Section A2.10.2

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection 2.10

Official use only

2.10.2 Environmental exposure towards active substance

In the European Union, the Integrated Pollution Prevention and Control (IPPC) Directive requires the operator to use the "Best Available Technique" (BAT) to protect the environment. This includes the concept that "the cost should not be excessive". The term technique covers both technology and operating/maintenance practices. Thus, a new plant is expected to comply with BAT, which will change as advances are made. An existing plant will be required to up-grade to the BAT (which may differ from that for a new plant) after an appropriate period.

2.10.2.1 Production

(i) Releases into water

Aqueous discharges from limestone quarrying and processing do not present a significant environmental hazard. The most common contaminant is suspended matter, which can be removed by settling in sumps or slurry ponds.

Discharges from lime production and processing include drainage and effluent from wet scrubbers. Such effluents are generally of low volume. They should be processed to meet the discharge requirements for pH and biological oxygen demand.

(ii) Releases into air

Quarrying:

In the quarrying process, drilling is the main potential source of dust. The preferred method for de-dusting the air carrying pulverised rock up the hole is the use of bag filters. Dust emission from blasting is controlled by sealing the top of the holes with "stemming".

Limestone Processing and Storage:

Crushing, screening and conveying of limestone can give rise to dust. Dust emission from one of these operations should be prevented by enclosure or extraction. Bag filters are generally favoured. Belt conveyors should be partially or totally enclosed to control wind-whip or water should be added to control dust.

Production, Processing and Storage of Quicklime:

To prevent dust emission during production of quicklime, different dust collecting systems are used, depending on dust concentration and composition, which can vary depending on the feedstone and the kiln design. Processing and storage of quicklime should be performed in closed systems or by using suitable dust extraction methods.

Production and Storage of Hydrated Lime:

The exhaust gas of from hydration of quicklime to hydrated lime is the main source of dust emission from the process. As the gas consists principally of steam, dust can be removed by using wet scrubbers. Hydrated lime should be stored in closed bunkers fitted with filters.

Production of Milk of Lime:

Slaking quicklime is not an inherently dusty operation and the

Section A2.10.2 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

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volume of gaseous effluent is small. In addition it is a good practice to keep slakers under suction to ensure that dust and steam do not escape.

Vehicle loading:

Loading of Limestone into road vehicles should be done in such way as to minimise the amount of airborne dust generated. The vehicle should be sheeted before leaving the site.

(iii) Waste disposal

The wastes from quarrying are generally of clay or limestone and can, therefore, be disposed to land.

Wastes from lime production and processing contain alkaline components such as Calcium oxide and hydroxide. They may contain slightly soluble salts, such as Calcium sulphate, as well as insoluble Calcium carbonate, clay and fuel ash related products. Water draining through "lime tips" becomes alkaline and precipitated carbonate hardness in ground waters. As a minimum requirement, lime tips should, therefore, be built on sites which do not have any significant natural springs and the surface layer be contoured so that it is self-draining.

2.10.2.2 Intended use(s)

Affected compartment(s):

A level III fugacity modelling according to Mackay was conducted using EPI suite v.3.12. According to this model calculation, the distribution into the environment is as follows:

water	38.9 %
sediment	0.07 %
air	0.0032 %
soil	61 %

Predicted concentration in the affected compartment(s)

Sewage sludge or manure treated with Burnt lime, Burnt dolomitic lime or the respective hydroxides can be applied to agricultural land as a replacement of agricultural liming. Burnt lime and Burnt dolomitic lime form the respective hydroxides immediately upon contact with water, i.e. when mixed into the sewage sludge or manure. During the storage of treated sewage sludge or manure, the hydroxides are partly transformed to calcium or magnesium carbonates. Because the storage time can be short (hours), as a worst case approach it is assumed that no carbonisation occurs during storage. Consequently, in the sewage sludge or manure applied to land, lime is only present in the hydrated form.

As a worst case scenario, it is assumed that sewage sludge at an application rate of 5000 kg (dry matter)/ ha is applied to agricultural land and that the sewage sludge has been treated with burnt lime/ burnt dolomitic lime at a maximum application rate. Application rate is equal to dry matter multiplied by 1.2.

After application to agricultural land, the lime treated manure or sewage sludge is incorporated into the upper twenty centimetres of the soil. The hydrated lime is transformed into the respective carbonates with an estimated DT_{50} of 3 days.

Run-off is considered to be the major route by which surface waters

Section A2.10.2 **Annex Point IIA2.10**	**Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC**
	get exposed. The PEC_{sw} was calculated using the German model EXPOSIT 2.0c.
water	The initial PEC_{sw} of hydrated lime/ hydrated dolomitic lime due to a single run-off event three days after application to bare soil were calculated to be 17.45 mg/L, 14.18 mg/L and 5.67 mg/L for buffer zones of 0 m, 5 m and 10 m, respectively. This calculation refers to a maximum application rate of burnt lime/ burnt dolomitic lime to sewage sludge (120% of dry matter of sewage sludge applied as lime). As the application rates for burnt lime are higher than those for hydrated lime and because burnt lime is transformed to hydrated lime upon contact with water, this calculation covers as a worst case approach also the hydrated forms. In natural water with a medium hardness ($c(HCO_3^-) = 100$ mg/L = 1.64 mmol/L) the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. The carbonate anions will not contribute to a HCO_3^- / CO_3^{2-} buffer system, but form $CaCO_3$ by reaction with Ca^{2+}.
sediment	As described under point 8.3.4.1, in natural waters the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. CO_3^{2-} forms $CaCO_3$ by reacting with Ca^{2+} The calcium carbonate precipitates and deposits on or in the sediment. Calcium carbonate is of low solubility and a constituent of natural soils and has no biocidal activity.
air	All lime variants are not volatile. Their respective vapour pressures can be assumed to be below the value of 10^{-5} Pa..
soil	The initial predicted environmental concentrations of hydrated lime/ hydrated dolomitic lime in the top 0-20 cm layer of the soil were calculated to be 1067.6 mg/kg assuming a deposition rate of 100 %. Actual and time weighted average PEC values for hydrated lime/ hydrated dolomitic lime decrease to < 0.0001 and 46.2 mg/kg after 100 days, respectively.

Section A2.10.2 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25/09/2009
Materials and methods	Applicant's version is accepted, noting that within the UK CA document II-B additional calculations and assumptions details the final values accepted for risk assessment purposes.
Conclusion	Adopt Applicant's version noting statement above.
Reliability	N/A
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A2.10.1: Workplace exposure / Inhalation exposure

Exposure scenario	**Workplace operation**	**PPE**	**Year(s) of measurement**	**Number of measurements**	**Type of measurements**	**Exposure concentration**
Production	**In the confidential part of the dossier a table is included which provides a "Consolidation on Companies' monitoring data available on dust inhalation of workers in lime production plants".**					
Formulation	Not relevant because Lime is not formulated into biocidal products.					
Application Scenarios	Use 1 (treatment of sewage sludge): manual and automated mixing and loading ; automated application Use 2 (treatment of manure and other digestive tract contents): automated mixing and loading and automated application	Use 1: protective clothing including gloves, goggles and mask during manual mixing and loading Use 2: As the application is an automated process, no protective equipment is needed. Due to possible release of gases form treated slurry, masks are recommended during application.	n.a.	n.a.	n.a.	Calculated values from Doc. IIB, chapter 8.2.2: **Inhalation:** Use 1 and 2: 0.023 mg/kg bw per day **Dermal:** Use 1 and 2: 0.049 mg/kg bw per day

Section A2 Identity of Active Substance

Annex Point IIA, II.

Subsection (Annex Point)			**Official use only**
2.1	**Common name (IIA2.1)**	The substance name as provided in ESIS is Calcium magnesium oxide. In this dossier, Calcium magnesium oxide is referred to as “Burnt dolomitic lime”. Calce dolomitica in zolle, calce dolomitica viva, calce viva, calce in zolle, Dolime, Dolomitic lime, Dolomite calcinata, Ossido di calcio e magnesio. Please note that this list may not be exhaustive.	
2.2	**Chemical name (IIA2.2)**	Calcium magnesium oxide	X
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable: manufacturers have not assigned development code numbers.	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	37247-91-9	X
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.2	**EC-No**	253-425-0	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.3	**Other**	Not applicable	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	Burnt dolomitic lime does not consist of discrete molecules, but crystallises in a 3-dimensional ion lattice. Furthermore, the Ca/Mg ratio is not constant for different sources of Limestone (precursor for Burnt dolomitic lime). In this dossier, $CaO \cdot MgO$ is used as a “molecular formula” for Burnt dolomitic lime.	
2.5.2	**Structural formula**	Not relevant. See above.	
2.5.3	**Molecular mass**	96.38 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	Calcium magnesium oxide is generated by heating Dolomitic lime stone (Calcium magnesium carbonate) to 1100 °C). Upon dissociation of CO_2, $CaO \cdot MgO$ is formed.	

