229 **P** ☐ **NP** ☐ **DM2**
Programme décennal d'épandage de phytocides par voie aérienne en milieu forestier sur des terrains privés de Smurfit-Stone inc. sur le territoire de La Tuque et de la MRC du Domaine-du-Roy
Mauricie **6211-13-011**

MÉMOIRE PRÉSENTÉ
À LA
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SUR L'ENVIRONNEMENT

Commentaires sur le document :

Programme décennal d'épandage de phytocides par voie aérienne en milieu forestier sur les terrains privés de Smurfit Stone Inc., sur le territoire de La Tuque et de la MRC du Domaine-du-Roy

par : Michael Cunningham ing.for.

Monsanto Canada Inc.

Mai 2006

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1.0 INTRODUCTION :

Monsieur le Président, monsieur le Commissionnaire, mesdames et messieurs;

Je vous remercie de me fournir l'occasion de vous présenter notre point de vue sur la question qui préoccupe la Commission.

Monsanto Canada fabrique trois phytocides homologués pour utilisation en forêt : Vision[MD], VisionMAX [MD] et Catena[MD]. Les deux premiers sont homologués pour les applications de dégagement de conifères et aussi pour la préparation de terrain, avant la mise-en-terre des plants. Le troisième est homologué seulement pour la préparation de terrain.

Durant la première partie des audiences du BAPE, du 10 au 13 avril dernier, j'ai noté quelques points, amenés par certains participants, sur lesquels il me semblait important de vous faire part de certaines clarifications.

Dans un premier temps, j'aimerais donc apporter quelques précisions sur certaines affirmations faites précédemment devant la Commission. Par la suite, je vous ferai voir un court vidéo, préparé par le Ministère des Ressources Naturelles de la Nouvelle-Écosse, qui montre comment se déroule leur programme d'épandage des phytocides par voie aérienne. Finalement je vais terminer par quelques mots sur l'utilisation de nos produits et leur impact sur la possibilité forestière.

2.0 PROPRIÉTÉS TOXICOLOGIQUES

2.1 TOXICITÉ DU VISION vs LE PUBLIC EN GÉNÉRAL

Paracelsus, le médecin suisse du 16^{ième} siècle, est connu comme « le Père de la toxicologie » Il avait compris que la relation entre la dose et la réponse est inséparable. Ce que nous comprenons aujourd'hui comme « *la dose fait le poison* » (Annexe B1).

Ce concept s'applique évidemment aux pesticides. Il est vrai de dire que l'ingrédient actif des phytocides Monsanto, le glyphosate, est moins toxique que l'agent tension actif, le POEA. Il n'est pas vrai d'affirmer que la toxicité du mélange n'a jamais été évaluée. D'ailleurs, dans le cas de la toxicité aiguë, la DL_{50} (dose létale 50 %), indiquée comme étant de 5 000 mg/kg de poids corporel, est bien celle de la formulation complète (Monsanto Fiche Technique).

De plus, avant l'application, cette même formulation complète est diluée avec de l'eau afin de préparer la bouillie de pulvérisation. La dilution est d'un facteur variant entre 5 et 100 fois, ce qui diminue d'autant la toxicité aiguë de la solution qui est pulvérisée.

Il est important de souligner que les règlements fédéraux et provinciaux régissant l'application des phytocides exigent que l'accès aux zones traitées, aux sites de

chargement ainsi qu'aux sites d'entreposage soit réservé aux personnes autorisées seulement. On exige que le public se tienne à l'écart de ces zones. Ceci élimine non seulement la possibilité d'entrer en contact avec le produit, mais cela diminue aussi la possibilité de blessure sur un site industriel. Limiter l'accès du public n'est pas unique à l'épandage des phytocides; pour les raisons de sécurité, on trouve des restrictions semblables autour des sites de construction, des ports et des aéroports, par exemple. La différence, quant aux sites d'épandage de phytocide, c'est que ces restrictions sont temporaires; le public peut entrer sur les sites traités 24 heures après l'application.

2.2 TOXICITÉ DU GLYPHOSATE

Le glyphosate est l'ingrédient actif que Monsanto Canada utilise dans ses produits forestiers et certains de ses produits agricoles. L'ingrédient actif contrôle les plantes visées en inhibant une enzyme, l'acide 5-énolpyruvylshikimique-3-phosphate synthétase, une enzyme impliquée dans le mécanisme de l'acide shikimique. Ce mécanisme n'existe que chez les plantes, et il est nécessaire à la biosynthèse des acides aminés aromatiques (Carlisle et Trevors, 1987).

Certaines références déposées à cette Commission affirment que le glyphosate interfère dans le métabolisme plus général du pyruvate (présent chez les plantes et les animaux) en empêchant la liaison du phosphoénol pyruvate avec une autre enzyme. Il est vrai que le phosphoénol pyruvate est un composé important pour le métabolisme du pyruvate chez presque tous les animaux et les plantes, mais aucun effet du glyphosate sur le métabolisme du pyruvate dans les cellules de mammifères n'a été jamais démontré (Annexe B2).

De nombreux organismes qui font autorité de par le monde, comme l'Organisation Mondiale de la Santé (OMS), la Direction Générale pour la Santé et la Protection du Consommateur de la Commission Européenne, et l'Environmental Protection Agency des Etats-Unis (U.S.EPA)), ainsi que notre Agence canadienne de réglementation de la lutte antiparisitaire, Santé Canada (ARLA) confirment que le glyphosate ne cause pas de tumeurs, ni le cancer, ne perturbe pas le système endocrinien et qu'il n'a pas d'effet négatif sur la reproduction et le développement des mammifères (Annexe B2, Annexe B5, Annexe B7, Annexe B8, Annexe B9). Les animaux qui mangent le feuillage traité avec Vision éliminent le produit naturellement dans les fèces et l'urine (Legris et Couture, 1991, Annexe 15). D'autres études, menées sur les adjuvants présents dans nos produits, n'indiquent aucun effet toxique sur les organes ni d'effets sur les embryons, les fœtus ou le placenta (Williams et al. 2000).

En 2004, l'OMS a réexaminé les faits connus sur certains phytocides. Elle a examiné les données sur le glyphosate, et elle a pris la décision extraordinaire de tripler la dose journalière permissible, la faisant passer de 0.3 à 1.0 mg/kg de poids corporelle. Il a été conclu que la consommation à long terme des résidus de glyphosate ne représentait pas un risque significatif pour le public (JMPR, 2005).

2.3 TOXICITÉ PAR RAPPORT AUX TRAVAILLEURS

Les travailleurs présents sur les sites d'applications représentent la population ayant le plus haut potentiel d'exposition au Vision (Samuel, 1988). En comparaison, les travailleurs forestiers utilisant des scies mécaniques sont exposés à des concentrations d'hydrocarbures multiples, dont le benzène et différents composés hydrocarbures aromatiques polycycliques semblables à ceux qu'on trouve dans les sites industriels (Phaneuf/Samuel 1994, Dost 2003). Ces derniers peuvent augmenter le risque de certains cancers (Dost 2003, #9). Il est aussi intéressant de noter qu'environ 30% de l'essence consommée par la scie mécanique s'échappe de la scie sans avoir été brûlée (Kangas, 1998). Le toxicologue Frank Dost (2003, #3) recommande même que les travailleurs forestiers utilisant la scie mécanique soient informés des risques associés à leur santé avec ce type de travail.

Acquavella *et al.* (2004) ont suivi plusieurs familles de producteurs agricoles suite à des pulvérisations de glyphosate. Ils ont mesuré une moyenne de 3 ppb (ou 0.003ppm) comme concentration de glyphosate dans l'urine après l'application; la plus haute concentration de glyphosate dans l'urine, 233 ppb (ou 0,223 ppm) a été mesurée chez un producteur qui ne mettait pas ses gants pour faire ni le mélange ni l'épandage de la bouillie. Une faible proportion des enfants et des épouses des producteurs, qui avaient aidé ou qui étaient présents pendant l'application, avaient une concentration de glyphosate mesurable dans leur urine. Aucune des doses mesurées dans l'étude ne se rapproche de la dose de référence de l'U.S.EPA, qui est de 2 mg/kg/jour pour le glyphosate.

3.0 VISION DANS L'ENVIRONNEMENT :

3.1 VISION DANS LE SOL

Durant les séances précédentes, il y a eu beaucoup de discussions concernant l'activité des molécules du phytocide dès qu'elles viennent en contact avec le sol. Quelques points :

A) Les documents déposés par le promoteur ont omis de mentionner les volumes de Vision qui atteignent le sol après la pulvérisation. Les volumes réels sont très petits. Dans le cadre d'une application normale, terrestre ou aérienne, entre 75% et 95% du produit pulvérisé est intercepté par la végétation traitée (McCormack conv.pers.) Pour la dose maximale de Vision dans le dégagement des conifères, soit 6 L/ha, la quantité qu'on peut détecter qui vient en contact avec le sol est équivalente à entre 0,175 g et 0,035 g/m^2 respectivement.

B) Le Vision est adsorbé quand la molécule vient en contact avec les particules du sol. Cette adsorption est forte, l'équivalent d'un lien chimique qui se formerait avec la particule de sol. Le lien peut être seulement brisé par des méthodes spécifiques dans le laboratoire. Dès que la molécule de Vision vient en contact avec le sol, elle perd toutes

ses propriétés phytosanitaires (Carlisle et Trevors, 1987). Autrement dit, le produit n'est plus biodisponible pour les plantes (Annexe 10, Annexe 11). La molécule demeure attachée à une particule de sol en attendant d'être décomposer par les microbes (Annexe 11).

C) Dans les documents déposés devant La Commission, il a été affirmé que le formaldéhyde est un des produits de décomposition du Vision. En fait, des études utilisant du glyphosate radiomarqué (au carbone-14) ont clairement démontré que le formaldéhyde n'est pas un produit de décomposition du glyphosate. (Annexe 12)

3.2 VISION DAND L'EAU

Une fois dans l'eau, les agents qui contrôle l'adsorption et la dégradation du produit sont les mêmes que dans le sol. Le glyphosate est adsorbé par les sédiments et les particules en suspension dans l'eau. La dégradation microbienne se continue, une fois que les particules en suspension aient sédimenté (Annexe 11).

