

Vitasterol S-80® Esterified Non GMO
(Mixed phytosterol esters concentrate)**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Vitasterol S-80® Esterified Non GMO

Chemical name: Mixed Phytosterols Esterified

Synonyms: Concentrate of fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Food additive, food supplement.

Vitasterol S-80® Esterified Non GMO is widely used in food preparations or supplements as LDL cholesterol reducer.

1.3. Details of the supplier of the safety data sheet

Vitae Caps, S.A.U. (Kensing)

C/ Gutenberg 356. Polígono Torrehierro

45600 Talavera de la Reina. Toledo. Spain.

Tel: +34 925 85 10 13

www.kensingsolutions.com

customercare@kensingsolutions.com

1.4. Emergency telephone number

International emergency number CHEMTREC: +44 20 3807 3798

Local Spain number: 900-868-538

For “CHEMTREC country dial numbers”, please check annex I.

SECTION 2: Hazards Identification.

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

According to Regulation 1994 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

According to Regulation (EC) N° 1272/2008 (CLP)

According to Directive 67/548/EEC or 1999/45/EC

2.1. Classification of the substance or mixture

Not needed for this product according to GHS.

2.2. Label elements

Not required a hazard warning label for this product according to GHS

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Vitasterol S-80® Esterified Non GMO
(Mixed phytosterol esters concentrate)**2.3. Other hazards**

High risk of slipping due to leakage/spillage of the product

SECTION 3. Composition/information on ingredients**3.1. Substances**

Not applicable

3.2. Mixtures

Concentrate of fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides.

No particular hazards known.

SECTION 4: First aid measures**4.1. Description of first aid measures**

Removal and handling of contaminated clothing and shoes from the individual is recommended.

Inhalation: If symptomatic, move to fresh air. Get medical attention if symptoms persist.

Ingestion: Induction of vomiting should not be necessary (material is of sufficiently low toxicity). Wash out mouth with water. If adverse health effects develop seek medical attention.

Eyes: They should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms persist. Assure adequate flushing of the eyes by separating the eyelids with fingers.

Skin: Wash with soap and copious amounts of water. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed.

No reactions are known for the human body

4.3. Indication of immediate medical attention and special treatment needed.

Not necessary

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Water spray, Carbon dioxide, Dry chemical powder or appropriate foam.

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Vitasterol S-80® Esterified Non GMO
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The following substances can be released during the burning of this product: 2-propenal, carbon oxides and harmful vapours. Burning produces harmful and toxic fumes.

5.3. Advice for firefighters

Wear self-contained breathing apparatus as well as protective clothing because water or foam may cause frothing and it is necessary to prevent contact with skin and eyes.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Use suitable protective clothing and equipment to prevent any contamination on skin or eyes.

6.1. Personal precautions, protective equipment and emergency procedures

Do not discharge the product into drains, surfaces or ground water.

6.3. Methods and materials for containment and cleaning up

Pump off the product in case of large amount. For residual quantities, use adsorbent material (vermiculite, sand, silica gel etc) and once product has been adsorbed, then place in a closed container for its disposal. Ventilate area and wash spill site with soap and water after material pickup is complete.

6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

No special measures are necessary.

Anyway, avoid all sources of ignition like heat, sparks, flames and static discharges

7.2. Conditions for safe storage, including any incompatibilities.

Keep in a tightly closed container. Store at ambient temperature (max. 30°C) and under dry conditions. Keep protected from light and heat. Protect from contamination. Keep away from odorous and toxic substances. If opened, a nitrogen blanket should be applied prior to closing the container.

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Suitable materials for containers: Approved plastic containers, stainless steel, polyethylene containers, HDPE (High Density Polyethylene containers, phenol-epoxy resin Müller 79/14/3 (CH).

Unsuitable materials for containers: Nonferrous metals, Iron, zinc, steel, copper, copper alloys.

7.3. Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Components with occupational exposure limits: Not available

8.2. Exposure controls**8.2.1 Appropriate engineering controls**

No special precautions are necessary.

8.2.2 Individual protection measures, such as personal protective equipment.

Respiratory protection: If engineering controls do not maintain airborne concentrations to an acceptable level, an approved respirator must be worn. No applicable with adequate ventilation.

