

POTASSIUM HYDROXIDE FLAKES 90%**OCTOBER 2020****Synonyms:** Potasse causte 90% ecailles, caustic potash flakes**Description:** White flakes**CAS NO:** 1310-58-3**FORMULA:** KOH**EINECS NO:** 215-181-3**MW:** 56

<u>Test</u>	<u>Specification</u>
KOH (%)	≥89.5
NaOH (%)	≤1.5
K ₂ CO ₃ (%)	≤1
Chlorides (Cl ⁻) (ppm)	≤80
Typical Impurities:	
Iron (Fe) (ppm)	≤5
Nickel (Ni) (ppm)	≤5
Lead (Pb) (ppm)	≤1

Revision 00

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Refer to the appropriate Safety Data Sheet for health, safety and environmental information



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Regulatory Information

Potassium Hydroxide Flakes

CAS Name:	Potassium Hydroxide
CAS-Number:	1310-58-3
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1 PRODUCT DEFINITION

Potassium hydroxide flakes of Vynova, refers to Caustic Potash Solid 90% or Potassium Hydroxide Flakes 90%, hereafter referred to as the PRODUCT as per "Caustic Potash Solid 90% – Potassium Hydroxide Flakes 90% Sales Specification" – version 01M191218, dd. 18 December 2019.

For more information on the product specification, contact your Area Sales Manager or Representative.

2 PRODUCT ORIGIN

2.1 Production Process

The PRODUCT is synthetically manufactured by membrane electrolysis of a potassium chloride solution from which water is evaporated to obtain potassium hydroxide flakes as per PRODUCT specification.

2.2 Product Traceability

The PRODUCT is manufactured in batch process. Batches are sampled and analyzed on a daily basis. PRODUCT is released upon confirmation that analysis results are within specification limits.

Vynova tracks the batch number(s) of the PRODUCT shipped to the CUSTOMER.

2.3 Mercury Statement

The production process is mercury free, which results in mercury levels in the PRODUCT typically < 0.001 mg/kg (detection limit)

2.4 Declaration of Non-Animal, Non-Human, Non-Cell-Culture or Non-Enzyme Origin Statement

The PRODUCT is chemically synthesized and does not contain any animal, human, cell culture or enzyme derived products. The PRODUCT is not derived from animal, human, cell culture or enzyme derived products.

2.5 Conflict Mineral Sources Statement

To the best of our today's knowledge we can state that none of our products is intentionally manufactured with or using any conflict minerals in the aforementioned meaning.

2.6 Palm Oil Statement

No raw materials based on palm oil or palm kernel oil derivatives are used in during the production of the PRODUCT. The PRODUCT is produced in dedicated manufacturing plant.

3 REACH

3.1 EU – REACH and CLP

We certify that the PRODUCT is in compliance with REACH Regulation (EC) No. 1907/2006.

The substance in this PRODUCT is registered. The REACH registration number and the identified safe uses are communicated in the Safety Data Sheet (SDS).

The PRODUCT is classified as hazardous, meaning that an exposure assessment is required. Please refer to the Safety Data Sheet.

3.2 EU - REACH Registration

The substance in the PRODUCT is produced or imported at a volume of > 1000 ton/year.

A full registration was submitted in 2010, under the registration number 01-2119487136-33-xxxx.

3.3 Substance of Very High Concern Statement – Candidate List

We hereby certify that the PRODUCT does not contain any Substance of Very High Concern (SVHC) in amounts > 0.1% (w/w) listed on the most current Candidate list according to Art. 59 (<https://echa.europa.eu/candidate-list-table> – last update: 19 January 2021).

3.4 REACH Annex XIV Statement - Authorization List

We hereby certify that the PRODUCT does not contain any substances in amounts > 0.1% (w/w) listed on the most current Authorization List (Annex XIV) published on the ECHA website <https://echa.europa.eu/authorisation-list> – last update: 28 August 2020).

