eliciting dose for soy allergens than for peanut, egg or milk.

[16] Ibid.
[17] Bock, S.A. 1987. Pediatrics, 79:638.
[18] Ibid.; and Host, A. 1990. Allergy. 45:587.
[19] Sicherer, S.H. 2000. Allergy. 55:515.
[20] Bindslev-Jensen et al. 2002. Allergy. 57: 741.

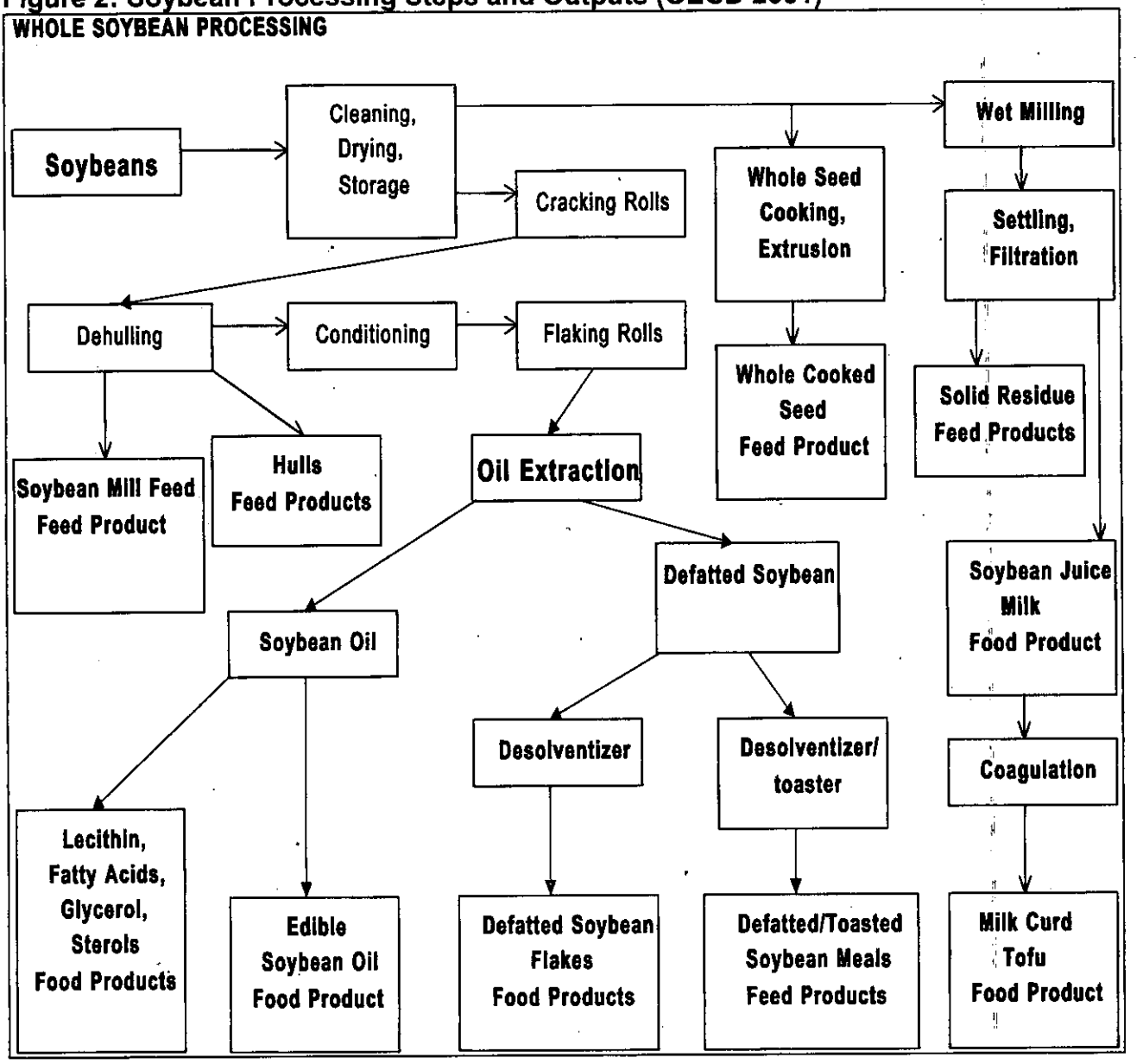
- It is appropriate to exercise good manufacturing practices with soy lecithin, as those employed when milk- and/or egg-containing foods or ingredients are handled.

Soy Lecithin Characterization and Use

Commercial sources of lecithin are predominantly vegetable oil seeds, with soybean being the largest contributor to commercial lecithin in the United States. Lecithins are derived from oil manufacturing whereby crude lecithins are separated from oils according to the process illustrated in Figure 2[21].

[21] OECD 2001. Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients, Organization for the Economic and Cooperative Development, Paris, FR.

Figure 2: Soybean Processing Steps and Outputs (OECD 2001)



The following Figures (3, 4, and 5) illustrate the lecithin manufacturing processes and the component steps for three classes of SOLEC™ (refined lecithin, reacted lecithin, deoiled lecithin).

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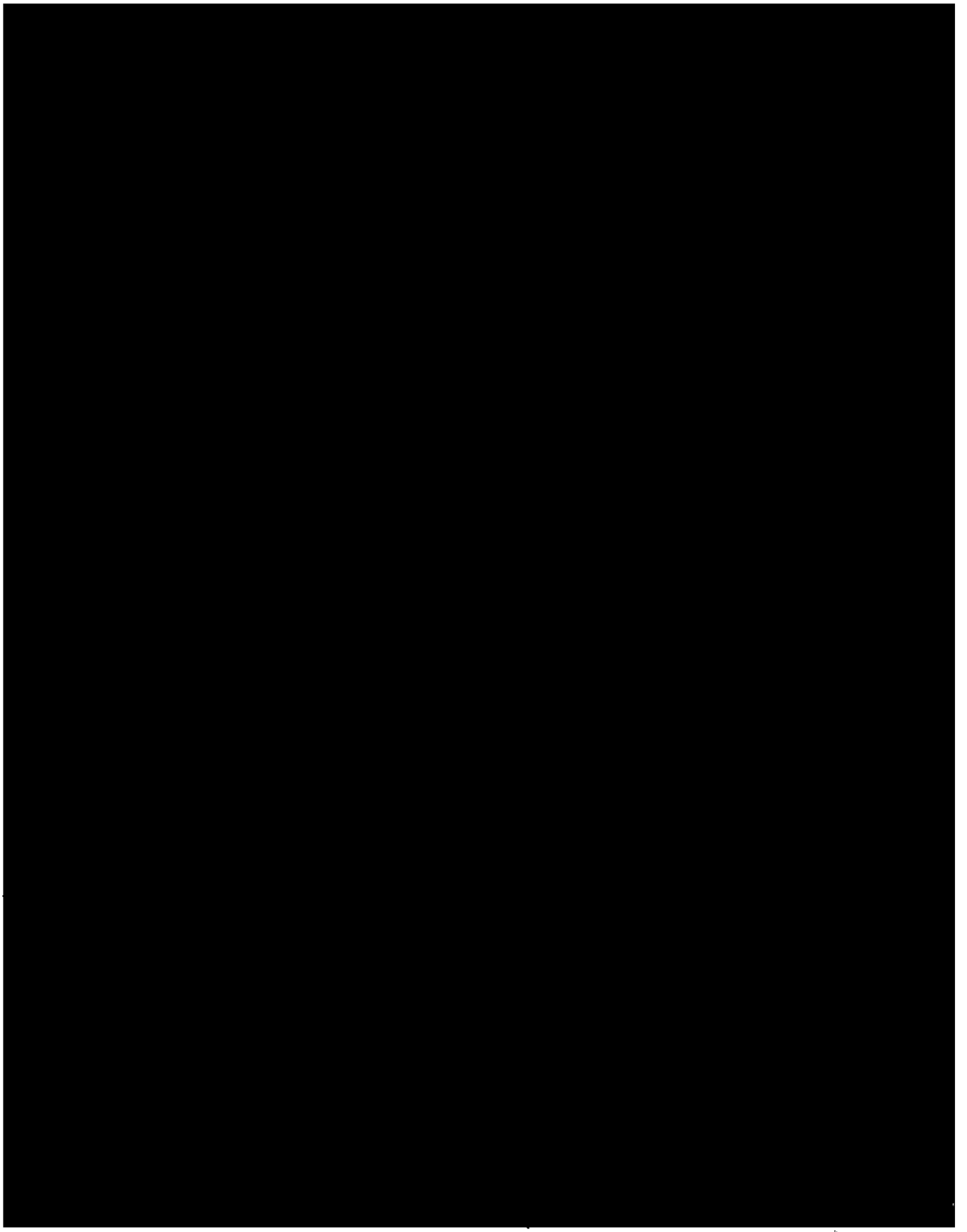

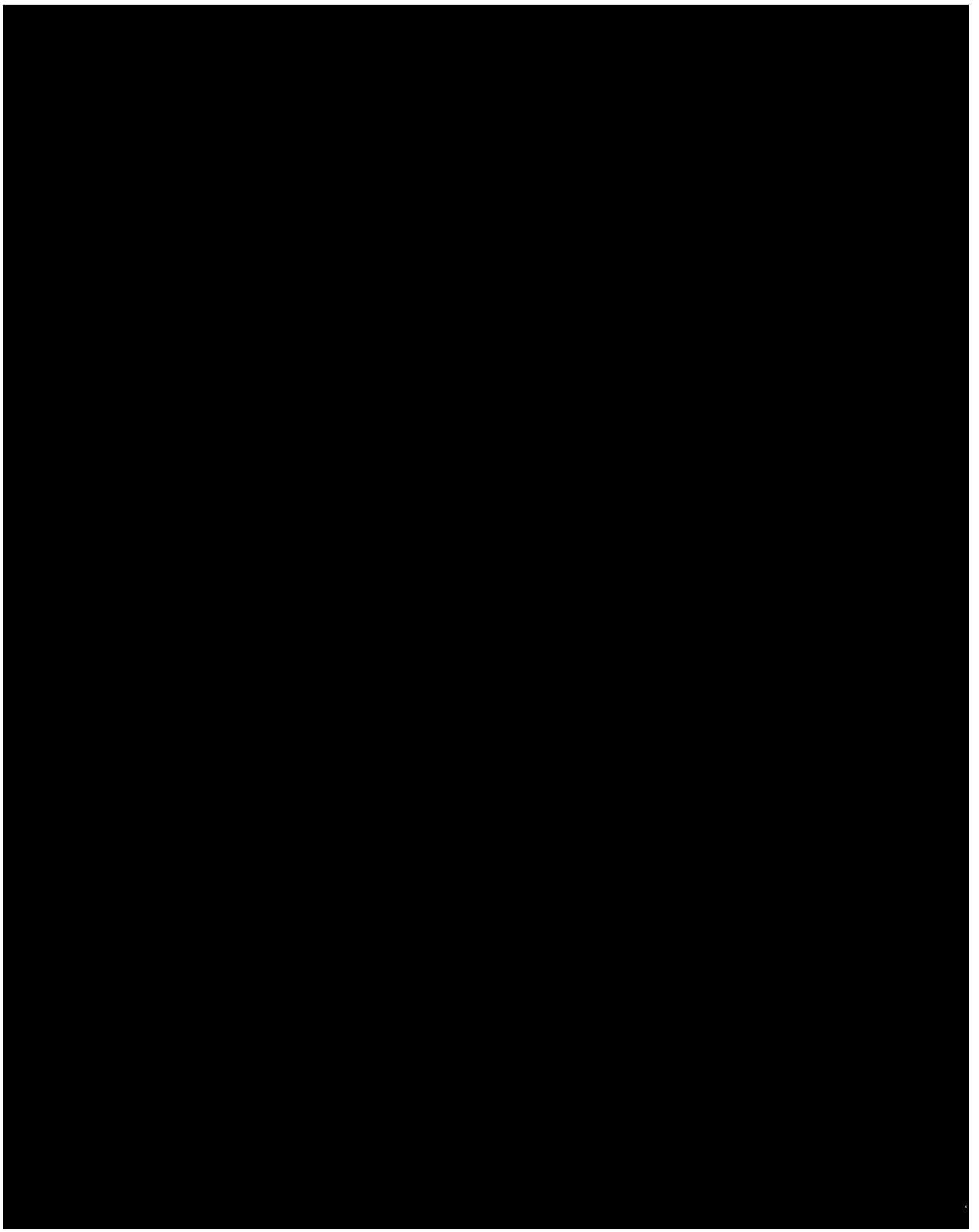

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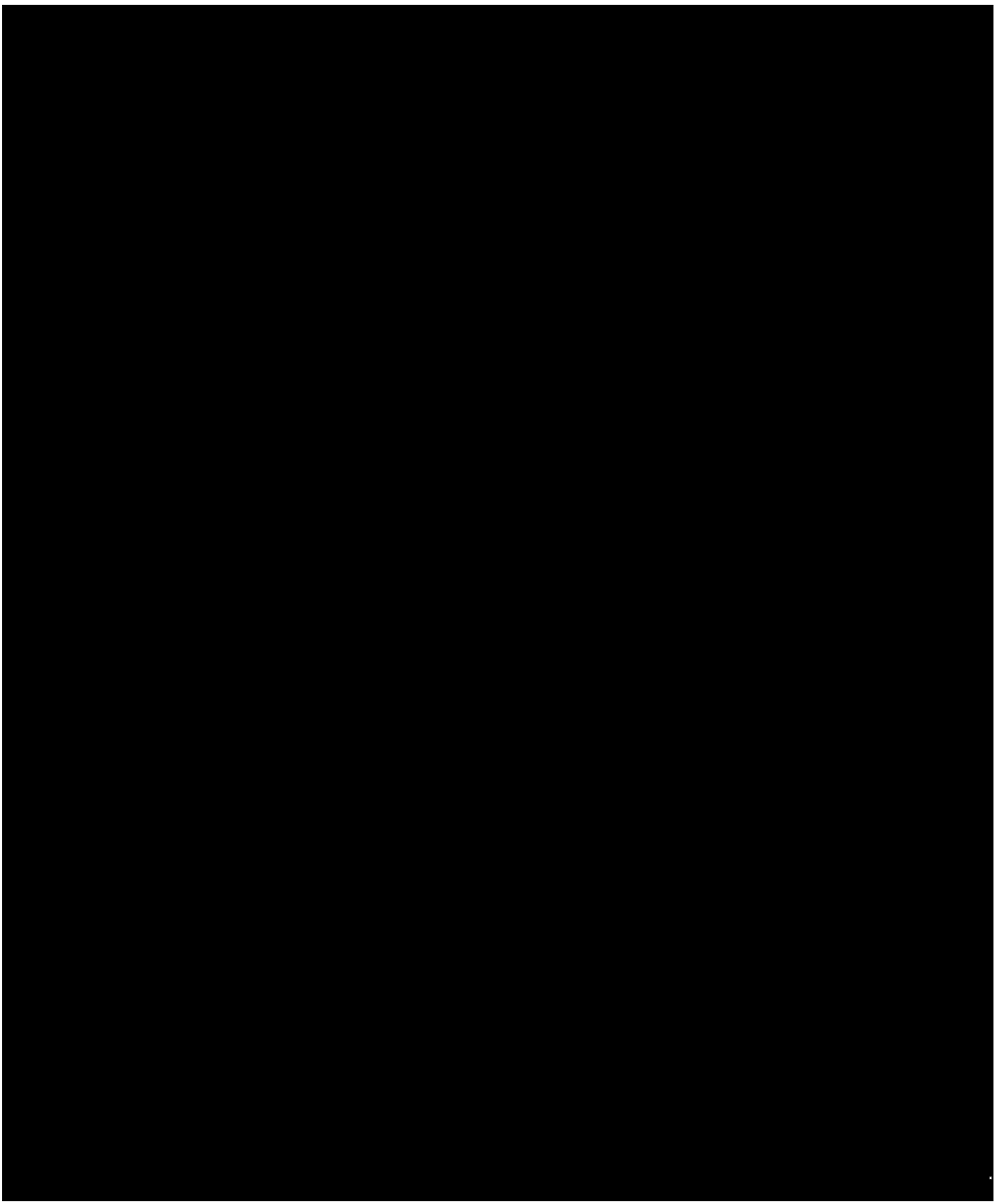