3.2.1 RESTRICTIONS AU DANEMARK

Il a été dit devant cette Commission que le Danemark avait interdit l'utilisation du glyphosate après que l'Agence pour la Protection de l'Environnement danoise eut trouvé du glyphosate dans les eaux souterraines. La situation n'est pas tout à fait ce qui vous a été décrit. Le Danemark a un programme de surveillance des eaux souterraines; le but est de s'assurer qu'aucun pesticide, quelqu'il soit, ne se retrouve dans l'eau potable au-delà de la limite européenne qui est de 0,1 µg par litre. Je me permets de vous faire remarquer que cette limite est extrêmement basse; en comparaison, la recommandation canadienne quant à la concentration maximale de glyphosate dans l'eau potable est de 280 µg par litre (Règlement sur la qualité de l'eau potable, Québec), et celle aux Etats-Unis est de 700 µg par litre.

Le programme danois visait à déterminer s'il était possible que le pesticide percole à travers le sol et se retrouve dans l'eau souterraine. En 2003, l'agence danoise a effectué des prélèvements suite à des pulvérisations sur des champs déjà récoltés. En aucun cas le glyphosate n'a été détecté en concentration excédant le standard européen de 0.1µg/L dans les eaux souterraines prélevées à des distances variant entre 1 et 5,5 m sous la surface du sol. Le seul endroit où la présence du glyphosate a été détectée en excès de ce standard extrêmement sévère, c'était dans les eaux des fossés de drainage de champs à fort pourcentage d'argile. Suite à ces mesures le ministère de l'Environnement danois a proposé d'interdire l'application de glyphosate sur certains sols argileux durant l'automne (après le 15 septembre). Après des séries de consultations avec des organismes tels que la Fédération nationale d'agriculture danoise et l'Université Royale de médecine vétérinaire et d'agriculture du Danemark, le ministère danois de l'Environnement a renversé sa proposition et a déclaré, en date du 14 décembre 2004, que l'utilisation du glyphosate en agriculture, telle qu'elle se pratique présentement, ne posait pas de risque inacceptable de pollution des eaux souterraines et qu'il n'y avait pas de raison de restreindre les applications de glyphosate en automne (Annexe 13, Annexe 14).

3.3. BIODIVERSITÉ

Le maintien de la biodiversité, suite à l'utilisation du Vision, est une question qui a été abordée à plusieurs reprises durant ces audiences. On affirme souvent que très peu d'études ont été menées sur ce sujet. En fait, un grand nombre d'études a examiné se sujet. Permettez-moi de vous en citer quelques unes :

A) Giesy et all (2000) ont conclu que l'application des phytocides ne posait pas de risques significatifs pour les mammifères, les populations aquatiques et les oiseaux. (Annexe 15).

B) Lautenschlager et Sullivan (2002) ont indiqué que la végétation concurrente est réduite pour une période de 2 à 5 ans. Ensuite, on retrouve la végétation sur les sites au même niveau qu'avant le traitement. Les effets des traitements sont de courte durés et la plupart des populations d'animaux ne sont pas affectées. Certaines espèces bénéficient même du traitement; par exemple, l'orignal est une espèce qui profite du traitement, parce que le volume total de végétation disponible pour broutage sur les sites traités est plus élevé que les sites non traités.

C) Boetang *et al* (2000) ont démontré que la diversité des espèces de plantes sur les sites traités, de même que la structure des communautés de plantes, n'étaient pas affecté significativement en comparaison aux sites non traités, lorsqu'on les évaluait entre 10 à 12 ans après l'application de Vision,.

4.0 VIDÉO

La vidéo que je vais présenter a été conçue en 1992 par le Ministère des Ressources Naturelles de la Nouvelle-Écosse afin d'informer le public sur la pulvérisation aérienne des phytocides. La vidéo est encore utilisée aujourd'hui pour éduquer et informer le public de leurs programmes.

5.0 CONCLUSIONS

Pendant la première phase des audiences, les représentants du Ministère des ressources naturel et de la faune (MRNF) ont indiqué «qu'il y avait un bonne pourcentage de nos plantations qui sont rendu comme des forêts naturelles». Un aspect important cette information n'a pas été suffisamment soulignée, et c'est le coût de la présente stratégie du Ministère des ressources Naturelles et Faune du Québec. Les représentants du ministère on dit que la décision d'abandonner les plantations a pour effet de changer la productivité de 141 m³ par hectare, pour les plantations, à 82 m³ l'hectare pour les forêt naturelles, ou un baisse de productivité de 42% par hectare. Leurs indications sur la productivité et la baisse de la possibilité forestière sont semblables à celles d'autres rapports sur la productivité des forêts québécoises et le succès de ses plantations (Meunier *et al* 2003).

La valeur des exportations forestières au Canada en 2004 était de 44,6 milliards de dollars. La contribution du Québec était de 11,9 milliards de dollars ou 26 pourcent, deuxième dernière la Colombie-britannique (L'État des forêts au Canada 2004-2005). Les coûts de la présente stratégie du Ministère des ressources Naturelles et Faune du Québec auront un impact négatif sur l'économie québécoise dans 10 à 15 ans, lorsque les sites en question devraient commencer à apparaître dans les plans d'exploitation et de récolte. Ce manque de fibre va réduire la capacité des compagnies, et probablement réduire la valeur des exportations par 5 milliards, ce qui placerait le Québec au troisième ou même au quatrième rang des provinces canadiennes.

Un autre point est le coût du reboisement. Le Québec a reboisé 60 866 ha en 2003 (Programme national de données sur les forets). Les coûts approximatifs pour les plants est 1$/plant (production et la mise-en-terre). Si on estime, avec l'information disponible, qu'au moins 50% des plantations sont abandonnées et laissées pour forêts naturelles dans la province, le coût perdu pour les travaux de reboisement est un chiffre étonnant de 76 millions de dollars. On a beaucoup entendu parler du fait que l'utilisation des pesticides en forêt serait « socialement inacceptable ». Est-il vraiment plus socialement acceptable de gaspiller de telles sommes ?

Et, pour reprendre les chiffres avancés selon lesquels le dégagement mécanique sur les superficies considérées ici exigerait environ 80 000 litres d'essence, est-ce vraiment plus socialement acceptable? Si le Vision avait les mêmes caractéristiques toxicologiques que les diverses composantes de l'essence, croyez-vous vraiment qu'il faudrait tenir des audiences publiques pour savoir s'il est socialement acceptable de répandre 80 000 litres d'un produit contenant des cancérogènes reconnus (le benzène dans l'essence, par exemple), des tératogènes reconnus (comme le toluène, le xylène, etc., toujours dans l'essence)? Il peut sembler plus socialement acceptable de brûler de l'essence, parce que tout le monde s'en sert régulièrement, mais ce n'est sûrement pas à cause de la grande innocuité des composantes de l'essence!

L'année 2006 marque la 22ème année que le Vision est homologué pour utilisation forestière au Canada. Durant cette période, plus de 4 millions d'hectares ont été traités avec nos produits. Après la préparation mécanique des sites et la mise en terre des plantes, le traitement de sites avec les phytocides est le troisième plus importante travail sylvicole au pays, par rapport aux superficies sur lesquelles des travaux sont exécutés; c'est donc dire que nos produits sont utilisés sur la plus part des sites (Programme national de données sur les forêts).

Les effets du Vision sur un site sont de courte durée, mais les retombées potentielles sont énormes en terme de gains de croissances et d'aménagement forestier.

Merci pour votre attention.
Michael Cunningham ing. for.
Monsanto Canada Inc.

ANNEXE A

Fiche technique pour Vision[md], VisionMAX[md] et Catena[md]

Monsanto Canada

Fiche de Données de Sécurité
Produit Commercial

1. IDENTIFICATION DE LA SUBSTANCE ET DE LA SOCIÉTÉ

Nom du produit
Herbicide Catena[TM]

No. Homologation PCP
27199
Utilisation du produit
Herbicide
Dénomination chimique
Non applicable
Synonymes
Néant
Société
Monsanto Canada, 67 Scurfield Boulevard, Winnipeg, MB, R3Y 1G4
Téléphone: 204-985-1000 or 800-667-4944, **Fax/Télécopieur:** 204-488-9599
Numéros d'urgence
EN CAS D'URGENCE D'ORDRE CHIMIQUE, DE DÉVERSEMENT, D'INCENDIE, D' EXPOSITION OU D'ACCIDENT, APPELER CANUTEC - Jour et Nuit: 613-996-6666 (appels à frais virés acceptés) ou MONSANTO: 314-694-4000 (appels à frais virés acceptés).
APPEL MEDICAL D'URGENCE - Jour et Nuit: 314-694-4000 (appels en PCV acceptés).

2. COMPOSITION/INFORMATIONS SUR LES COMPOSANTS

Principe actif
Sel d'isopropylamine de N-(phosphonométhyl)glycine; {Sel d'isopropylamine de glyphosate}

Composition

COMPOSANT	No. CAS	% pondéraux (approximatif)
Sel d'isopropylamine de glyphosate	38641-94-0	41
Autres ingrédients		59

L'identité chimique exacte du produit reste une donnée confidentielle appartenant à la société Monsanto.

3. IDENTIFICATION DES DANGERS

Résumé des mesures d'urgence
Aspect et odeur (couleur/forme/odeur): Vert / Liquide, (visqueux) / Léger

PRUDENCE!
PROVOQUE UNE IRRITATION DES YEUX

Effets possibles sur la santé
Voies d'exposition probables
Contact avec la peau, contact avec les yeux, inhalation
Contact avec les yeux, court terme
Peut provoquer une irritation oculaire temporaire.
Contact avec la peau, court terme
Aucun effet nocif important n'est à prévoir si les recommandations d'utilisation sont respectées.

Inhalation, court terme
Aucun effet nocif important n'est à prévoir si les recommandations d'utilisation sont respectées.
Prise unique
Aucun effet nocif important n'est à prévoir si les recommandations d'utilisation sont respectées.

Voir la section 11 pour toute information toxicologique et la section 12 pour toute information écologique.

4. PREMIERS SECOURS

Contact avec les yeux
Rincer immédiatement à grande eau.
Continuer pendant au moins 15 minutes.
Si possible, retirer les lentilles de contact.
Consulter un ophtalmologue.

Contact avec la peau
Laver la peau atteinte à grande eau.
Laver les vêtements avant réutilisation.

Inhalation
Transporter à l'air libre.

Ingestion
Faire boire de l'eau immédiatement.
Ne jamais rien administrer par voie orale à une personne inconsciente.
NE PAS faire vomir sauf avis médical contraire.
Pour un avis médical, contacter un médecin ou un centre anti-poison.

Recommandations pour les médecins
Ce produit n'est pas un inhibiteur de la cholinestérase.

Antidote
Un traitement à l'atropine et aux oximes n'est pas indiqué.

5. MESURES DE LUTTE CONTRE L'INCENDIE

Point éclair
Néant.

Moyens d'extinction
Recommandé: Eau, mousse, poudre sèche, dioxyde de carbone (CO2)

Risques inhabituels d'incendie et d'explosion
Utiliser le moins possible d'eau afin d'éviter toute contamination de l'environnement.
Précautions pour l'environnement: voir section 6.