3.5 REACH Annex XVII Statement - Restricted Substance List

We hereby certify that the PRODUCT does not contain any substances in amounts > 0.1% (w/w) listed on the most current list of substances restricted under REACH (Annex XVII) published on the ECHA website (<https://echa.europa.eu/substances-restricted-under-reach> – last update: 10 August 2020).

3.6 Carcinogen, Mutagen, Reprotoxic Substance Statement

The PRODUCT does not contain any Carcinogen, Mutagen, Reprotoxic (CMR) substances above classification limits specified in Regulation (EU) No. 1272/2008 on classification, labelling and packaging of substances and mixtures.

4 FOOD & FOOD CONTACT CONFORMITY

4.1 Non-HACCP statement

Vynova has NOT established a food quality and safety assurance system, like Hazard Analysis and Critical Control Points (HACCP), for the PRODUCT.

Vynova would like to point out that it is the sole responsibility of the manufacturer of food/feed (contact) materials or articles, containing this PRODUCT as a component, to ascertain that these finished materials or articles meet all relevant regulatory requirements and that they do not endanger human/animal health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

4.2 Europe

4.2.1 European Community / Declaration of Compliance (DoC)

The PRODUCT complies with the regulation (EC) No. 1935/2004 and regulation (EC) 10/2011 as follows:

FCM Substance No.	399
Ref. No.	81600
CAS - No.	1310-58-3
Substance name	Potassium hydroxide
Use as additive or polymer production aid	yes
Use as monomer or other starting substance	no
FRF applicable	no
SML	not applicable
SML(T)	not applicable
Restrictions and specifications	not applicable
Notes for the verification of compliance	no restrictions or SML

The PRODUCT meets the purity criteria specified in regulation (EC) No. 231/2012, laying down specifications for food additives listed in Annex II and III of regulation (EC) No. 1333/2008:

E525 – Potassium Hydroxide

Component	Purity requirement
Water insoluble matter	A 5 % solution is completely clear and colorless
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

Additional Information: Finished food contact materials or articles containing this PRODUCT as a component, need to comply inter alia with Overall Migration Limit (OML) requirements - as specified in EU - Regulation 10/2011. Verification of compliance with migration limits (OML and SML) should be carried out in accordance with the rules laid down there. We would like to point out that it is the sole responsibility of the manufacturer of the final material or article to assure compliance with the OML and SML requirements under actual and foreseeable conditions of use, and to check it on a regular basis. The manufacturer of food contact materials or articles, containing this PRODUCT as a component, must in particular ascertain that these finished materials or articles meet the general regulatory requirement that they do not endanger human health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

4.2.2 Maximum Impurity Levels for Foodstuffs

Regulation (EC) 1881/2006 and its amendments sets the maximum levels for certain contaminants in foodstuffs. Our PRODUCT is not foodstuff as such, however may be used for the production of it. It is the responsibility of the foodstuff manufacturer to ensure content levels of these contaminants, listed in the Annex of Regulation (EC) 1881/2006, do not exceed the permitted maximum content for their intended foodstuff application.

1. Nitrate: *not present*
2. Mycotoxins: *not present*
3. Metals:
 - ✓ **Lead** : present, see Product Specification for their respective typical concentration levels
 - ✓ **Cadmium** : present, see Product Specification for their respective typical concentration levels
 - ✓ **Mercury** : present, see Product Specification for their respective typical concentration levels
 - ✓ Tin (inorganic) : not present
4. 3-monochloropropane-1,2-diol: *not present*
5. Dioxins (PCDDs), Furans (PCDFs) and polychlorinated biphenyls (PCBs): *not present*
6. Polycyclic aromatic hydrocarbons (PAH): *not present*
7. Melamine and its structural analogues: *not present*
8. Inherent plant toxins: *not present*

Possible contaminants listed as "not present" are analyzed not to be present in our PRODUCT and therefore are not analyzed on a regular basis. Changes in raw materials, process aids, production process, installation changes may trigger a need for us to re-evaluate impurity presence and concentrations.

