

ANNEX B

Metam-sodium

B.4 Proposals for classification and labelling

August 2007

Revision August 2010

B.4.0 Introductory note [added in August 2010]

Following the evaluation of the resubmission dossier introduced in 2010 according to the legal provisions of Commission Regulation (EC) No. 33/2008 no revisions were made.

B.4.1 Proposals for the classification and labelling of the active substance (Annex IIA 10)

Table B.4.1-1: Classification and labelling of metam-sodium made by the Rapporteur

Classification :	Repr. Cat 3; R63: Carc. Cat 3; R 40: Xn; R20/22: C; R31:R34; R43; N, R50/53	
Hazard symbols :	C, Xn, N	
Indication of danger :	Corrosive, Harmful, Dangerous for the environment	
Risk phrases :	R20/22	Harmful by inhalation and if swallowed
	R31	Contact with acids liberates toxic gases
	R34	Causes burns
	R43	May cause sensitisation by skin contact
	R40	Limited evidence of a carcinogenic effect
	R63	Possible risk of harm to the unborn child
	R50	Very toxic to aquatic organisms
	R53	May cause long-term effects in the aquatic environment
Safety phrases :	S28	After contact with skin, wash immediately with plenty of water and seek medical advice
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
	S42	During fumigation wear suitable respiratory equipment
	S45	In case of accident or if you feel unwell, seek medical advice immediately
	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions/ safety data sheets

Table B.4.1-2: Justification for the proposal made by the Rapporteur concerning the classification and labelling of metam-sodium

R31	Based on physico-chemical properties (MITC produced by hydrolysis)
C; R34	Acute skin irritation study in rabbits
Xn R20/22	Acute oral rat study; acute inhalation rat study
R43	Skin sensitisation study, M&K
Repr. Cat 3; R63	Developmental rat and rabbit studies
Carc. Cat 3; R40	Long term mice study
N, R50	Based upon the toxicity for <i>Lepomis macrochirus</i> ($LC_{50} > 0.175$ mg a.s./L), <i>Daphnia magna</i> ($EC_{50} = 0.99$ mg a.s./L) and <i>Pseudokirchneriella subcapitata</i> ($E_bC_{50} = 0.556$ mg a.s./L and $E_tC_{50} = 1.08$ mg a.s./L).
R53	By default; an acceptable ready biodegradability study is necessary.

Table B.4.1-3: Classification and labelling of MITC made by the Rapporteur

Classification :	C ; R34 : T; R23/25: Xn ; R21 : R43; N, R50/53	
Hazard symbols :	C, T, N	
Indication of danger :	Corrosive, Toxic, Dangerous for the environment	
Risk phrases :	R23/25	Toxic by inhalation and if swallowed
	R34	Causes burns
	R43	May cause sensitisation by skin contact
	R21	Harmful in contact with skin
	R50	Very toxic to aquatic organisms
	R53	May cause long-term effects in the aquatic environment
Safety phrases :	S28	After contact with skin, wash immediately with plenty of water and seek medical advice
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
	S42	During fumigation wear suitable respiratory equipment
	S45	In case of accident or if you feel unwell, seek medical advice immediately
	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions/ safety data sheets

Table B.4.1-4: Justification for the proposal made by the Rapporteur concerning the classification and labelling of MITC

C; R34	Acute skin irritation study in rabbits
T; R25	Acute oral rat study
T; R23	Acute inhalation rat study
Xn R23/25	Acute oral rat study; acute inhalation rat study
Xn; R21	Acute dermal rat study
R43	Skin sensitisation study, M&K
N, R50	Based upon the toxicity for <i>Oncorhynchus mykiss</i> ($LC_{50} = 0.0531$ mg MITC/L), <i>Daphnia magna</i> ($EC_{50} = 0.076$ mg MITC/L), <i>Pseudokirchneriella subcapitata</i> ($E_bC_{50} = 0.28$ mg MITC/L, $E_rC_{50} = 0.58$ mg MITC/L) and <i>Lemna gibba</i> ($E_bC_{50} = 0.59$ mg MITC/L, $E_rC_{50} = 1.18$ mg MITC/L)
R53	By default; an acceptable ready biodegradability study is necessary.

B.4.2 Proposals for the classification and labelling of the formulations (Annex IIIA 12.3)

See point B.4.1: the product is equivalent to the technical active substance as manufactured.

B.4.3 References relied on

None

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