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PRODUCT LICENCE APPLICATION FORM

Natural Health Products Directorate

NOTES:

* denotes mandatory

** if yes, complete Animal Tissue Form

Primary Brand Name	Tracking Number	Tracking Version
nanOsteo	2 M V 8 H 2 2	

PART 1 - APPLICANT AND CONTACT INFORMATION

A - APPLICANT OR LICENSEE (This is the product licence holder) ?

Applicant/Company Name *		Company Code (if known)	
Nutrican Inc.			
Address: Street/Suite/Land Location *		City/Town *	
675 Cochrane Drive, East Tower, 6th Floor		Markham	
Country *	Province *	Postal Code *	
Canada	Ontario	L3R 0B8	

B - SENIOR OFFICIAL (This is the name of the principal contact person for the applicant/company)

Salutation *	Surname *	Given Name *	Title	Language preferred *
Mr.	Lee	Stephen	Executive Director	English
Company Name (* if different from Applicant / Licensee) *			Address same as Applicant/Licensee	
Nutrican Inc.			Yes	
Street/Suite/P.O. Box *			City/Town *	
675 Cochrane Drive, East Tower, 6th Floor			Markham	
Country *		Province *	Postal Code *	
Canada		Ontario	L3R 0B8	
Telephone Number *	Extension	Fax Number *	E-mail *	
905-530-2383		905-530-2001	stephen@nutricaninc.com	

C - CONTACT FOR THIS APPLICATION (This is the contact person for product-specific questions)

Contact 1					
Contact same as Senior Official No					
Salutation *	Surname *	Given Name *	Title	Language preferred *	
Mr.	Parshad	Andrew	Consultant	English	
Company Name (* if different from Applicant / Licensee) *				Address same as Applicant/Licensee	
Quality Smart Solutions Inc.				No	
Street/Suite/P.O. Box *				City/Town *	
1309 Renfield Drive				Burlington	
Country *		Province *		Postal Code *	
Canada		Ontario		L4M 4Z3	
Telephone Number *	Extension	Fax Number *	E-mail *		
905-818-3457		480-393-5627	aparshad@qualitysmartsolutions.com		

PART 2 - APPLICATION TYPE**A - PRODUCT LICENCE APPLICATION** ?

Type of Application *	Hypothetical Formulation
Compendial	

B - REFERENCE SUBMISSION ?**C - NHPD MASTER FILE** ?

PART 3 - SITE INFORMATION

Site 1

Company Name

Street/Suite/P.O. Box

City/Town

Country

Province/State

Postal Code/ZIP Code

Site Activity Type

Site Licence Number

Manufacturer

Packager

Labeller

Importer

Distributor

PART 4 - PRODUCT INFORMATION

Primary Brand Name *			
nanOsteo			
Other Brand Names			
Philatom nanOsteo			
Philatom 7030 nanOsteo			
Philatom 7030 BonFiller			
7030 nanOsteo			
7030 BonFiller			
Route of Administration *	Dosage Form (one only) *	Sterile *	
Oral	Capsule	<input type="radio"/> Yes <input checked="" type="radio"/> No	
A - MEDICINAL INGREDIENT(S)			
MI 1: Phosphorus			
Proper Name *		Common Name *	
Phosphorus		Phosphorus	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		25	Milligrams
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Calcium phosphate, dibasic			
Source Material(s)			
MI 2: Calcium			
Proper Name *		Common Name *	
Calcium		Calcium	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		200	Milligrams
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Source			
Calcium			
Source Material(s)			
Ostreidae - Shell			

MI 3: Magnesium			
Proper Name *		Common Name *	
Magnesium		Magnesium	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		30	Milligrams
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Magnesium citrate			
Source Material(s)			
MI 4: Zinc			
Proper Name *		Common Name *	
Zinc		Zinc	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		8	Milligrams
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Zinc citrate			
Source Material(s)			
MI 5: Copper			
Proper Name *		Common Name *	
Copper		Copper	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		200	Micrograms
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Copper (II) citrate			
Source Material(s)			