Produits de combustion dangereux
Monoxyde de carbone (CO), oxydes de phosphore (PxOy), oxydes d'azote (NOx)

Équipement de lutte contre l'incendie
Appareil respiratoire autonome.
L'équipement doit être minutieusement décontaminé après utilisation.

6. MESURES À PRENDRE EN CAS DE DISPERSION ACCIDENTELLE

Précautions individuelles
Utiliser la protection individuelle recommandée dans la section 8.

Précautions pour l'environnement
Réduire la dispersion au minimum.
Retenir les écoulements à l'aide de sacs de sable ou par d'autres moyens.
Eviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.
Peu de danger pour l'environnement.

Méthodes de nettoyage
PETITES QUANTITÉS:
Laver la zone contaminée à l'eau.
GRANDES QUANTITÉS:
Absorber avec de la terre, du sable ou des matières absorbantes.
Creuser le sol fortement contaminé.
Rassembler dans des conteneurs pour l'élimination.
Voir la section 7 pour les types de conteneurs.
Rincer les déchets à l'aide de petites quantités d'eau.
Utiliser le moins possible d'eau afin d'éviter toute contamination de l'environnement.

Voir la section 13 pour l'élimination du produit déversé.

7. MANIPULATION ET STOCKAGE

Suivre les pratiques courantes dans l'industrie en matière de propreté et d'hygiène personnelle.

Manipulation
Eviter tout contact avec les yeux, la peau et les vêtements.
Se laver soigneusement les mains après manipulation ou contact.
Nettoyer minutieusement l'équipement après utilisation.
Ne pas contaminer les égouts, les canalisations et les cours d'eau avec l'eau de rinçage de l'équipement.
Voir la section 13 pour l'élimination de l'eau de rinçage.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
APPLIQUER LES RECOMMENDATIONS SUR L'ÉTIQUETTE MÊME APRÈS AVOIR VIDÉ LE CONTENEUR.

Entreposage
Température minimale d'entreposage: -15 °C
Température maximale d'entreposage: 50 °C
Matériaux compatibles pour l'entreposage: acier inoxydable, aluminium, fibre de verre, plastique, parois intérieures en verre
Matériaux incompatibles pour l'entreposage: acier galvanisé, acier doux non revêtu, voir section 10.
Conserver hors de portée des enfants.
Conserver à l'écart des aliments et boissons, y compris pour animaux.
Conserver uniquement dans le récipient d'origine.
Une cristallisation partielle peut se produire lors de l'entreposage prolongé en-dessous de la température minimale d'entreposage.
S'il gèle, le placer dans une pièce tiède et secouer souvent pour le remettre en solution.

8. CONTRÔLE DE L'EXPOSITION/PROTECTION INDIVIDUELLE

Limites d'exposition dans l'air

Composants	Directives d'Exposition
Sel d'isopropylamine de glyphosate	Aucune limite spécifique d'exposition professionnelle n'a été établie.

Autres ingrédients	Aucune limite spécifique d'exposition professionnelle n'a été établie.

Contrôles techniques
Aucune consigne particulière si les recommandations d'utilisation sont respectées.

Protection des yeux
En cas de risque important de contact:
Porter des lunettes chimiques.

Protection de la peau
En cas de contact répété ou prolongé:
Porter des gants résistants aux produits chimiques.

Protection respiratoire
Aucune consigne particulière si les recommandations d'utilisation sont respectées.

Si c'est conseillé, consulter le fabricant des équipements de protection individuelle afin de connaître le type d'équipement approprié pour une application donnée.

9. PROPRIÉTÉS PHYSIQUES ET CHIMIQUES

Ces données physiques sont des valeurs types basées sur le produit testé mais peuvent varier d'un échantillon à l'autre. Elles ne constituent ni une garantie d'analyse d'un échantillon ni les spécifications du produit.

Couleur/gamme de couleurs:	Vert
Forme:	Liquide (visqueux)
Odeur:	Léger
Point éclair:	Néant.
Densité spécifique:	1.17
pH:	4.9 10 g/l
Coefficient de partition (log Pow):	< 0.000 (glyphosate)

10. STABILITÉ ET RÉACTIVITÉ

Stabilité
Stable dans des conditions normales de manipulation et d'entreposage.

Décomposition dangereuse
Décomposition thermique: Produits de combustion dangereux: voir section 5.

Polymérisation dangereuse
Ne se produit pas.

11. INFORMATIONS TOXICOLOGIQUES

Cette section est réservée à l'usage des toxicologues et autres professionnels de la santé.

Les données obtenues sur le produit et les composants sont résumées ci-dessous.

Toxicité orale aiguë
Rat, DL50: 5,108 mg/kg de poids corporel
Presque pas toxique.
catégorie FIFRA IV.
Toxicité cutanée aiguë
Rat, DL50 (test limite): > 5,000 mg/kg de poids corporel
Presque pas toxique.
catégorie FIFRA IV.
Aucune mortalité.
Irritation cutanée
Lapin, 6 animaux, Test OCDE 404:
Nombre de jours nécessaires à la guérison: 3
Indice Primaire d'Irritation (PII): 0.5/8.0
Essentiellement non irritant.
catégorie FIFRA IV.
Irritation oculaire
Lapin, 6 animaux, test OCDE 405:
Nombre de jours nécessaires à la guérison: 3
Irritation légère.
catégorie FIFRA III.
Toxicité aiguë par inhalation
Rat, CL50, 4 heures, aérosol: 2.9 mg/L
Autres effets: perte de poids, difficulté respiratoire
Presque pas toxique.
catégorie FIFRA IV.
Sensibilisation de la peau
Cobaye, test de Buehler:
Incidence positive: 0 %

N-(phosphonométhyl)glycine; {glyphosate}

Mutagénicité
Test(s) de mutagénicité in vitro et in vivo:
Non mutagène.
Toxicité par administration répétée
Lapin, dermique, 21 jours:
Toxicité DSENO: > 5,000 mg/kg de poids corporel/jour
Organes/systèmes cibles: néant
Autres effets: néant
Rat, oral, 3 mois:
Toxicité DSENO: > 20,000 mg/kg alimentation
Organes/systèmes cibles: néant
Autres effets: néant
Carcinogénicité
Souris, oral, 24 mois:
Tumeur DSEO: > 30,000 mg/kg alimentation
Toxicité DSENO: ~ 5,000 mg/kg alimentation
Tumeurs: néant
Organes/systèmes cibles: foie
Autres effets: diminution de la prise de poids, effets histopathologiques
Rat, oral, 24 mois:
Tumeur DSEO: > 20,000 mg/kg alimentation
Toxicité DSENO: ~ 8,000 mg/kg alimentation
Tumeurs: néant
Organes/systèmes cibles: yeux

Autres effets: diminution de la prise de poids, effets histopathologiques

Toxicité pour la reproduction/la fertilité

Rat, oral, 3 générations:

Toxicité DSENO: > 30 mg/kg de poids corporel
Reproduction DSENO: > 30 mg/kg de poids corporel
Organes/systèmes cibles chez les parents: néant
Autres effets chez les parents: néant
Organes/systèmes cibles chez les jeunes: néant
Autres effets chez les jeunes: néant

Toxicité sur le développement/tératogénicité

Rat, oral, 6 - 19 jours de gestation:

Toxicité DSENO: 1,000 mg/kg de poids corporel
Développement DSENO: 1,000 mg/kg de poids corporel
Autres effets sur l'animal mère: diminution de la prise de poids, survie réduite
Effets sur le développement: perte de poids, perte post-implantatoire, ossification tardive
Les effets sur la progéniture sont uniquement observés en cas de toxicité maternelle.

Lapin, oral, 6 - 27 jours de gestation:

Toxicité DSENO: 175 mg/kg de poids corporel
Développement DSENO: 175 mg/kg de poids corporel
Organes/systèmes cibles chez l'animal mère: néant
Autres effets sur l'animal mère: survie réduite
Effets sur le développement: néant

12. INFORMATIONS ÉCOLOGIQUES

Cette section est réservée à l'usage des écotoxicologues et autres spécialistes de l'environnement.

Les données obtenues sur des produits similaires et sur les composants sont résumées ci-dessous.

Formulation similaire

Toxicité aquatique, poissons

Truite arc-en-ciel (Oncorhynchus mykiss):

Toxicité aiguë, 96 heures, statique, CL50: 5.4 mg/L
Relativement toxique.

Crapet arlequin (Lepomis macrochirus):

Toxicité aiguë, 96 heures, statique, CL50: 7.3 mg/L
Relativement toxique.

Toxicité aquatique, invertébrés

Daphnie (Daphnia magna):

Toxicité aiguë, 48 heures, statique, CE50: 11 mg/L
Légèrement toxique.

Toxicité aviaire

Canard colvert (Anas platyrhynchos):

Toxicité alimentaire, 5 jours, CL50: > 5,620 mg/kg alimentation
Presque pas toxique.

Colin de Virginie (Colinus virginianus):

Toxicité alimentaire, 5 jours, CL50: > 5,620 mg/kg alimentation
Presque pas toxique.

Toxicité pour les arthropodes

Abeille commune (Apis mellifera):

Oral/contact, 48 heures, DL50: > 100 µg/abeille
Presque pas toxique.

Toxicité pour les organismes du sol, invertébrés

Ver de terre (Eisenia foetida):

Toxicité aiguë, 14 jours, CL50: > 1,250 mg/kg sol
Presque pas toxique.

Sel d'isopropylamine de glyphosate (62%)

Toxicité aquatique, algues/plantes aquatiques
Algue verte (Scenedesmus subspicatus):
Toxicité aiguë, 72 heures, statique, CEr50 (rytlime de croissance): 166 mg/L
Presque pas toxique.

N-(phosphonométhyl)glycine; (glyphosate)

Bioaccumulation
Crapet arlequin (Lepomis macrochirus):
Poisson entier: FBC: < 1
Aucune bioaccumulation significative n'est à prévoir.

Dissipation
Sol, champs :
Demi-vie : 2 - 174 jours
Koc: 884 - 60,000 L/kg
Se lie fortement au sol.
Eau, aérobique:
Demi-vie : < 7 jours

13. CONSIDÉRATIONS RELATIVES À L'ÉLIMINATION

Produit
Eviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.
Recycler si les installations/l'équipement appropriés sont disponibles.
Brûler dans un incinérateur approprié.
Brûler dans un incinérateur spécial à haute température contrôlée.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.