Section A2 Identity of Active Substance

Annex Point IIA, II.

$$CaMg(CO_3)_2 + \text{Heat} \rightarrow CaO{\cdot}MgO + CO_2$$

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

General remark:

By consent within the lime industry, the composition of lime is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides. Please note that the analytical methods used for the determination of the composition of lime do not allow for the determination of the specific forms in which the constituents occur in lime.

The contents of Ca and Mg are expressed as CaO and MgO. Because in Burnt dolomitic lime, Ca and Mg are actually present in the form of these oxides, the indicated values of CaO and MgO reflect the actual composition of Burnt dolomitic lime.

The contents of the other constituents are calculated and expressed as oxides:

- The content of Silicon (Si) is expressed as SiO_2,
- the content of Aluminium (Al) as Al_2O_3,
- the content of Iron (Fe) as F_2O_3,
- the content of Manganese (Mn) as Mn_3O_4, and
- the Sulphur (S) content as SO_3.

However, these indicated oxides are not identical with the actual forms in which these elements are present in Burnt dolomitic lime:

- Silicon (Si) can be present in the form of $Ca_2(SiO_4)$, $Ca_2Mg_2(Si_2O_7)$ or in other forms.
- Aluminium (Al) can be present in the form of $Ca_3Al_2O_6$ (Dicalciumaluminate) or in other forms.
- Iron (Fe) can be present in the form of $Ca_4Al_2Fe_2O_{10}$ (Braunmuellerit), $Ca_2Fe_2O_5$ (Dicalciumferrit), or other forms.
- Manganese (Mn) can be present as Ca_2MnO_4 (Dicalciummanganate) or in other forms.
- Sulphur (S) is present as sulphates.

The loss on ignition comprises water (from $Ca(OH)_2$, formed during water absorption of CaO) and CO_2 (from carbonate residues not transformed to oxides during the burning of limestone or from re-carbonisation of CaO due to contact of Burnt dolomitic lime to atmospheric CO_2).

The purity of Burnt dolomitic lime from the producers lies in the following range (% w/w): 85 – 98 %.

The value provides the content of Ca and Mg expressed as the sum of CaO and MgO. Minimum value for MgO in Burnt dolomitic lime is 30 % based on Magnesium content.

Section A2 Identity of Active Substance

Annex Point IIA, II.

2.8 Identity of impurities and additives, as appropriate (IIA2.8) x

Loss on ignition (H_2O and CO_2)	< 7.5 % (< 0.5 % H_2O, < 7 % CO_2)
Silicon (Si) (expressed as SiO_2)	< 4 %
Aluminium (Al) (expressed as Al_2O_3)	< 2 %
Iron (Fe) (expressed as Fe_2O_3)	< 0.6 %
Sulphur (S) (expressed as SO_3)	< 0.8 %

2.8.1 Isomeric composition

There are no isomers.

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9) x

The source for Calcium magnesium oxide is Dolomitic limestone, a natural material consisting predominantly of Calcium magnesium carbonate. For a detailed description of the production process see section 2.10.1.1.

The large variation in impurities in limestone can be explained as follows:

Limestone is a natural material resulting from sedimentation processes in shallow waters. Evaporation leads to the formation of supersaturated solutions where minerals like Calcite and Dolomite precipitate and fall out. Organogenic or zoogenic limestone formed as a result of the sedimentation of shells from crustaceans and molluscs. These sedimentation processes ultimately resulting in the formation of limestone have taken place at various parts of the world. The local environment during the formation and compaction of the limestone has influenced its exact composition, thus defining the specification of each lot of limestone.

Several impurities are found in limestone. These can be ascribed to the incorporation of defined materials during the formation of limestone. The relative amount of each of these materials can differ considerably and determines the limestone's structure and colour.

- Clay: formed as the result of weathering / decomposition of Silicon oxide where the silicon is isomorphically replaced by Aluminium.
- Limonite / Haematite: Iron oxide formed as the result of weathering of iron-containing rock / stone.
- Glauconite: forms during reducing conditions and contains Potassium, Sodium, Iron, Aluminium, and Silicon.
- Pyrite: the replacement mineral Iron sulphide was formed in acidic environments in the presence of organic material.
- Carbon / Bitumen: after sedimentary deposition of plant materials anaerobic decomposition of proteins, pigments, lipids and carbohydrates leads to the formation of carbon polymers.
- Sand: small particles of various minerals.

Section A2 Identity of Active Substance

Annex Point IIA, II.

In addition to impurities listed here, also other elements like manganese or cobalt can be present and determine the pigmentation of the limestone.

In the case of Dolomitic limestone, a high amount of Calcium magnesium carbonate has been incorporated during the sedimentation. This type of limestone contains similar impurities as described above for the Calcium carbonate limestone.

The impurities described for limestone are contained during the production of Burnt dolomitic lime except for a large part of the Carbon-containing material that will be discharged as CO_2 during the burning process.

The characterisation of Lime products is complicated, as the methods to determine the different ingredients and impurities do often not directly determine the amount of real existing species, but rather the content expressed in equivalents of the respective oxides of elements of interest. For silicon, aluminium, iron, manganese, carbon and sulphur, the equivalent content referred to their oxides is typically stated for the characterisation of the Lime product.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 September 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **2.2** CAS uses the name calcium magnesium oxide and the calcium/magnesium ratio is not specified. The calcium/magnesium ratio in this AI will vary because of the natural origin of the material and in the case of some products one of the following CAS numbers might be more appropriate if they match the calcium/magnesium ratio more precisely. 201014-62-2 Ca0-1 Mg0-1 O 144047-08-5 Ca0-0.15 Mg0.85-1 O 121754-60-7 Ca0.79-0.87 Mg0.13-0.21 O 121754-59-4 Ca0.04-0.14 Mg0.86-0.96 O **2.8** Manganese can also be present and is reported as Mn_3O_4 – but has not been listed here as the typical concentration is <0.1% Detailed analysis, including screening for any heavy metal content should be provided at product authorisation. A typical analysis of a Burnt dolomitic lime product is reproduced as confidential data in DOCIIIB. **2.9** Further details on the method of manufacture can be found in section A2.10 of the Dossier on Hydrated Lime A typical analysis of 2 products is reproduced as confidential data in DOCIIIB. As no formulations of this substance are supplied, these analyses will be typical of the AI.
Conclusion	Acceptable
Reliability	N/A
Acceptability	The applicant's version is considered acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Carbon dioxide	
2.8.1.2	**Function**	Carbon dioxide is the calculation basis for expressing the content of Carbonate residues. CO_2 itself is not present. The sum of CO_2 and water content is “Loss on ignition”.	
2.8.2	**IUPAC name**	Carbon dioxide	
2.8.3	**CAS-No**	124-38-9	
2.8.4	**EC-No**	204-696-9	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	CO_2	
2.8.7	**Structural formula**	$O{=}C{=}O$	
2.8.8	**Molecular mass**	44.01 g/mol	
	Concentration of the impurity or additive	< 7 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			Official use only
2.8.1.1	**Common name**	Silicon dioxide Please note that the content of Silicon is calculated and expressed as Silicon dioxide although Silicon is present in different forms of silicates in Burnt dolomitic lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Silicon dioxide	
2.8.3	**CAS-No**	11126-22-0	
2.8.4	**EC-No**	234-368-0	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SiO_2	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	60.08 g/mol	
	Concentration of the impurity or additive	< 4 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Aluminium oxide Please note that the content of Aluminium is calculated and expressed as Aluminium oxide although Aluminium is present in different forms in Burnt dolomitic lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Aluminium oxide	
2.8.3	**CAS-No**	1344-28-1	
2.8.4	**EC-No**	215-691-6	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Al_2O_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	101.96 g/mol	
	Concentration of the impurity or additive	< 2 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Iron oxide Please note that the content of Iron is calculated and expressed as Iron oxide although Iron is present in different forms in Burnt dolomitic lime.	
2.8.1.2	**Function**	Iron is a natural constituent of limestone	
2.8.2	**IUPAC name**	Iron oxide	
2.8.3	**CAS-No**	1345-25-1	X
2.8.4	**EC-No**	215-721-8	X
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Fe_2O_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	159.69 g/mol	
	Concentration of the impurity or additive	< 0.6 %	

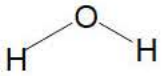
Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Sulphur trioxide Please note that the content of Sulphur is calculated and expressed as Sulphur trioxide although Sulphur is present as sulphate.	
2.8.1.2	**Function**	Sulphur is a natural constituent of limestone	
2.8.2	**IUPAC name**	Sulphur trioxide	
2.8.3	**CAS-No**	7446-11-9	
2.8.4	**EC-No**	231-197-3	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SO_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	80.06 g/mol	
	Concentration of the impurity or additive	< 0.8 %	

Section A2.8 Identity of impurities and additives (active substance)