Skin protection: Hand protection is not needed under normal conditions. Wear clean and closed body-covering clothing. Body protection must be chosen based on level of exposure.

Eye/face protection: Use safety glasses with side-shields

No eating, drinking or smoking in the working area. Work clothing must be stored separately.

8.2.3 Environmental exposure controls

Data not available.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Appearance/Color:	Pale yellow when “liquid” (>45°C) Creamy white when “oily paste” (Between 10-45°C) Creamy white when “solid” (<10°C)
Odor:	Slightly vegetable oil

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pH:	Not applicable
Melting point:	43 – 48 °C
Flash point:	265°C
Evaporation rate:	Not available
Flammability:	Not highly flammable
Lower explosive limit:	Not relevant for classification and labelling
Upper explosive limit:	Not relevant for classification and labelling
Vapor Pressure:	Not available
Vapor Density (Air=1):	Not available
Specific gravity (at 25 °C):	0.91 – 0.98 g/cm ³
Solubility in water:	Insoluble
Partition coefficient: n-octanol/water:	Not applicable for mixtures
Auto ignition temperature:	Not available. Study does not need to be conducted
Thermal decomposition:	No decomposition is stored and handled as indicated
Viscosity (60°C):	150 mPa·s
Viscosity, kinematic:	Not available
Particle characteristics:	Not applicable

9.2 Other information

No further information available.

SECTION 10: Stability and Reactivity**10.1. Reactivity**

No hazardous reactions if stored and handled as indicated previously

The product is not classified as oxidizing

Corrosive effects to metals are not established.

10.2. Chemical stability

The product is stable if stored and handled as indicated previously.

10.3. Possibility of hazardous reactions

None if used for intended purpose. When finely distributed, self-ignition is possible.

10.4. Conditions to avoid

Air, sunlight, moisture and heat. See Section 7.- Handling and Storage

10.5. Incompatible materials

Strong oxidizing agents

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Vitasterol S-80® Esterified Non GMO
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No hazardous decomposition products will occur if stored and handled as indicated previously. Hazardous polymerization will not occur.

Possible thermal decomposition: None if stored and handled as prescribed/indicated

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Routes of exposure**Assessment of acute toxicity

Virtually nontoxic after a single ingestion.

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

Acute oral toxicity

Experimental/calculated data:

LD50 rat (oral): > 2,000 mg/kg

The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition.

Symptoms

(Further) symptoms and / or effects are not known so far

Irritation

Assessment of irritating effects:

Not irritating to eyes and skin.

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

Experimental/calculated data:

Skin corrosion/irritation rabbit: (OECD Guideline 404)

The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition.

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

Experimental/calculated data:

Serious eye damage/irritation rabbit:

The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition.

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Vitasterol S-80® Esterified Non GMO
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Assessment of sensitization:

A sensitizing effect on particularly sensitive individuals cannot be excluded.

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

Assessment of sensitization:

The chemical structure does not suggest a sensitizing effect.

Germ cell mutagenicity

Assessment of mutagenicity:

Based on the ingredients, there is no suspicion of a mutagenic effect.

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides

Experimental/calculated data:

Ames-test negative

The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition.

Carcinogenicity

Assessment of carcinogenicity:

Not classified, due to lack of data.

Reproductive toxicity

Assessment of reproduction toxicity:

Not classified, due to lack of data.

Developmental toxicity

Assessment of teratogenicity:

Not classified, due to lack of data.

Specific target organ toxicity (single exposure)

Based on the available information there is no specific target organ toxicity to be expected after asingle exposure.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

Based on available data, the classification criteria are not met.

Aspiration hazard

No data available.

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Vitasterol S-80® Esterified Non GMO
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The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition.

SECTION 12. Ecological information**12.1. Toxicity**

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms.
Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides.

Toxicity to fish:

LC50 (48 h) 5,500 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static)

The details of the toxic effect relate to the nominal concentration. The product has not been tested.

The statement has been derived from substances/products of a similar structure or composition

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides
Microorganisms/Effect on activated sludge:

EC0 (30 min) 10,000 mg/l, activated sludge, domestic (DIN 38412 Part 27 (draft), aerobic)

The details of the toxic effect relate to the nominal concentration. The product has not been tested.