Conteneur
Voir l'étiquette du conteneur pour les informations relatives à l'élimination.
Vider complètement les emballages.
Rincer les conteneurs vides trois fois ou à la pression.
NE PAS contaminer l'eau lors de l'élimination des eaux de rinçage.
S'assurer que les emballages ne peuvent pas être réutilisés.
NE PAS réutiliser les conteneurs.
Entreposer jusqu'au ramassage par un service officiel chargé de l'élimination des déchets.
Recycler si les installations/l'équipement appropriés sont disponibles.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
Respecter toutes les consignes de sécurité jusqu'au nettoyage, au recyclage ou à la destruction du conteneur.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.

14. INFORMATIONS RELATIVES AU TRANSPORT

Les données reprises dans cette section servent uniquement d'information. Prière de suivre les réglementations appropriées afin de classer correctement votre cargaison pour le transport.

Non dangereux selon le DOT, ICAO/IATA, IMO, TDG et la réglementation Mexicaine.

15. INFORMATIONS RÉGLEMENTAIRES

PCPA enregistré.

16. AUTRES INFORMATIONS

L'information présentée ici n'est pas nécessairement exhaustive mais représente des données pertinentes et fiables.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.
Prière de contacter le fournisseur pour obtenir de plus amples informations.

Dénomination complète des acronymes les plus utilisés: FBC (Facteur de Bioconcentration), DBO (Demande Biochimique en Oxygène), DCO (Demande Chimique en Oxygène), CE50 (Concentration d'Effet 50%), DE50 (Dose d'Effet 50%), I.M. (Intramusculaire), I.P. (Intrapéritonéal), I.V. (Intraveineux), Koc (Coefficient d'adsorption au sol), CL50 (Concentration Létale 50%), DL50 (Dose Létale 50%), DLmin (Dose létale min.), LEI (Limite d'Explosion Inférieure), CMENO (Concentration Minimale produisant un Effet Nocif Observable), DMENO (Dose Minimale produisant un Effet Nocif Observable), CMEO (Concentration Minimale produisant un Effet Observable), DMEO (Dose Minimale produisant un Effet Observable), LEM (Limite d'Exposition Maximale), DMT (Dose Maximale Tolérée), CSEAO (Concentration Sans Effet Adverse Observé), DSENO (Dose Sans Effet Nocif Observé), CSEO (Concentration Sans Effet Observable), DSEO (Dose Sans Effet Observable), LEP (Limite d'Exposition Professionelle), LE (Limite d'Exposition), PII (Index d'Irritation Primaire), Pow (Coefficient de partition n-octanol/eau), S.C. (Sous-Cutané), LECT (Limite d'Exposition à Court Terme), TLV-C (Limite d'Exposition-Plafond), TLV-TWA (Limite d'Exposition-Moyenne rectifiée par rapport au temps), LSE (Limite Supérieure d'Explosion)

Cette fiche de données de sécurité (MSDS) diffère de l'ETIQUETTE DU PRODUIT APPROUVEE PAR la Réglementation sur la gestion des pesticides (PMRA) dans ses objectifs, et NE REMPLACE NI NE MODIFIE CETTE DERNIERE (attachée et accompagnant le conteneur du produit). Cet MSDS fournit d'importantes informations sur la santé, la sécurité et l'environnement aux employeurs, employés, personnes intervenant en cas d'urgence et personnes manipulant de grandes quantités de produit dans des activités qui diffèrent généralement de l'utilisation même du produit, alors que l'étiquette fournit des informations spécifiques sur l'utilisation normale du produit. L'utilisation, l'entreposage et l'élimination des pesticides sont réglementés par la législation provinciale et l'étiquette du produit , qui fournit toutes les informations nécessaires et appropriées sur les précautions à suivre, l'utilisation, l'entreposage et l'élimination. Tout pesticide ne portant pas l'étiquette approuvée par la PMRA représente à nos yeux une violation de la loi fédérale.

La société MONSANTO ne garantit ni la complétude ni l'exactitude des informations et recommandations présentées ici (et ci-après dénommées "informations") même si celles-ci sont établies de bonne foi et supposées justes à la date citée. Ces informations sont fournies à la condition que les destinataires déterminent eux-mêmes si elles conviennent à l'usage souhaité. La société MONSANTO ne pourra en aucun cas être rendue responsable de quelque dommage que ce soit qui résulterait de l'utilisation des informations ou de toute action basée sur ces informations. AUCUNE DÉCLARATION NI GARANTIE, EXPRESSE OU IMPLICITE, N'A ÉTÉ ÉTABLIE QUANT A LA COMMERCIABILITÉ, L'APTITUDE POUR UNE UTILISATION SPÉCIFIQUE OU AUTRE DES INFORMATIONS OU DU PRODUIT AUXQUELLES IL SE RÉFÈRE.

Monsanto Canada

Fiche de Données de Sécurité
Produit Commercial

1. IDENTIFICATION DE LA SUBSTANCE ET DE LA SOCIÉTÉ

Nom du produit
Vision®

No. Homologation PCP
19899
Utilisation du produit
Herbicide
Dénomination chimique
Non applicable
Synonymes
Néant
Société
Monsanto Canada, 67 Scurfield Boulevard, Winnipeg, MB, R3Y 1G4
Téléphone: 204-985-1000 or 800-667-4944, **Fax/Télécopieur:** 204-488-9599
Numéros d'urgence
EN CAS D'URGENCE D'ORDRE CHIMIQUE, DE DÉVERSEMENT, D'INCENDIE, D' EXPOSITION OU D'ACCIDENT, APPELER CANUTEC - Jour et Nuit: 613-996-6666 (appels à frais virés acceptés) ou MONSANTO: 314-694-4000 (appels à frais virés acceptés).
APPEL MEDICAL D'URGENCE - Jour et Nuit: 314-694-4000 (appels en PCV acceptés).

2. COMPOSITION/INFORMATIONS SUR LES COMPOSANTS

Principe actif
Sel d'isopropylamine de N-(phosphonométhyl)glycine; {Sel d'isopropylamine de glyphosate}

Composition

COMPOSANT	No. CAS	% pondéraux (approximatif)
Sel d'isopropylamine de glyphosate	38641-94-0	41
Autres ingrédients		59

L'identité chimique exacte du produit reste une donnée confidentielle appartenant à la société Monsanto.

3. IDENTIFICATION DES DANGERS

Résumé des mesures d'urgence
Aspect et odeur (couleur/forme/odeur): Ambre - Brun / Liquide, (visqueux) / Léger

ATTENTION!
PEUT PROVOQUER UNE IRRITATION OCULAIRE
NOCIF EN CAS D'INGESTION

Effets possibles sur la santé
Voies d'exposition probables
Contact avec la peau, contact avec les yeux, inhalation
Contact avec les yeux, court terme
Peut provoquer une irritation oculaire temporaire.
Contact avec la peau, court terme

Aucun effet nocif important n'est à prévoir si les recommandations d'utilisation sont respectées.

Inhalation, court terme

Aucun effet nocif important n'est à prévoir si les recommandations d'utilisation sont respectées.

Voir la section 11 pour toute information toxicologique et la section 12 pour toute information écologique.

4. PREMIERS SECOURS

Contact avec les yeux

Rincer immédiatement à grande eau.
Si les symptômes persistent, obtenir un avis médical.

Contact avec la peau

Retirer les vêtements, montres et bijoux contaminés.
Laver la peau atteinte à grande eau.
Laver les vêtements et nettoyer les chaussures avant réutilisation.
Si les symptômes persistent, obtenir un avis médical.

Inhalation

Transporter à l'air libre.

Ingestion

Faire boire de l'eau immédiatement.
NE PAS faire vomir sauf avis médical contraire.
Si des symptômes apparaissent, consulter un médecin.

Recommandations pour les médecins

Ce produit n'est pas un inhibiteur de la cholinestérase.

Antidote

Un traitement à l'atropine et aux oximes n'est pas indiqué.

5. MESURES DE LUTTE CONTRE L'INCENDIE

Point éclair

Néant.

Moyens d'extinction

Recommandé: Eau, mousse, poudre sèche, dioxyde de carbone (CO2)

Risques inhabituels d'incendie et d'explosion

Utiliser le moins possible d'eau afin d'éviter toute contamination de l'environnement.
Précautions pour l'environnement: voir section 6.

Produits de combustion dangereux

Monoxyde de carbone (CO), oxydes de phosphore (PxOy), oxydes d'azote (NOx)

Équipement de lutte contre l'incendie

Appareil respiratoire autonome.
L'équipement doit être minutieusement décontaminé après utilisation.

6. MESURES À PRENDRE EN CAS DE DISPERSION ACCIDENTELLE

Précautions individuelles

Utiliser la protection individuelle recommandée dans la section 8.

Précautions pour l'environnement
PETITES QUANTITÉS:
Peu de danger pour l'environnement.
GRANDES QUANTITÉS:
Réduire la dispersion au minimum.
Eviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.

Méthodes de nettoyage
PETITES QUANTITÉS:
Laver la zone contaminée à l'eau.
GRANDES QUANTITÉS:
Absorber avec de la terre, du sable ou des matières absorbantes.
Rassembler dans des conteneurs pour l'élimination.
Creuser le sol fortement contaminé.
Voir la section 7 pour les types de conteneurs.
Rincer les déchets à l'aide de petites quantités d'eau.

Voir la section 13 pour l'élimination du produit déversé.

7. MANIPULATION ET STOCKAGE

Suivre les pratiques courantes dans l'industrie en matière de propreté et d'hygiène personnelle.

Manipulation
Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
Se laver soigneusement les mains après manipulation ou contact.
Nettoyer minutieusement l'équipement après utilisation.
Ne pas contaminer les égouts, les canalisations et les cours d'eau avec l'eau de rinçage de l'équipement.
Voir la section 13 pour l'élimination de l'eau de rinçage.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
APPLIQUER LES RECOMMENDATIONS SUR L'ÉTIQUETTE MÊME APRÈS AVOIR VIDÉ LE CONTENEUR.

Entreposage
Température minimale d'entreposage: -15 °C
Température maximale d'entreposage: 50 °C
Matériaux compatibles pour l'entreposage: acier inoxydable, aluminium, fibre de verre, plastique, parois intérieures en verre
Matériaux incompatibles pour l'entreposage: acier galvanisé, acier doux non revêtu, voir section 10.
Conserver hors de portée des enfants.
Conserver à l'écart des aliments et boissons, y compris pour animaux.
Conserver uniquement dans le récipient d'origine.
Une cristallisation partielle peut se produire lors de l'entreposage prolongé en-dessous de la température minimale d'entreposage.
S'il gèle, le placer dans une pièce tiède et secouer souvent pour le remettre en solution.
Durée minimale de conservation: 5 ans.