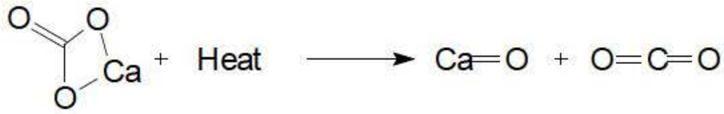
Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Water	
2.8.1.2	**Function**	Natural constituent of the atmosphere. The sum of CO_2 and water content is "Loss on ignition".	
2.8.2	**IUPAC name**	Water	
2.8.3	**CAS-No**	7732-18-5	
2.8.4	**EC-No**	231-791-2	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	H_2O	
2.8.7	**Structural formula**		
2.8.8	**Molecular mass**	18.0 g/mol	
	Concentration of the impurity or additive	< 0.5 %	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 September 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **Impurity 4** – Iron **2.83/2.84 -** iron is present in various reacted forms but is reported for analysis as ferric oxide (Fe_2O_3).However, the CAS and EINECS numbers given refer to iron oxide (FeO). The CAS and EINECS numbers for ferric oxide are 1309-37-1 and 215-168-2. The additional impurity Manganese is mentioned (calculated and expressed as Mn_3O_4) It has not been listed as an impurity in 2.8 because the typical purity is <0.1% (DocIII A4.1/01). A typical analysis of a burnt dolomitic lime product is reproduced as confidential data in DOCIIIB. As no formulations of this substance are supplied, these analyses will be typical of the AI.
Conclusion	Acceptable. Due to the nature of the active (derived from naturally occurring limestone) the impurities will be a mixture of inorganic salts and minerals in various forms (eg simple or mixed oxides &/or hydroxides of the elements stated in section A2 2.7) and expressing them in the normal format is difficult. As the applicant states it is practice used by the industry to run elemental analysis but express the composition as oxide equivalents as simple analytical methods used cannot determine the form in which the element is present. The UK CA therefore concludes that this approach is acceptable.
Reliability	N/A
Acceptability	The applicant's version is considered acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2 Identity of Active Substance

Annex Point IIA, II.

Subsection (Annex Point)			**Official use only**
2.1	**Common name (IIA2.1)**	The substance name as provided in ESIS is Calcium oxide. In this dossier, Calcium oxide is referred to as "Burnt lime". The following synonyms are found in literature: Quick lime, Branntkalk, Brændt kalk, Cal Viva, Calce in zolle, Ossido di calcio, Calciumoxide, Chaux vive, Oxyde de calcium, Chaux calcinée, Chaux grasse, Chaux aérienne, gebrannter Kalk, gebrande kalk, unslaked lime, Ätzkalk, Turbokalk. Please note that this list may not be exhaustive.	
2.2	**Chemical name (IIA2.2)**	Calcium oxide	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable: manufacturers have not assigned development code numbers.	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	1305-78-8	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.2	**EC-No**	215-138-9	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.3	**Other**	Not applicable	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	CaO	
2.5.2	**Structural formula**	$Ca=O$	
2.5.3	**Molecular mass**	56.077 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	Calcium oxide is generated by heating lime stone ($CaCO_3$ to 1100 °C). Upon dissociation of CO_2, CaO is formed. 	

Section A2 Identity of Active Substance

Annex Point IIA, II.

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

General remarks:

By consent within the lime industry, the composition of lime is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides. Please note that the analytical methods used for the determination of the composition of lime do not allow for the determination of the specific forms in which their constituents occur in lime.

The contents of Ca and Mg are expressed as CaO and MgO. Because in Burnt lime, Ca and Mg are actually present in the form of these oxides, the indicated values of CaO and MgO reflect the actual composition of the Burnt lime.

The contents of the other constituents are calculated and expressed as oxides:

- The content of Silicon (Si) is expressed as SiO_2,
- the content of Aluminium (Al) as Al_2O_3,
- the content of Iron (Fe) as F_2O_3,
- the content of Manganese (Mn) as Mn_3O_4, and
- the Sulphur (S) content as SO_3.

However, these indicated oxides are not identical with the actual forms in which these elements are present in Burnt lime:

- Silicon (Si) can be present in the form of $Ca_2(SiO_4)$, Ca_2Mg_2 (Si_2O_7) or in other forms.
- Aluminium (Al) can be present in the form of $Ca_3Al_2O_6$ (Dicalciumaluminate) or in other forms.
- Iron (Fe) can be present in the form of $Ca_4Al_2Fe_2O_{10}$ (Braunmuellerit), $Ca_2Fe_2O_5$ (Dicalciumferrit), or other forms.
- Manganese (Mn) can be present as Ca_2MnO_4 (Dicalciummanganate) or in other forms.
- Sulphur (S) is present as sulphates.

The loss on ignition comprises water (from $Ca(OH)_2$, formed during water absorption of CaO) and CO_2 (from carbonate residues not transformed to oxides during the burning of limestone or from re-carbonisation of CaO due to contact of the product to atmospheric CO_2).

The purity of Burnt lime from the producers lies in the following range (% w/w): 80-98 %

The value provides the content of Ca expressed as CaO.

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

Section A2 Identity of Active Substance

Annex Point IIA, II.

Magnesium oxide (MgO)	< 5 %
Loss on ignition (H_2O and CO_2)	< 7.5 % (< 0.5 % H_2O, < 7 % CO_2)
Silicon (Si) (expressed as SiO_2)	< 4 %
Aluminium (Al) (expressed as Al_2O_3)	< 2 %
Iron (Fe) (expressed as Fe_2O_3)	< 0.8 %
Sulphur (S) (expressed as SO_3)	< 0.8 %

2.8.1 Isomeric composition

There are no isomers.

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)

The source for Calcium oxide is limestone, a natural material consisting predominantly of Calcium carbonate. For a detailed description of the production process see section 2.10.1.1.

The large variation in impurities in limestone can be explained as follows:

Limestone is a natural material resulting from sedimentation processes in shallow waters. Evaporation leads to the formation of supersaturated solutions where minerals like Calcite and Dolomite precipitate and fall out. Organogenic or zoogenic limestone formed as a result of the sedimentation of shells from crustaceans and molluscs. These sedimentation processes ultimately resulting in the formation of limestone have taken place at various parts of the world. The local environment during the formation and compaction of the limestone has influenced its exact composition, thus defining the specification of each lot of limestone.

Several impurities are found in limestone. These can be ascribed to the incorporation of defined materials during the formation of limestone. The relative amount of each of these materials can differ considerably and determines the limestone's structure and colour.

- Clay: formed as the result of weathering / decomposition of Silicon oxide where the silicon is isomorphically replaced by Aluminium.
- Limonite / Haematite: Iron oxide formed as the result of weathering of iron-containing rock / stone.
- Glauconite: forms during reducing conditions and contains Potassium, Sodium, Iron, Aluminium and Silicon.
- Pyrite: the replacement mineral Iron sulphide was formed in acidic environments in the presence of organic material.
- Carbon / Bitumen: after sedimentary deposition of plant materials anaerobic decomposition of proteins, pigments, lipids and carbohydrates leads to the formation of carbon polymers.
- Sand: small particles of various minerals.

In addition to impurities listed here, also other elements like manganese or cobalt can be present and determine the pigmentation of the limestone.

Section A2 Identity of Active Substance

Annex Point IIA, II.

In the case of Dolomitic limestone, a high amount of $CaMg(CO_3)_2$ has been incorporated during the sedimentation. This type of limestone contains similar impurities as described above for the Calcium carbonate limestone.

The impurities described for limestone are contained during the production of Burnt (dolomitic) lime except for a large part of the Carbon-containing material that will be discharged as CO_2 during the burning process.

