

CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

Substance Name: Perestane

EC Number: 432-790-1

CAS Number: N/A

Index Number: 607-613-00-8

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Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	<i>Perestane</i> Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water
EC number:	<i>432-790-1</i>
CAS number:	<i>N/A</i>
Annex VI Index number:	<i>607-613-00-8</i>
Degree of purity:	<i>95.6-99%</i>
Impurities:	<i>None reported</i>

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation	Directive 67/548/EEC (Dangerous Substances Directive; DSD)
Current entry in Annex VI, CLP	Muta. 2 H341	Muta. Cat. 3; R68 -

Regulation	Skin Corr. 1B H314 Acute Tox. 4 * H332 Acute Tox. 4 * H312 Acute Tox. 4 * H302	C; R34 - Xn; R20/21/22
Current proposal for consideration by RAC	Removal of Muta.2 H341 and addition of STOT-SE 2 H371 ⁽¹⁾	Removal of Muta. Cat.3; R68 and addition of Xn; R68/20/21/22 ⁽¹⁾
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)		

⁽¹⁾ NB. This proposal only deals with the removal of the Muta 2 classification and addition of STOTE-SE 2 H371.

1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or DSD criteria

CLP Regulation:

Skin Corr. 1B H314
 Acute Tox. 4* H332
 Acute Tox. 4* H312
 Acute Tox 4* H302
 STOT-SE 2 H371

DSD:

C; R34; R20/21/22-68/20/21/22

NB: This proposal only covers the removal of the Muta 2 H341 classification, which should be replaced with STOT-SE 2 H371.

Table 3: Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
3.1.	Acute toxicity - oral	Acute Tox 4 * H302	Not applicable	Acute Tox 4 H302	Not applicable
	Acute toxicity - dermal	Acute Tox 4 * H312	Not applicable	Acute Tox 4 * H312	Not applicable
	Acute toxicity - inhalation	Acute Tox 4 * H332	Not applicable	Acute Tox 4 * H332	Not applicable
3.2.	Skin corrosion / irritation	Skin Corr 1B H314	Not applicable	Skin Corr 1B H314	Not applicable
3.3.	Serious eye damage / eye irritation	Not applicable as Skin Corr 1B H314	Not applicable	Not classified	Not applicable
3.5.	Germ cell mutagenicity	Not classified	Not applicable	Muta 2 H341	conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	STOT – SE 2 H371	Not applicable	Not classified	Not applicable

¹⁾ Including specific concentration limits (SCLs) and M-factors

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word: Danger
 Hazard statements: H314 H302 H312 H332 H371
 Precautionary statements: To be assigned

Proposed notes assigned to an entry:

None

Table 4: Proposed classification according to DSD

Hazardous property	Proposed classification	Proposed SCLs	Current classification ¹⁾	Reason for no classification ²⁾
Acute toxicity	R20/21/22	Not applicable	R20/21/22	Not applicable
Acute toxicity – irreversible damage after single exposure	R68/20/21/22	Not applicable	Not classified	Not applicable
Irritation / Corrosion	R34	Not applicable	R34	Not applicable
Mutagenicity – Genetic toxicity	Not classified	Not applicable	Muta Cat 3; R68	conclusive but not sufficient for classification

¹⁾ Including SCLs

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Indication of danger: C; Xn
R-phrases: R34 20/21/22-68/20/21/22
S-phrases: 1/2, 26, 28, 36/37/39, 45

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

Perestane was notified under the Notification of New Substance (NONS) Regulations in the UK in 2000 (Notification number 00-06-1353). The UK originally proposed to classify this substance with C; R34; R20/21/22-40/20/21/22, with the R20/21/22-40/20/21/22 coming from the presence of methanol in the substance at levels $\geq 3\%$ and $< 10\%$. When the wording of the R40 phrase was changed from “possible evidence of irreversible effects” to 'limited evidence of a carcinogenic effect' at the 28th ATP, the proposed classification of Perestane should have been amended to C;R34 R20/21/22-68/20/21/22. However, the R40 classification was mistakenly translated to include Muta. Cat. 3; R68, Xn; R20/21/22 instead. This was agreed at the 13th Working Group on the classification and labelling of new notified substances in May 2003 and was included in the 1st ATP to CLP.

2.2 Short summary of the scientific justification for the CLH proposal

The available data on Perestane, as presented in this report and technical dossier, do not support classification with Muta 2 H341 (Muta. Cat. 3;R68) and therefore this proposal seeks to amend the classification of this substance to reflect the original UK proposal of STOT-SE 2 H371 (R68/20/21/22).