with no limitation other than good manufacturing practice.[23] The GRAS affirmation specifies that soy lecithin must meet the specifications of the Food Chemicals Codex which stipulates that food grade lecithin may not contain more than 0.3% hexane-insolubles [HI (300mg HI/100g lecithin)][24]. As Solae has improved its manufacturing processes, we have further refined and improved the method of measuring HI. Using a finer mesh filter for separation, hexane-insoluble material [HIM[25] (a more refined measure of hexane insolubles in soy lecithins)] also may be measured in order to establish low levels of insolubles for customer quality control information. Those data for a number of SOLEC™ soy lecithin products also are provided. Methods for HI and HIM analyses are in Appendix A.

Lecithins are used in a variety of commercial processed food products for several functional effects. When used as ingredients for functional purposes, lecithins serve largely as emulsifiers and stabilizers. The use of lecithins as processing aids such as releasing agents for baked products, chewing gum, ham nets and other "non-stick" food applications (such as extrusion aids) also is important (Table 1). Specific detailed information concerning each processing aid application is provided in Appendix B, including the specific SOLEC™ ingredient used.

[23] GRAS. 21 CFR 184.1400. Lecithin is Generally Recognized as Safe.
[24] Solae. (2006). Inspection Method; Hexane Insoluble Material in Lecithin, code CM705
[25] Solae (2006). Inspection Method; Quantitative Hexane Insoluble Material by Millipore Filters, code CM707.

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Table 1: Soy Lecithin Use and Food Categories [Solae Customers (2006) [26]]

Product	Processing Aid Function	Typical *inclusion* level, % by weight
Ham Net Release Agent	Release of ham netting from smoked hams	10 – 34% solution for dipping nets
Sausage casing release	Prevent tearing of sausage on removal of casing	5 – 15% aqueous solution; 10 – 20% oil-based mixture
Chewing gum	Multiple, e.g., viscosity modifier of gum base	0.6%
Sliced processed cheese	Anti-sticking / release aid (slices do not stick to one another)	1 lb of lecithin per 2800 ft^2 of cheese
Natural cheese	To improve yield	0.045- 0.066%
Dry-Blended Beverages	Instantizing powders for anti-dust	0.5%; up to 2% in dry blend, prior to reconstitution
Waffles	Release during cooking	0.5%
Applications requiring food-contact surface release	Aerosol Spray Release Agent (pan release)	5-10% of aerosol release product
Protein stabilized foams Cottage cheese	Antifoam to destabilize protein stabilized foams	≤0.1% by weight
Doughnuts and other fried cakes/breads	Prevents oil absorption in yeast and cake-type doughnuts	0.5 - 1% of the weight of the flour
Cereals, snacks and pasta	Extrusion aid to help in release of product from extruder	0.2- 1.75% of the weight of the flour
Meatballs	To prevent sticking to equipment	0.5%
Gravies and sauces	To prevent fat crystallization	0.3 – 0.5%
Sugars and syrups	To reduce evaporation and increase yield	<200ppm
Processing equipment	Sprayed or dipped on processing belt and other equipment to prevent food sticking to the belt	0.1 to 20% in liquid or oil base
Spice blend-oleoresin	To disperse and stabilize spice extracts	≥50% of oleoresin spice blend

[26] Solae, LLC 2006. St. Louis, MO.

Soy Lecithin Chemical Analysis

Lecithin is a complex mixture of fat soluble and insoluble components; its characteristic function is to serve as an emulsifier and it also serves as a processing aid (incidental additive) in a variety of processes. The FDA standard of identity for soy lecithin characterizes soy chemistry by relating its identity to quantity of hexane insoluble materials (21 CFR 184.1400). By standard of identity, soy lecithin can not exceed 0.3% or 300mg/100g (3000ppm) lecithin of hexane insoluble matter (HI). Analytical methods reported in the literature and used historically, [as recently as 2005 (Martin-Hernandez et al., 2005),[27]] used separation methods designed to extract the "protein" fraction, believed to be precipitated in the hexane fraction, and quantify proteins using a variety of methods.

A summary of SOLEC™ product data, presented in Table 2, demonstrates the low level of HI and HIM in existing SOLEC™ lecithin products used by our customers. These data will be used later to demonstrate potential contribution of protein from soy lecithin, when used as a processing aid, in finished food products. Those data are presented graphically by product over time of manufacture in Appendix C so as to demonstrate relative consistency within product(s) and among times tested. It is important to note that the values are highly consistent within products over time, and that SOLEC™ HI values are for the most part, substantially lower than the HI 'standard' within the Food Chemicals Codex.

[27] Ibid.

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Specific manufacturing (lot-by-lot quality assurance) data points of analysis, covering approximately 40 months of manufacturing data at multiple manufacturing sites, for several SOLEC™ lecithins are presented graphically in Appendix C. The data presented in Table 2 and when graphed by product (Appendix C) demonstrate not only the low levels of HI/HIM present in the lecithin products, but also the relative degree of consistency of HI and HIM levels among measurements taken over time for each of the products. It is clear from these data that the HI/HIM levels in the SOLEC™ lecithins do not vary widely within product or among time periods of analysis and that they are consistently far below the FCC specification standard for soy lecithin.

Historically, it has been assumed that the protein component(s) of lecithin are contained in the hexane insolubles fraction, and thus, hexane extraction has been used in methods designed to quantify protein in soy lecithin (the FDA standard of identify for soy lecithin relates protein content to HI for which a limit exists). As of 2005, Martin-Hernandez et al. (2005), reported no validated methods were available to quantify protein in soy lecithin, and further the first step in the analysis typically is extraction using aqueous/organic solvents with protein content determined using different assays, including Bio-Rad Protein Assay, ELISA, and electrophoretic tests (Bradford[28]; Paschke et al[29].; Lowry[30]; Awazuhara et al[31]; Gu et al.[32]; Porras et al.[33]; and Muller et al.[34]). According to Martin-Hernandez et al. (2005), extraction with hexane-2-propanol-water, followed by amino acid analysis is the most suitable method for isolation and quantification of proteins from lecithins. The detection limit of this analytic method is 15mg protein/kg lecithin and a quantification limit of 50mg protein/kg lecithin. Using this method, commercial soy lecithins used in this study ranged between 232mg and 1338mg protein/kg soy lecithin (232-1338ppm protein). Hexane extraction is the

[28] Bradford, M.M. 1976. Anal. Biochem. 72: 248.
[29] Paschke et al. 2001. J. Chromatogr. B. 756: 249.
[30] Lowry et al. 1951. J. Biol. Chem. 193: 265.
[31] Awazuhara et al. 1998. Clin. Exp. Allergy. 28: 1559.
[32] Gu et al. 2001. Int. Arch. Allergy Appl. Immunol. 126: 218
[33] Porras et al. 1985. Int. Arch. Allergy Appl. Immunol. 78: 30.
[34] Muller et al. 1998. Z. Lebensm.-Unters. Forsch. A. 207: 341.

standard method used for analysis of protein in lecithin.[35] However, it is important to recall that the hexane extraction process would be expected to result in a mixture which contains protein, non-protein nitrogen and other materials, including ash; the entire HI or HIM, therefore, would not be 100% protein. We will make some assumptions about the relative protein content in the Conclusions section.

In development of a data package to demonstrate protein levels in SOLEC™ lecithins, we also collected data to assess relative amino acid contribution when comparing soy lecithin products to soy protein isolate. These experiments were conducted to assess total protein and also to establish similarities and differences in amino acid composition of soy lecithin and soy protein isolate (Figures 6 and 7) in order to determine whether allergenic proteins (as characterized by their respective amino acid composition) were diluted or concentrated in lecithin during extraction and processing of the soy lecithin.

[35] Smith, A.K. and Circle, S.J. editors. 1972. Soybeans: Chemistry and Technology. AVI Publishing Company, Inc. Westport, CT.

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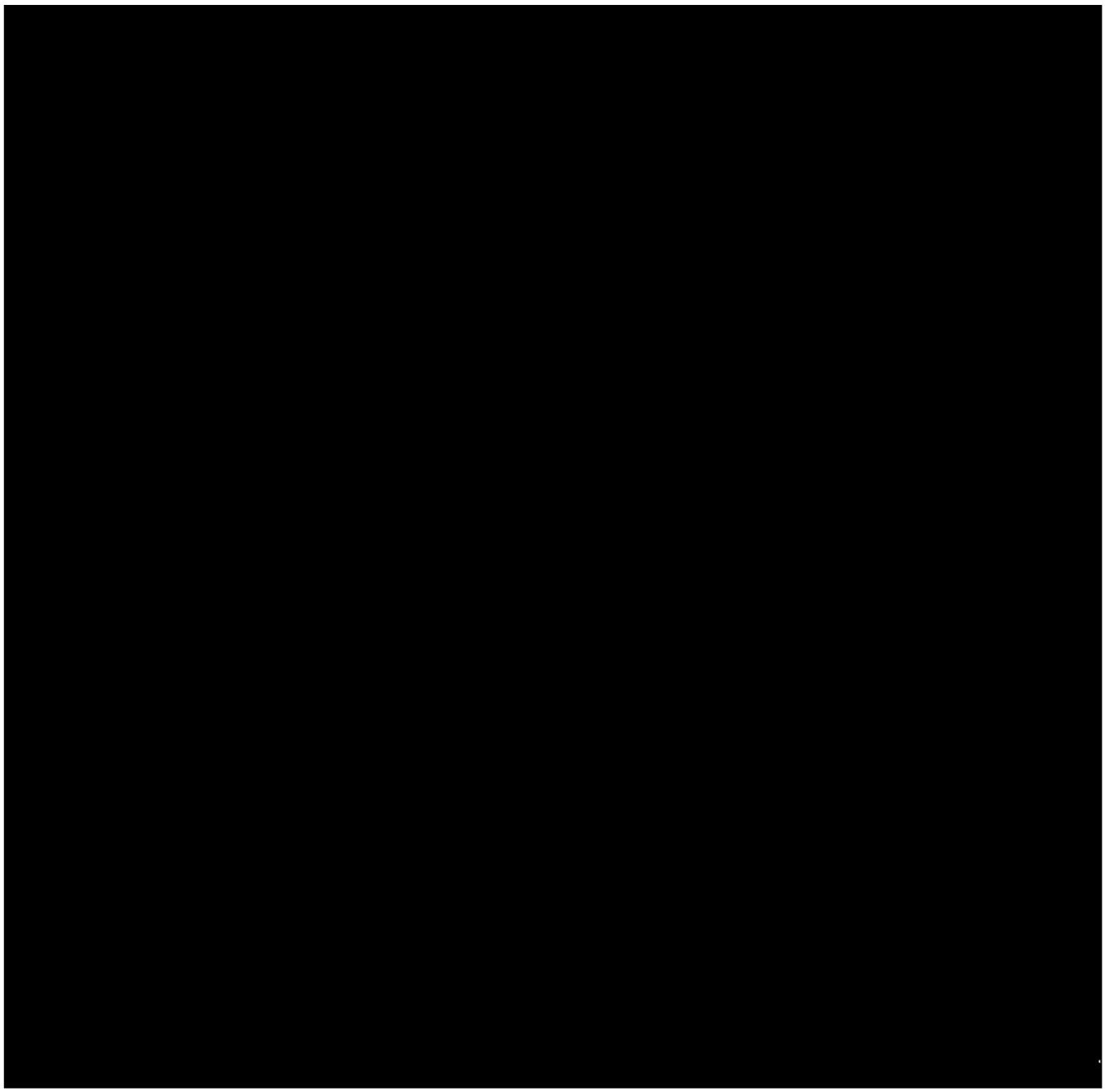

These data demonstrate a significantly higher relative amount of the amino acids phenylalanine and tyrosine (aromatic amino acids) and glutamic acid and aspartic acid (acidic amino acids) in soy lecithin when compared with soy isolate. It is not entirely clear what is the significance of these findings, but there would appear to be a difference among proteins in these lecithin products when compared with soy isolates using these analytic methods. Once the amino acid content is determined, the relative amount of protein in these products is estimated by multiplying the amount of glutamic acid determined by analysis of samples; that value is then multiplied by an agreed-to factor to estimate the total protein.