The characterisation of Lime products is complicated, as the methods to determine the different ingredients and impurities do often not directly determine the amount of real existing species, but rather the content expressed in equivalents of the respective oxides of elements of interest. For silicon, aluminium, iron, manganese, carbon and sulfur, the equivalent content referred to their oxides is typically stated for the characterisation of the Lime product.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	7 September 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **2.8** These are typical values. Analysis of actual products may vary. Manganese can also be present and is reported as Mn_3O_4 – but has not been listed here as the typical concentration is <0.1%. Detailed analysis, including screening for any heavy metal content should be provided at product authorisation. **2.9** Further details on the method of manufacture can be found in section A2.10 of the Dossier on Hydrated Lime. A typical analysis of 2 products is reproduced as confidential data in DOCIIIB. As no formulations of this substance are supplied, these analyses will be typical of the AI.
Conclusion	Acceptable
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection

			Official use only
2.8.1.1	**Common name**	Magnesium oxide	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Magnesium oxide	
2.8.3	**CAS-No**	1309-48-4	
2.8.4	**EC-No**	215-171-9	
2.8.5	**Other**	Not available	
	CIPAC		
2.8.6	**Molecular formula**	MgO	
2.8.7	**Structural formula**	$Mg{=}O$	
2.8.8	**Molecular mass**	40.30 g/mol	
	Concentration of the impurity or additive	< 5 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Carbon dioxide	
2.8.1.2	**Function**	Carbon dioxide is the calculation basis for expressing the content of Carbonate residues. CO_2 itself is not present. The sum of CO_2 and water content is “Loss on ignition”.	
2.8.2	**IUPAC name**	Carbon dioxide	
2.8.3	**CAS-No**	124-38-9	
2.8.4	**EC-No**	204-696-9	
2.8.5	**Other**	No other numbers available	
	CIPAC		
2.8.6	**Molecular formula**	CO_2	
2.8.7	**Structural formula**	$O=C=O$	
2.8.8	**Molecular mass**	44.01 g/mol	
	Concentration of the impurity or additive	< 7 %	

Section A2.8/03 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			Official use only
2.8.1.1	**Common name**	Silicon dioxide Please note that the content of Silicon is calculated and expressed as Silicon dioxide although Silicon is present in different forms of silicates in Hydrated lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Silicon dioxide	
2.8.3	**CAS-No**	11126-22-0	
2.8.4	**EC-No**	234-368-0	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SiO_2	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	60.08 g/mol	
	Concentration of the impurity or additive	< 5 % w/w	

Section A2.8/04 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Aluminium oxide Please note that the content of Aluminium is calculated and expressed as Aluminium oxide although Aluminium is present in different forms in Hydrated lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Aluminium oxide	
2.8.3	**CAS-No**	1344-28-1	
2.8.4	**EC-No**	215-691-6	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Al_2O_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	101.96 g/mol	
	Concentration of the impurity or additive	< 1 % w/w	

Section A2.8/05 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Iron oxide Please note that the content of Iron is calculated and expressed as Iron oxide although Iron is present in different forms in Hydrated lime.	
2.8.1.2	**Function**	Iron is a natural constituent of limestone	
2.8.2	**IUPAC name**	Iron oxide	
2.8.3	**CAS-No**	1345-25-1	X
2.8.4	**EC-No**	215-721-8	X
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Fe_2O_3	
2.8.7	**Structural formula**	Not applicable:	
2.8.8	**Molecular mass**	159.69 g/mol	
	Concentration of the impurity or additive	< 0.6 % w/w	

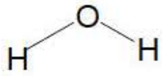
Section A2.8/06 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection		**Official use only**
2.8.1.1 Common name	Sulphur trioxide Please note that the content of Sulphur is calculated and expressed as Sulphur trioxide although Sulphur is present as sulphate.	
2.8.1.2 Function	Sulphur is a natural constituent of limestone	
2.8.2 IUPAC name	Sulphur trioxide	
2.8.3 CAS-No	7446-11-9	
2.8.4 EC-No	231-197-3	
2.8.5 Other CIPAC	No other numbers available	
2.8.6 Molecular formula	SO_3	
2.8.7 Structural formula	Not applicable	
2.8.8 Molecular mass	80.06 g/mol	
Concentration of the impurity or additive	< 0.6 % *w/w*	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Water	
2.8.1.2	**Function**	Natural constituent of the atmosphere. The sum of CO_2 and water content is “Loss on ignition”.	
2.8.2	**IUPAC name**	Water	
2.8.3	**CAS-No**	7732-18-5	
2.8.4	**EC-No**	231-791-2	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	H_2O	
2.8.7	**Structural formula**		
2.8.8	**Molecular mass**	18.0 g/mol	
	Concentration of the impurity or additive	< 0.5 %	

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	7 September 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **Impurity 5** – Iron **2.83/2.84 -** iron is present in various reacted forms but is reported for analysis as ferric oxide (Fe_2O_3).However, the CAS and EINECS numbers given refer to iron oxide (FeO). The CAS and EINECS numbers for ferric oxide are 1309-37-1 and 215-168-2. The additional impurity Manganese is mentioned (calculated and expressed as Mn_3O_4) It has not been listed as an impurity in 2.8 because the typical purity is <0.1% (DocIII A4.1/01). The products consist only of the AI as manufactured and typical analyses for 2 of these are given in Doc IIIB confidential.
Conclusion	Acceptable. Due to the nature of the active (derived from naturally occurring limestone) the impurities will be a mixture of inorganic salts and minerals in various forms (eg simple or mixed oxides &/or hydroxides of the elements stated in section A2 2.7) and expressing them in the normal format is difficult. As the applicant states it is practice used by the industry to run elemental analysis but express the composition as oxide equivalents as simple analytical methods used cannot determine the form in which the element is present. The UK CA therefore concludes that this approach is acceptable.
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2 Identity of Active Substance

Annex Point IIA, II.

Subsection (Annex Point)			**Official use only**
2.1	**Common name (IIA2.1)**	The substance name as provided in ESIS is Calcium magnesium tetrahydroxide. In this dossier, Calcium magnesioum tetrahydroxide is referred to as "Hydrated dolomitic lime". Calce spenta, Calce idrata, gracello, Idrato di calcio, Idrossido di calcio. Please note that this list may not be exhaustive.	
2.2	**Chemical name (IIA2.2)**	Calcium magnesium tetrahydroxide	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable: manufacturers have not assigned development code numbers.	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	39445-23-3	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.2	**EC-No**	254-454-1	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.3	**Other**	No other numbers available	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	Hydrated dolomitic lime does not consist of discrete molecules, but crystallises in a 3-dimensional ion lattice. Furthermore, the Ca/Mg ratio is not constant for different sources of Limestone (precursor for Hydrated dolomitic lime). In this dossier, $Ca(OH)_2 \cdot Mg(OH)_2$ is used as a "molecular formula" for Hydrated dolomitic lime.	
2.5.2	**Structural formula**	Not relevant. See above.	
2.5.3	**Molecular mass**	132.43 g/mol	
2.6	**Method of manufacture of the**	Calcium magnesium tetrahydroxide is generated by addition of water to Burnt dolomitic lime. Hydrolysis results in the generation of	

Section A2 Identity of Active Substance

Annex Point IIA, II.

active substance (IIA2.1)

Hydrated dolomitic lime and heat.

$CaO \cdot MgO + H_2O \rightarrow Ca(OH)_2 \cdot Mg(OH)_2$ + heat

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

General remark:

By consent within the lime industry, the composition of lime is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides. Please note that the analytical methods used for the determination of the composition of lime products do not allow for the determination of the specific forms in which their constituents occur in lime.

The contents of Ca and Mg are expressed as $Ca(OH)_2$ and $Mg(OH)_2$., which are the forms actually present in Hydrated dolomitic lime.

The contents of the other constituents are calculated and expressed as oxides:

- The content of Silicon (Si) is expressed as SiO_2,
- the content of Aluminium (Al) as Al_2O_3,
- the content of Iron (Fe) as F_2O_3,
- the content of Manganese (Mn) as Mn_3O_4, and
- the Sulphur (S) content as SO_3.

However, these indicated oxides are not identical with the actual forms in which these elements are present in Hydrated dolomitic lime:

- Silicon (Si) can be present in the form of $Ca_2(SiO_4)$, Ca_2Mg_2 (Si_2O_7) or in other forms.
- Aluminium (Al) can be present in the form of $Ca_3Al_2O_6$ (Dicalciumaluminate) or in other forms.
- Iron (Fe) can be present in the form of $Ca_4Al_2Fe_2O_{10}$ (Braunmuellerit), $Ca_2Fe_2O_5$ (Dicalciumferrit), or other forms.
- Manganese (Mn) can be present as Ca_2MnO_4 (Dicalciummanganate) or in other forms.
- Sulphur (S) is present as sulphates.

The loss on ignition comprises water (from $Ca(OH)_2$ and $Mg(OH)_2$, formed during water absorption of CaO and MgO) and CO_2 (from carbonate residues not transformed to oxides during the burning of limestone or from re-carbonisation of CaO and MgO due to contact of Hydrated dolomitic lime to atmospheric CO_2).

The purity of Hydrated dolomitic lime from the producers lies in the following range (% w/w): 85 – 98 %.

The value provides the content of Ca and Mg expressed as $Ca(OH)_2$ and $Mg(OH)_2$. Typical values for $Mg(OH)_2$ in Hydrated dolomitic

Section A2 Identity of Active Substance

Annex Point IIA, II.

lime are in the range of 25 – 39 %.

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

Loss on ignition (H_2O and CO_2)	< 9 % (< 2 % H_2O, < 7 % CO_2)
Silicon (Si) (expressed as SiO_2)	< 3 %
Aluminium (Al) (expressed as Al_2O_3)	< 1 %
Iron (Fe) (expressed as Fe_2O_3)	< 0.6 %
Sulphur (S) (expressed as SO_3)	< 0.6 %

2.8.1 Isomeric composition

There are no isomers.