8. CONTRÔLE DE L'EXPOSITION/PROTECTION INDIVIDUELLE

Limites d'exposition dans l'air

Composants	Directives d'Exposition
Sel d'isopropylamine de glyphosate	Aucune limite spécifique d'exposition professionnelle n'a été établie.

Autres ingrédients	Aucune limite spécifique d'exposition professionnelle n'a été établie.

Contrôles techniques
Prévoir une fontaine oculaire à proximité des endroits où un contact avec les yeux peut se produire.

Protection des yeux
En cas de risque de contact:
Porter des lunettes chimiques.

Protection de la peau
En cas de contact répété ou prolongé:
Porter des gants résistants aux produits chimiques.

Protection respiratoire
Aucune consigne particulière si les recommandations d'utilisation sont respectées.

Si c'est conseillé, consulter le fabricant des équipements de protection individuelle afin de connaître le type d'équipement approprié pour une application donnée.

9. PROPRIÉTÉS PHYSIQUES ET CHIMIQUES

Ces données physiques sont des valeurs types basées sur le produit testé mais peuvent varier d'un échantillon à l'autre. Elles ne constituent ni une garantie d'analyse d'un échantillon ni les spécifications du produit.

Couleur/gamme de couleurs:	Ambre - Brun
Forme:	Liquide (visqueux)
Odeur:	Léger
Point éclair:	Néant.
Densité spécifique:	1.1743 20 °C / 15.6 °C
Solubilité:	Eau: Soluble
pH:	4.9
Coefficient de partition (log Pow):	< 0.000 (glyphosate)

10. STABILITÉ ET RÉACTIVITÉ

Stabilité
Stable dans des conditions normales de manipulation et d'entreposage.

Décomposition dangereuse
Décomposition thermique: Produits de combustion dangereux: voir section 5.

Matières à éviter/Réactivité
Réagit avec l'acier galvanisé ou l'acier doux non-revêtu en dégageant de l'hydrogène, gaz très inflammable susceptible d'exploser.

11. INFORMATIONS TOXICOLOGIQUES

Cette section est réservée à l'usage des toxicologues et autres professionnels de la santé.

Les données obtenues sur des produits similaires et sur les composants sont résumées ci-dessous.

Formulation similaire

Toxicité orale aiguë
Rat, DL50 (test limite): > 5,000 mg/kg de poids corporel
Autres effets: difficulté respiratoire, diminution de l'activité, selles molles
Presque pas toxique.
catégorie FIFRA IV.
Aucune mortalité.

Toxicité cutanée aiguë
Rat, DL50 (test limite): > 5,000 mg/kg de poids corporel
Organes/systèmes cibles: néant
Autres effets: néant
Presque pas toxique.
catégorie FIFRA IV.
Aucune mortalité.

Irritation cutanée
Lapin, 6 animaux, Test OCDE 404:
Nombre de jours nécessaires à la guérison: 1
Indice Primaire d'Irritation (PII): 0.4/8.0
Autres effets: néant
Essentiellement non irritant.
catégorie FIFRA IV.

Irritation oculaire
Lapin, 6 animaux, test OCDE 405:
Nombre de jours nécessaires à la guérison: 10
Irritation modérée.
catégorie FIFRA II.

Toxicité aiguë par inhalation
Rat, CL50, 4 heures, aérosol: 2.6 mg/L
Organes/systèmes cibles: néant
Autres effets: difficulté respiratoire, diminution de l'activité, effets locaux
Presque pas toxique.
catégorie FIFRA IV.

Sensibilisation de la peau
Cobaye, test de Buehler:
Incidence positive: 0 %

12. INFORMATIONS ÉCOLOGIQUES

Cette section est réservée à l'usage des écotoxicologues et autres spécialistes de l'environnement.

Les données obtenues sur des produits similaires et sur les composants sont résumées ci-dessous.

Formulation similaire

Toxicité aquatique, poissons
Crapet arlequin (Lepomis macrochirus):
Toxicité aiguë, 96 heures, flux continu, CL50: 5.8 mg/L
Relativement toxique.
Truite arc-en-ciel (Oncorhynchus mykiss):
Toxicité aiguë, 96 heures, flux continu, CL50: 8.2 mg/L
Relativement toxique.

Toxicité aquatique, invertébrés
Daphnie (Daphnia magna):
Toxicité aiguë, 48 heures, statique, CE50: 11 mg/L

Légèrement toxique.

Toxicité aquatique, algues/plantes aquatiques

Algue verte (Selenastrum capricornutum):

Toxicité aiguë, 96 heures, statique, CE50: 2.6 mg/L

Relativement toxique.

Lentille d'eau (Lemna minor):

Toxicité aiguë, 7 jours, statique, CE50: > 6 mg/L

Toxicité aviaire

Colin de Virginie (Colinus virginianus):

Toxicité alimentaire, 5 jours, CL50: > 5,620 mg/kg alimentation

Presque pas toxique.

Canard colvert (Anas platyrhynchos):

Toxicité alimentaire, 5 jours, CL50: > 5,620 mg/kg alimentation

Presque pas toxique.

Toxicité pour les arthropodes

Abeille commune (Apis mellifera):

Oral/contact, 48 heures, DL50: > 100 µg/abeille

Presque pas toxique.

Toxicité pour les organismes du sol, invertébrés

Ver de terre (Eisenia foetida):

Toxicité aiguë, 14 jours, CL50: > 5,000 mg/kg de sol sec

Presque pas toxique.

N-(phosphonométhyl)glycine; {glyphosate}

Bioaccumulation

Crapet arlequin (Lepomis macrochirus):

Poisson entier: FBC: < 1

Aucune bioaccumulation significative n'est à prévoir.

Dissipation

Sol, champs:

Demi-vie: 2 - 174 jours

Koc: 884 - 60,000 L/kg

Se lie fortement au sol.

Eau, aérobique:

Demi-vie: < 7 jours

13. CONSIDÉRATIONS RELATIVES À L'ÉLIMINATION

Produit

Le produit en surplus peut être éliminé en suivant les instructions de l'étiquette.
Éviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.
Recycler si les installations/l'équipement appropriés sont disponibles.
Brûler dans un incinérateur approprié.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.

Conteneur

Voir l'étiquette du conteneur pour les informations relatives à l'élimination.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
Respecter toutes les consignes de sécurité jusqu'au nettoyage, au recyclage ou à la destruction du conteneur.
Vider complètement les emballages.
Rincer les conteneurs vides trois fois ou à la pression.
Les eaux de rinçage peuvent être éliminées par voies agricoles selon les instructions de l'étiquette.
Recycler si les installations/l'équipement appropriés sont disponibles.
NE PAS contaminer l'eau lors de l'élimination des eaux de rinçage.
S'assurer que les emballages ne peuvent pas être réutilisés.

Appliquer toutes les réglementations locales/régionales/nationales/internationales.

14. INFORMATIONS RELATIVES AU TRANSPORT

Les données reprises dans cette section servent uniquement d'information. Prière de suivre les réglementations appropriées afin de classer correctement votre cargaison pour le transport.

Non dangereux selon le DOT, ICAO/IATA, IMO, TDG et la réglementation Mexicaine.

15. INFORMATIONS RÉGLEMENTAIRES

PCPA enregistré.

16. AUTRES INFORMATIONS

L'information présentée ici n'est pas nécessairement exhaustive mais représente des données pertinentes et fiables.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.
Prière de contacter le fournisseur pour obtenir de plus amples informations.

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Notes de fin de documem:
(a) Etiquetage UE (classification établie par le fabricant)
(b) Etiquetage UE (Annexe I)
(c) Classification nationale

Dénomination complète des acronymes les plus utilisés: FBC (Facteur de Bioconcentration), DBO (Demande Biochimique en Oxygène), DCO (Demande Chimique en Oxygène), CE50 (Concentration d'Effet 50%), DE50 (Dose d'Effet 50%), I.M. (Intramusculaire), I.P. (Intrapéritonéal), I.V. (Intraveineux), Koc (Coefficient d'adsorption au sol), CL50 (Concentration Létale 50%), DL50 (Dose Létale 50%), DLmin (Dose létale min.), LEI (Limite d'Explosion Inférieure), CMENO (Concentration Minimale produisant un Effet Nocif Observable), DMENO (Dose Minimale produisant un Effet Nocif Observable), CMEO (Concentration Minimale produisant un Effet Observable), DMEO (Dose Minimale produisant un Effet Observable), LEM (Limite d'Exposition Maximale), DMT (Dose Maximale Tolérée), CSEAO (Concentration Sans Effet Adverse Observé), DSENO (Dose Sans Effet Nocif Observé), CSEO (Concentration Sans Effet Observable), DSEO (Dose Sans Effet Observable), LEP (Limite d'Exposition Professionelle), LE (Limite d'Exposition), PII (Index d'Irritation Primaire), Pow (Coefficient de partition n-octanol/eau), S.C. (Sous-Cutané), LECT (Limite d'Exposition à Court Terme), TLV-C (Limite d'Exposition-Plafond), TLV-TWA (Limite d'Exposition-Moyenne rectifiée par rapport au temps), LSE (Limite Supérieure d'Explosion)

Cette fiche de données de sécurité (MSDS) diffère de l'ETIQUETTE DU PRODUIT APPROUVEE PAR la Réglementation sur la gestion des pesticides (PMRA) dans ses objectifs, et NE REMPLACE NI NE MODIFIE CETTE DERNIERE (attachée et accompagnant le conteneur du produit). Cet MSDS fournit d'importantes informations sur la santé, la sécurité et l'environnement aux employeurs, employés, personnes intervenant en cas d'urgence et personnes manipulant de grandes quantités de produit dans des activités qui diffèrent généralement de l'utilisation même du produit, alors que l'étiquette fournit des informations spécifiques sur l'utilisation normale du produit. L'utilisation, l'entreposage et l'élimination des pesticides sont réglementés par la législation provinciale et l'étiquette du produit, qui fournit toutes les informations nécessaires et appropriées sur les précautions à suivre, l'utilisation, l'entreposage et l'élimination. Tout pesticide ne portant pas l'étiquette approuvée par la PMRA représente à nos yeux une violation de la loi fédérale.