Quantification of total protein in foods is calculated by measuring amino acids, corrected by conversion related to the amount of glutamic acid as a control. When the protein in soy lecithin is calculated in this way, there may be a fundamental over calculation for protein because of the relatively high level of glutamic acid in the lecithin extract analyzed. Given the data presented in Figures 8 and 9, it appears that the amount of protein in the lecithin, when reported using this method of estimating protein content, total protein may be over stated by up to 40%. This factor will be taken into account in the risk assessment discussion below.

Using data provided in Tables 1 and 2 and applying usage levels from SOLEC™ soy lecithin the total range of HI/HIM, expressed as mg/RACC[36], from SOLEC™ lecithins used as processing aids in formulation of processed food products is calculated (Table 3).

[36] 21CFR 101.12 Table 1

It can be seen from the calculated data provided in Table 3 that the potential soy exposure, reported as HI, to the final food using various SOLEC™ commercial lecithin products as processing aids, is very low, making the presence of soy protein in the finished foods non-detectable by current methods. It is important to note that, for each example presented in Table 3, the most conservative factors were used to calculate the levels of exposure. This included selecting the highest HI or HIM value of the SOLEC™ soy lecithin with the highest HI or HIM quality control specification and applying it at the highest rate of use. In addition, it was assumed that in the case where lecithin is used as a release agent, the entire amount of SOLEC™ soy lecithin that was applied was transferred to the food product and consumed. Assuming consumption of multiple servings of each of the foods listed in the table, the total estimated potential exposure to HI from the SOLEC™ soy lecithins

would be 6mg. Specific product production methods for inclusion of SOLEC™ in the food categories are provided in Appendix B.

In the FDA Draft Report on thresholds for allergens in foods[37] several methods are described for attempting to assess a threshold for reaction to an allergen among the major allergens and for gluten. With respect to potential allergenicity of soy-derived lecithin when used as a processing aid, several factors need to be taken into account in establishing a product content level or serving size of specific products which would be presumed to be safe for consumption by the general population, and thus would not require labeling as to the presence of 'soy.' The factors which should be considered, and will be discussed as a basis for establishing the relative risk of consumption and thus an acceptable exposure level include:

- HI/protein level comparisons (mg/ serving) with those reportedly present in highly refined oils. Soybean oils are exempt from labeling,
- the FCC definition of soy lecithin and its characterizing levels of protein,
- the processing steps used in manufacture of Solae brand soy lecithins,
- comparative levels of HI/HIM in foods, as consumed, when SOLEC™ soy lecithins are used as processing aids when compared with minimum eliciting dose for allergic response in sensitive populations versus the general population, and,
- the nature of methods for establishing threshold levels differ from those methods historically used to establish toxicologic thresholds (the dose at or below which an adverse effect is not seen in an experimental setting).

[37] FDA 2005. Draft Report- The US FDA Threshold Working Group (7); Approaches to establish thresholds for major food allergens and for gluten in food: Washington DC.

Relative Risk Assessment for SOLEC™ Lecithins when used as Processing Aids

1- Protein level comparisons per serving with those reportedly present in highly refined oils that are exempt from labeling,

Appendix 3 of the FDA Threshold Working Group (2006)[38] expert draft report provides a summary of published data for the measurement of HI/HIM (reported as protein content) in edible oils, including soybean oil. The values cited for the degummed oils reported by Nordlee et al. (2002)[39] provide a range of protein content in degummed oil of 0.16 to 20.8 ug/g (0.16 – 20.8 mg/kg or ppm). If we calculate exposure to the HI from the degummed oil to be an average of 10ug/g oil or 10ppm, we extrapolate to 140ppm/serving of this oil (one tablespoon). Soybean oil represents the largest source of oil in the US diet.[40] If we assume that the 'average' American diet contains 40% of its 2500 calories from fat, and that approximately 60% of the total fat is from vegetable sources, and 80% of that fat is from soybean oil, we arrive at a figure of 1000 kcal from fat, equaling approximately 110g total fat, equaling 66g fat from plant sources and 52g soybean oil. This 52g of soybean oil would translate to about 520ppm HI using the Nordlee values for HI in degummed oil. With few exceptions, the exposure of an individual to foods processed with SOLEC™ products as processing aids (Table 2) would be less than the calculated exposure using the degummed soybean oil values of Nordlee. Exposure to the entire list of foods with SOLEC™ as a processing aid would result in exposure to HI at only at about 50-65% of the FCC standard for soy lecithin. Based on a single exposure to one of the foods, it could be argued that these numbers fall within the range of values determined to statutorily exempt soybean and other oil sources from FALCPA labeling.

[38] The Center for Food Safety and Applied Nutrition, Food and Drug Administration, US. Department of Health and Human Services. 2006. Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food. College Park, MD. USA.

[39] Nordlee, J.A., Neimann, L.M., Hefle, S.L. and Taylor, S.L. 2002. Determination of proteins in soyubean oil from distinct processing steps. Abstracts from the Annual Meeting.

[40] USDA ARS. 2002. USDA National Nutrient Database for Standard References. Rel 15. US. Department of Agriculture. http://www.nal.usda.gov/fnic/foodcomp.

2- FCC definition of soy lecithin and its characterizing levels of protein

Lecithin, affirmed as GRAS, has no limitation to use other than current good manufacturing practices (21CFR 184.1400). Enzyme-modified lecithin is also GRAS (21 CFR 184.1063). Hydroxylated lecithin is a permitted direct food additive (21 CFR 172.814). The regulations specify that the ingredient meets the specifications of the Food Chemical Codex. The FCC Monograph specifies that food-grade lecithins contain not more than 0.3% hexane-insoluble matter. Table 2 provides data (and Appendix B graphic information) demonstrating that representative samples of SOLEC™ brand lecithin products contain no more than a maximum mean level of 0.1% HI among 12 different lecithin products, with a maximum of 0.3% in only production lot, and in one SOLEC™ soy lecithin product. The average level of HI/HIM in SOLEC™ lecithins, as documented with manufacturing data from quality control history covering over 40 months of production data, is an exponential order of magnitude less than the standard as specified in the FCC monograph on soy lecithin. Furthermore, the HI/HIM data include not only the protein material that is measured but also the non-protein nitrogen and ash. It is reasonable to assert that we have conservatively and adequately built into the consumption level calculations safeguards to address the known risk. We also have demonstrated that given the relative amino acid content of SOLEC™ lecithins, it is likely that the total protein calculated from the amino acids, when compared to the standard method of calculating protein using glutamic acid as the baseline, over estimates the amount of total protein in lecithin. Lecithin is roughly 35-50% higher in glutamic acid than is, for example, soy protein isolate. Therefore, the protein calculation for lecithin would overestimate total protein.

3- Processing steps used in manufacture of Solae brand soy lecithins

Figures 2, 3, 4 and 5 characterize the processing methods used to produce several SOLEC™ soy lecithin products from crude oil. According to the OECD flow chart, soybeans are processed, oil removed, and from the extracted oil, lecithin and other products are produced. Figure 3 demonstrates the SOLEC™ process for production of refined lecithin, with three different filtration processes, each of which removes a portion of the protein and other non-lipid materials from lecithin. Figures 4 and 5 further demonstrate, for reacted and deoiled lecithin products, the degumming process and sequential filtration processes used

refine the soy lecithins and remove HI. In the comparative manufacturing process (to soy oils), SOLEC™ products are systematically 'cleaned,' and during that process, protein(s) is removed.

4- Comparative levels of protein in SOLEC™ soy lecithins compared with minimum eliciting dose for allergic response in sensitive populations versus the general population

The FDA "Threshold Working Group" draft report provides summary information for published LOAELs for food allergens, with a range of 88 to 522mg protein reported for soy to elicit an allergic response. Taylor[41] briefly reported on an as yet-to-be published report out of the EU, in which a subjective symptom of allergy was reported at 10mg soybean (or approximately 5mg protein). We have demonstrated that a diet containing a serving from each of the categories of product use documented in this Petition would exposure the consumer to less than 3mg HI (reported as protein in the literature) per day- this level is less than 5% of the LOAEL reported in the literature.

In the Report, the LOAEL for soy was listed as 88-522mg protein, based on studies by Ziegler (1999)[42] and Magnolfi (1996)[43]. The subject population studied were otherwise sensitive populations, infants and young children, were reported. In the study of Fiocchi et al. (2003)[44], infants and children also were studied. Among these three clinical studies, the lowest minimal eliciting dose was 88 mg soy protein. It should be noted, however, that eight of the total 36 infants and children studied had histories (pre-study) of severe reaction to soybean as well as clinically established milk allergy, and thus demonstrate the nature of these acutely sensitive populations. The minimum eliciting doses were 522mg, 216 mg, and 88mg soy protein as reported by Ziegler et al. (1999), Fiocchi et al. (2003), and Magnolfi et

[41] Ibid.
[42] Ziegler, R.S., Sampson, H.A., Bock, S.A., Burks, A.W., Harden, K., Noone, S., Martin, D., Leung, S. and Wilson, G. 1999. Soy allergy in infants and children with IgE-associated cow's milk allergy. J. Pediatrics. 134: 614-622.
[43] Magnolfi, C.F., Zani, G., Lacava, L., Patria, M.F., and Bardare, M. 1996. Soy allergy in atopic children. Ann. Allergy Asthma and Immunology. 77: 197-201.
[44] Fiocchi, A., Travaini, M., D'Auria, E., Banderali, G., Bernardo, L., and Riva, E. 2003. Tolerance to a rice hydrolysate formula in children allergic to cow's milk and soy. Clin. Exp. Allergy. 33: 1576-1580.

al. (1996), respectively. It should be noted that the minimum eliciting dose range among the subjects, within each of the studies was 522-2160mg, 216-3240mg, and 88-3600mg soy protein [(Ziegler et al., 1996), (Fiocchi et al., 2003), and (Magnolfi et al., 1996), respectively]. As noted in the Report, it is unclear how best to report allergic reactions or symptoms because research data typically use the first "objective symptom" as the level of reported first reaction. The first subjective reaction noted by subjects in a study is not always reported, and unless followed by some objective measure may not accurately pinpoint the 'true' reaction. In summary, the value of 88mg protein represents that lowest level of exposure reported to elicit a response in the most sensitive individuals in these studies, and the response was reportedly a mild, objective symptom.

According to Taylor and Hefle (2004),[45] in a low-dose challenge trial of more than 50 soy-allergic individuals, the minimal provoking dose was 88mg of soy protein (220mg of soybean) to elicit a mild, objective symptom. Further, they report the clinical evidence indicates a majority of soy-allergic individuals have minimal eliciting doses *above 500 mg soybean*. Therefore, not only is the amount of soy protein (or its allergenic protein) a factor to be considered but also the effective (allergenic) dose- which for soybean protein is roughly 100 fold lower than for minimal dose response from allergenic protein in egg, peanut and cows' milk.

In conclusion, we submit that these data and calculated HI values for processed foods clearly demonstrate that, when applying a conservative approach to account for risk of exposure, SOLEC™ soy lecithins, when used as processing aids for ham net and sausage casing release, chewing gum and processed cheese slice anti-stick, antifoam applications in protein containing foams, anti-crystallization applications in gravies and sauces, moisture retention aid in sugars and syrups, and anti-dust agents in dry blended beverages, expose the consumer to a level one to two orders of magnitude below the level required to elicit mild objective symptoms. The potential exposure of individuals to protein derived from soy lecithin when used as a processing aid in these applications would be less than 0.1mg/ serving. If

[45] Taylor and Hefle. 2004. Soy lecithin: An Expert Opinion on its Potential Allergenicity.

one were to consume a serving of each of the products listed in Table 3, at the levels provided, the exposure to HI, overall would be less than 3mg/day. This exposure is exponentially lower than that reported in the literature to elicit an allergic response. The cumulative effect of consuming all of the foods, at levels indicated on Table 3, demonstrates an exposure of only 6mg total HI.

The data provided clearly demonstrate that use of SOLEC™ soy lecithins, as processing aids over a range of food processing applications, does not pose a risk to public health. We request that SOLEC™ soy lecithins be exempted from FALCPA food allergen labeling requirements when used as processing aids.

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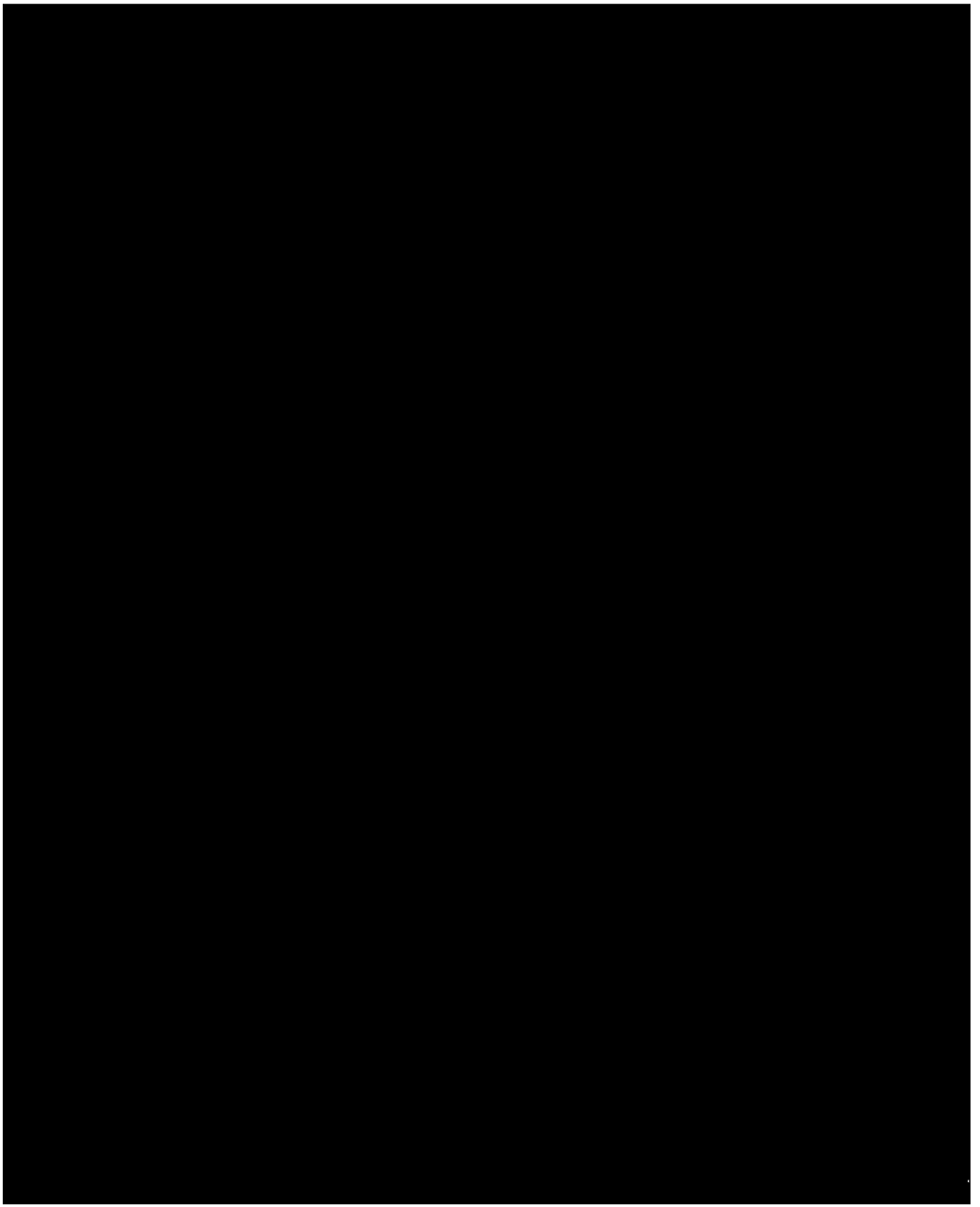