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)

The source for Calcium magnesium tetrahydroxide (Hydrated dolomitic lime) is Calcium magnesium oxide (Burnt dolomitic lime) that was produced by heating Dolomitic limestone, a natural material consisting predominantly of Calcium magnesium carbonate. For a detailed description of the production process see section 2.10.1.1.

The large variation in impurities in limestone can be explained as follows:

Limestone is a natural material resulting from sedimentation processes in shallow waters. Evaporation leads to the formation of supersaturated solutions where minerals like Calcite and Dolomite precipitate and fall out. Organogenic or zoogenic limestone formed as a result of the sedimentation of shells from crustaceans and molluscs. These sedimentation processes ultimately resulting in the formation of limestone have taken place at various parts of the world. The local environment during the formation and compaction of the limestone has influenced its exact composition, thus defining the specification of each lot of limestone.

Several impurities are found in limestone. These can be ascribed to the incorporation of defined materials during the formation of limestone. The relative amount of each of these materials can differ considerably and determines the limestone's structure and colour.

- Clay: formed as the result of weathering / decomposition of Silicon oxide where the silicon is isomorphically replaced by Aluminium.
- Limonite / Haematite: Iron oxide formed as the result of weathering of iron-containing rock / stone.
- Glauconite: forms during reducing conditions and contains Potassium, Sodium, Iron, Aluminium, and Silicon.
- Pyrite: the replacement mineral Iron sulphide was formed in

Section A2 Identity of Active Substance

Annex Point IIA, II.

acidic environments in the presence of organic material.

- Carbon / Bitumen: after sedimentary deposition of plant materials anaerobic decomposition of proteins, pigments, lipids and carbohydrates leads to the formation of carbon polymers.
- Sand: small particles of various minerals.

In addition to impurities listed here, also other elements like manganese or cobalt can be present and determine the pigmentation of the limestone.

In the case of Dolomitic limestone, a high amount of $CaMg(CO_3)_2$ has been incorporated during the sedimentation. This type of limestone contains similar impurities as described above for the Calcium carbonate limestone.

The impurities described for limestone are contained during the production of Burnt dolomitic lime except for a large part of the Carbon-containing material that will be discharged as CO_2 during the burning process.

The characterisation of Lime products is complicated, as the methods to determine the different ingredients and impurities do often not directly determine the amount of real existing species, but rather the content expressed in equivalents of the respective oxides of elements of interest. For silicon, aluminium, iron, manganese, carbon and sulfur, the equivalent content referred to their oxides is typically stated for the characterisation of the Lime product.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 August 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **2.2** CAS uses the name calcium magnesium tetrahydroxide and refers to a specific calcium/magnesium ratio. The calcium/magnesium ratio in this AI will vary because of the natural origin of the material **2.6** Further details on the method of manufacture can be found in section A2.10 **2.8** Manganese can also be present and is reported as Mn_3O_4 – but has not been listed here as the typical concentration is <0.1% Detailed analysis, including screening for any heavy metal content should be provided at product authorisation. A typical analysis of a Hydrated dolomitic lime product is reproduced as confidential data in DOCIIIB. As no formulations of this substance are supplied, these analyses will be typical of the AI.
Conclusion	Acceptable
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Carbon dioxide	
2.8.1.2	**Function**	Carbon dioxide is the calculation basis for expressing the content of Carbonate residues. CO_2 itself is not present. The sum of CO_2 and water content is "Loss on ignition".	
2.8.2	**IUPAC name**	Carbon dioxide	
2.8.3	**CAS-No**	124-38-9	
2.8.4	**EC-No**	204-696-9	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	CO_2	
2.8.7	**Structural formula**	$O=C=O$	
2.8.8	**Molecular mass**	44.01 g/mol	
	Concentration of the impurity or additive	< 7 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Silicon dioxide Please note that the content of Silicon is calculated and expressed as Silicon dioxide although Silicon is present in different forms of silicates in Hydrated dolomitic lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Silicon dioxide	
2.8.3	**CAS-No**	11126-22-0	
2.8.4	**EC-No**	234-368-0	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SiO_2	
2.8.7	**Structural formula**	Not applicable: Please note that the content of Silicon is calculated and expressed as Silicon dioxide although Silicon is present in different forms of silicates in Hydrated dolomitic lime.	
2.8.8	**Molecular mass**	60.08 g/mol	
	Concentration of the impurity or additive	< 3 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Aluminium oxide Please note that the content of Aluminium is calculated and expressed as Aluminium oxide although Aluminium is present in different forms in Hydrated dolomitic lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Aluminium oxide	
2.8.3	**CAS-No**	1344-28-1	
2.8.4	**EC-No**	215-691-6	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Al_2O_3	
2.8.7	**Structural formula**	Not applicable: Please note that the content of Aluminium is calculated and expressed as Aluminium oxide although Aluminium is present in different forms in Hydrated dolomitic lime.	
2.8.8	**Molecular mass**	101.96 g/mol	
	Concentration of the impurity or additive	< 1 %	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Iron oxide Please note that the content of Iron is calculated and expressed as Iron oxide although Iron is present in different forms in Hydrated dolomitic lime.	
2.8.1.2	**Function**	Iron is a natural constituent of limestone	
2.8.2	**IUPAC name**	Iron oxide	
2.8.3	**CAS-No**	1345-25-1	X
2.8.4	**EC-No**	215-721-8	X
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Fe_2O_3	
2.8.7	**Structural formula**	Not applicable: Please note that the content of Iron is calculated and expressed as Iron oxide although Iron is present in different forms in Hydrated dolomitic lime.	
2.8.8	**Molecular mass**	159.69 g/mol	
	Concentration of the impurity or additive	< 0.6 %	

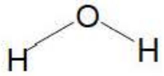
Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Sulphur trioxide Please note that the content of Sulphur is calculated and expressed as Sulphur trioxide although Sulphur is present as sulphate.	
2.8.1.2	**Function**	Sulphur is a natural constituent of limestone	
2.8.2	**IUPAC name**	Sulphur trioxide	
2.8.3	**CAS-No**	7446-11-9	
2.8.4	**EC-No**	231-197-3	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SO_3	
2.8.7	**Structural formula**	Not applicable: Please note that the content of Sulphur is calculated and expressed as Sulphur trioxide although Sulphur is present as sulphate.	
2.8.8	**Molecular mass**	80.06 g/mol	
	Concentration of the impurity or additive	< 0.6 %	

Section A2.8 Identity of impurities and additives (active substance)

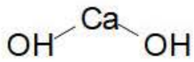
Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Water	
2.8.1.2	**Function**	Residue from the slaking process. The sum of CO_2 and water content is "Loss on ignition".	
2.8.2	**IUPAC name**	Water	
2.8.3	**CAS-No**	7732-18-5	
2.8.4	**EC-No**	231-791-2	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	H_2O	
2.8.7	**Structural formula**		
2.8.8	**Molecular mass**	18.0 g/mol	
	Concentration of the impurity or additive	< 2 %	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 August 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **Impurity 4** – Iron **2.83/2.84 -** iron is present in various reacted forms but is reported for analysis as ferric oxide (Fe_2O_3).However, the CAS and EINECS numbers given refer to iron oxide (FeO). The CAS and EINECS numbers for ferric oxide are 1309-37-1 and 215-168-2. The additional impurity Manganese is mentioned (calculated and expressed as Mn_3O_4) It has not been listed as an impurity in 2.8 because the typical purity is <0.1% (DocIII A4.1/01). The products consist only of the AI as manufactured and a typical analysis is given in Doc IIIB confidential.
Conclusion	Acceptable. Due to the nature of the active (derived from naturally occurring limestone) the impurities will be a mixture of inorganic salts and minerals in various forms (eg simple or mixed oxides &/or hydroxides of the elements stated in section A2 2.7) and expressing them in the normal format is difficult. As the applicant states it is practice used by the industry to run elemental analysis but express the composition as oxide equivalents as simple analytical methods used cannot determine the form in which the element is present. The UK CA therefore concludes that this approach is acceptable.
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2 Identity of Active Substance

Annex Point IIA, II.

Subsection (Annex Point)			**Official use only**
2.1	**Common name (IIA2.1)**	The substance name as provided in ESIS is Calcium dihydroxide. In this dossier, Calcium dihydroxide is referred to as "Hydrated lime". The following synonyms are found in literature: Weißkalkhydrat, Kalkhydrat, Löschkalk, Gelöschter kalk, Calce apagada, Calce hidratada, Calce idrata, Calce spenta, Calcium hydroxide, Calcium hydrate, Calciumhydroxid, Chaux hydratée, Chaux éteinte, Fleur de chaux, Chaux blutée, Hydrate de calcium, Chaux hydratée, Hydroxide de calcium, Hydrate de chaux, Fiore di calce, Slaked lime, Hydratkalk, Hydraulischer kalk, Kalk hydraad, Idrossido di calcio, Calce idratato, Kalkschlamm, Lime, Lime water, Læsket kalk, Wasserkalkhydrat. Please note that this list may not be exhaustive.	
2.2	**Chemical name (IIA2.2)**	Calcium dihydroxide	x
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable: manufacturers have not assigned development code numbers.	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	1305-62-0	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.2	**EC-No**	215-137-3	
	Isomer 1	There are no isomers.	
	Isomer n		
2.4.3	**Other**	No other numbers available	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$Ca(OH)_2$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	74.09 g/mol	
2.6	**Method of manufacture of the active substance**	Calcium dihydroxide is generated by addition of water to Burnt lime. Hydrolysis results in the generation of Hydrated lime and heat.	x

Section A2 Identity of Active Substance

Annex Point IIA, II.