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Monsanto Canada

Fiche de Données de Sécurité
Produit Commercial

1. IDENTIFICATION DE LA SUBSTANCE ET DE LA SOCIÉTÉ

Nom du produit
VisionMax[TM] Phytocide Sylvicole

No. Homologation PCP
27736
Utilisation du produit
Herbicide
Dénomination chimique
Non applicable.
Synonymes
Néant.
Société
Monsanto Canada, 67 Scurfield Boulevard, Winnipeg, MB, R3Y 1G4
Téléphone: 204-985-1000 or 800-667-4944, **Fax/Télécopieur:** 204-488-9599
Numéros d'urgence
EN CAS D'URGENCE D'ORDRE CHIMIQUE, DE DÉVERSEMENT, D'INCENDIE, D' EXPOSITION OU D'ACCIDENT, APPELER CANUTEC - Jour et Nuit: 613-996-6666 (appels à frais virés acceptés) ou MONSANTO: 314-694-4000 (appels à frais virés acceptés).
APPEL MEDICAL D'URGENCE - Jour et Nuit: 314-694-4000 (appels en PCV acceptés).

2. COMPOSITION/INFORMATIONS SUR LES COMPOSANTS

Principe actif
Sel de potassium de N-(phosphonométhyl)glycine; {Sel de potassium de glyphosate}

Composition

COMPOSANT	No. CAS	% pondéraux (approximatif)
Sel de potassium de glyphosate	70901-12-1	49
Autres ingrédients		51

L'identité chimique exacte du produit reste une donnée confidentielle appartenant à la société Monsanto.

3. IDENTIFICATION DES DANGERS

Résumé des mesures d'urgence
Aspect et odeur (couleur/forme/odeur): Bleu / Liquide / Inodore

PRUDENCE!
POISON
NOCIF EN CAS D'INGESTION
NOCIF EN CAS D'INHALATION
PROVOQUE UNE IRRITATION DES YEUX
PROVOQUE UNE IRRITATION DE LA PEAU

Effets possibles sur la santé
Voies d'exposition probables
Contact avec la peau, contact avec les yeux

Contact avec les yeux, court terme
Peut provoquer une irritation oculaire temporaire.
Contact avec la peau, court terme
Irritant pour la peau.
Inhalation, court terme
Nocif par inhalation.
Prise unique
Nocif en cas d'ingestion.

Voir la section 11 pour toute information toxicologique et la section 12 pour toute information écologique.

4. PREMIERS SECOURS

Contact avec les yeux
Rincer immédiatement à grande eau.
Continuer pendant au moins 15 minutes.
Consulter un ophtalmologue.

Contact avec la peau
Laver immédiatement la peau atteinte à grande eau.
Retirer les vêtements, montres et bijoux contaminés.
Laver les vêtements et nettoyer les chaussures avant réutilisation.

Inhalation
En cas d'inhalation, transporter la personne à l'air libre. Si la personne ne respire pas, appeler le numéro d'urgence ou une ambulance, puis effectuer une respiration artificielle, de préférence du bouche à bouche, si c'est possible.

Ingestion
Faire boire de l'eau immédiatement.
NE PAS faire vomir sauf avis médical contraire.
Si des symptômes apparaissent, consulter un médecin.

Recommandations pour les médecins
Ce produit n'est pas un inhibiteur de la cholinestérase.

Antidote
Un traitement à l'atropine et aux oximes n'est pas indiqué.

5. MESURES DE LUTTE CONTRE L'INCENDIE

Point éclair
Aucun point éclair.

Moyens d'extinction
Recommandé: Eau, mousse, poudre sèche, dioxyde de carbone (CO2)

Risques inhabituels d'incendie et d'explosion
Utiliser le moins d'eau possible afin d'éviter toute contamination de l'environnement.
Précautions pour l'environnement: voir section 6.

Produits de combustion dangereux
Monoxyde de carbone (CO), oxydes de phosphore (PxOy), oxydes d'azote (NOx)

Équipement de lutte contre l'incendie

Appareil respiratoire autonome.
L'équipement doit être minutieusement décontaminé après utilisation.

6. MESURES À PRENDRE EN CAS DE DISPERSION ACCIDENTELLE

Précautions individuelles
Utiliser la protection individuelle recommandée dans la section 8.

Précautions pour l'environnement
PETITES QUANTITÉS:
Peu de danger pour l'environnement.
GRANDES QUANTITÉS:
Réduire la dispersion au minimum.
Eviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.

Méthodes de nettoyage
PETITES QUANTITÉS:
Laver la zone contaminée à l'eau.
GRANDES QUANTITÉS:
Absorber avec de la terre, du sable ou des matières absorbantes.
Creuser le sol fortement contaminé.
Rassembler dans des conteneurs pour l'élimination.
Voir la section 7 pour les types de conteneurs.
Rincer les déchets à l'aide de petites quantités d'eau.
Utiliser le moins d'eau possible afin d'éviter toute contamination de l'environnement.

Voir la section 13 pour l'élimination du produit déversé.

7. MANIPULATION ET STOCKAGE

Suivre les bonnes pratiques industrielles en matière de propreté et d'hygiène personnelle.

Manipulation
Eviter tout contact avec les yeux, la peau et les vêtements.
Eviter de respirer de la vapeur ou de la brume.
Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
Se laver soigneusement les mains après manipulation ou contact.
Nettoyer minutieusement l'équipement après utilisation.
Ne pas contaminer les égouts, les canalisations et les cours d'eau avec l'eau de rinçage de l'équipement.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
APPLIQUER LES RECOMMENDATIONS SUR L'ÉTIQUETTE MÊME APRÈS AVOIR VIDÉ LE CONTENEUR.

Entreposage
Matériaux compatibles pour l'entreposage: acier inoxydable, aluminium, fibre de verre, plastique, parois intérieures en verre
Matériaux incompatibles pour l'entreposage: acier galvanisé, acier doux non revêtu, voir section 10.
Conserver hors de portée des enfants.
Conserver à l'écart des aliments et boissons, y compris pour animaux.
Conserver uniquement dans le récipient d'origine.

8. CONTRÔLE DE L'EXPOSITION/PROTECTION INDIVIDUELLE

Limites d'exposition dans l'air

Composants	Directives d'Exposition

Sel de potassium de glyphosate	Aucune limite spécifique d'exposition professionnelle n'a été établie.
Autres ingrédients	Aucune limite spécifique d'exposition professionnelle n'a été établie.

Contrôles techniques
Aucune consigne particulière si les recommandations d'utilisation sont respectées.

Protection des yeux
En cas de risque important de contact:
Porter des lunettes chimiques.

Protection de la peau
Porter des gants résistants aux produits chimiques.
Les applicateurs et autres manipulateurs doivent porter:
Porter une chemise à manches longues, longs pantalons et chaussures avec chaussettes.
En cas de risque important de contact:
Porter une visière de protection.
Porter des vêtements/chaussures résistants aux produits chimiques.

Protection respiratoire
Aucune consigne particulière si les recommandations d'utilisation sont respectées.

Si c'est conseillé, consulter le fabricant des équipements de protection individuelle afin de connaître le type d'équipement approprié pour une application donnée.

9. PROPRIÉTÉS PHYSIQUES ET CHIMIQUES

Ces données physiques sont des valeurs types basées sur le produit testé mais peuvent varier d'un échantillon à l'autre. Elles ne constituent ni une garantie d'analyse d'un échantillon ni les spécifications du produit.

Couleur/gamme de couleurs:	Bleu
Forme:	Liquide
Odeur:	Inodore
Point éclair:	Aucun point éclair.
Densité spécifique:	1.3573 20 °C / 15.6 °C
pH:	4.5 - 4.9 67.7 g/l
Coefficient de partition (log Pow):	-3.2 @ 25 °C (glyphosate)

10. STABILITÉ ET RÉACTIVITÉ

Stabilité
Stable dans les conditions normales de manipulation et d'entreposage.

Décomposition dangereuse
Décomposition thermique: Produits de combustion dangereux: voir section 5.

Matières à éviter/Réactivité
Réagit avec l'acier galvanisé ou l'acier doux non-revêtu en dégageant de l'hydrogène, gaz très inflammable susceptible d'exploser.

11. INFORMATIONS TOXICOLOGIQUES

Cette section est réservée à l'usage des toxicologues et autres professionnels de la santé.

Les données obtenues sur des produits similaires et sur les composants sont résumées ci-dessous.

Formulation similaire

Toxicité orale aiguë
Rat, DL50: > 5,000 mg/kg de poids corporel
Presque pas toxique.
catégorie FIFRA IV.

Toxicité cutanée aiguë
Rat, DL50: > 5,000 mg/kg de poids corporel
Presque pas toxique.
catégorie FIFRA IV.

Irritation cutanée
Lapin, 3 animaux, Test OCDE 404:
Nombre de jours nécessaires à la guérison: 14
Indice Primaire d'Irritation (PII): 2.2/8.0
Irritation modérée.
catégorie FIFRA III.

Irritation oculaire
Lapin, 3 animaux, test OCDE 405:
Nombre de jours nécessaires à la guérison: 3
Irritation modérée.
catégorie FIFRA III.

Toxicité aiguë par inhalation
Rat, CL50, 4 heures, aérosol: > 1.20 mg/L
Légèrement toxique.
catégorie FIFRA III.
Aucune mortalité. Pour le test d'inhalation, le produit a été conçu sous forme d'aérosol. Etant donné que pendant le transport le produit ne sera pas sous la forme d'un aérosol avec une concentration dangereuse, il est classé comme non dangereux par les règlements de transport, conformément aux articles 2.6.2.2.4.7(b) et (c) des Recommandations des NU pour le Transport de Marchandises Dangereuses.

Sensibilisation de la peau
Cobaye, test de Buehler:
Incidence positive: 0 %

N-(phosphonométhyl)glycine; {glyphosate}

Mutagénicité
Test(s) de mutagénicité in vitro et in vivo:
Non mutagène.

Toxicité par administration répétée
Lapin, dermique, 21 jours:
Toxicité DSENO: > 5,000 mg/kg de poids corporel/jour
Organes/systèmes cibles: néant
Autres effets: néant
Rat, oral, 3 mois:
Toxicité DSENO: > 20,000 mg/kg d'aliment
Organes/systèmes cibles: néant
Autres effets: néant

Carcinogénicité
Souris, oral, 24 mois:
Tumeur DSEO: > 30,000 mg/kg d'aliment
Toxicité DSENO: ~ 5,000 mg/kg d'aliment

Tumeurs: néant
Organes/systèmes cibles: foie
Autres effets: diminution de la prise de poids, effets histopathologiques

Rat, oral, 24 mois:
Tumeur DSEO: > 20,000 mg/kg d'aliment
Toxicité DSENO: ~ 8,000 mg/kg d'aliment
Tumeurs: néant
Organes/systèmes cibles: yeux
Autres effets: diminution de la prise de poids, effets histopathologiques

Toxicité pour la reproduction/la fertilité

Rat, oral, 3 générations:
Toxicité DSENO: > 30 mg/kg de poids corporel
Reproduction DSENO: > 30 mg/kg de poids corporel
Organes/systèmes cibles chez les parents: néant
Autres effets chez les parents: néant
Organes/systèmes cibles chez les jeunes: néant
Autres effets chez les jeunes: néant

Toxicité sur le développement/tératogénicité

Rat, oral, 6 - 19 jours de gestation:
Toxicité DSENO: 1,000 mg/kg de poids corporel
Développement DSENO: 1,000 mg/kg de poids corporel
Autres effets sur l'animal mère: diminution de la prise de poids, survie réduite
Effets sur le développement: perte de poids, perte post-implantatoire, ossification tardive
Les effets sur la progéniture sont uniquement observés en cas de toxicité maternelle.