4.2.3 Maximum Levels for Undesirable Substances in Animal Feed

Directive 2002/32/EC lists the maximum permitted content of undesirable substances in animal feed. Our PRODUCT is not animal feed as such, however may be used for the production of it. It is the responsibility of the animal feed manufacturer to ensure content levels of these undesirable substances, listed in Annex I of Directive 2002/32/EC, do not exceed the permitted maximum content for their intended feed application.

1. **Arsenic:** *present, see Product Specification for their respective typical concentration level*
2. **Lead:** *present, see Product Specification for their respective typical concentration level*
3. Fluorine: *not present*
4. **Mercury:** *present, see Product Specification for their respective typical concentration level*
5. Nitrites: *not present*
6. **Cadmium:** *present, see Product Specification for their respective typical concentration levels*
7. Aflatoxin B1: *not present*
8. Hydrocyanic acid: *not present*
9. Free gossypol: *not present*
10. Theobromine: *not present*
11. Volatile mustard oil: *not present*
12. Vinal thiooxazolidone: *not present*
13. Rye ergot: *not present*
14. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination: *not present*
15. Castor oil plant – *Ricinus communis L.: not present*
16. *Crotalaria spp.: not present*
17. Aldrin: *not present*
18. Dieldrin: *not present*
19. Camphechlor: *not present*
20. Chlordane: *not present*
21. DDT: *not present*
22. Endosulfan: *not present*
23. Endrin: *not present*
24. Heptachlor: *not present*
25. Hexachlorobenzene (HCB): *not present*
26. Hexachlorocyclohexane (HCH): *not present*
27. Dioxins (PCDDs), Furans (PCDFs) and Polychlorinated Biphenyls (PCBs): *not present*
28. Apricots: *not present*
29. Bitter almond: *not present*
30. Unhusked beech mast: *not present*
31. Camelina: *not present*
32. Mowrah, Bassia, Madhuca: *not present*
33. Purguera: *not present*
34. Croton: *not present*
35. Indian mustard: *not present*
36. Sareptian mustard: *not present*
37. Chinese mustard: *not present*
38. Black mustard: *not present*
39. Ethiopian mustard: *not present*

Possible contaminants listed as “*not present*” are analyzed not to be present in our PRODUCT and therefore are not analyzed on a regular basis, with an exception of (27) dioxins, furans and polychlorinated biphenyls. Changes in raw materials, process aids, production process, installation changes may trigger a need for us to re-evaluate impurity presence and concentrations.

4.2.4 Germany Food / Food Contact Statement

The PRODUCT fulfils the requirements of the German recommendations of the BfR (Federal Institute for risk assessment) on contact with food, limits on concentration in final product may [apply](#):

- XIV. Polymer Dispersions
- XV. Silicones
- XXI. Commodities based on Natural and Synthetic Rubber
- XLVIII. Materials for Coating the Outside of Hollow Glassware

4.2.5 Genetically Modified Organisms (GMO) Statement

We confirm that the PRODUCT is a synthetic chemical that is free from Genetically Modified Organisms (GMO). No Genetically Modified Materials are used in the manufacture of the PRODUCT..

We further confirm that in the PRODUCT no GMO substances are present in amounts of:

- > 0.9% according to Regulation (EG) No. 1829/2003 and 1830/2003.
- > 0.1% according to national German EG - Gentechnik - Durchführungsgesetz (EGGenTDurchfG)

4.2.6 Substances or Products causing Allergies, Intolerances or Cross - allergies

We confirm that the PRODUCT does not contain any allergens or other substances causing intolerances according to Annex II of Regulation (EU) No. 1169/2011 and amendments.

4.3 United States

4.3.1 US Food Statement – GRAS

The PRODUCT fulfils the requirements of [US CFR21 §184.1631](#) on direct food substances affirmed as Generally Recognized As Safe (GRAS) – potassium hydroxide – last update: 1 April 2019.