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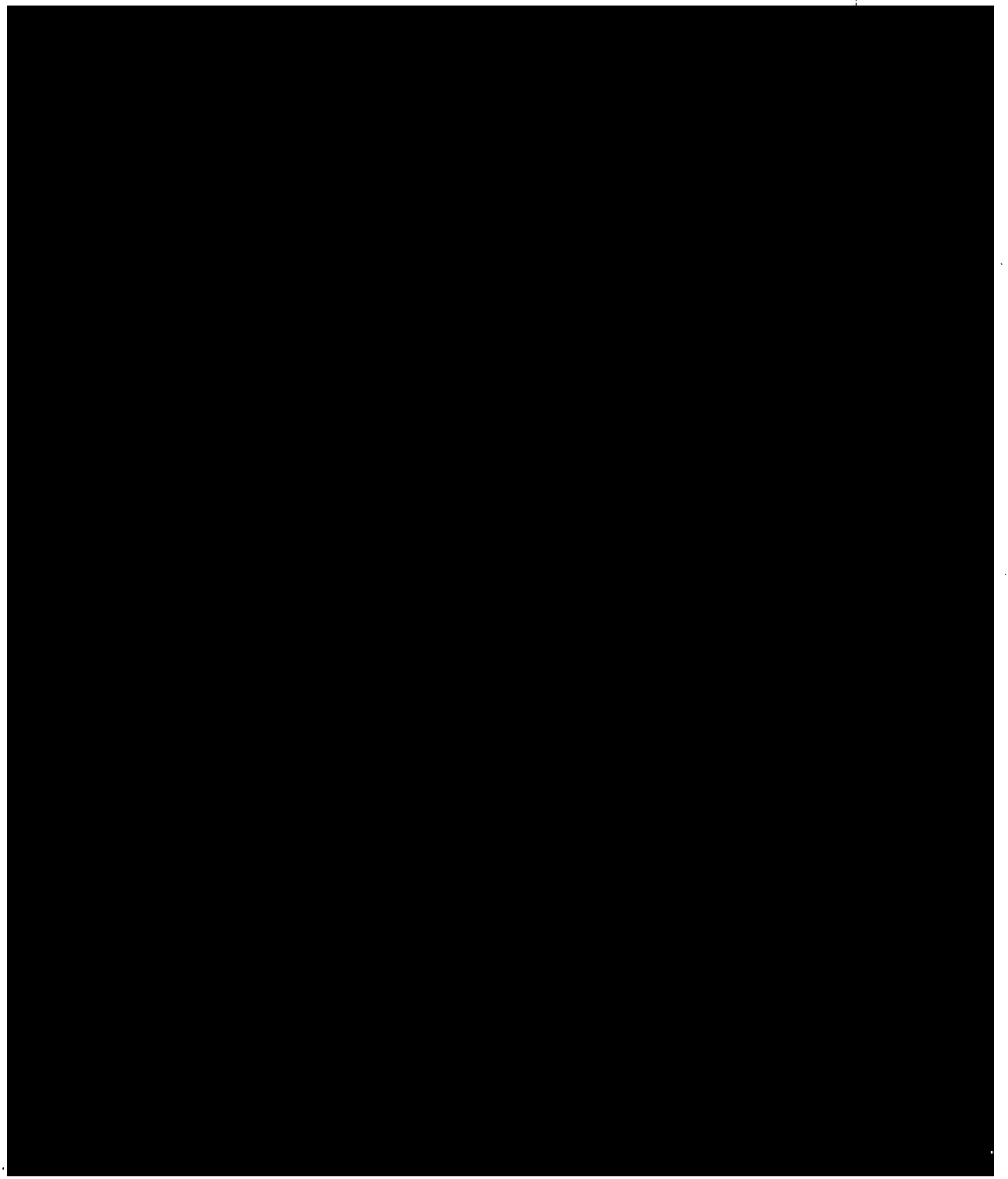

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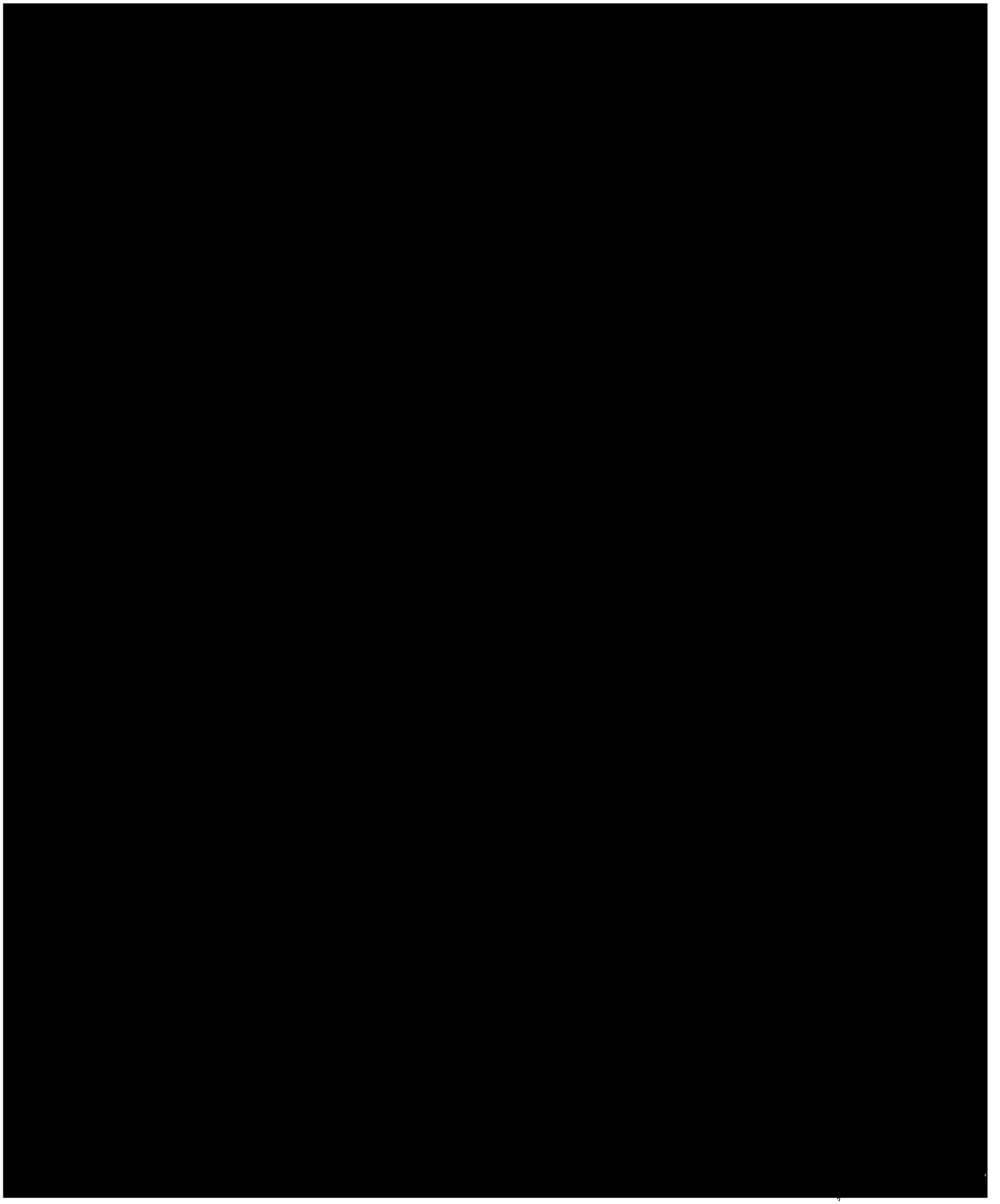