MI 6: Vanadium			
Proper Name *		Common Name *	
Vanadium		Vanadium	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		8	Micrograms
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Vanadyl sulfate			
MI 7: Silicon			
Proper Name *		Common Name *	
Silicon		Silicon	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		0.7	Milligrams
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Source			
Source Material(s)			
Equisetum arvense - Herb top			
MI 8: Boron			
Proper Name *		Common Name *	
Boron		Boron	
Standard or Grade			
Ingredient Type		Quantity per Dosage Unit *	Unit of Measure *
Chemical Substance		200	Micrograms
Animal Tissue Used	Synthetic *	Additional Quantity	Additional Unit
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Source			
Boron citrate			
Source Material(s)			
MI 9: Vitamin D			
Proper Name *		Common Name *	
Vitamin D		Vitamin D	

Standard or Grade			
Ingredient Type Chemical Substance		Quantity per Dosage Unit * 5	Unit of Measure * Micrograms
Animal Tissue Used <input type="radio"/> Yes <input checked="" type="radio"/> No	Synthetic * <input checked="" type="radio"/> Yes <input type="radio"/> No	Additional Quantity	Additional Unit
Source Cholecalciferol			
Source Material(s)			
B - NON-MEDICINAL INGREDIENT(S)			
NMI 1: Hypromellose			
Standard or Grade		Common Name * Hydroxypropylmethylcellulose	
Quantity per Dosage Unit	Unit of Measure		
Purpose * Encapsulating Agent			Animal Tissue ** <input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			
NMI 2: Magnesium stearate			
Standard or Grade		Common Name * Magnesium stearate	
Quantity per Dosage Unit	Unit of Measure		
Purpose * Anticaking Agent			Animal Tissue ** <input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			
NMI 3: Cellulose - microcrystalline			
Standard or Grade		Common Name * Microcrystalline cellulose	
Quantity per Dosage Unit	Unit of Measure		
Purpose * Filler			Animal Tissue ** <input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			

NMI 4: Acacia Senegal Gum

Standard or Grade		Common Name *	
		Gum arabic	
Quantity per Dosage Unit	Unit of Measure		
Purpose *			Animal Tissue **
Binder			<input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			

NMI 5: Sucrose

Standard or Grade		Common Name *	
		Sucrose	
Quantity per Dosage Unit	Unit of Measure		
Purpose *			Animal Tissue **
Sweetening Agent			<input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			

NMI 6: Calcium phosphate, tribasic

Standard or Grade		Common Name *	
		Tricalcium phosphate	
Quantity per Dosage Unit	Unit of Measure		
Purpose *			Animal Tissue **
Anticaking Agent			<input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			

NMI 7: dl-alpha Tocopherol

Standard or Grade		Common Name *	
		dl-alpha Tocopherol	
Quantity per Dosage Unit	Unit of Measure		
Purpose *			Animal Tissue **
Preservative Antioxidant			<input type="radio"/> Yes <input checked="" type="radio"/> No
Source Information			

C - INGREDIENT(S) USED IN PROCESSING

Was animal tissue used in the processing of this **product**, although not present in the final product? ** ☐ Yes ☒ No

D - RECOMMENDED CONDITIONS OF USE

Recommended Use and Purpose *

Helps in the development and maintenance of bones and teeth (especially in childhood, adolescence and young adulthood). Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may reduce the risk of developing osteoporosis (in peri- and postmenopausal women) (in later life).