4.3.2 USDA National Organic Program Statement

With regards to [§205.105](#) ("Allowed and prohibited substances, methods, and ingredients in organic production and handling"), Vynova PRODUCT:

1. Is listed on the [National List of Allowed and Prohibited Substances](#)
 - ✓ §205.601 Synthetic substances allowed for use in organic crop production: (j) As plant or soil amendments - (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of **potassium hydroxide** or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
 - ✓ §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))": **Potassium hydroxide**—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.
2. is manufactured synthetically and not grown with the use of sewage sludge.
3. is manufactured synthetically and is not derived from a genetically modified organism (GMO).
4. does not contain any residual synthetic solvents.
5. is not processed with ionizing radiation – see Statement 6.10, in this document

4.4 General

4.4.1 Food Chemicals Codex Statement

The PRODUCT meets the specifications and maximum impurities indicated in the Food Chemicals Codex 11th Ed.

Component	Purity requirement
Total alkali	Not less than 85,0% and no more than 100,5% (as KOH)
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Lead	Not more than 2 mg/kg
Mercury	Not more than 0,1 mg/kg

4.4.2 TSE/BSE Statement

We confirm that the PRODUCT is produced solely synthetically, and no material used in the manufacture is of bovine or animal origin.

We further confirm that no materials of animal origin are present at any time during production or are used for production in the same plant.

Therefore, with regards to the conditions of our production process and the raw materials used, the BSE/TSE risk is, according to our knowledge, is not considered as relevant.

4.4.3 Kosher Statement

The PRODUCT is synthetically manufactured by membrane electrolysis of a potassium chloride solution from which water is evaporated to obtain potassium hydroxide flakes. It is not derived from nor does it contain any animal products, including those derived from wheat, barley, spelt, rye or oats that are excluded from Kosher for Passover. None of the raw materials used in its manufacture are derived from animal products. Our manufacturing plants are dedicated to the manufacture of the PRODUCT and no animal materials are used when cleaning operations are conducted. During the evaporation process, very small quantity of plant-based process aid is added. This process aid is Kosher certified.

4.4.4 Halal Statement

The PRODUCT is not derived from, nor does it contain, any product of animal origin or ethyl alcohol. The manufacturing plants are dedicated to the manufacture of the PRODUCT and no animal materials or ethyl alcohol are used when cleaning operations are conducted.

4.4.5 Gluten, Aflatoxins, Mycotoxins, Melamine and Latex Statement

The PRODUCT and associated packaging are free of gluten, aflatoxins, mycotoxins, melamine and latex.

4.4.6 Bacteria and microorganisms

The high pH property of the PRODUCT does not make it a viable environment for bacteria and microorganisms.

5 CONSUMER GOODS & PHARMACEUTICALS STATEMENTS

5.1 Cosmetics / Allergens Statement

The PRODUCT is listed on the EU Cosmetic Ingredients Inventory – see <http://ec.europa.eu/growth/tools-databases/cosing>

INCI Name	POTASSIUM HYDROXIDE
Description	Potassium Hydroxide is the inorganic base KOH
INN Name	potassium hydroxide
Ph. Eur. Name	kalii hydroxidum
CAS #	1310-58-3
EC #	215-181-3
Chemical/IUPAC Name	Potassium hydroxide
Cosmetic Restriction	Annex III/15a, 15d
Other Restriction(s)	
Functions	BUFFERING
SCCS opinions	1527/14 - Opinion on Potassium hydroxide (KOH) as callosity softener/remover
Identified INGREDIENTS or substances e.g.	

We hereby confirm that the PRODUCT is neither listed on Annex II of Regulation (EC) No. 1223/2009.

5.2 Residual Solvents Statement

None of the solvents listed in the §5.4 Residual Solvents (EP9.5) and <467> Residual Solvents (USP 42) are used or produced during the manufacture of the PRODUCT.

5.3 Animal testing

The PRODUCT manufactured by Vynova has never been tested on animals on our behalf.

5.4 Elemental Impurities Statement

All elemental impurities in the PRODUCT are compliant with the Class 1, Class 2A/2B and Class 3 permitted oral concentrations for the individual component option (USP) and option 1 (ICH).