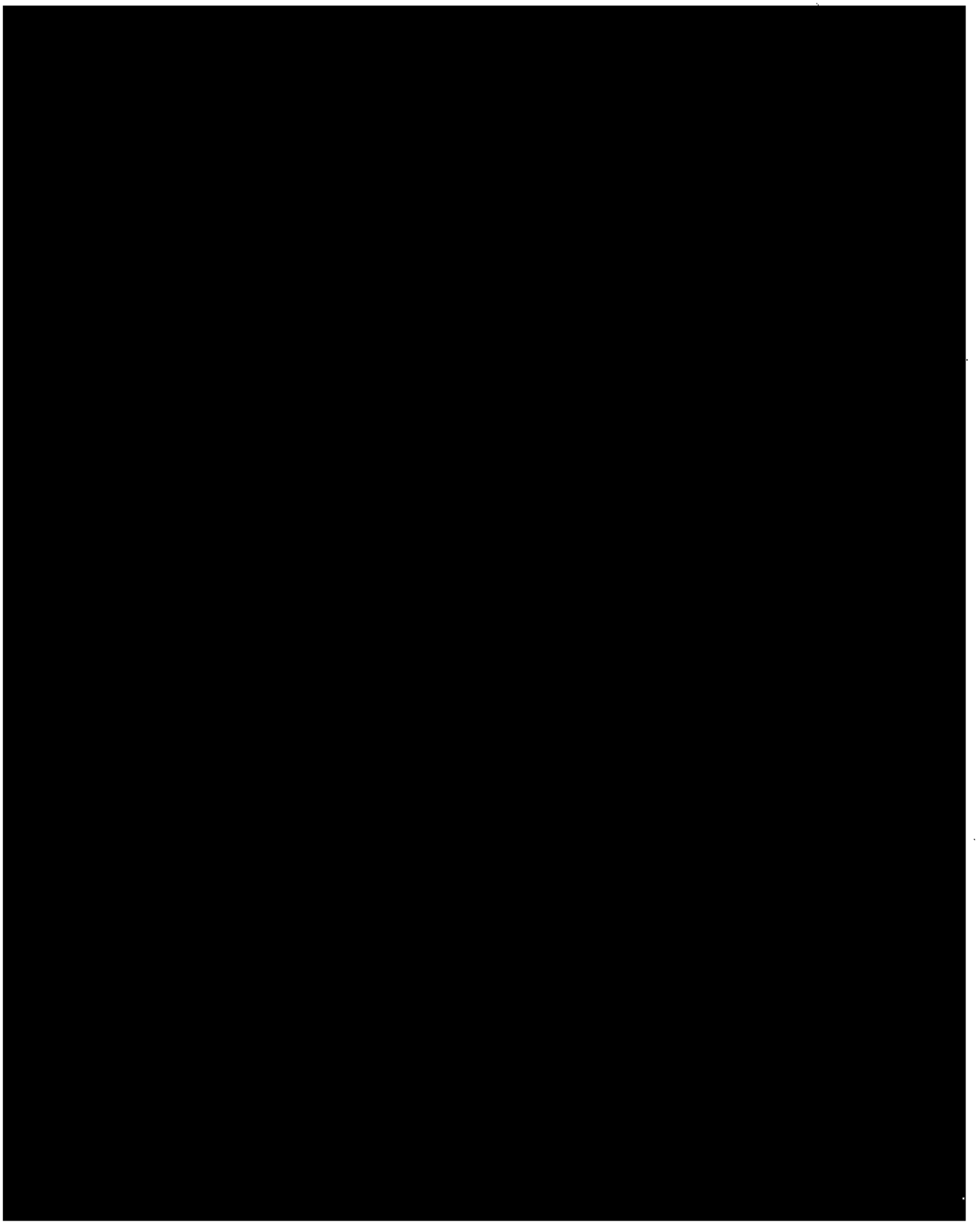

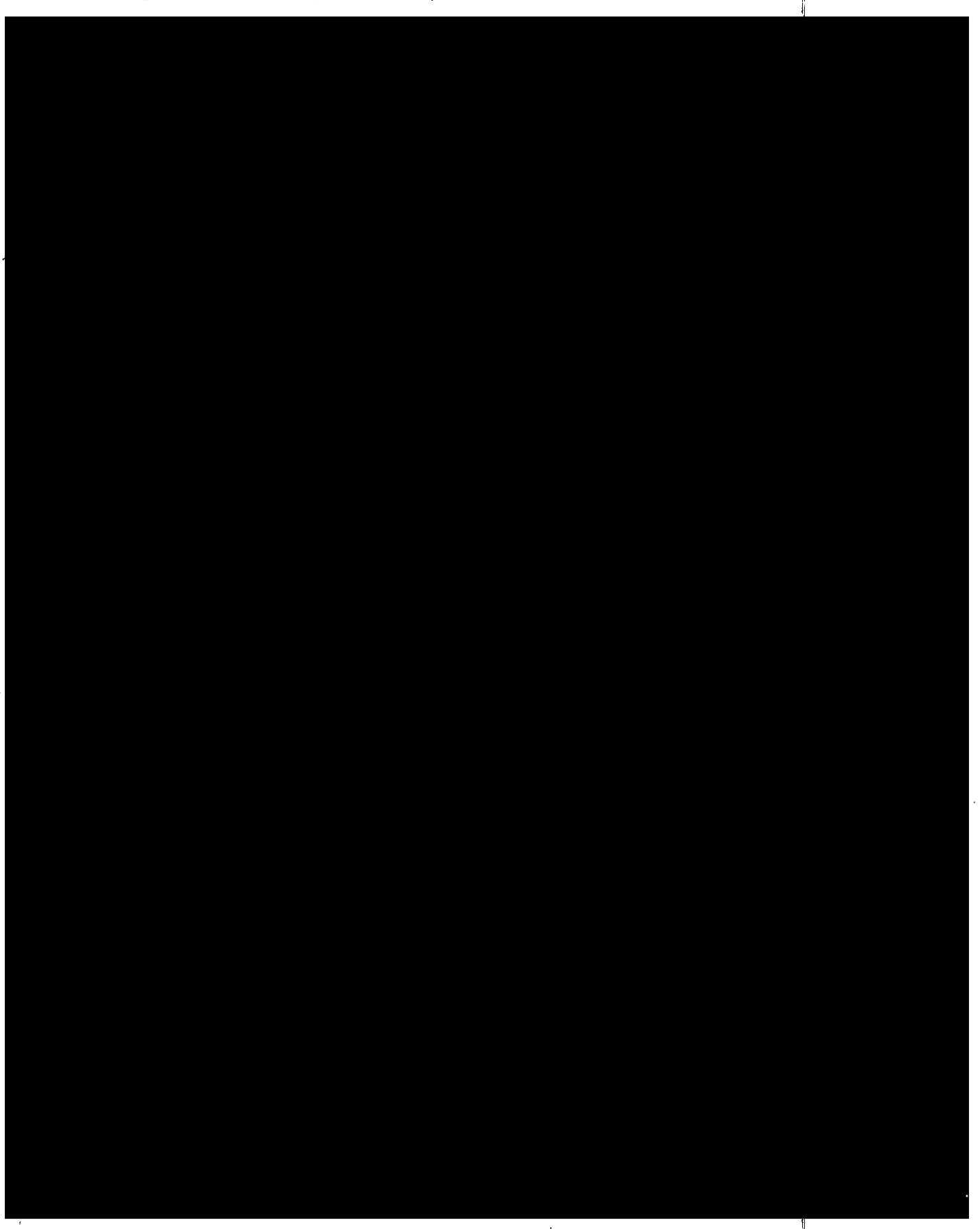

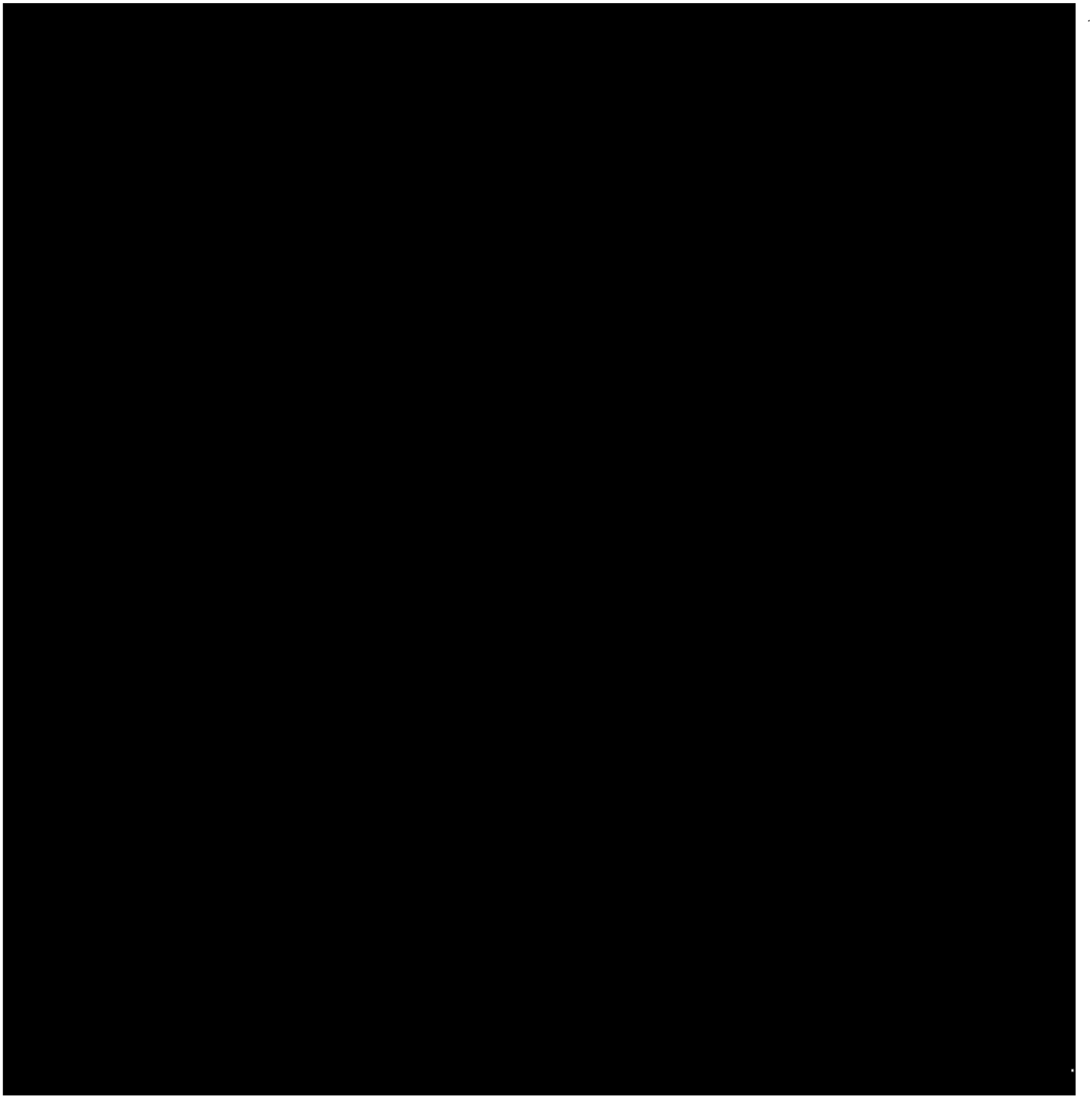

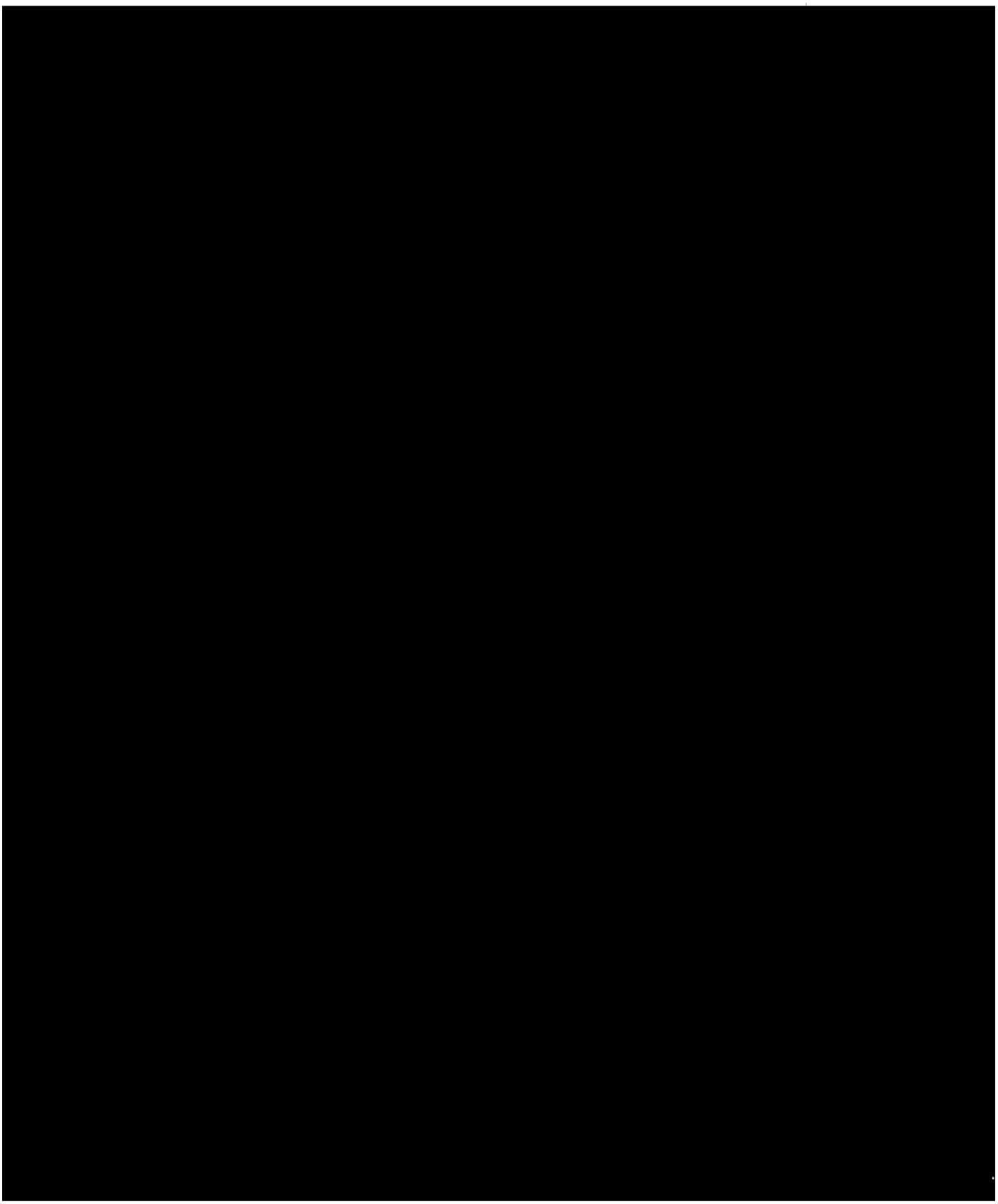

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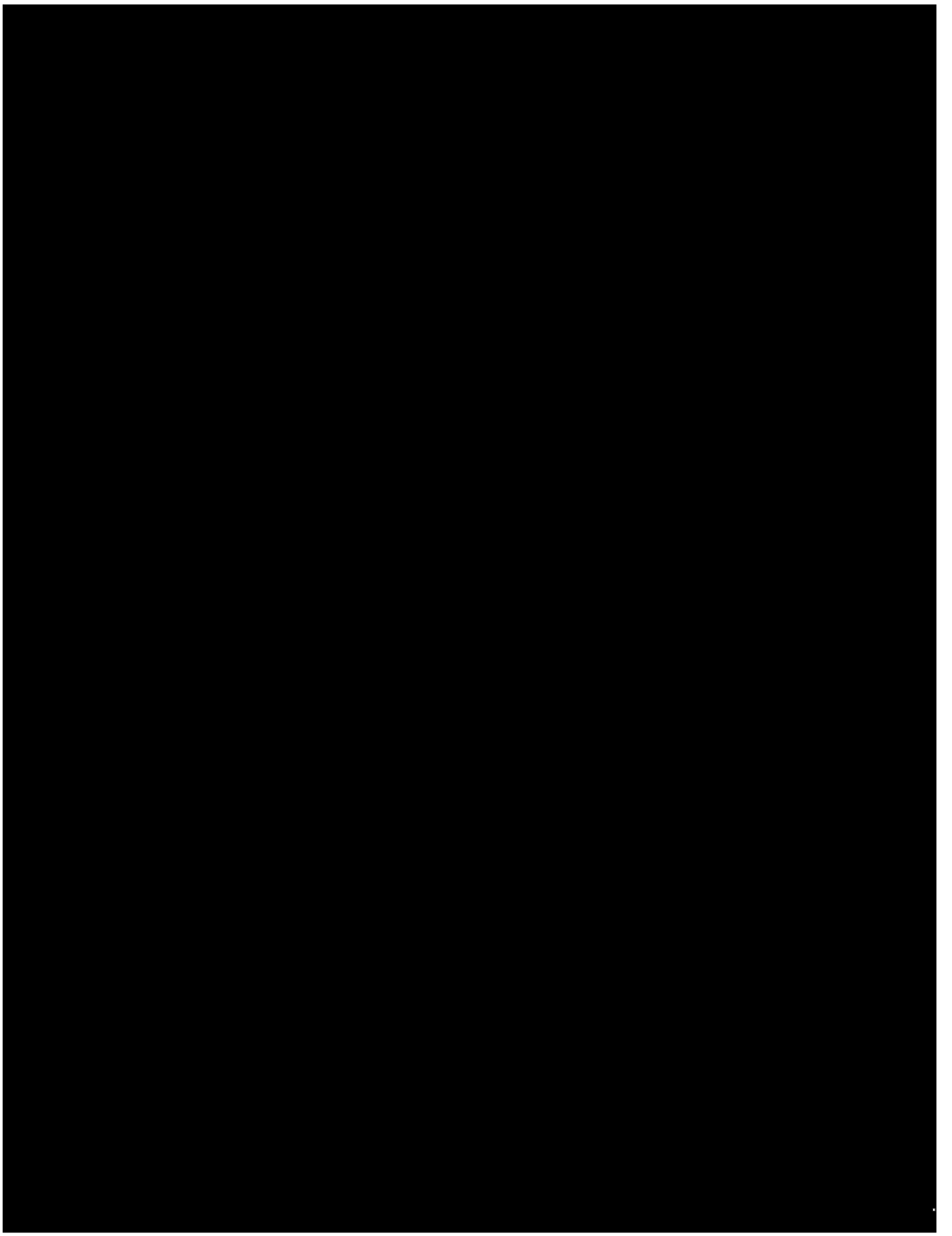