<p>Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may help prevent bone loss/osteoporosis (in peri- and postmenopausal women) (in later life).</p> <p>Source of/An electrolyte for the maintenance of good health.</p> <p>Helps to maintain normal muscle function.</p> <p>Helps in the process of normal regulation of cell division and specialisation.</p>					
<p>Helps in the development and maintenance of bones and teeth.</p> <p>Helps in tissue formation.</p> <p>Helps to maintain proper muscle function, including the heart muscle.</p> <p>Helps in energy metabolism, tissue formation and bone development.</p> <p>Helps to maintain normal electrolyte balance.</p>					
<p>Helps in connective tissue formation.</p> <p>Helps to maintain immune function.</p> <p>Helps to maintain normal DNA synthesis.</p> <p>Helps to maintain normal acid-base metabolism.</p> <p>Helps to maintain healthy bones, hair, nail and/or skin.</p> <p>Helps to prevent zinc deficiency.</p> <p>Helps to maintain the body's ability to metabolize nutrients.</p>					
<p>Helps to produce and repair connective tissue</p> <p>Helps to form red blood cells.</p> <p>Helps to maintain normal iron transport in the body.</p>					
<p>Helps in the absorption and use of calcium and phosphorus</p> <p>Calcium intake, when combined with sufficient Vitamin D, a healthy diet and regular exercise may reduce the risk of developing osteoporosis.</p> <p>Helps to build strong bones and teeth.</p> <p>Helps in the process of normal cell division.</p>					
Recommended Dose (repeat for each sub-population group)					
Sub-Population 1					
Sub-population group *					
Adults					
Dosage		Frequency			
Min *	Max *	Dosage Units *	Min *	Max *	Frequency Units *
2	- 2	Capsule(s)	1	- 1	times a day
Additional Dosage Information (ex. 1 scoop = 30g)					
<p>Directions of Use</p> <p>Take a few hours before or after taking other medications or natural health products. Take with food. Store in airtight container, protected from light.</p>					
Duration Statement					
Risk Information					
Cautions and Warnings					
If you are pregnant or breastfeeding, consult a health care practitioner prior to use.					
Contraindications					
Known Adverse Reactions					

E - NANOMATERIAL INGREDIENTS *

Does this product contain any ingredients (medicinal or non-medicinal) that would be considered nanomaterials? If you are unsure, please consult the *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials* for more information. *

☐ Yes ☒ No

If yes, please list the ingredients:

PART 5 - LABEL TEXT

Label Text Validation completed

☐ Label Text Submitted Separately

Any labels used in the marketing of this product must reflect the information outlined on the product licence and must comply with the labelling requirements as per Part 5 of the Natural Health Products Regulations.

MONOGRAPH ATTESTATION

When submitting a **Class I** product licence application in respect of a natural health product for which one Natural Health Products Directorate (NHPD) monograph exists in the *Compendium of Monographs*:

I attest that the information provided in this product licence application [proper name(s), common name(s), source material(s), route(s) of administration, dosage form(s), use(s) or purpose(s), dose(s), duration of use, risk information, etc.] respects the information contained in one NHPD monograph;

I attest that the non-medicinal ingredients in the product do not exhibit pharmacological effects, do not have any effect contradictory to the product's recommended purpose, do not exceed the minimum concentration required for the formulation, do not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients, and that they are safe;

I attest that the label text is acceptable as per sections 86-94 of the Natural Health Products Regulations and the information on the label text is identical to the information provided in this product licence application;

I attest that the natural health product's brand name(s) submitted in this product licence application is consistent with my product licence application, does not pose a risk to health and safety, and is not false and misleading;

I fully understand that I must comply with the conditions of this attestation. Upon receipt of a product licence, if the conditions of this attestation are not appropriately reflected on the product licence, I agree to immediately notify the NHPD;

I fully understand that if I were to operate outside of this attestation that I will be subject to compliance and enforcement, which could include additional requests for safety data pursuant to section 16 of the Natural Health Products Regulations, direction to stop sale pursuant to section 17 of the Natural Health Products Regulations, or suspension or cancellation of my product licence pursuant to section 18 or 19 of the Natural Health Products Regulations; and

I accept any liabilities that may arise out of selling a product outside of the conditions of this attestation for which a product licence was issued based on this attestation.

☒ I Agree *

Attestation Code

2CP42

ATTESTATION

I attest that the natural health product that is the subject of this product licence application will be manufactured, packaged, labelled, distributed and stored according to the following two paragraphs.

If the natural health product is imported, in accordance with the 'Good Manufacturing Practices' requirements as set out in Part 3 of the Natural Health Products Regulations or in accordance with requirements that are equivalent to those set out in Part 3, or

If the natural health product is not imported, in accordance with the 'Good Manufacturing Practices' requirements set out in Part 3 of the Natural Health Products Regulations.

I, the undersigned, certify that the information and material that I have provided to be included in this product licence application is accurate, complete, and that I have not, in the present or future, modified or tampered with the form itself or the data populated within it in any way from its original version. By clicking on the I Agree button and generating the attestation code, this generated code is confirmation of my attestation and will serve as authentication of this fact in the future.