Element	Class	Oral Concentration(in µg/g)
Cd	1	0.5
Pb	1	0.5
As	1	1.5
Hg	1	3
Co	2A	5
V	2A	10
Ni	2A	20
Tl	2B	0.8
Au	2B	10
Pd	2B	10
Ir	2B	10
Os	2B	10
Rh	2B	10
Ru	2B	10
Se	2B	15
Ag	2B	15
Pt	2B	10
Li	3	55
Sb	3	120
Ba	3	140
Mo	3	300
Cu	3	300
Sn	3	600
Cr	3	1100

5.5 Pharmacopeia Statement

The PRODUCT meets the specifications and maximum impurities indicated in the Pharmacy Monographs:

USA – USP43 – NF38

Component	Purity requirement
Total alkali	Not less than 85,0% (as KOH)
Carbonate	Not more than 3,5 % (as K ₂ CO ₃)
Potassium	Not less than 59,9%
Sodium	Not more than 1%

EU – EP 10

Component	Purity requirement
Carbonate	Maximum 2,0% (as K ₂ CO ₃)
Chlorides	Maximum 200 ppm
Phosphates	Maximum 100 ppm
Sulfates	Maximum 200 ppm
Aluminum	Maximum 0,2%, if intended for manufacture of hemodialysis solutions
Iron	Maximum 10 ppm
Sodium	Maximum 1,0%

6 ADDITIONAL REGULATIONS / STATEMENTS

6.1 RoHS & WEEE Statement

The RoHS and WEEE Directives restrict the maximum concentrations of certain hazardous substances in electrical and electronic equipment, as listed below (directives EU/2011/65 and amendment EU/2015/863):

- Lead 0.1%
- Mercury 0.1%
- Cadmium 0.01%
- Hexavalent Chromium 0.1%
- Dibutyl phthalate 0.1%
- Polybrominated Biphenyls 0.1%
- Polybrominated Diphenyl Ethers 0.1%
- Bis(2-ethylhexyl)phthalate 0.1%
- Butyl benzyl phthalate 0.1%
- Diisobutyl phthalate 0.1%

Polybrominated biphenyls, polybrominated diphenyl ethers and phthalates are not used in the production the PRODUCT nor are they produced as impurities during the manufacturing processes. All metal residues in the PRODUCT are below the indicated limit values.

6.2 Biocide Statement

The PRODUCT does not contain any biocidal active substances.

6.3 Pesticides and Herbicides Statement

The product adheres to Regulation (EU) No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

The PRODUCT and starting raw materials as well as associated packaging, do not contain any pesticides and herbicides.

6.4 Benzene Statement

We confirm that the PRODUCT is free from Benzene.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.5 Phthalate Statement

To the best of our knowledge the PRODUCT, the raw materials or all other materials used in the manufacturing process do not contain the following substances:

- Diisobutyl phthalate (DIBP) CAS - No. 84-69-5
- Dibutyl phthalate (DBP) CAS - No. 84-74-2
- Bis(2-ethylhexyl)phthalate(DEHP) CAS - No. 117-81-7
- Dihexyl phthalate (DHP) CAS - No. 84-75-3
- Dicyclohexyl phthalate (DCHP) CAS - No. 84-61-7

These substances are not added during the synthesis steps. A formation of the above - mentioned substances during synthesis is unlikely. However, we want to point out that the products are not tested with respect to the mentioned substances.

6.6 Bisphenol- A-diglycidylether Statement

We confirm that the PRODUCT is free from BADGE (Bisphenol-A-diglycidylether, CAS: 1675-54-3).

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.7 Alkylphenols and Alkylphenoethoxylate Statement

We confirm that the PRODUCT is free from alkylphenols (APs) or alkylphenoethoxylates (APEOs) – including all isomers.