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

Muta. 2 H341
Skin Corr. 1B H314
Acute Tox. 4 * H332
Acute Tox. 4 * H312
Acute Tox. 4 * H302

2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

Muta. Cat. 3; R68 - C; R34 - Xn; R20/21/22

2.4 Current self-classification and labelling

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

Not currently classified in accordance with CLP. From the 1st December 2010 the Annex VI classification will apply:

Muta. 2 H341
Skin Corr. 1B H314
Acute Tox. 4 H332
Acute Tox. 4 H312
Acute Tox. 4 H302

2.4.2 Current self-classification and labelling based on DSD criteria

The current self classification is C ; R34 R20-68/20/21/22. From the 1st December 2010 the Annex VI classification will apply: Muta. Cat. 3; R68 - C; R34 - Xn; R20/21/22

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

The available data on Perestane, as presented in this report and technical dossier, do not support classification with Muta 2 H341 (Muta. Cat. 3;R68) and therefore this proposal seeks to amend the classification of this substance to reflect the original UK proposal of STOT-SE 2 H371 (R68/20/21/22).

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 5: Substance identity

EC number:	432-790-1
EC name:	Perestane Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water
CAS number (EC inventory):	N/A
CAS number:	N/A
CAS name:	N/A
IUPAC name:	Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate, adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water
CLP Annex VI Index number:	607-613-00-8
Molecular formula:	Not applicable
Molecular weight range:	Not applicable

Structural formula: Not applicable.

1.2 Composition of the substance

Table 6: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
Succinic acid	Confidential	Confidential	Confidential
Monopersuccinic acid	Confidential	Confidential	Confidential
Dipersuccinic acid	Confidential	Confidential	Confidential
Monomethyl ester of succinic acid	Confidential	Confidential	Confidential
Monomethyl ester of persuccinic acid	Confidential	Confidential	Confidential
Dimethyl succinate	Confidential	Confidential	Confidential
Glutaric acid	Confidential	Confidential	Confidential
Monoperglutaric acid	Confidential	Confidential	Confidential
Diperglutaric acid	Confidential	Confidential	Confidential
Monomethyl ester of glutaric acid	Confidential	Confidential	Confidential
Monomethyl ester of perglutaric acid	Confidential	Confidential	Confidential
Dimethyl glutarate	Confidential	Confidential	Confidential
Adipic acid	Confidential	Confidential	Confidential
Monoperadipic acid	Confidential	Confidential	Confidential
Diperadipic acid	Confidential	Confidential	Confidential
Monomethyl ester of adipic acid	Confidential	Confidential	Confidential
Monomethyl ester of peradipic acid	Confidential	Confidential	Confidential
Dimethyl adipate	Confidential	Confidential	Confidential
Hydrogen Peroxide	Confidential	Confidential	Confidential
Methanol	Confidential	Confidential	Confidential
Water	Confidential	Confidential	Confidential

Perestane is a reaction mass containing the substances listed above. The details of the exact composition of perestane are confidential and are provided in the IUCLID dossier. The classification of the individual substituents has been taken into consideration in the classification and labelling proposed for perestane. Note that water is a constituent of the substance and can not be removed without affecting the composition of the other components which contribute to the overall desired effect of the substance.

Current Annex VI entry: As above.

Table 7: Impurities (non-confidential information)

Impurity	Typical concentration	Concentration range	Remarks

No impurities are reported.

Current Annex VI entry: As above.

Table 8: Additives (non-confidential information)

A number of additives are included in perestane. This information is confidential and is included in the IUCLID. The classification of the individual additives has been taken into consideration in the classification and labelling proposed for perestane.

Current Annex VI entry: As above.