The statement has been derived from substances/products of a similar structure or composition.

12.2. Persistence and degradability

Information on: Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides
Elimination information:

80 - 100 % BOD of the ThOD (15 d) (Directive 92/69/EEC, C.4-E) (aerobic, activated sludge, domestic)

The product has not been tested. The statement has been derived from substances/products of asimilar structure or composition

12.3. Bioaccumulative potencialAssessment bioaccumulation potential

The product has been tested.

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Vitasterol S-80® Esterified Non GMO
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Assessment transport between environmental compartments

No data available

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Endocrine disrupting properties

Not available.

12.7. Other adverse effects

Not available.

Other ecotoxicological advice:

The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

SECTION 13. Disposal considerations**13.1. Waste treatment methods**

Discharge, treatment or disposal may be subjected to national, state or local laws.

Containers which can be cleaned can be re-used. Containers that cannot be cleaned must be disposed in the same way as the substance.

SECTION 14: Transport information**Land transport**

ADR

Not classified as a dangerous good under transport regulations

UN number or ID Number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

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Vitasterol S-80® Esterified Non GMO
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Not classified as a dangerous good under transport regulations

UN number or ID Number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Inland waterway transport**ADN**

Not classified as a dangerous good under transport regulations

UN number or ID Number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Transport in inland waterway vessel

Not evaluated

Sea transport**IMDG**

Not classified as a dangerous good under transport regulations

UN number or ID Number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Air transport**IATA/ICAO**

Not classified as a dangerous good under transport regulations

UN number or ID Number:	Not applicable
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UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

14.1. UN number or ID Number

See corresponding entries for “UN number or ID Number” for the respective regulations in the tables above.

14.2. UN proper shipping name

See corresponding entries for “UN proper shipping name” for the respective regulations in the tables above.

14.3. Transport hazard class(es)

See corresponding entries for “Transport hazard class(es)” for the respective regulations in the tables above.

14.4. Packing group

See corresponding entries for “Packing group” for the respective regulations in the tables above.

14.5. Environmental hazards

See corresponding entries for “Environmental hazards” for the respective regulations in the tables above.

14.6. Special precautions for user

See corresponding entries for “Special precautions for user” for the respective regulations in the tables above.

14.7. Maritime transport in bulk according to IMO instruments

Regulation:	Not evaluated
Shipment approved:	Not evaluated
Pollution name:	Not evaluated
Pollution category:	Not evaluated

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Vitasterol S-80® Esterified Non GMO
(Mixed phytosterol esters concentrate)**SECTION 15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Relevant provisions of the European Union (EU)**

- **Restrictions according to REACH Annex XVII.**
None of the ingredients are listed.
- **List of substances subjected to authorisation (REACH, Annex XIV).**
None of the ingredients are listed.
- **Seveso-III-Directive (2012/18/EU).**
Dangerous substance/hazard categories: Not assigned.

Classification and labelling are according to Regulation 1272/2008/CE (CLP).

Hazard Symbols: Not subjected to the identification regulations.

The mixture covered by this SDS is not subjected to specific provisions in relation to the protection of human health or the environment at Union level.

Mixed Phytosterols have been registered in accordance with REACH legislation (EC n° 1907/2006). Registration number: 01-2119969654-22-0006.

Mixed Phytosterols are considered as a Novel Food ingredient in compliance with European Regulation 258/97/EC.

In Europe, Phytosterols can be added in the food categories stated in the Commission Implementing Regulation (EU) 2018/1023

Please, prior placing on the market products with phytosterols, consult the regulation of the country.

15.2. Chemical safety assessment:

Not required.

Vitasterol S-80® Esterified Non GMO
*(Mixed phytosterol esters concentrate)***SECTION 16. Other information**

If you have any queries relating to this SDS, its contents or any other product safety related questions, please write to the following e-mail address: customercare@kensingsolutions.com

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. This safety data sheet is neither a Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

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Kensing Safety Data Sheet according to Regulation (EC) No. 1907/2006 as amended from time to time.