(IIA2.1)

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

General remark:

By consent within the lime industry, the composition of lime is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides. Please note that the analytical methods used for the determination of the composition of lime do not allow for the determination of the specific forms in which their constituents occur in lime.

The content of Ca is expressed as $Ca(OH)_2$, which is the form actually present in Hydrated lime, and additionally as CaO.

The content of Mg is only expressed as MgO though the form in which it is present in Hydrated lime is $Mg(OH)_2$.

The contents of the other constituents are calculated and expressed as oxides:

- The content of Silicon (Si) is expressed as SiO_2,
- the content of Aluminium (Al) as Al_2O_3,
- the content of Iron (Fe) as F_2O_3,
- the content of Manganese (Mn) as Mn_3O_4, and
- the Sulphur (S) content as SO_3.

However, these indicated oxides are not identical with the actual forms in which these elements are present in Hydrated lime:

- Silicon (Si) can be present in the form of $Ca_2(SiO_4)$, $Ca_2Mg_2(Si_2O_7)$ or in other forms.
- Aluminium (Al) can be present in the form of $Ca_3Al_2O_6$ (Dicalciumaluminate) or in other forms.
- Iron (Fe) can be present in the form of $Ca_4Al_2Fe_2O_{10}$ (Braunmuellerit), $Ca_2Fe_2O_5$ (Dicalciumferrit), or other forms.
- Manganese (Mn) can be present as Ca_2MnO_4 (Dicalciummanganate) or in other forms.
- Sulphur (S) is present as sulphates.

The loss on ignition comprises water (from $Ca(OH)_2$, formed during water absorption of CaO) and CO_2 (from carbonate residues not transformed to oxides during the burning of limestone or from re-carbonisation of CaO due to contact of the product to atmospheric CO_2).

Section A2 Identity of Active Substance

Annex Point IIA, II.

The purity of Hydrated lime from the producers lies in the range (% w/w) of 80 – 98 %

The value provides the content of Ca expressed as $Ca(OH)_2$.

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

Magnesium oxide (MgO)	< 5 %	
Loss on ignition (H_2O and CO_2)	< 9 % (< 2 % H_2O, < 7 % CO_2)	
Silicon (Si) (expressed as SiO_2)	< 5 %	
Aluminium (Al) (expressed as Al_2O_3)	< 1 %	
Iron (Fe) (expressed as Fe_2O_3)	< 0.6 %	
Sulphur (S) (expressed as SO_3)	< 0.6 %	x

2.8.1 Isomeric composition

There are no isomers.

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)

The source for Calcium hydroxide (Hydrated lime) is Calcium oxide (Burnt lime) that was produced by heating limestone, a natural material consisting predominantly of Calcium carbonate. For a detailed description of the production process see section 2.10.1.1.

The large variation in impurities in limestone can be explained as follows:

Limestone is a natural material resulting from sedimentation processes in shallow waters. Evaporation leads to the formation of supersaturated solutions where minerals like Calcite and Dolomite precipitate and fall out. Organogenic or zoogenic limestone formed as a result of the sedimentation of shells from crustaceans and molluscs. These sedimentation processes ultimately resulting in the formation of limestone have taken place at various parts of the world. The local environment during the formation and compaction of the limestone has influenced its exact composition, thus defining the specification of each lot of limestone.

Several impurities are found in limestone. These can be ascribed to the incorporation of defined materials during the formation of limestone. The relative amount of each of these materials can differ considerably and determines the limestone's structure and colour.

- Clay: formed as the result of weathering / decomposition of Silicon oxide where the silicon is isomorphically replaced by Aluminium.
- Limonite / Haematite: Iron oxide formed as the result of weathering of iron-containing rock / stone.
- Glauconite: forms during reducing conditions and contains Potassium, Sodium, Iron, Aluminium and Silicon.
- Pyrite: the replacement mineral Iron sulphide was formed in

Section A2 Identity of Active Substance

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acidic environments in the presence of organic material.

- Carbon / Bitumen: after sedimentary deposition of plant materials anaerobic decomposition of proteins, pigments, lipids and carbohydrates leads to the formation of carbon polymers.
- Sand: small particles of various minerals.

In addition to impurities listed here, also other elements like manganese or cobalt can be present and determine the pigmentation of the limestone.

In the case of Dolomitic limestone, a high amount of $CaMg(CO_3)_2$ has been incorporated during the sedimentation. This type of limestone contains similar impurities as described above for the Calcium carbonate limestone.

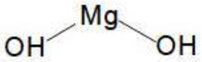
The impurities described for limestone are contained during the production of Burnt (dolomitic) lime except for a large part of the Carbon-containing material that will be discharged as CO_2 during the burning process.

The characterisation of Lime products is complicated, as the methods to determine the different ingredients and impurities do often not directly determine the amount of real existing species, but rather the content expressed in equivalents of the respective oxides of elements of interest. For silicon, aluminium, iron, carbon and sulphur, the equivalent content referred to their oxides is typically stated for the characterisation of the Lime product.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	18 June 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **2.2** CAS uses the name calcium hydroxide. **2.6** Further details on the method of manufacture can be found in section A2.10. **2.8** Manganese can also be present and is reported as Mn_3O_4 – but has not been listed here as the typical concentration is <0.1%. Detailed analysis, including screening for any heavy metal content should be provided at product authorisation. A typical analysis of 2 products is reproduced as confidential data in DOCIIIB. As no formulations of this substance are supplied, these analyses will be typical of the AI.
Conclusion	Acceptable
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2.8/01 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Magnesium oxide	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Magnesium oxide The content of Mg is calculated and expressed as MgO. However, the form in which Mg is present in Hydrated lime is as Mg(OH)$_2$.	
2.8.3	**CAS-No**	MgO: 1309-48-4 Mg(OH)$_2$: 1309-42-8	
2.8.4	**EC-No**	MgO: 215-171-9 Mg(OH)$_2$:215-170-3	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	The content of Mg is calculated and expressed as MgO. However, the form in which Mg is present in Hydrated lime is as Mg(OH)$_2$.	
2.8.7	**Structural formula**		
2.8.8	**Molecular mass**	MgO: 40.30 g/mol	X
	Concentration of the impurity or additive	< 5 % w/w	

Section A2.8/02 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			Official use only
2.8.1.1	**Common name**	Carbon dioxide	
2.8.1.2	**Function**	Carbon dioxide is the calculation basis for expressing the content of Carbonate residues. CO_2 itself is not present. The sum of CO_2 and water content is "Loss on ignition".	
2.8.2	**IUPAC name**	Carbon dioxide	
2.8.3	**CAS-No**	124-38-9	
2.8.4	**EC-No**	204-696-9	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	CO_2	
2.8.7	**Structural formula**	$O=C=O$	
2.8.8	**Molecular mass**	44.01 g/mol	
	Concentration of the impurity or additive	< 7 % w/w	

Section A2.8/03 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Silicon dioxide Please note that the content of Silicon is calculated and expressed as Silicon dioxide although Silicon is present in different forms of silicates in Hydrated lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Silicon dioxide	
2.8.3	**CAS-No**	11126-22-0	
2.8.4	**EC-No**	234-368-0	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SiO_2	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	60.08 g/mol	
	Concentration of the impurity or additive	< 5 % w/w	

Section A2.8/04 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Aluminium oxide Please note that the content of Aluminium is calculated and expressed as Aluminium oxide although Aluminium is present in different forms in Hydrated lime.	
2.8.1.2	**Function**	Natural constituent of limestone	
2.8.2	**IUPAC name**	Aluminium oxide	
2.8.3	**CAS-No**	1344-28-1	
2.8.4	**EC-No**	215-691-6	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Al_2O_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	101.96 g/mol	
	Concentration of the impurity or additive	< 1 % w/w	

Section A2.8/05 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			Official use only
2.8.1.1	**Common name**	Iron oxide Please note that the content of Iron is calculated and expressed as Iron oxide although Iron is present in different forms in Hydrated lime.	
2.8.1.2	**Function**	Iron is a natural constituent of limestone	
2.8.2	**IUPAC name**	Iron oxide	
2.8.3	**CAS-No**	1345-25-1	X
2.8.4	**EC-No**	215-721-8	X
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	Fe_2O_3	
2.8.7	**Structural formula**	Not applicable:	
2.8.8	**Molecular mass**	159.69 g/mol	
	Concentration of the impurity or additive	< 0.6 % w/w	