1.2.1 Composition of test material

As above

1.3 Physico-chemical properties

Table 9: Summary of physico - chemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance at 20°C and 101,3 kPa	Colourless liquid	IUCLID	Observation
Melting/freezing point	< -22 °C	IUCLID	92/69/EEC A1 (Pour point)
Boiling point	≤ 103 °C at 101.3kPa	IUCLID	92/69/EEC A2 (DSC) Value is thought to be due to the presence of water.
Relative density	1.09 at 20 °C	IUCLID	92/69/EEC A3 (pycnometer)
Vapour pressure	5600 Pa at 25 °C	IUCLID	92/69/EEC A4 (isoteniscope)
Surface tension	71.7 mN/m at 20 °C	IUCLID	92/69/EEC A5 (ring method)
Water solubility	Miscible in all proportions	IUCLID	Not measured
Partition coefficient n-octanol/water	Log Pow: ≤ 1.45 at 25 °C	IUCLID	92/69/EEC A8 (HPLC)
Flash point	> 102 °C	IUCLID	92/69/EEC A9
Flammability	The substance is not flammable. The substance is not pyrophoric and will not spontaneously ignite on contact with water.	IUCLID	Experience in handling and use
Explosive properties	Not explosive	IUCLID	92/69/EEC A14
Self-ignition temperature	Autoflammability: 268 °C	IUCLID	92/69/EEC A15
Oxidising properties	Not oxidising	IUCLID	Substance contains < 0.5% available oxygen from organic peroxide

2 MANUFACTURE AND USES

2.1 Manufacture

The substance is manufactured in the EU.

2.2 Identified uses

The substance is a general purpose disinfectant that is used in hard surface cleaners.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

3.1.1 Summary and discussion of

3.1.2 Comparison with criteria

3.1.3 Conclusions on classification and labelling

The classification for physico-chemical properties is not considered in this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

4.1.1 Non-human information

4.1.2 Human information

4.1.3 Summary and discussion on Toxicokinetics

Not relevant for this dossier.

4.2 Acute toxicity

4.2.1 Non-human information

4.2.1.1 Acute toxicity: oral

Species	LD50	Observations and remarks
Rat 3/sex/group 200 and 2000 mg/kg OECD 473 IUCLID 7.2.1	> 2000 mg/kg	No adverse effects or signs of toxicity.

4.2.1.2 Acute toxicity: inhalation

No data are available.

4.2.1.3 Acute toxicity: dermal

Species	LD50	Observations and remarks
Rat 5/sex/group 2000 mg/kg OECD 402 IUCLID 7.2.3	> 2000 mg/kg	Signs of skin irritation included very slight erythema, light brown discoloration of the epidermis, desquamation, crust formation, small superficial scattered scabs and haemorrhage of the dermal capillaries. Treatment sites appeared normal five to seven days after dosing.

4.2.1.4 Acute toxicity: other routes

No data are available.

4.2.2 Human information

No human data are available on perestane itself. However, methanol is a known constituent in the substance and can be present at a concentration of between $\geq 3\%$ and $< 10\%$. Methanol is listed in Annex VI of CLP and is classified with T; R23/24/25-39/23/24/25. The acute toxicity of methanol in humans and primates is clearly different to that in non-primates. Humans are more susceptible

due to differences in metabolism, in particular the production of formic acid and the consequent metabolic acidosis. The classification for potential irreversible effects following a single exposure (R39/23/24/25) is also justified due to evidence of permanent visual loss in humans. Since the classification for the acute toxicity of methanol is based on adequate, reliable and representative human data, a substance or preparation containing methanol as a component, impurity or additive should be classified accordingly even though animal data (non-primate) on that substance or preparation are available.

4.2.3 Summary and discussion of acute toxicity

This proposal does not address the acute toxicity classification. However, please note that methanol is currently listed on Annex VI of CLP and is classified with T; R23/24/25. However it has a specific concentration limit such that at concentrations of $\geq 3\%$ and $< 10\%$ this changes to Xn; R20/21/22

4.2.4 Comparison with criteria

4.2.5 Conclusions on classification and labelling

4.3 Specific target organ toxicity – single exposure (STOT SE)

4.3.1 Summary and discussion of Specific target organ toxicity – single exposure

The available animal data on perestane do not indicate that classification for STOT-SE is applicable. However, perestane contains methanol at concentrations of $\geq 3\%$ and $< 10\%$. Methanol is listed on Annex VI of CLP with a specific concentration limit such that when present at concentrations of $\geq 3\%$ but $< 10\%$ it should be classified with STOT-SE 2 H371 under CLP (or R68/20/21/22 under DSD) due to evidence of permanent visual loss in humans.

4.3.2 Comparison with criteria

Methanol is listed in Annex VI of CLP and at concentrations of $\geq 3\%$ but $< 10\%$ it should be classified with STOT-SE 2 H371 under CLP or R68/20/21/22 under DSD due to evidence of permanent visual loss in humans. Therefore perestane, which contains methanol in such a concentration, should be classified accordingly.