☒ I Agree *

Attestation Code

2C542

Name of Authorized Senior Official (print)

Signature

 Date (yyyy-mm-dd)
 null. Date (yyyy-mm-dd)
 2018-06-05

If the signing official is a third party acting on behalf of the Senior Official of the applicant company designated in Part 1 of the application, a designated Party Authorization form must be signed by the Senior Official and filed with the complete application.

The form has been completed. Please save your form and submit it to the NHPD via mail or using PosteCS.

Label Text

Appropriate text must be in English and in French as per Part 5, Section 87 of the NHP Regulations

PRINCIPAL DISPLAY PANEL

nanOsteo

Philatom nanOsteo, Philatom 7030 nanOsteo, Philatom 7030 BonFiller, 7030 nanOsteo, 7030 BonFiller

60 Capsule(s)

ANY PANEL

Nutrican Inc.

L3R 0B8

Canada

Oral

Medicinal Ingredients (per dose unit)

Phosphorus (Calcium phosphate, dibasic) 25 Milligrams

Calcium (Calcium, Ostreidae - Shell) 200 Milligrams

Magnesium (Magnesium citrate) 30 Milligrams

Zinc (Zinc citrate) 8 Milligrams

Copper (Copper (II) citrate) 200 Micrograms

Vanadium (Vanadyl sulfate) 8 Micrograms

Silicon (Equisetum arvense - Herb top) 0.7 Milligrams

Boron (Boron citrate) 200 Micrograms

Vitamin D (Cholecalciferol) 5 Micrograms

Recommended Use

Helps in the development and maintenance of bones and teeth (especially in childhood, adolescence and young adulthood).

Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may reduce the risk of developing osteoporosis (in peri- and postmenopausal women) (in later life).

Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may help prevent bone loss/osteoporosis (in peri- and postmenopausal women) (in later life).

Source of/An electrolyte for the maintenance of good health.

Helps to maintain normal muscle function.

Helps in the process of normal regulation of cell division and specialisation.

Helps in the development and maintenance of bones and teeth.

Helps in tissue formation.

Helps to maintain proper muscle function, including the heart muscle.

Helps in energy metabolism, tissue formation and bone development.

Helps to maintain normal electrolyte balance.

Helps in connective tissue formation.

Helps to maintain immune function.

Helps to maintain normal DNA synthesis.

Helps to maintain normal acid-base metabolism.

Helps to maintain healthy bones, hair, nail and/or skin.

Helps to prevent zinc deficiency.

Helps to maintain the body's ability to metabolize nutrients.

Helps to produce and repair connective tissue

Helps to form red blood cells.

Helps to maintain normal iron transport in the body.

Helps in the absorption and use of calcium and phosphorus

Calcium intake, when combined with sufficient Vitamin D, a healthy diet and regular exercise may reduce the risk of developing

osteoporosis.

Helps to build strong bones and teeth.

Helps in the process of normal cell division.

Recommended Dose

Adults: 2 Capsule(s) 1 time(s) per day

Take a few hours before or after taking other medications or natural health products. Take with food. Store in airtight container, protected from light.