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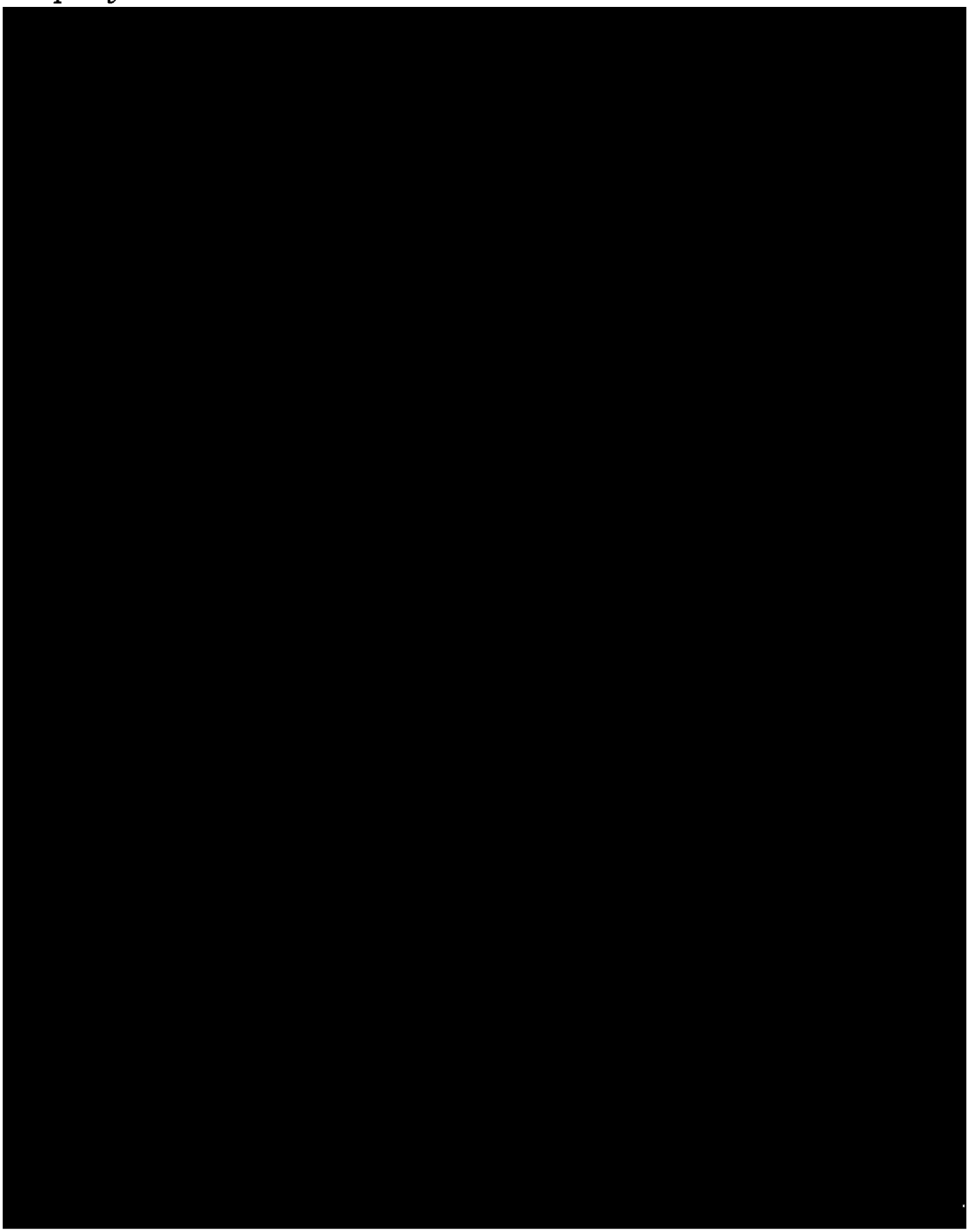

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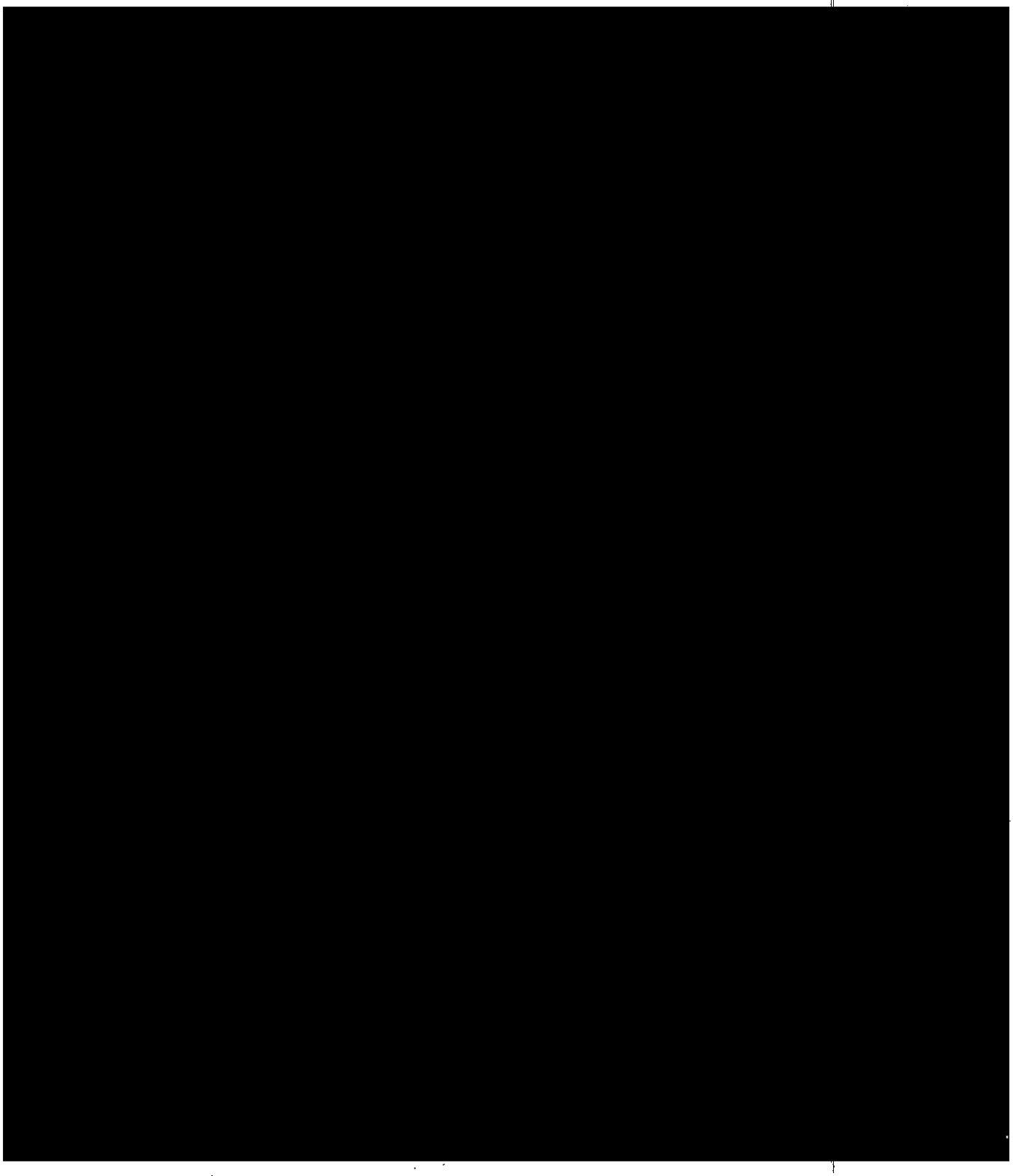

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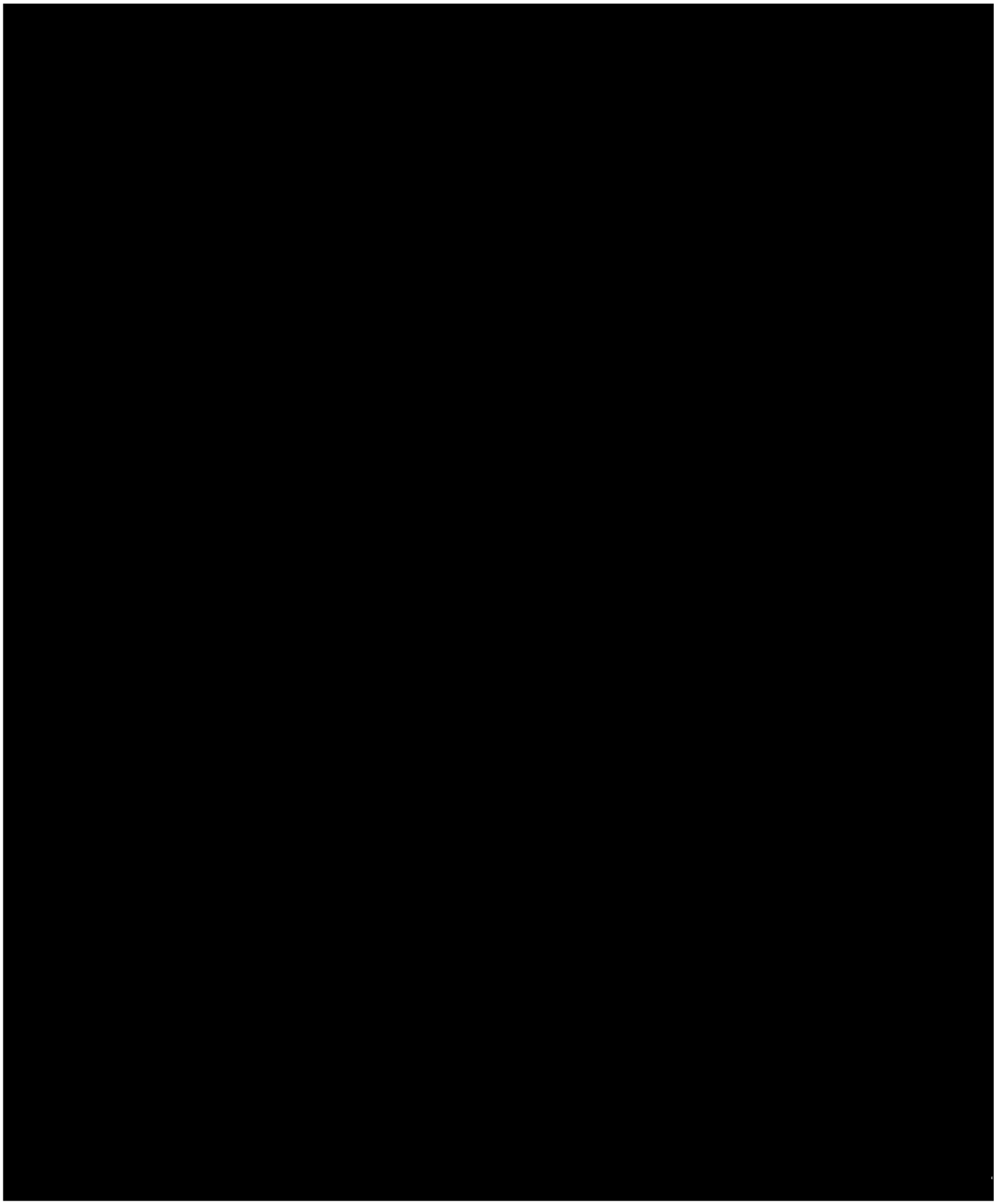