Lapin, oral, 6 - 27 jours de gestation:
Toxicité DSENO: 175 mg/kg de poids corporel
Développement DSENO: 175 mg/kg de poids corporel
Organes/systèmes cibles chez l'animal mère: néant
Autres effets sur l'animal mère: survie réduite
Effets sur le développement: néant

12. INFORMATIONS ÉCOLOGIQUES

Cette section est réservée à l'usage des écotoxicologues et autres spécialistes de l'environnement.

Les données obtenues sur des produits similaires et sur les composants sont résumées ci-dessous.

Formulation similaire

Toxicité aquatique, poissons

Truite arc-en-ciel (Oncorhynchus mykiss):
Toxicité aiguë, 96 heures, semi-statique, CL50: 3.13 mg/L
Relativement toxique.

Toxicité aquatique, algues/plantes aquatiques

Algue verte (Selenastrum capricornutum):
Toxicité aiguë, 72 heures, statique, CEb50 (biomasse): 0.124 mg/L
Hautement toxique.

Toxicité pour les arthropodes

Abeille commune (Apis mellifera):
Contact, 48 heures, DL50: > 250 µg/abeille
Presque pas toxique.

Abeille commune (Apis mellifera):
Oral, 48 heures, DL50: > 238.8 µg/abeille
Presque pas toxique.

Toxicité pour les organismes du sol, invertébrés

Ver de terre (Eisenia foetida):
Toxicité aiguë, 14 jours, CL50: > 10,000 mg/kg de sol sec
Presque pas toxique.

Toxicité pour les organismes du sol, micro-organismes

Test de transformation de l'azote et du carbone:
40 L/ha, 28 jours: Moins de 25% des effets sur les processus de transformation de l'azote et du carbone contenus dans le sol.

Formulation similaire

Toxicité aquatique, invertébrés

Daphnie (Daphnia magna):
Toxicité aiguë, 48 heures, statique, CE50: 8.0 mg/L
Relativement toxique.

N-(phosphonométhyl)glycine; {glyphosate}

Toxicité aviaire

Colin de Virginie (Colinus virginianus):
Toxicité alimentaire, 5 jours, CL50: > 4,640 mg/kg d'aliment
Seulement légèrement toxique.

Canard colvert (Anas platyrhynchos):
Toxicité alimentaire, 5 jours, CL50: > 4,640 mg/kg d'aliment
Seulement légèrement toxique.

Colin de Virginie (Colinus virginianus):
Toxicité orale aiguë, dose unique, DL50: > 3,851 mg/kg de poids corporel
Presque pas toxique.

Bioaccumulation

Crapet arlequin (Lepomis macrochirus):
Poisson entier: FBC: < 1
Aucune bioaccumulation significative n'est à prévoir.

Dissipation

Sol, champs:
Demi-vie: 2 - 174 jours
Koc: 884 - 60,000 L/kg
Se lie fortement au sol.

Eau, aérobique:
Demi-vie: < 7 jours

13. CONSIDÉRATIONS RELATIVES À L'ÉLIMINATION

Produit

Eviter la contamination des égouts, des canalisations, des fossés et des cours d'eau.
Recycler si les installations/l'équipement appropriés sont disponibles.
Brûler dans un incinérateur approprié.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.

Conteneur

Voir l'étiquette du conteneur pour les informations relatives à l'élimination.
Les conteneurs vidés contiennent encore de la vapeur et des résidus du produit.
Respecter toutes les consignes de sécurité jusqu'au nettoyage, au recyclage ou à la destruction du conteneur.
Vider complètement les emballages.
Rincer les conteneurs vides trois fois ou à la pression.
NE PAS contaminer l'eau lors de l'élimination des eaux de rinçage.
S'assurer que les emballages ne peuvent pas être réutilisés.
NE PAS réutiliser les conteneurs.

Entreposer jusqu'au ramassage par un service officiel chargé de l'élimination des déchets.
Recycler si les installations/l'équipement appropriés sont disponibles.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.

14. INFORMATIONS RELATIVES AU TRANSPORT

Les données reprises dans cette section servent uniquement d'infonnation. Prière de suivre les réglementations appropriées afin de classer correctement votre cargaison pour le transport.

Ce produit n'est pas classé dangereux selon les réglementations DOT, ICAO/IATA ou IMDG en vigueur.

15. INFORMATIONS RÉGLEMENTAIRES

PCPA enregistré.

16. AUTRES INFORMATIONS

L'information présentée ici n'est pas nécessairement exhaustive mais représente des données pertinentes et fiables.
Appliquer toutes les réglementations locales/régionales/nationales/internationales.
Prière de contacter le fournisseur pour obtenir de plus amples informations.

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ANNEXE B1: Monsanto Backgrounder, Glyphosate and Standard Toxicology Studies, September, 2002.

MONSANTO

Backgrounder
Glyphosate and Standard Toxicology Studies
September 2002

Monsanto Company

Toxicology is the study of the harmful effects of substances on living organisms: humans, plants and animals. Toxicological testing evaluates the biological response of living organisms to different routes and durations of exposure to a substance. Modern toxicology contributes to clinical, legal, occupational and veterinary medicine and plays a key role in the development of drugs, food additives, home products, cosmetics, industrial chemicals, agrochemicals, pesticides, etc. Paracelsus, a 16th Century Swiss physician recognized as the "father of toxicology," is noted for his principle that all substances are poisons if the dose is sufficiently high – "the dose makes the poison." He understood that the relationship between dose and response are inseparable. At very low doses, even notorious toxins such as arsenic will not cause harm. Conversely, at very high doses, essential substances such as water will harm or kill.

The story is no different for pesticides; at some dose they are harmful and at some dose they are harmless.

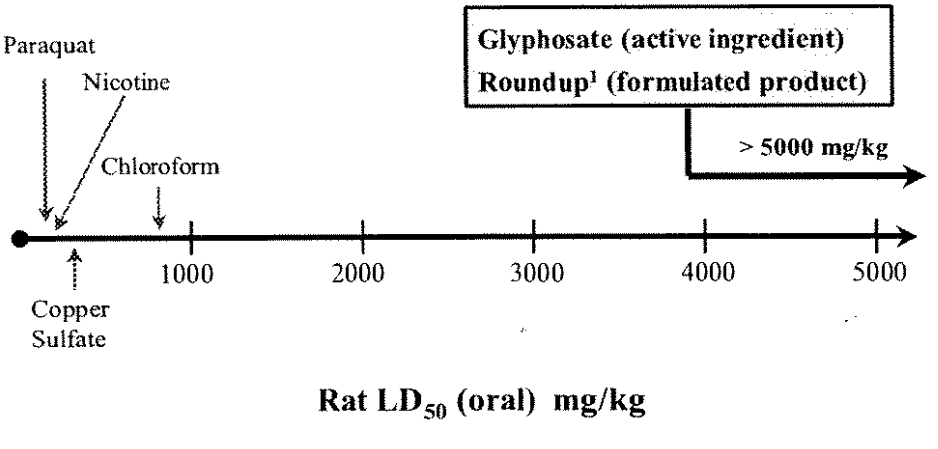
Pesticides (herbicides, insecticides, rodenticides, fungicides, etc.) cannot be categorized simply as "dangerous" just because they are classified as substances that kill pests. Likewise, no chemical, either natural (made by plants or other organisms) or synthetic (made by man), can be determined to be completely "safe." The study of toxicology determines what doses are harmful and what doses would not be expected to pose unreasonable risk. Pesticides are strictly regulated by governmental agencies around the world. In the United States, the U.S. Environmental Protection Agency has that responsibility and requires a battery of toxicological and environmental studies. On average, a pesticide active ingredient must undergo at least 120 tests before it can be registered for use. During the many years that glyphosate and glyphosate herbicides have been used, hundreds of toxicology studies have been conducted.

All pesticides are evaluated for acute, sub-chronic and chronic effects. Acute toxicological testing evaluates whether a single high-dose exposure to a substance will produce acute effects. (An acute effect could be anything from a skin rash to death.) Sub-chronic effects are related to several days or weeks of continuous exposure to a substance. Chronic effects occur after a long period (approaching a lifetime) of continuous exposure. Longer-term studies evaluate whether continual exposure to a substance has the potential to cause adverse effects, such as cancer, neurotoxicity, birth defects or reproductive problems.

Acute toxicity studies

Acute toxicity studies evaluate the risk from a single exposure to a substance, typically at a high dose. Acute oral and dermal toxicity studies are frequently designed to express the potency of a substance in terms of a median lethal dose or LD_{50}. The LD_{50} is the dose that is lethal to 50 percent of the laboratory animals in the test. The higher the LD_{50} value, the lower the toxicity. The dose is calculated as milligrams of the test substance per kilogram of body weight of the tested animals (mg/kg bw).

Figure 1. Acute Toxicology- Comparative



Selected from NIOSH Registry of Toxic Effects of Chemical Substances, 1979
Handbook of Pesticide Toxicology, Second Edition – Agents
[1]"Roundup"refers to the original single active ingredient formulation.

Laboratory studies show that glyphosate has acute rat oral and dermal LD_{50s} of greater than 5,000 mg/kg. The major use of the LD_{50} study is a comparative one, allowing an investigator to assess the relative toxicity of one substance with others tested in the same species (Figure 1). Accepted toxicology standards classify substances with an LD_{50} greater than 5,000 mg/kg as "practically non-toxic." (Remember, nothing can be considered *completely* non-toxic, because as Paracelsus knew, everything is toxic at some dose.)

In addition to acute rat oral and dermal studies, inhalation exposure also is evaluated to determine a spray concentration that is lethal to 50 percent of the test animals (LC_{50}). The dose is measured in milligrams of the test substance per liter of water (mg/L). Acute rat inhalation studies with glyphosate show that a high concentration is required to produce lethality.