ANNEX I. CHEMTREC COUNTRY DIAL NUMBERS

Country	Greeting Language	Number Type	City	Local Number	Toll-Free Number	Zone
Argentina	Latin American Spanish	Local (City)	Buenos Aires	+54 11 5983-9431		Zone 3 - South America
Australia	English	Local (City)	Sydney	+61 2 9037 2994		Zone 9 - Oceania
Australia*	English	Toll Free			1800 862 115	Zone 9 - Oceania
Austria	Austro-Bavarian and German	Local (City)	Vienna	+43 1 3649237		Zone 6 - Western Europe
Austria*	Austro-Bavarian and German	Toll Free - Mobile Enabled			0800 293702	Zone 6 - Western Europe
Belgium	French, Flemish, and German	Local (City)	Brussels	+32 2 808 32 37		Zone 6 - Western Europe
Bolivia*	Latin American Spanish	Toll Free			800 10 1913	Zone 3 - South America
Brazil	Portuguese	Local (City)	Rio De Janeiro	+55 21 3958-1449		Zone 3 - South America
Brazil	Portuguese	Local (City)	Sao Paulo	+55 11 4349-1359		Zone 3 - South America
Brazil*	Portuguese	Toll Free - Mobile Enabled			0800 892 0479	Zone 3 - South America
Bulgaria	Bulgarian	Local (City)	Plovdiv	+359 32 570 104		Zone 5 - Eastern Europe
Canada	English	Local (City)	Northern Virginia	+1 703-741-5970		Zone 1 - North America
Canada*	English	Toll Free			1-800-424-9300	Zone 1 - North America
Cayman Islands	English	Local (National)		1 (345) 749-8392		Zone 2 - Central America
Chile	Latin American Spanish	Local (City)	Santiago	+56 2 2581 4934		Zone 3 - South America
China	Mandarin	Local (National)		400 120 4937		Zone 7 - Asia
Colombia*	Latin American Spanish	Toll Free			01-800-7102151	Zone 3 - South America
Costa Rica*	Latin American Spanish	Local (National)		+506 4000 3869		Zone 2 - Central America
Croatia	Croatian	Local (City)	Zagreb	+385 1 7776 920		Zone 5 - Eastern Europe
Czech Republic	Czech	Local (City)	Prague	+420 228 880 039		Zone 6 - Western Europe
Denmark	Danish	Local (National)		+45 69 91 85 73		Zone 6 - Western Europe
Dominican Republic*	Latin American Spanish	Local (City)	Santo Domingo	1 (829) 956-7588		Zone 2 - Central America
El Salvador*	Latin American Spanish	Local (City)	San Salvador	+503 2136 7633		Zone 2 - Central America
Estonia*	Estonian	Local (National)		+372 668 1294		Zone 5 - Eastern Europe
Finland	Finnish	Local (City)	Helsinki	+358 9 42419014		Zone 6 - Western Europe
France	French	Local (National)		+33 9 75 18 14 07		Zone 6 - Western Europe
Germany	German	Local (City)	Frankfurt	+49 69 643508409		Zone 6 - Western Europe
Germany*	German	Toll Free - Mobile Enabled			0800 1817059	Zone 6 - Western Europe
Greece	Greek	Local (City)	Athens	+30 21 1176 8478		Zone 5 - Eastern Europe
Grenada*	English	Local (City)	St George	1 (473) 230-0165		Zone 2 - Central America
Guinea*	French	Local (Mobile Restricted)		+224 660 71 03 00		Zone 10 - Africa
Hong Kong*	Cantonese	Toll Free			800 968 793	Zone 7 - Asia
Hungary*	Hungarian	Local (City)	Budapest	+36 1 808 8425		Zone 6 - Western Europe
Iceland*	Icelandic	Local (City)	Reykjavik	+354 539 0655		Zone 6 - Western Europe
India*	Hindi, Bengali, and English	International Toll Free (NON-RETAIL)			000 800 1007 141	Zone 8 - India
Ireland	English	Local (City)	Dublin	+353 1 901 4670		Zone 6 - Western Europe
Israel	Hebrew	Local (City)	Tel Aviv	+972 3-763-0639		Zone 4 - Middle East
Italy	Italian	Local (City)	Milan	+39 02 4555 7031		Zone 6 - Western Europe