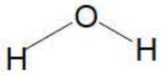
Section A2.8/06 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Sulphur trioxide Please note that the content of Sulphur is calculated and expressed as Sulphur trioxide although Sulphur is present as sulphate.	
2.8.1.2	**Function**	Sulphur is a natural constituent of limestone	
2.8.2	**IUPAC name**	Sulphur trioxide	
2.8.3	**CAS-No**	7446-11-9	
2.8.4	**EC-No**	231-197-3	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	SO_3	
2.8.7	**Structural formula**	Not applicable	
2.8.8	**Molecular mass**	80.06 g/mol	
	Concentration of the impurity or additive	< 0.6 % *w/w*	

Section A2.8/07 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			**Official use only**
2.8.1.1	**Common name**	Water	
2.8.1.2	**Function**	Residue from the slaking process. The sum of CO_2 and water content is "Loss on ignition".	
2.8.2	**IUPAC name**	Water	
2.8.3	**CAS-No**	7732-18-5	
2.8.4	**EC-No**	231-791-2	
2.8.5	**Other** CIPAC	No other numbers available	
2.8.6	**Molecular formula**	H_2O	
2.8.7	**Structural formula**		
2.8.8	**Molecular mass**	18.0 g/mol	
	Concentration of the impurity or additive	< 2 % w/w	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	18 June 2010
Materials and methods	The applicant's version is considered acceptable with the following comments; **Impurity 1** – Magnesium **2.8.8** – For consistency the molecular mass of $Mg(OH)_2$ should also be reported; 58.32 g/mol. **Impurity 5** – Iron **2.83/2.84 -** iron is present in various reacted forms but is reported for analysis as ferric oxide (Fe_2O_3).However, the CAS and EINECS numbers given refer to iron oxide (FeO). The CAS and EINECS numbers for ferric oxide are 1309-37-1 and 215-168-2. The additional impurity Manganese is mentioned (calculated and expressed as Mn_3O_4) It has not been listed as an impurity in 2.8 because the typical purity is <0.1% (DocIII A4.1/01). The products consist only of the AI as manufactured and typical analyses for 2 of these are given in Doc IIIB confidential.
Conclusion	Acceptable. Due to the nature of the active (derived from naturally occurring limestone) the impurities will be a mixture of inorganic salts and minerals in various forms (eg simple or mixed oxides &/or hydroxides of the elements stated in section A2 2.7) and expressing them in the normal format is difficult. As the applicant states it is practice used by the industry to run elemental analysis but express the composition as oxide equivalents as simple analytical methods used cannot determine the form in which the element is present. The UK CA therefore concludes that this approach is acceptable.
Reliability	N/A
Acceptability	The applicant's version is considered acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2.10.2 Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

Subsection 2.10

Official use only

2.10.2 Environmental exposure towards active substance

In the European Union, the Integrated Pollution Prevention and Control (IPPC) Directive requires the operator to use the "Best Available Technique" (BAT) to protect the environment. This includes the concept that "the cost should not be excessive". The term technique covers both technology and operating/maintenance practices. Thus, a new plant is expected to comply with BAT, which will change as advances are made. An existing plant will be required to up-grade to the BAT (which may differ from that for a new plant) after an appropriate period.

2.10.2.1 Production

(i) Releases into water

Aqueous discharges from limestone quarrying and processing do not present a significant environmental hazard. The most common contaminant is suspended matter, which can be removed by settling in sumps or slurry ponds.

Discharges from lime production and processing include drainage and effluent from wet scrubbers. Such effluents are generally of low volume. They should be processed to meet the discharge requirements for pH and biological oxygen demand.

(ii) Releases into air

Quarrying:

In the quarrying process, drilling is the main potential source of dust. The preferred method for de-dusting the air carrying pulverised rock up the hole is the use of bag filters. Dust emission from blasting is controlled by sealing the top of the holes with "stemming".

Limestone Processing and Storage:

Crushing, screening and conveying of limestone can give rise to dust. Dust emission from one of these operations should be prevented by enclosure or extraction. Bag filters are generally favoured. Belt conveyors should be partially or totally enclosed to control wind-whip or water should be added to control dust.

Production, Processing and Storage of Quicklime:

To prevent dust emission during production of quicklime, different dust collecting systems are used, depending on dust concentration and composition, which can vary depending on the feedstone and the kiln design. Processing and storage of quicklime should be performed in closed systems or by using suitable dust extraction methods.

Production and Storage of Hydrated Lime:

The exhaust gas of from hydration of quicklime to hydrated lime is the main source of dust emission from the process. As the gas consists principally of steam, dust can be removed by using wet scrubbers. Hydrated lime should be stored in closed bunkers fitted with filters.

Production of Milk of Lime:

Slaking quicklime is not an inherently dusty operation and the

Section A2.10.2
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

volume of gaseous effluent is small. In addition it is a good practice to keep slakers under suction to ensure that dust and steam do not escape.

Vehicle loading:

Loading of Limestone into road vehicles should be done in such way as to minimise the amount of airborne dust generated. The vehicle should be sheeted before leaving the site.

(iii) Waste disposal

The wastes from quarrying are generally of clay or limestone and can, therefore, be disposed to land.

Wastes from lime production and processing contain alkaline components such as Calcium oxide and hydroxide. They may contain slightly soluble salts, such as Calcium sulphate, as well as insoluble Calcium carbonate, clay and fuel ash related products. Water draining through "lime tips" becomes alkaline and precipitated carbonate hardness in ground waters. As a minimum requirement, lime tips should, therefore, be built on sites which do not have any significant natural springs and the surface layer be contoured so that it is self-draining.

2.10.2.2 Intended use(s)

Affected compartment(s):

A level III fugacity modelling according to Mackay was conducted using EPI suite v.3.12. According to this model calculation, the distribution into the environment is as follows:

water	38.9 %
sediment	0.07 %
air	0.0032 %
soil	61 %

Predicted concentration in the affected compartment(s)

Sewage sludge or manure treated with Burnt lime, Burnt dolomitic lime or the respective hydroxides can be applied to agricultural land as a replacement of agricultural liming. Burnt lime and Burnt dolomitic lime form the respective hydroxides immediately upon contact with water, i.e. when mixed into the sewage sludge or manure. During the storage of treated sewage sludge or manure, the hydroxides are partly transformed to calcium or magnesium carbonates. Because the storage time can be short (hours), as a worst case approach it is assumed that no carbonisation occurs during storage. Consequently, in the sewage sludge or manure applied to land, lime is only present in the hydrated form.

As a worst case scenario, it is assumed that sewage sludge at an application rate of 5000 kg (dry matter)/ ha is applied to agricultural land and that the sewage sludge has been treated with burnt lime/ burnt dolomitic lime at a maximum application rate. Application rate is equal to dry matter multiplied by 1.2.

After application to agricultural land, the lime treated manure or sewage sludge is incorporated into the upper twenty centimetres of the soil. The hydrated lime is transformed into the respective carbonates with an estimated DT_{50} of 3 days.

Run-off is considered to be the major route by which surface waters

Section A2.10.2 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

	get exposed. The PEC_{sw} was calculated using the German model EXPOSIT 2.0c.
water	The initial PEC_{sw} of hydrated lime/ hydrated dolomitic lime due to a single run-off event three days after application to bare soil were calculated to be 17.45 mg/L, 14.18 mg/L and 5.67 mg/L for buffer zones of 0 m, 5 m and 10 m, respectively. This calculation refers to a maximum application rate of burnt lime/ burnt dolomitic lime to sewage sludge (120% of dry matter of sewage sludge applied as lime). As the application rates for burnt lime are higher than those for hydrated lime and because burnt lime is transformed to hydrated lime upon contact with water, this calculation covers as a worst case approach also the hydrated forms. In natural water with a medium hardness ($c(HCO_3^-) = 100$ mg/L = 1.64 mmol/L) the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. The carbonate anions will not contribute to a HCO_3^- / CO_3^{2-} buffer system, but form $CaCO_3$ by reaction with Ca^{2+}.
sediment	As described under point 8.3.4.1, in natural waters the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. CO_3^{2-} forms $CaCO_3$ by reacting with Ca^{2+} The calcium carbonate precipitates and deposits on or in the sediment. Calcium carbonate is of low solubility and a constituent of natural soils and has no biocidal activity.
air	All lime variants are not volatile. Their respective vapour pressures can be assumed to be below the value of 10^{-5} Pa.
soil	The initial predicted environmental concentrations of hydrated lime/ hydrated dolomitic lime in the top 0-20 cm layer of the soil were calculated to be 1067.6 mg/kg assuming a deposition rate of 100 %. Actual and time weighted average PEC values for hydrated lime/ hydrated dolomitic lime decrease to < 0.0001 and 46.2 mg/kg after 100 days, respectively.