Cautions and Warnings

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Exp: YY MM/: XXXX

OUTER LABEL TEXT ONLY

Non-Medicinal Ingredients

Hydroxypropylmethylcellulose

Magnesium stearate

Microcrystalline cellulose

Gum arabic

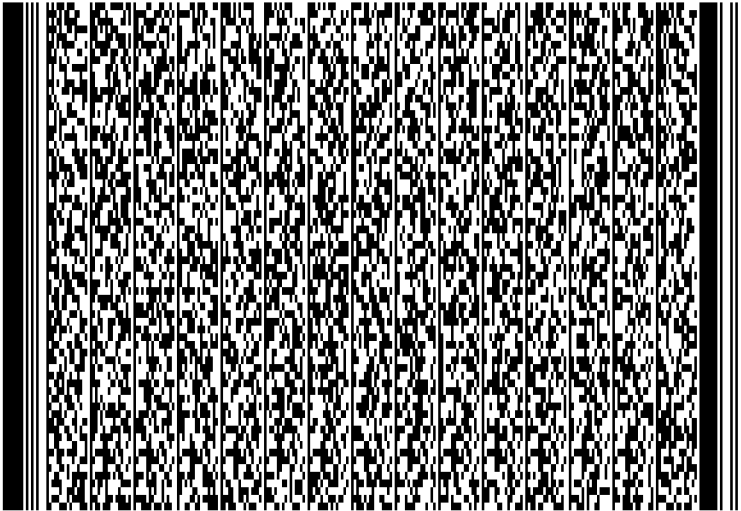
Sucrose

Tricalcium phosphate

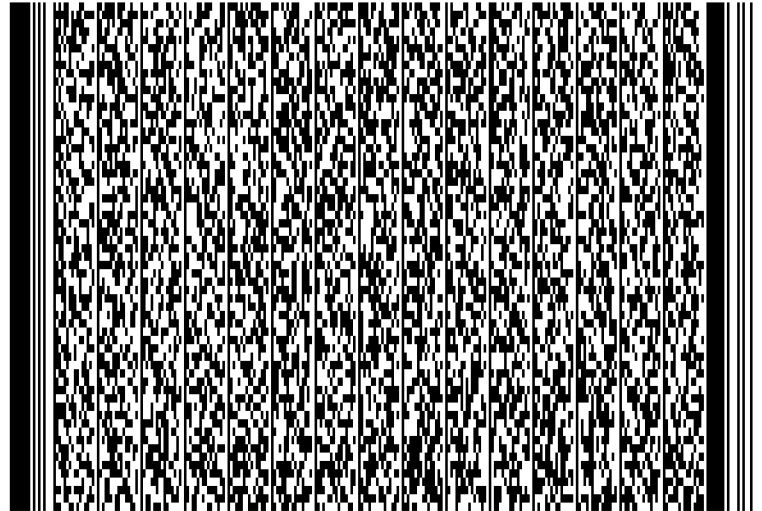
dl-alpha Tocopherol

SECURITY PACKAGE

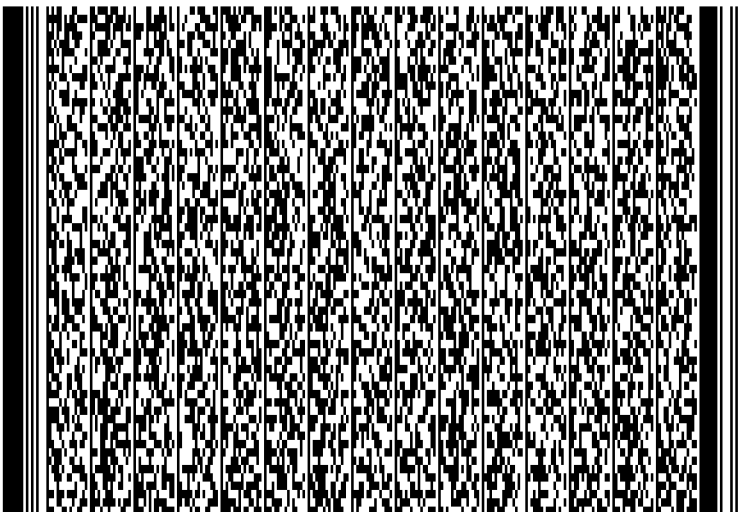
Security feature is self-evident.