4.3.3 Conclusions on classification and labelling

CLP: STOT-SE 2 H371 – May cause damage to organs

DSD: Xn R68/R20/21/22

4.4 Irritation

4.4.1 Skin irritation

4.4.1.1 Non-human information

4.4.1.2 Human information

4.4.1.3 Summary and discussion of skin irritation

4.4.1.4 Comparison with criteria

4.4.1.5 Conclusions on classification and labelling

This proposal does not address the classification for skin irritation.

4.4.2 Eye irritation

4.4.2.1 Non-human information

4.4.2.2 Human information

4.4.2.3 Summary and discussion of eye irritation

4.4.2.4 Comparison with criteria

4.4.2.5 Conclusions on classification and labelling

This proposal does not address the classification for eye irritation.

4.4.3 Respiratory tract irritation

4.4.3.1 Non-human information

4.4.3.2 Human information

4.4.3.3 Summary and discussion of respiratory tract irritation

4.4.3.4 Comparison with criteria

4.4.3.5 Conclusions on classification and labelling

This proposal does not address the classification for respiratory tract irritation.

4.5 Corrosivity

4.5.1 Non-human information

4.5.2 Human information

4.5.3 Summary and discussion of corrosivity

4.5.4 Comparison with criteria

4.5.5 Conclusions on classification and labelling

This proposal does not address the classification for corrosivity.

4.6 Sensitisation

4.6.1 Skin sensitisation

4.6.1.1 Non-human information

4.6.1.2 Human information

4.6.1.3 Summary and discussion of skin sensitisation

4.6.1.4 Comparison with criteria

4.6.1.5 Conclusions on classification and labelling

This proposal does not address the classification for skin sensitisation.

4.6.2 Respiratory sensitisation

4.6.2.1 Non-human information

4.6.2.2 Human information

4.6.2.3 Summary and discussion of respiratory sensitisation

4.6.2.4 Comparison with criteria

4.6.2.5 Conclusions on classification and labelling

This proposal does not address the classification for respiratory tract irritation.

- 4.7 Repeated dose toxicity**
- 4.7.1 Non-human information**
 - 4.7.1.1 Repeated dose toxicity: oral**
 - 4.7.1.2 Repeated dose toxicity: inhalation**
 - 4.7.1.3 Repeated dose toxicity: dermal**
 - 4.7.1.4 Repeated dose toxicity: other routes**
 - 4.7.1.5 Human information**
 - 4.7.1.6 Other relevant information**
 - 4.7.1.7 Summary and discussion of repeated dose toxicity**
 - 4.7.1.8 Summary and discussion of repeated dose toxicity findings relevant for classification according to DSD**
 - 4.7.1.9 Comparison with criteria of repeated dose toxicity findings relevant for classification according to DSD**
 - 4.7.1.10 Conclusions on classification and labelling of repeated dose toxicity findings relevant for classification according to DSD**
- 4.8 Specific target organ toxicity (CLP Regulation) – repeated exposure (STOT RE)**
 - 4.8.1 Summary and discussion of repeated dose toxicity findings relevant for classification as STOT RE according to CLP Regulation**
 - 4.8.2 Comparison with criteria of repeated dose toxicity findings relevant for classification as STOT RE**
 - 4.8.3 Conclusions on classification and labelling of repeated dose toxicity findings relevant for classification as STOT RE**

This proposal does not address the classification repeat dose toxicity.

4.9 Germ cell mutagenicity (Mutagenicity)

Table 18: Summary table of relevant in vitro and in vivo mutagenicity studies

4.9.1 Non-human information

4.9.1.1 In vitro data

Method	Organism/Strain	Concentration	Result
Bacterial Mutation Assay (Ames) OECD 471 IUCLID 7.6.1 (1) (Thompson and Bowles 1999)	S. typhimurium (TA1535, TA1537, TA98 and TA100) and E.coli WP2 uvrA	5-5000 µg/plate Cytotoxicity at 5000 µg/plate + S9 and at 500 µg/plate – S9	Negative ± S9 metabolic activation
Mammalian chromosome aberration test OECD 473 IUCLID 7.6.1 (2) (Durward and Jenkinson 2001)	Human lymphocytes	625-2500 µg/ml Cytotoxicity at >2500 µg/ml + S9 and 1875 µg/ml – S9	Negative ± metabolic activation
Mammalian cell gene mutation test OECD 476 IUCLID 7.6.1 (3) (Durward 2001)	L5178Y TK +/- mouse lymphoma cells	160-2560 µg/ml + Metabolic activation. Cytotoxicity at >2500 µg/ml 5- 160 µg/ml - Metabolic activation. Cytotoxicity at 160 µg/ml	Positive ± metabolic activation The response was more pronounced in the absence of metabolic activation. The increase in mutant frequency was primarily due to small colony formation.