Section A2.10.2 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25/09/2009
Materials and methods	Applicant's version is accepted, noting that within the UK CA document II-B additional calculations and assumptions details the final values accepted for risk assessment purposes.
Conclusion	Adopt Applicant's version noting statement above.
Reliability	N/A
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A2.10.1: Workplace exposure / Inhalation exposure

Exposure scenario	**Workplace operation**	**PPE**	**Year(s) of measurement**	**Number of measurements**	**Type of measurements**	**Exposure concentration**
Production	**In the confidential part of the dossier a table is included which provides a "Consolidation on Companies' monitoring data available on dust inhalation of workers in lime production plants".**					
Formulation	Not relevant because Lime is not formulated into biocidal products.					
Application Scenarios	Use 1 (treatment of sewage sludge): manual and automated mixing and loading ; automated application Use 2 (treatment of manure and other digestive tract contents): automated mixing and loading and automated application	Use 1: protective clothing including gloves, goggles and mask during manual mixing and loading Use 2: As the application is an automated process, no protective equipment is needed. Due to possible release of gases form treated slurry, masks are recommended during application.	n.a.	n.a.	n.a.	Calculated values from Doc. IIB, chapter 8.2.2: **Inhalation:** Use 1 and 2: 0.023 mg/kg bw per day **Dermal:** Use 1 and 2: 0.049 mg/kg bw per day

Section A2.10.2 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

Subsection 2.10

Official use only

2.10.2 Environmental exposure towards active substance

In the European Union, the Integrated Pollution Prevention and Control (IPPC) Directive requires the operator to use the "Best Available Technique" (BAT) to protect the environment. This includes the concept that "the cost should not be excessive". The term technique covers both technology and operating/maintenance practices. Thus, a new plant is expected to comply with BAT, which will change as advances are made. An existing plant will be required to up-grade to the BAT (which may differ from that for a new plant) after an appropriate period.

2.10.2.1 Production

(i) Releases into water

Aqueous discharges from limestone quarrying and processing do not present a significant environmental hazard. The most common contaminant is suspended matter, which can be removed by settling in sumps or slurry ponds.

Discharges from lime production and processing include drainage and effluent from wet scrubbers. Such effluents are generally of low volume. They should be processed to meet the discharge requirements for pH and biological oxygen demand.

(ii) Releases into air

Quarrying:

In the quarrying process, drilling is the main potential source of dust. The preferred method for de-dusting the air carrying pulverised rock up the hole is the use of bag filters. Dust emission from blasting is controlled by sealing the top of the holes with "stemming".

Limestone Processing and Storage:

Crushing, screening and conveying of limestone can give rise to dust. Dust emission from one of these operations should be prevented by enclosure or extraction. Bag filters are generally favoured. Belt conveyors should be partially or totally enclosed to control wind-whip or water should be added to control dust.

Production, Processing and Storage of Quicklime:

To prevent dust emission during production of quicklime, different dust collecting systems are used, depending on dust concentration and composition, which can vary depending on the feedstone and the kiln design. Processing and storage of quicklime should be performed in closed systems or by using suitable dust extraction methods.

Production and Storage of Hydrated Lime:

The exhaust gas of from hydration of quicklime to hydrated lime is the main source of dust emission from the process. As the gas consists principally of steam, dust can be removed by using wet scrubbers. Hydrated lime should be stored in closed bunkers fitted with filters.

Production of Milk of Lime:

Slaking quicklime is not an inherently dusty operation and the

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volume of gaseous effluent is small. In addition it is a good practice to keep slakers under suction to ensure that dust and steam do not escape.

Vehicle loading:

Loading of Limestone into road vehicles should be done in such way as to minimise the amount of airborne dust generated. The vehicle should be sheeted before leaving the site.

(iii) Waste disposal

The wastes from quarrying are generally of clay or limestone and can, therefore, be disposed to land.

Wastes from lime production and processing contain alkaline components such as Calcium oxide and hydroxide. They may contain slightly soluble salts, such as Calcium sulphate, as well as insoluble Calcium carbonate, clay and fuel ash related products. Water draining through "lime tips" becomes alkaline and precipitated carbonate hardness in ground waters. As a minimum requirement, lime tips should, therefore, be built on sites which do not have any significant natural springs and the surface layer be contoured so that it is self-draining.

2.10.2.2 Intended use(s)

Affected compartment(s):

A level III fugacity modelling according to Mackay was conducted using EPI suite v.3.12. According to this model calculation, the distribution into the environment is as follows:

water	38.9 %
sediment	0.07 %
air	0.0032 %
soil	61 %

Predicted concentration in the affected compartment(s)

Sewage sludge or manure treated with Burnt lime, Burnt dolomitic lime or the respective hydroxides can be applied to agricultural land as a replacement of agricultural liming. Burnt lime and Burnt dolomitic lime form the respective hydroxides immediately upon contact with water, i.e. when mixed into the sewage sludge or manure. During the storage of treated sewage sludge or manure, the hydroxides are partly transformed to calcium or magnesium carbonates. Because the storage time can be short (hours), as a worst case approach it is assumed that no carbonisation occurs during storage. Consequently, in the sewage sludge or manure applied to land, lime is only present in the hydrated form.

As a worst case scenario, it is assumed that sewage sludge at an application rate of 5000 kg (dry matter)/ ha is applied to agricultural land and that the sewage sludge has been treated with burnt lime/ burnt dolomitic lime at a maximum application rate. Application rate is equal to dry matter multiplied by 1.2.

After application to agricultural land, the lime treated manure or sewage sludge is incorporated into the upper twenty centimetres of the soil. The hydrated lime is transformed into the respective carbonates with an estimated DT_{50} of 3 days.

Run-off is considered to be the major route by which surface waters

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	get exposed. The PEC_{sw} was calculated using the German model EXPOSIT 2.0c.
water	The initial PEC_{sw} of hydrated lime/ hydrated dolomitic lime due to a single run-off event three days after application to bare soil were calculated to be 17.45 mg/L, 14.18 mg/L and 5.67 mg/L for buffer zones of 0 m, 5 m and 10 m, respectively. This calculation refers to a maximum application rate of burnt lime/ burnt dolomitic lime to sewage sludge (120% of dry matter of sewage sludge applied as lime). As the application rates for burnt lime are higher than those for hydrated lime and because burnt lime is transformed to hydrated lime upon contact with water, this calculation covers as a worst case approach also the hydrated forms. In natural water with a medium hardness ($c(HCO_3^-) = 100$ mg/L = 1.64 mmol/L) the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. The carbonate anions will not contribute to a HCO_3^- /CO_3^{2-} buffer system, but form $CaCO_3$ by reaction with Ca^{2+}.
sediment	As described under point 8.3.4.1, in natural waters the hydroxide ions react with HCO_3^- to form water and CO_3^{2-}. CO_3^{2-} forms $CaCO_3$ by reacting with Ca^{2+} The calcium carbonate precipitates and deposits on or in the sediment. Calcium carbonate is of low solubility and a constituent of natural soils and has no biocidal activity.
air	All lime variants are not volatile. Their respective vapour pressures can be assumed to be below the value of 10^{-5} Pa.
soil	The initial predicted environmental concentrations of hydrated lime/ hydrated dolomitic lime in the top 0-20 cm layer of the soil were calculated to be 1067.6 mg/kg assuming a deposition rate of 100 %. Actual and time weighted average PEC values for hydrated lime/ hydrated dolomitic lime decrease to < 0.0001 and 46.2 mg/kg after 100 days, respectively.

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	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25/09/2009
Materials and methods	Applicant's version is accepted, noting that within the UK CA document II-B additional calculations and assumptions details the final values accepted for risk assessment purposes.
Conclusion	Adopt Applicant's version noting statement above.
Reliability	N/A
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A2.10.1: Workplace exposure / Inhalation exposure

Exposure scenario	**Workplace operation**	**PPE**	**Year(s) of measurement**	**Number of measurements**	**Type of measurements**	**Exposure concentration**
Production	**In the confidential part of the dossier a table is included which provides a "Consolidation on Companies' monitoring data available on dust inhalation of workers in lime production plants".**					
Formulation	Not relevant because Lime is not formulated into biocidal products.					
Application Scenarios	Use 1 (treatment of sewage sludge): manual and automated mixing and loading ; automated application Use 2 (treatment of manure and other digestive tract contents): automated mixing and loading and automated application	Use 1: protective clothing including gloves, goggles and mask during manual mixing and loading Use 2: As the application is an automated process, no protective equipment is needed. Due to possible release of gases form treated slurry, masks are recommended during application.	n.a.	n.a.	n.a.	Calculated values from Doc. IIB, chapter 8.2.2: **Inhalation:** Use 1 and 2: 0.023 mg/kg bw per day **Dermal:** Use 1 and 2: 0.049 mg/kg bw per day