

THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

Annex XV dossier

Transitional Dossier

Substance Name: Amines, hydrogenated tallow alkyl-

EC Number: 262-976-6

CAS Number: 61788-45-2

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RESTRICTION PROPOSAL

Substance Name: Amines, hydrogenated tallow alkyl-

EC Number: 262-976-6

CAS number: 61788-45-2

Restriction proposal: None

For other risk reduction measures see attached Risk Reduction Strategy (Draft of November 2008).

INFORMATION ON HAZARD AND RISKS

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Chemical Name: Amines, hydrogenated tallow alkyl-
EC Name: Amines, hydrogenated tallow alkyl-
CAS Number: 61788-45-2
IUPAC Name: hydrogenated tallow alkyl amine

1.2 Composition of the substance

For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.

Chemical Name: Amines, hydrogenated tallow alkyl-
EC Number: 262-976-6
CAS Number: 61788-45-2
IUPAC Name: hydrogenated tallow alkyl amine
Molecular Formula: unspecified
Structural Formula:
Molecular Weight: 263 g/mol as average

Concentration range (% w/w):

The typical chain length distribution is (a single prime indicates one double bond):

C ₁₂	1 %
C ₁₄	4 %
C ₁₄ '	0.5 %
C ₁₅	0.5 %
C ₁₆	30 %
C ₁₆ '	0.5 %
C ₁₇	1.5 %
C ₁₈	60 %
C ₁₈ '	2 % (Ullmann, 1985)

The content of primary amines is > 99 %.

Possible impurities:

small amounts of non reacted tallow nitriles, secondary and tertiary fatty amines, bis(hydrogenated tallow alkyl amines), water.

Additives: none

1.3 Physico-chemical properties

For the physico-chemical properties see the attached Risk Assessment Report (Draft of October 2008).

2 MANUFACTURE AND USES

See attached Risk Assessment Report (Draft of October 2008)

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

See attached Risk Assessment Report (Draft of October 2008)

3.2 Self classification(s)

This should include the classification, the labelling and the specific concentrations limits. The reason and justification for no classification should be reported here.

It should be stated whether the classification is made according to Directive 67/548/EEC criteria or according to GHS criteria.

4 ENVIRONMENTAL FATE PROPERTIES

See attached Risk Assessment Report (Draft of October 2008)

5 HUMAN HEALTH HAZARD ASSESSMENT

See attached Risk Assessment Report (Draft of October 2008)

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

See attached Risk Assessment Report (Draft of October 2008).

7 ENVIRONMENTAL HAZARD ASSESSMENT

See attached Risk Assessment Report (Draft of October 2008)

8 PBT AND VPVB ASSESSMENT

See attached Risk Assessment Report (Draft of October 2008)

9 EXPOSURE ASSESSMENT

See attached Risk Assessment Report (Draft of October 2008)

10 RISK CHARACTERISATION

See attached Risk Assessment Report (Draft of October 2008)

INFORMATION ON ALTERNATIVES

- 11 INFORMATION ON THE RISKS TO HUMAN HEALTH AND THE ENVIRONMENT RELATED TO THE MANUFACTURE OF USE OF THE ALTERNATIVES**
- 12 AVAILABILITY OF ALTERNATIVE, INCLUDING THE TIME SCALE**
- 13 TECHNICAL AND ECONOMICAL FEASIBILITY**

JUSTIFICATION FOR RESTRICTION AT COMMUNITY LEVEL

14 JUSTIFICATION THAT ACTION IS REQUIRED ON THE COMMUNITY-WIDE BASIS

None

Other measures see attached Risk Reduction Strategy (Draft of November 2008).

15 JUSTIFICATION FOR THE PROPOSES RESTRICTION

15.1 Effectiveness

15.2 Practicality

15.3 Monitorability

SOCIO ECONOMIC ASSESSMENT

OTHER INFORMATION

It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g registration dossiers, other published sources) used for the dossier could also be indicated here.

REFERENCES

See attached Risk Assessment Report (Draft of October 2008)

ANNEX

Risk Assessment Report (Draft of October 2008)

Risk Reduction Strategy (Draft of November 2008)