4.9.1.2 In vivo data

Method	Organism/Strain	Concentration	Result
Mouse Micronucleus Test OECD 474 IUCLID 7.6.2 (1) (Durward and Nolan 2002)	Mouse CD-1 (7 males/group)	0,500, 1000 and 2000 mg/kg Oral in water Sacrifice times 24 hours for all doses and 48 hours for (0 and 2000 mg/kg).	Negative Clinical signs observed at the top dose included hunched posture, lethargy and decreased respiratory rate. However there was no effect on the PCE/NCE ratio.
Liver Unscheduled DNA Synthesis OECD 486 IUCLID 7.6.2(2) (Durward 2002)	Rat 4 males/group (6 in negative controls)	0, 666.7 and 2000 mg/kg	Negative

Positive and negative controls produced the expected results.

4.9.2 Human information

None.

4.9.3 Other relevant information

None.

4.9.4 Summary and discussion of mutagenicity

Three standard *in vitro* studies have been performed on perestane. There was no evidence of genotoxicity in the Ames test or in the mammalian cell chromosome aberration test. However, a positive result was observed in a mammalian cell gene mutation test both with and without metabolic activation.

An *in vivo* liver UDS assay and a mouse micronucleus study were also conducted on perestane. A negative result was obtained in both studies.

4.9.5 Comparison with criteria

Substances are classified in Category 2 for germ cell mutagenicity when they cause concern owing to the possibility that they may induce heritable mutations in the germ cells of humans, but insufficient evidence is available to place them in Category 1A or 1B. Classification in Category 2 is based on positive evidence obtained from experiments in mammals and/or, in some cases, from *in vitro* experiments. Such evidence is obtained from somatic cell mutagenicity tests *in vivo* in mammals or other *in vivo* somatic cell genotoxicity tests which are supported by positive results in *in vitro* mutagenicity assays.

An *in vivo* mouse micronucleus assay conducted on perestane at concentrations up to 2000mg/kg was negative. In addition, an *in vivo* rat liver UDS assay also gave a negative response. Therefore, based on these results, there is no positive evidence from *in vivo* somatic cell mutagenicity or genotoxicity tests. A positive result was obtained in an *in vitro* mammalian cell gene mutation test only.

4.9.6 Conclusions on classification and labelling

In conclusion, as a positive result was only obtained in one *in vitro* study and a negative result was obtained in two other *in vitro* studies and in two *in vivo* studies, the available data on perestane do not meet the criteria for classification with Muta 2 H341 under CLP or with Muta Cat 3 R68 under DSD.

Classification under CLP: No classification based on available data

Classification under DSD: No classification based on available data

4.10 Carcinogenicity

4.10.1 Non-human information

4.10.1.1 Carcinogenicity: oral

4.10.1.2 Carcinogenicity: inhalation

4.10.1.3 Carcinogenicity: dermal

4.10.2 Human information

4.10.3 Other relevant information

4.10.4 Summary and discussion of carcinogenicity

4.10.5 Comparison with criteria

4.10.6 Conclusions on classification and labelling

This proposal does not address the classification for carcinogenicity.

4.11 Toxicity for reproduction

4.11.1 Effects on fertility

4.11.1.1 Non-human information

4.11.1.2 Human information

4.11.2 Developmental toxicity

4.11.2.1 Non-human information

4.11.2.2 Human information

4.11.3 Other relevant information

4.11.4 Summary and discussion of reproductive toxicity

4.11.5 Comparison with criteria

4.11.6 Conclusions on classification and labelling

This proposal does not address the classification for reproductive toxicity.

4.12 Other effects

4.12.1 Non-human information

4.12.1.1 Neurotoxicity

4.12.1.2 Immunotoxicity

4.12.1.3 Specific investigations: other studies

4.12.1.4 Human information

4.12.2 Summary and discussion

4.12.3 Comparison with criteria

4.12.4 Conclusions on classification and labelling

This is not considered in this proposal.

5 ENVIRONMENTAL HAZARD ASSESSMENT

The environmental classification is not considered in this proposal.

6 OTHER INFORMATION

No other information is available to support this proposal.

7 REFERENCES

Reference should be made the dataset presented in the IUCLID.

8 ANNEXES

Not applicable.