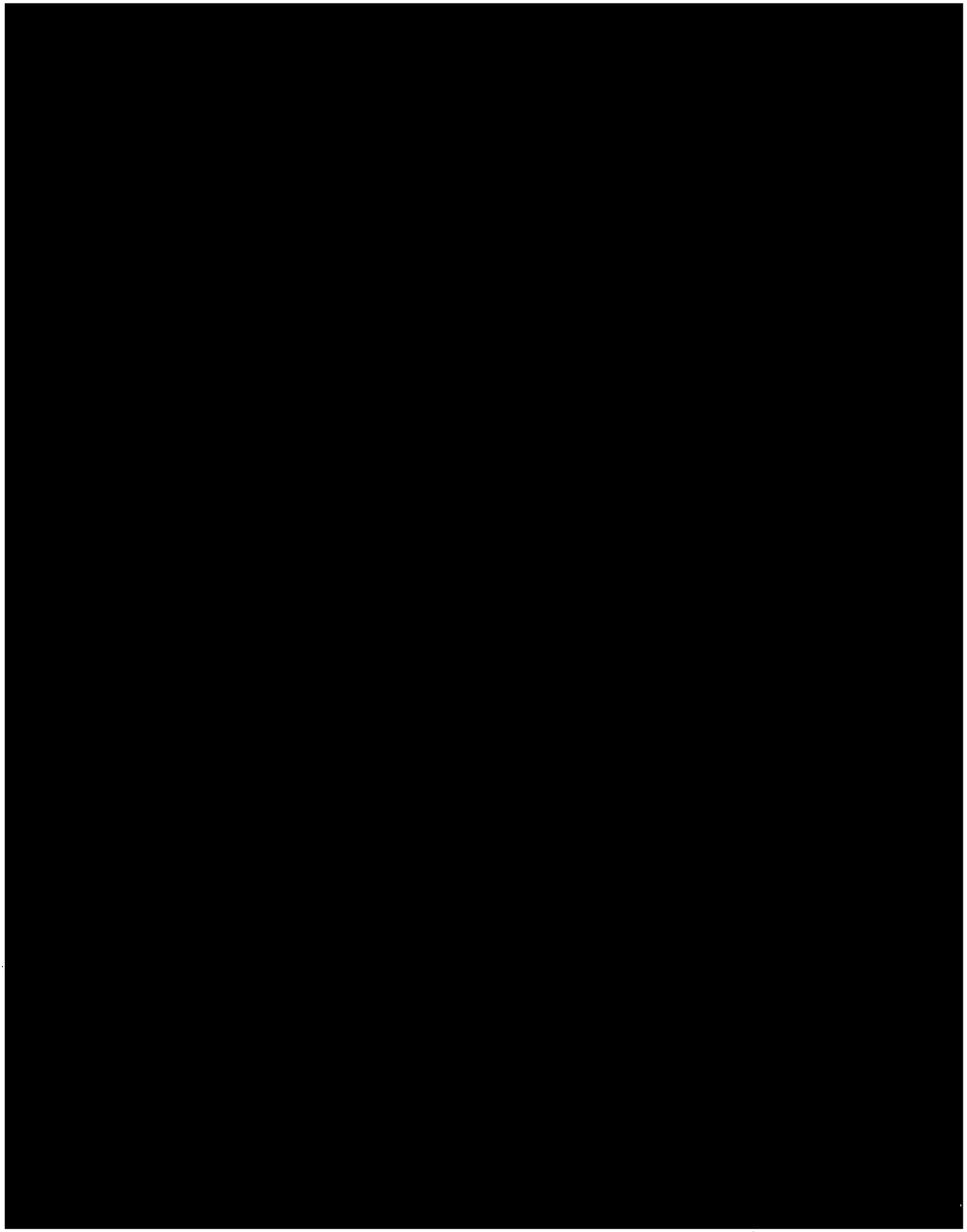

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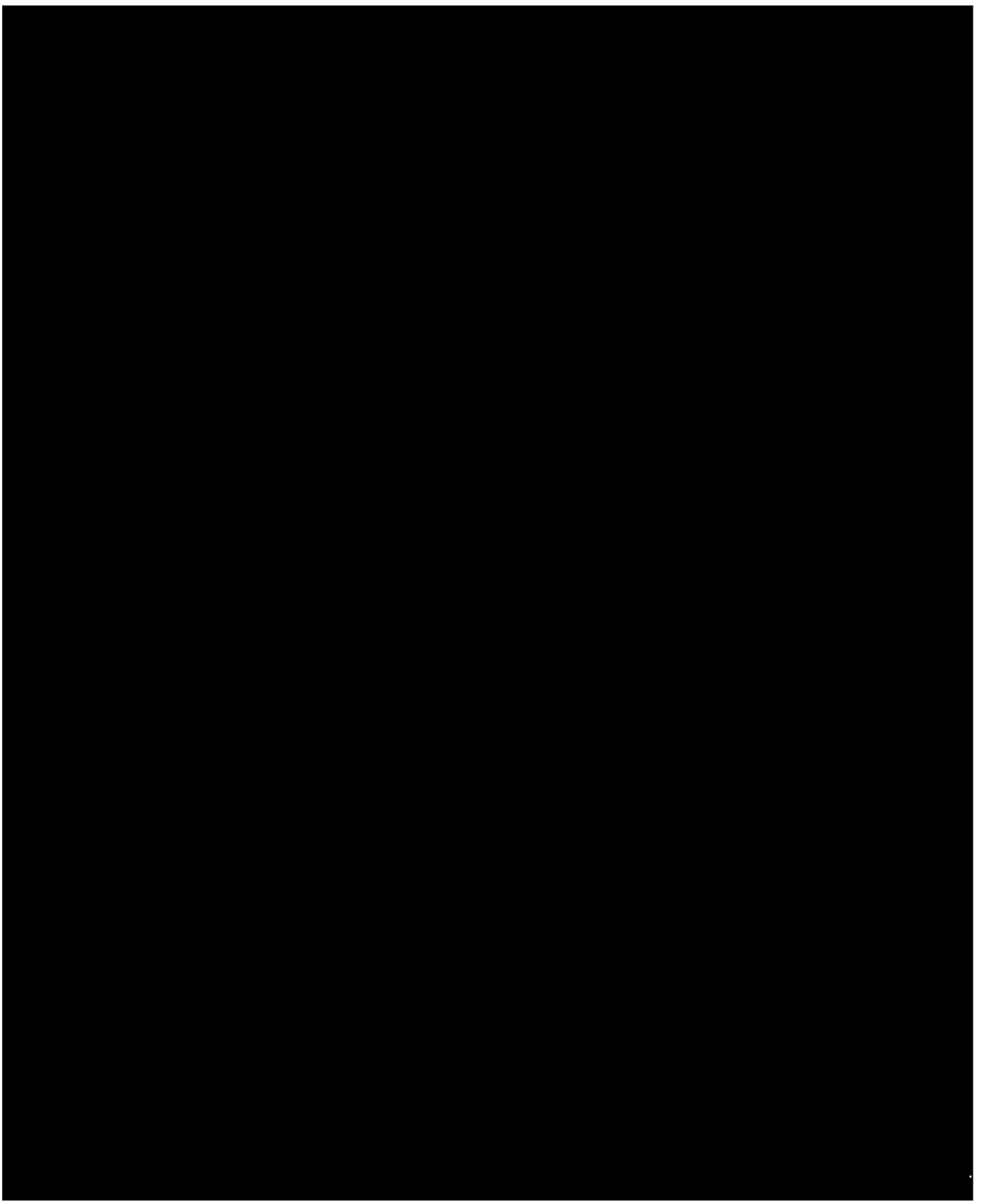

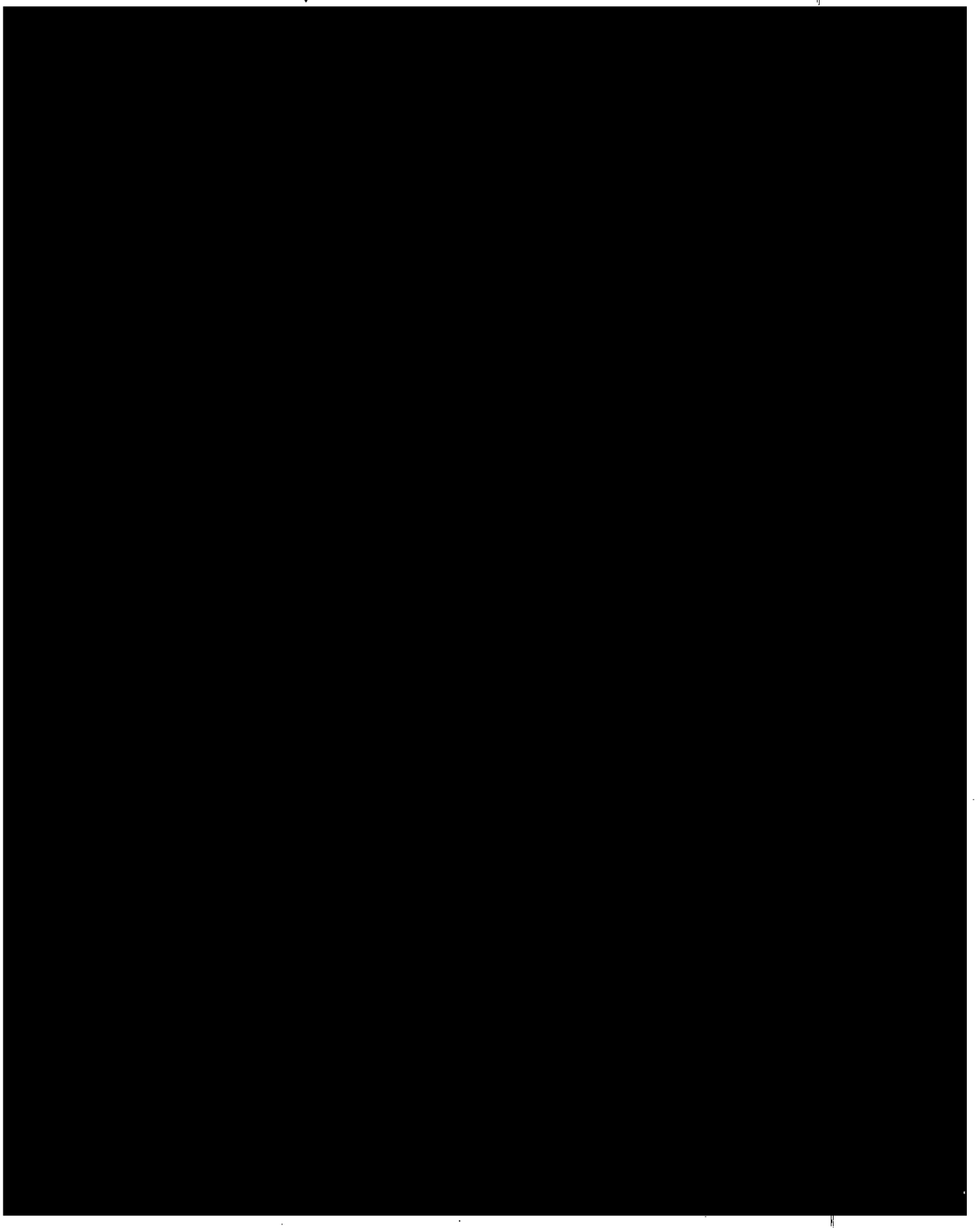

Appendix D: Protein Composition of Lecithin Products

1. Summary

Amino acid profiles of spiked and unspiked deoiled lecithins and the soy protein isolate used for spiking are presented in Figures 26 and 27. Lecithins showed characteristic large serine an ethanol amine peaks. This is an expected result due to the phosphatidyl serine and ethanol amine fractions of lecithin. The remaining amino acids occurred in about the same relative proportions in both lecithin and whole soy protein. This indicates that allergenic fractions of soy protein are not concentrated in lecithin products. In other words, soy lecithin protein is no more allergenic than soy protein in general. The relative contribution of each of the amino acids is represented in Figures 28 and 29.

2. Procedure

Lecithin and soy isolate samples (25-40 mg) were weighed in triplicate into 50 ml tubes. Hydrochloric acid (8 ml, 6N) was added to each tube, the tubes sparged with nitrogen and then sealed with an acid-resistant closure cap. The samples were heated at 110 ° C for 20 hours, cooled, and evaporated to dryness. The residue was dissolved in base, mixed thoroughly, and a portion filtered. The sample was further diluted if needed to provide a solution within the calibrated range of the instrument. The final solution was analyzed by an HPLC procedure using pre-column derivatization with o-phthalaldehyde (OPA) – mercaptoethanol (MCE) with fluorescence detection for high sensitivity detection.

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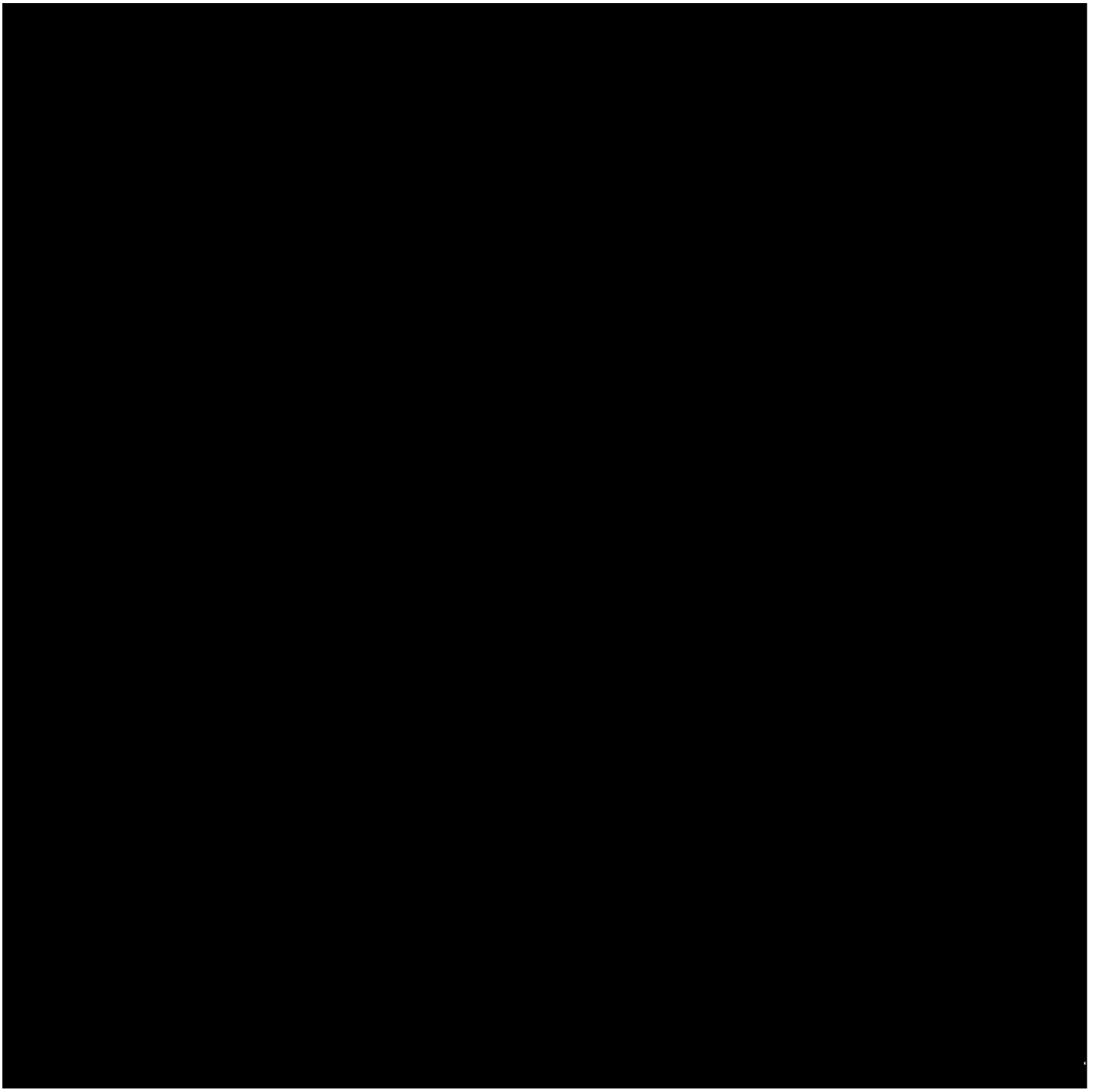