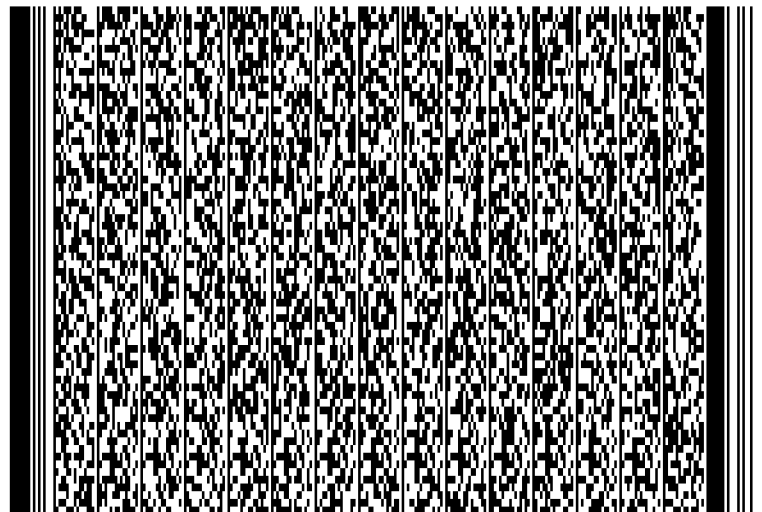
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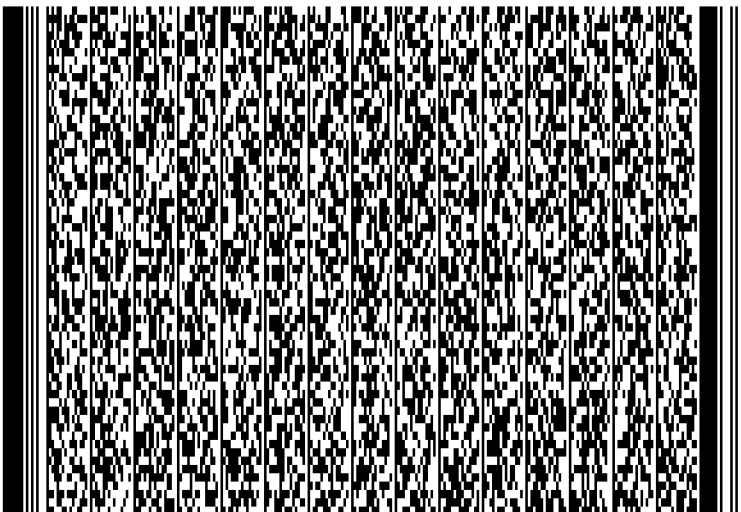
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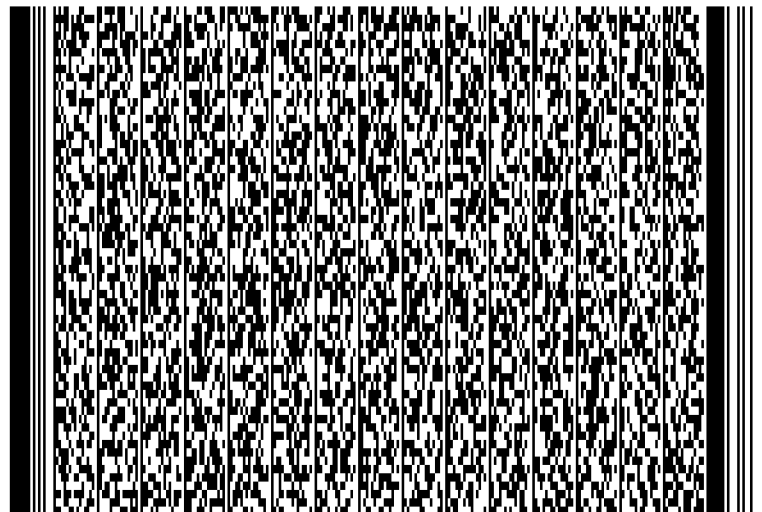
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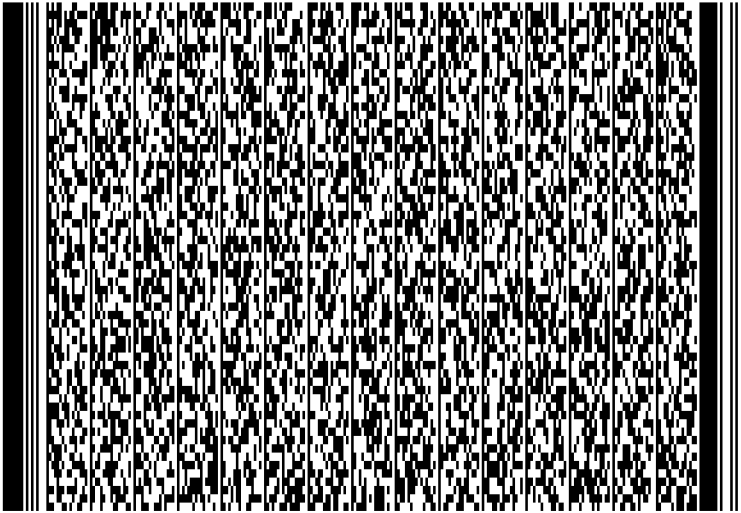