They are not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.8 Fluorinated compounds Statement

Herewith we confirm that the PRODUCT is free from:

- Pentadecafluorooctanoic acid (PFOA)
- Perfluorooctane sulfonate (PFOS)
- Fluorotelomeric alcohol FTOH 8-2
- Fluorotelomeric alcohol FTOH 10-2
- Other fluorinated compounds

These substances are not intentionally added or produced during the manufacturing process of the PRODUCT and therefore are not analyzed on a regular basis

6.9 Asbestos Statement

The PRODUCT and starting raw materials as well as associated packaging, do not contain any asbestos.

6.10 Ionizing Radiation / Irradiation / EO / Natural Radiation Statement

The products is not treated by ionizing radiation according to Directive 1999/2/EC and amendments concerning food and food ingredients.

The PRODUCT is not sterilized by radiation or treated with Ethylene Oxide (EO) at any point of our manufacturing process.

We declare that there is no external contamination of radioactivity in the PRODUCT supplied by Vynova Belgium NV. However the element K in KOH contains 99.988% K-39 and K-41 isotopes which are not radioactive and 0.012% K-40 which is a radioactive isotope with a very long half-life of 1.251×10^9 years. K-40 is the largest source of natural radioactivity in animals, including humans

6.11 Volatile Organic Compounds Statement

We confirm that the PRODUCT does not contain any Volatile Organic Compounds (VOC).

6.12 Aldehyde Statement

Vynova confirms that the PRODUCT does not contain any aldehydes.

6.13 Paraben Statement

Vynova confirms that the PRODUCT is free from paraben.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.14 Dichlorobenzene Statement

Vynova confirms that the PRODUCT is free from dichlorobenzene.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

6.15 Nitrosamines Statement

Vynova confirms that the PRODUCT is free from nitrosamines.

It is not intentionally added or produced during the manufacturing process of the PRODUCT and therefore not analyzed on a regular basis.

7 INTERNATIONAL INVENTORY INFORMATION

Inventory status of the components of the PRODUCT

Inventory	Country / Region	Status ¹
AICS	Australia	In compliance
DSL / NDSL	Canada	In compliance
ECSI	Taiwan	In compliance
EINECS	European Union	In compliance
IECSC	China	In compliance
KECI	Korea	In compliance
ENCS	Japan	In compliance
NZIoC	New Zealand	In compliance
PICCS	Philippines	In compliance
TSCA	United States of America	In compliance

8 SAFETY DATA SHEETS

Vynova provides safety data sheets to its customers to inform about the PRODUCT's properties and potential hazardous effects on humans and the environment.

Vynova automatically emails safety data sheets to its customers in the following cases:

1. With the first delivery of the PRODUCT the most recent version of the safety data sheet is sent.
2. Whenever a new major version of a safety data sheet is available, it will be sent to all customers that have purchased the PRODUCT in the past 12 months
3. In case a customer that has purchased the PRODUCT in the past 12 months has not received a safety data sheet for 12 months, the most recent version of the safety data sheet is sent to the customer

Contact an account representative if you

- need a safety data sheet or
- would like to automatically receive safety data sheets via email.

¹ In compliance means: all components of the PRODUCT are listed on the above mentioned inventories or are exempted from listing and are not being offered in violation of any rule or order under the respective laws.

DISCLAIMER

Any advice or information contained herein is believed to be accurate at the date of publishing and is given in good faith but is for your general information only and should not be regarded as a substitute for detailed advice in any particular situation. Information may be changed or updated without notice. Accordingly, it remains your responsibility to ensure that prior to acting on any such advice or information, such action will not adversely affect your business and that you comply with all legal, safety and environmental requirements and any products are fit for your own particular purposes. Information in this publication is believed to be accurate and is given in good faith, but it is for the customer to satisfy itself of the suitability of any products for its own particular purposes. Accordingly, Vynova Belgium gives no warranty as to the fitness of any product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded to the fullest extent permitted by law. Vynova Belgium shall not be liable for any loss or liability including but not limited to any loss of profit or any indirect or consequential losses howsoever arising (including by way of negligence) as result of you acting upon any such advice or information, save for death or personal injury caused by its negligence or for any other liability which cannot be excluded by law.