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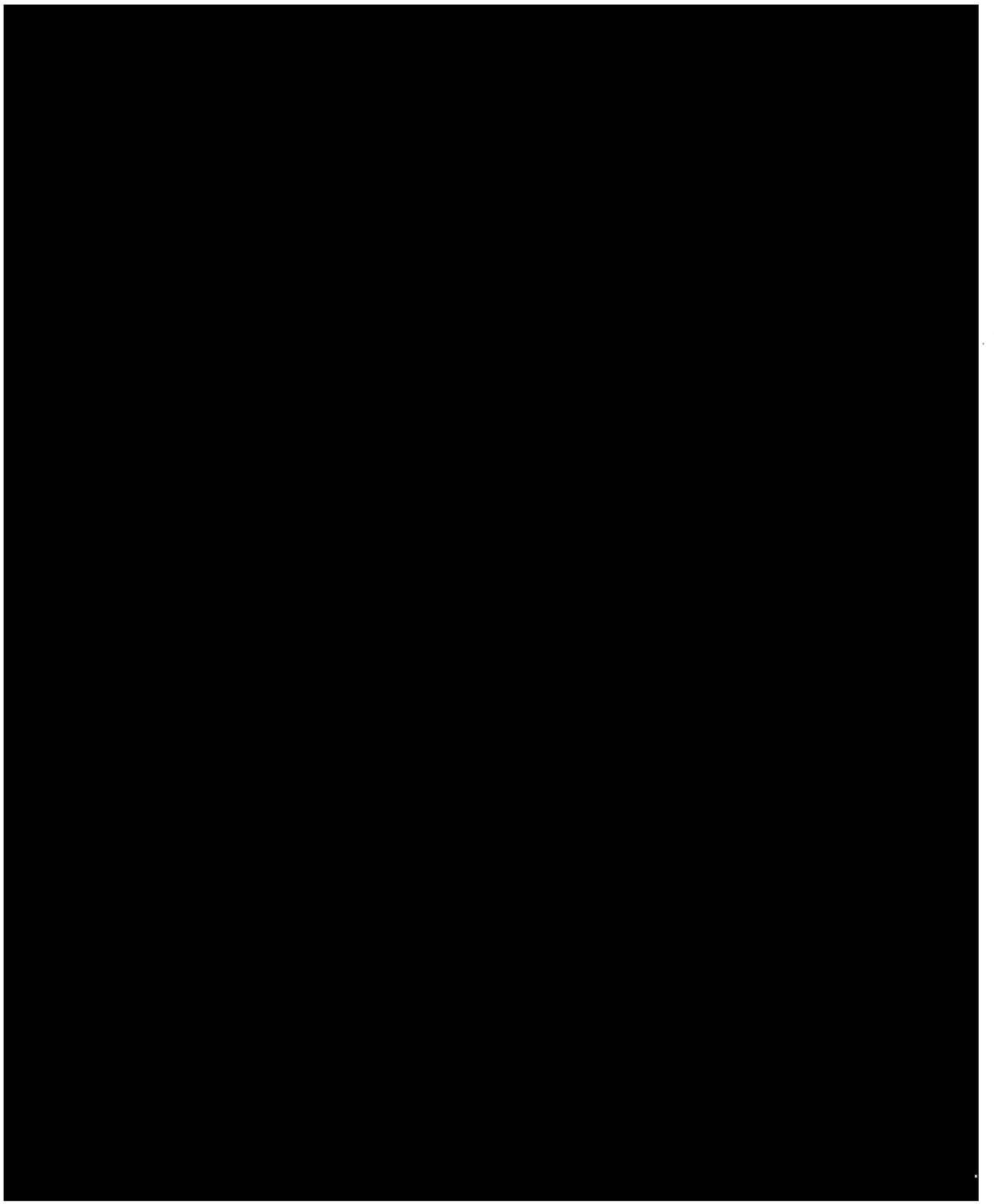

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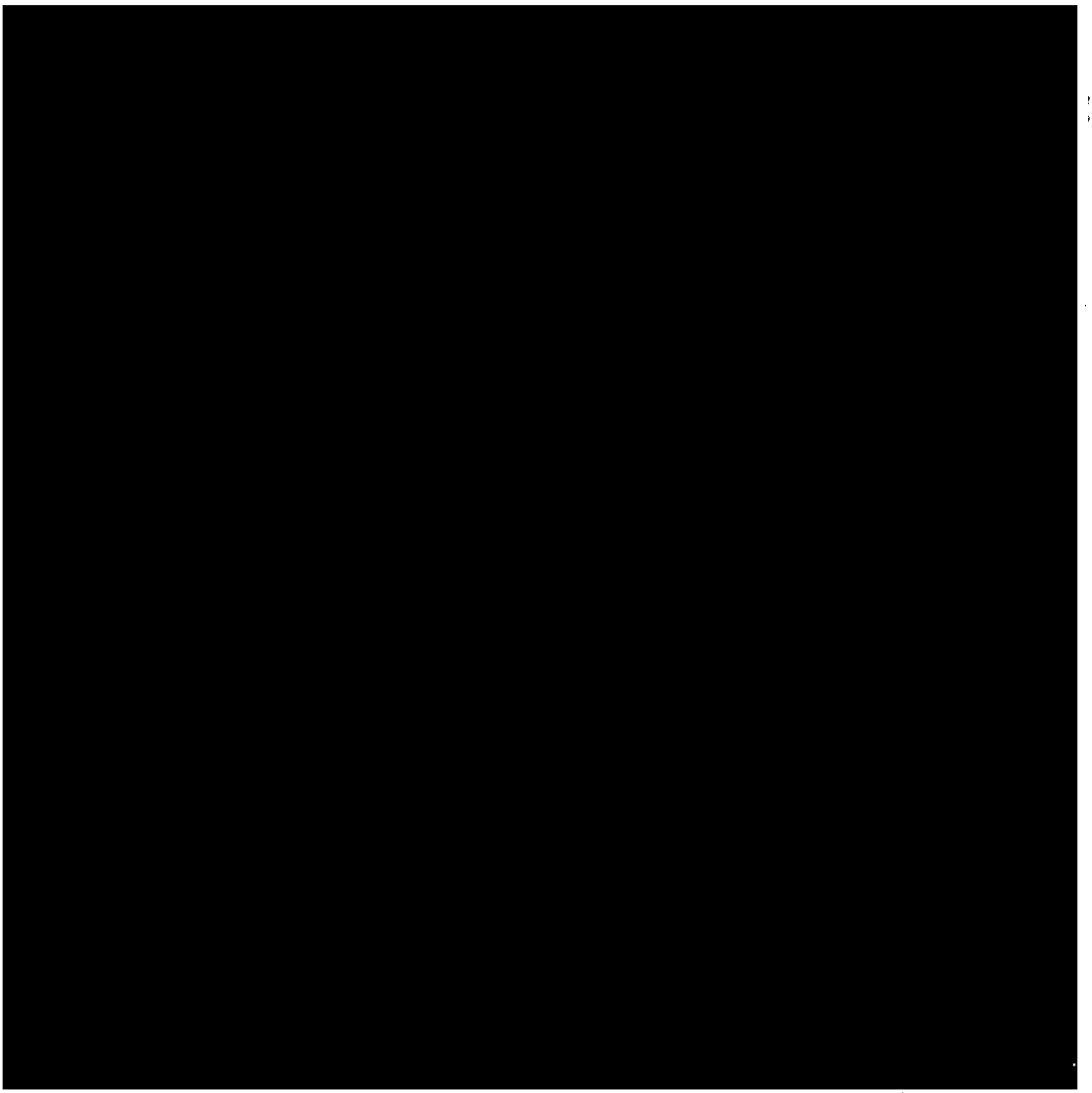

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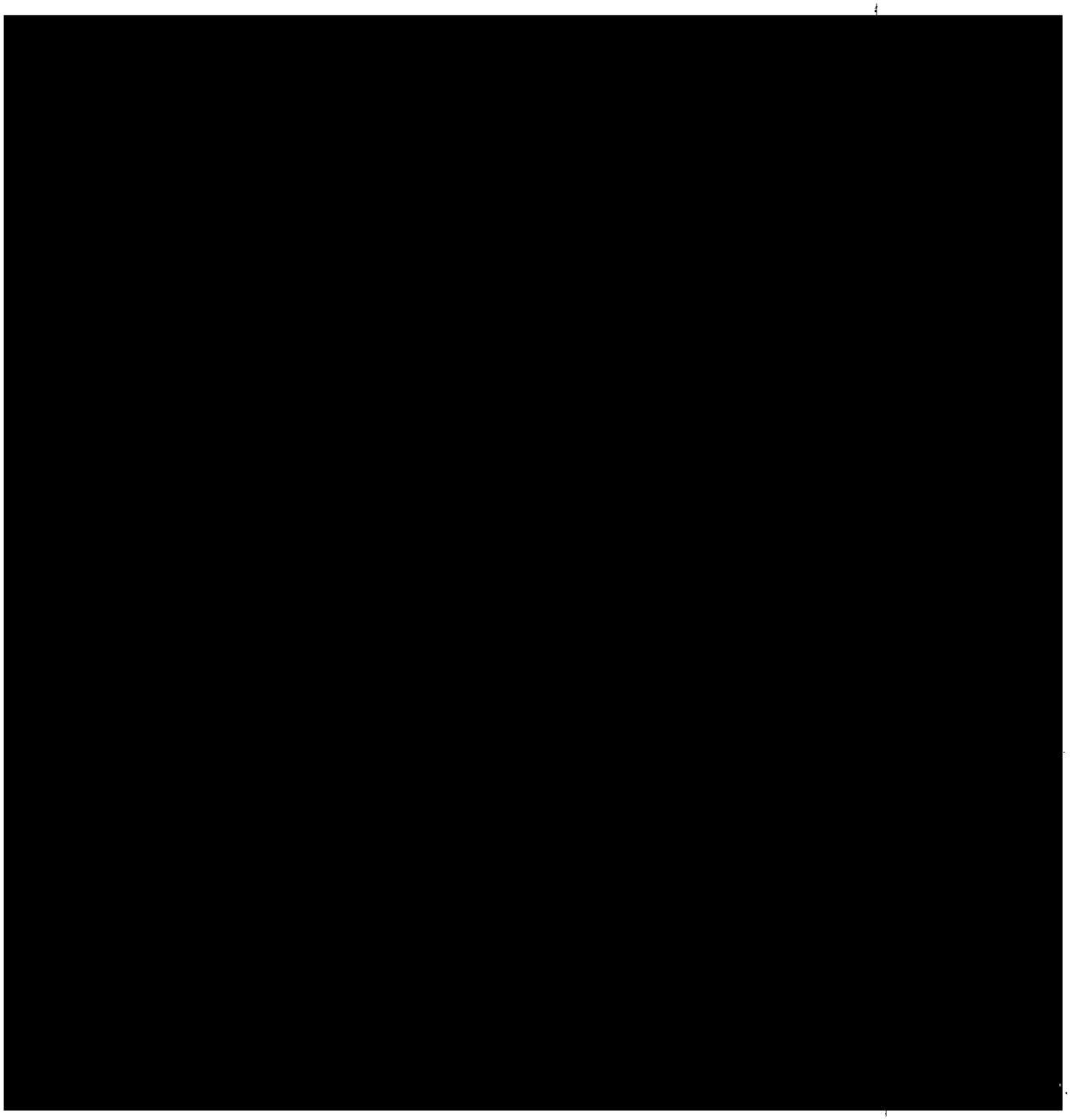

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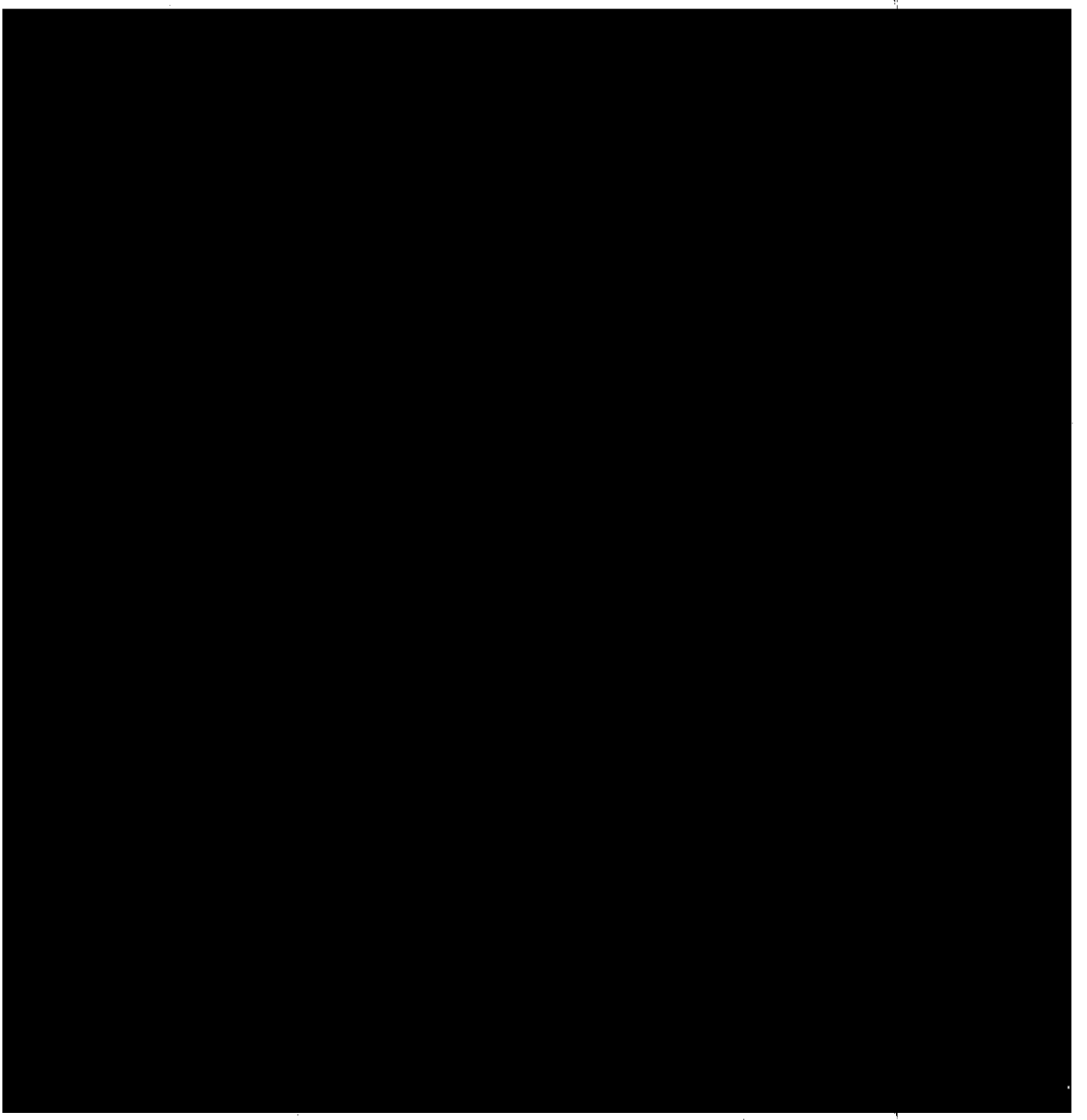

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