Italy*	Italian	Toll Free - Mobile Enabled			800 789 767	Zone 6 - Western Europe
Japan	Japanese	Local (City)	Tokyo	+81 3-4520-9637		Zone 7 - Asia
Latvia^	Latvian/Lettish	Local (City)	Riga	+371 66 165 504		Zone 5 - Eastern Europe
Lithuania	Lithuanian	Local (City)	Vilnius	+370 5 214 0238		Zone 5 - Eastern Europe
Luxembourg	Luxembourgish, French, and German	Local (National)		+352 20 20 24 16		Zone 6 - Western Europe
Macedonia*	Macedonian	Local (City)	Skopje	+389 2 551 7456		Zone 5 - Eastern Europe
Malaysia	Malay	Local (City)	Kuala Lumpur	+60 3-9212 5794		Zone 7 - Asia
Malaysia*	Malay	Toll Free			1-800-81-5308	Zone 7 - Asia
Mexico*	Latin American Spanish	Toll Free			800 681 9531	Zone 1 - North America
Netherlands	Dutch	Local (National)		+31 85 888 0596		Zone 6 - Western Europe
New Zealand*	English	Toll Free - Mobile Enabled			0800 425 459	Zone 9 - Oceania
New Zealand*	English	Local (City)	Auckland	+64 9-801 0034		Zone 9 - Oceania
Nigeria*	Hausa	Local (City)	Lagos	+234 1 227 8883		Zone 10 - Africa
Panama*	Latin American Spanish	Local (National)		+507 832-2475		Zone 2 - Central America
Peru	Latin American Spanish	Local (City)	Lima	+51 1 7071295		Zone 3 - South America
Philippines*	Tagalog	Local (City)	Manila	+63 2 8 395 3308		Zone 7 - Asia
Philippines*	Tagalog	Toll Free (High Volume)			1800 1 116 1020	Zone 7 - Asia
Poland	Polish	Local (City)	Warsaw	+48 22 398 80 29		Zone 5 - Eastern Europe
Portugal	Portuguese	Local (National)		+351 308 801 773		Zone 6 - Western Europe
Romania*	Romanian	Local (National)		+40 376 300 026		Zone 5 - Eastern Europe
Russia*	Russian	Toll Free - Mobile Enabled			8 (800) 100-63-46	Zone 5 - Eastern Europe
Singapore	English and Mandarin	Local (National)		+65 3158 1349		Zone 7 - Asia
Singapore*	English and Mandarin	Toll Free			800 101 2201	Zone 7 - Asia
Slovakia	Slovak	Local (City)	Bratislava	+421 2/330 579 72		Zone 6 - Western Europe
Slovenia*	Slovene/Slovenian	Local (City)	Ljubljana	+386 1 888 80 16		Zone 6 - Western Europe
South Africa*	English	Toll Free			080 098 3611	Zone 10 - Africa
South Korea*	Korean	Toll Free			080 822 1374	Zone 7 - Asia
Spain*	European Spanish	Toll Free - Mobile Enabled (NON-RETAIL)			900 868 538	Zone 6 - Western Europe
Sweden	Swedish	Local (City)	Stockholm	+46 8 525 034 03		Zone 6 - Western Europe
Taiwan	Mandarin	Local (City)	Taipei	+886 2 7741 4207		Zone 7 - Asia
Taiwan*	Mandarin	International Toll Free			00801-14-8954	Zone 7 - Asia
Thailand*	Thai	International Toll Free (High Volume)			001-800-13-203-9987	Zone 7 - Asia
Trinidad and Tobago*	English	Local (National)		1 (868) 224-5716		Zone 2 - Central America
Turkey	Turkish	Local (City)	Istanbul	+90 212 705 53 40		Zone 5 - Eastern Europe
Ukraine*	Ukrainian	Local (Mobile Restricted)		+380 94 710 1374		Zone 5 - Eastern Europe
United Kingdom	English	Local (City)	London	+44 20 3807 3798		Zone 6 - Western Europe
United States	English	Local (City)	Northern Virginia	+1 703-741-5970		Zone 1 - North America
United States*	English	Toll Free			1-800-424-9300	Zone 1 - North America
Phone Number Stipulations						
* Phone number must be dialed from within the country						
^ Phone number can only be dialed from within EU countries						
+ Phone number may be dialed from other countries, but is not guaranteed						