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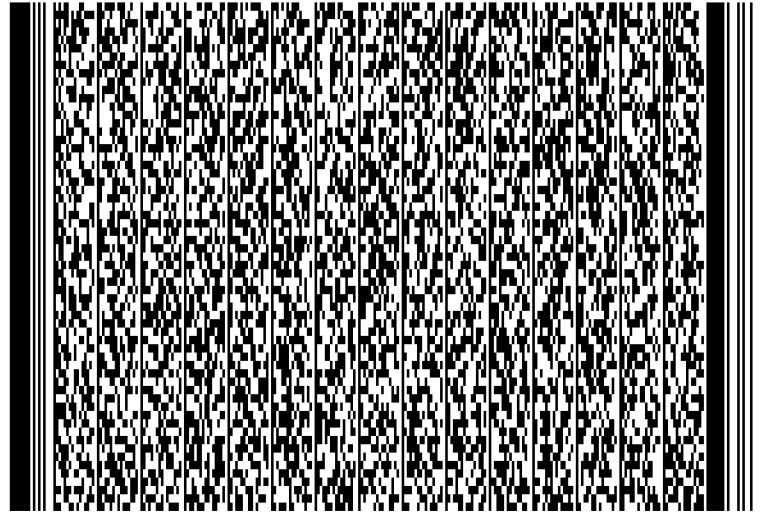
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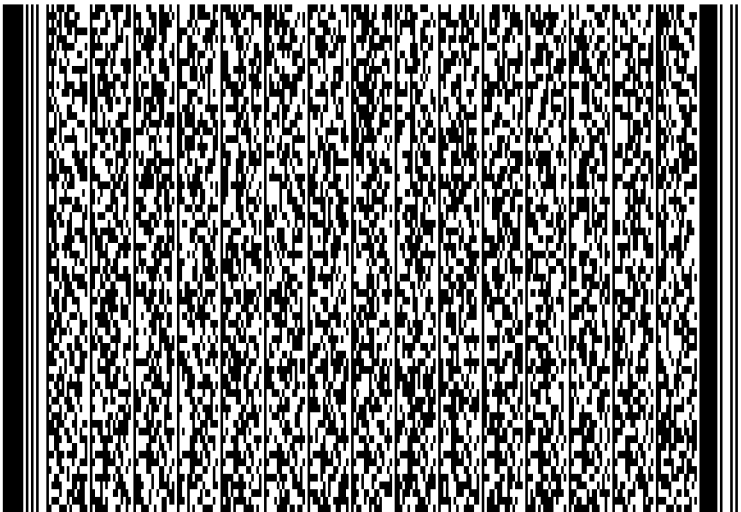
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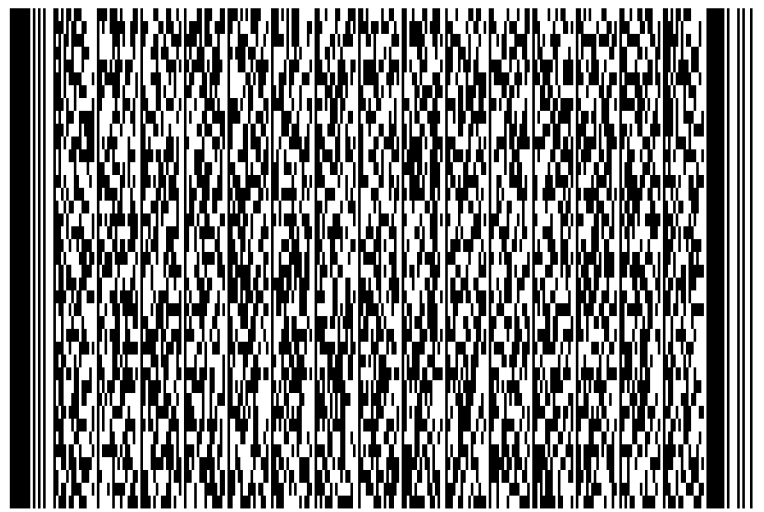
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