Section A9 **Classification and labelling**

Annex Point IIA9

Official use only

1 CLASSIFICATION PROPOSAL

1.1 Reference

A9/01:

[redacted] Rationale for R 38 "Irritating to skin" for potassium sorbate. [redacted]

1.2 Classification proposal

Xi, R 36/38

1.3 Justification of the proposals

Mild eye irritation was observed in rabbits for the active substance Potassium sorbate (ref. A6.1.4/02).

In addition to the conclusions from animal testing, R38 is proposed since slight skin erythema following dermal exposure to Sorbic acid and its salts are occasionally observed in humans (see Section A6.12.6).

2 LABELLING PROPOSAL

2.1 Reference

A9/02:

Label for the active substance (Potassium sorbate granules [redacted]

2.2 Labelling proposal

R 36/38

S 24/25, 26

3 PACKAGING

3.1 Reference

The original references are considered to constitute trade secrets of Nutrinova and are therefore submitted in the **confidential** file on Document IV level.

A9/03:

[redacted] Packmittelspezifikationen Faltschachtel (including English translation). [redacted]

A9/04:

[redacted] Packmittelspezifikationen PE-Seitenfaltsack (including English translation). [redacted]

A9/05:

Anonymous (2000) Packmittelspezifikationen Big Bag. [redacted]

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3.2	**Packaging proposal**	*Granular material, small units (25 kg):* Outer box: cardboard, polyethylene-lined Inner lining: high-density polyethylene, conforming to EU and US FDA food contact requirements. *Granular material, large units (1000 kg):* Fabric of UV-stabilised polypropylene. *Solution 50 % w/w:* Outer box: grid of steel pipes with zinc coating. Inner container: 1000 l polyethylene tank with polyethylene screw-cap and protected valve. Pallet: wood *General comment:* Polyethylene has been used as inner lining for potassium sorbate for decades. Polyethylene is inert to potassium sorbate and vice versa. Polyethylene containers as used for the supply of the 50 % solution as the active ingredient and the biocidal example product have also been used for supplies to the food industry for years without any signs of reactions or interaction between container and Potassium sorbate solution.

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE (*)

Date	2004-12-08
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	

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Materials and Methods	
Results and discussion	
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