The U.S. EPA places pesticides in one of four categories for acute toxicity, based on their LD_{50} and LC_{50} values. Category I is considered the most toxic, and category IV the least toxic. Glyphosate is assigned a Category IV ("practically non-toxic") for all three routes of exposure – oral, dermal and inhalation. Eye and skin irritation studies also are required to assess the potential for a substance to cause irritation. Glyphosate is assigned a Category IV for skin irritation. However because the technical material is an acid it can be moderately to severely irritating to the eyes. Glyphosate formulations are made not with the acid but with a salt of the acid. These salt solutions are considered practically non-irritating to the eyes and are assigned a Category IV. One other acute test is used to evaluate the potential of a pesticide to produce an allergic skin reaction after repeated skin contact. Glyphosate shows no evidence of causing a skin reaction.

Not only do the pesticide active ingredients undergo this battery of testing, but so does each product formulation containing the active ingredient. Most formulated herbicides in which

glyphosate is the active ingredient (e.g. Roundup UltraMAX® and Roundup Pro®) are also in Category IV for acute oral, dermal and inhalation toxicity.

Subchronic and chronic toxicity studies

The acute toxicity studies determine what dose is lethal to 50 percent of the test animals via a specific route of exposure, but they do not determine what dose poses no unreasonable risk. That determination is made by examining effects seen over a range of doses and durations of time. Sub-chronic studies last for a few weeks to months (~10 percent of the normal life span of the test animal), and chronic studies can last for a year or more (the expected lifetime of the test animal). Exposure routes are identical to those of acute testing programs (oral, dermal, inhalation). In sub-chronic and chronic oral toxicity studies, groups of test animals are given various daily doses, from zero to thousands of milligrams per kilogram of their body weight. At the end of a designated exposure period, virtually every organ system and physiological parameter is examined to determine any differences between exposed and non-exposed test animals. High doses must elicit sub-lethal effects, middle doses must evoke only minimal adverse effects and low doses should trigger no toxic effects whatsoever. Generally, three to five dose levels are tested. The highest tested dose level that produces no observed adverse effects is referred to as the NOAEL. Different toxicity studies produce different no-effect levels. The U.S. Environmental Protection Agency (EPA) bases its risk assessment on the lowest NOAEL recorded in the various studies. See the table below for a summary of NOAELs seen in various glyphosate toxicity studies submitted to the U.S. EPA.

Toxicity Study	**Glyphosate NOAEL (mg/kg/day)**[1]
Rat Subchronic	209
Rat Chronic	409
Rat Reproduction	694
Rabbit Developmental	175
U.S EPA - NOAEL	175

[1] Source: EPA, 1993

Between the NOAEL and the highest dose tested, there is usually a range of doses that produce a range of effects. Some effects can be quite serious, such as tumors or birth defects; others are minor and would be reversible with cessation of exposure. Through all of these studies, even very high sub-lethal doses of glyphosate have not produced effects such as cancer, birth defects, mutagenicity, neurotoxicity or reproductive abnormalities. Other effects, such as weight loss, elevated enzyme levels, etc. have been detected in those studies, almost always at very high doses. For example, in the rabbit developmental study, designed to determine if glyphosate causes adverse effects in pregnant animals and their developing offspring, no developmental effects were seen even at the highest dose which produced toxicity to the pregnant animal. The NOAEL for this study was considered to be the 175 mg dose. It was the lowest NOAEL from various studies.

Reference dose (RfD) includes uncertainty factors to reduce risk

After a NOAEL is determined the U.S. EPA applies uncertainty factors to account for differences between humans and test animals and individual variability. The agency also considers the types of effects that were seen at higher doses. Less serious effects normally constitute a lower margin of exposure. The margin for glyphosate has been set at 100-fold, as opposed to some other pesticides which have margins of exposure of 1,000 or more because of less favorable toxicological results. ***A 100-fold uncertainty factor means that acceptable human exposure for glyphosate has been established at a level that is 100 times lower than a tested dose that caused no observable adverse effect in tested animals.*** For glyphosate, the acceptable daily dietary exposure, referred to as reference dose (RfD) has been set at 2 mg/kg/day (175 mg/kg/day NOAEL divided by 100 = 1.75 mg/kg/day rounded up to 2 mg/kg/day).

In 1996, Congress unanimously passed landmark pesticide food safety legislation called the Food Quality Protection Act (FQPA). The FQPA mandated that allowable exposure levels more closely consider infants and children. The FQPA required the U.S. EPA to apply an additional 10-fold uncertainty factor to account for exposure to children, who have higher relative exposure because of their lower body weight. However, EPA was given the option of applying a lesser uncertainty factor "only if, on the basis of reliable data, such margin will be safe for infants and children" (FQPA, 1996). The additional uncertainty factor, when applied to the RfD, yields an exposure level called the chronic Population Adjusted Dose (cPAD).

EPA reviewed the toxicological database for glyphosate, determined that it was complete and concluded there was no indication of increased sensitivity to glyphosate among infants and children. Therefore, EPA used an FQPA uncertainty factor of 1, resulting in a cPAD for glyphosate of 2 mg/kg/day, the same as the RfD.

Calculating human exposure

In order to calculate human exposure to a pesticide, the U.S. EPA considers all possible routes, including food, water, applicator exposure, or bystander exposure from drift. Conservative assumptions are made throughout the process. Consider exposure through food, for example. EPA requires food residue studies for every crop on which a pesticide is to be used. For the study, the pesticide is applied at the maximum labeled rate. (Most farmers use rates much lower than the maximum allowed.) Crops are harvested and liquefied, and very sensitive equipment is used to seek traces of the pesticide. Multiple samples are taken from several test plots grown in various geographic regions. The sample with the highest amount of residue is recorded for the crop in question, even if some unusual condition may have been at play. If no residue is detected in any of the samples, EPA assumes a presence anyway. Based on these studies, EPA calculates how much residue could be present in crops treated with the pesticide. It is then assumed that every acre of every crop for which the pesticide is labeled receives an application of the pesticide (with no allowance for market share). Furthermore, EPA assumes that people consume every crop every day. (Glyphosate is labeled for use on more than 100 crops, so this is a very conservative assumption.) If adding up the residues from each crop yields a dose greater than the EPA's cPAD, the public is assumed to be at risk and some uses must be discontinued in order to reduce public exposure.

In September 2000, EPA approved a new crop use for glyphosate. At that time, the agency concluded that even non-nursing infants, whose food consumption relative to body weight is higher than adults, were exposed to no more than 3.2 percent of the allowable dose through food (U.S. EPA 2000).

Wildlife toxicology

In addition to many studies with laboratory animals to assess potential effects from human exposure, glyphosate has also been studied to determine effects on wildlife. The same toxicological principles apply – varying doses are given to representative species of birds, fish, insects and other invertebrates. The lethal dose or concentration is determined, and effects seen at lower doses are examined. A no-effect level is also determined. These studies show that glyphosate has very low toxicity to wildlife and that expected exposure from approved uses of glyphosate products would pose no unreasonable risk to wildlife.

Related Document:

Backgrounder: Glyphosate and Wildlife. December, 2002.

References

FQPA (Food Quality Protection Act). (1996) Title IV, Section 408 (a)(4)(c). http://www.fda.gov/opacom/laws/foodqual/fqpa4.htm

U.S. Environmental Protection Agency. (1993) Reregistration Eligibility Decision (RED): Glyphosate. EAP-738-F-93-011, September 1993, Washington, DC. http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf

U.S. EPA (2000) Final Rule: Glyphosate; Pesticide Tolerance. Federal Register 65(188): 57957, September 27.

ANNEXE B2: Monsanto Backgrounder, Response to "Glyphosate Toxic & Roundup Worse, Updated April, 2006.

MONSANTO imagine

Backgrounder
Response to "Glyphosate Toxic & Roundup Worse"
Updated April 2006

On March 7, 2005, The Institute of Science in Society (London, England) published an editorial by Dr. Mae-Wan Ho and Prof. Joe Cummins (see Appendix). This editorial called for urgent regulatory review of the most widely used herbicide in the light of new scientific evidence.

Ho and Cummins make the following statements:

- *"New research findings are raising serious concerns over the safety of the most commonly used herbicide, and should be sending shock waves through proponents of genetically modified (GM) crops made tolerant to the herbicide, which now account for 75% of all GM crops in the world."*
- *"There is now a wealth of evidence that glyphosate requires worldwide health warnings and new regulatory review. Meanwhile, its use should be reduced to a minimum as a matter of prudent precaution."*

This document provides d**irect responses** to six points that Ho and Cummins cite as evidence supporting a worldwide health warning, regulatory review and reduction in use of glyphosate and Roundup branded agricultural herbicides.

Point 1. *"However, glyphosate acts by preventing the binding of phosphoenol pyruvate to the active site of the enzyme, and phosphoenol pyruvate is a core metabolite present in all organisms; thus it has the potential to affect other metabolic pathways. This is borne out by many reports of toxicities associated with the herbicide reviewed in the Independent Science Panel Report, The Case for a GM-Free Sustainable World ."*[1]

Response:

- While the Independent Science Panel (ISP) could be considered "independent" as it is not formally affiliated with other organizations or institutions, the ISP members are opponents of plant biotechnology and have a long-standing position in opposition to this technology (see http://www.i-sis.org.uk/ispr-summary.php).

  While it is true that phosphoenol pyruvate is an important compound in the metabolism of virtually all plant and animal species, no effect of glyphosate on pyruvate metabolism in mammalian cells has ever been demonstrated. Glyphosate targets an enzyme not present in animal species and is not known to influence pyruvate metabolism by any other mechanism which would be relevant to humans or animals.

[1] The Case for a GM-Free Sustainable World, Chapter 7, ISIS & TWN, London & Penang, 2003. http://www.indsp.org/A GM-Free Sustainable World.pdf

Credible evaluations of Roundup branded agricultural herbicides and the active ingredient glyphosate can be obtained from the following:

- EPA Reregistration Eligibility Decision: Glyphosate (September 1993):
  Fact Sheet: http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf
  Full RED: http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf
- European Commission (2002) Report for the Active Substance Glyphosate, Directive 6511/VI/99, January 21.
  http://europa.eu.int/comm/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf
- WHO Environmental Health Criteria 159: Glyphosate (1994):
  http://www.inchem.org/documents/ehc/ehc/ehc159.htm
- Pesticide Residues in Food (2004). Report of the Joint FAO/WHO Meeting of Experts
  http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/2004_rep/report2004jmpr.pdf

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Point 2. *"An epidemiological study in the Ontario farming populations showed that glyphosate exposure nearly doubled the risk of late spontaneous abortions.*[2]*"*

Response:

- **Glyphosate does not cause miscarriages.**

Glyphosate is one of many pesticides mentioned in an epidemiological report that examined possible links between self-reported, on-farm pesticide use and self-reported reproductive outcomes. Savitz *et al.* (1997) used data from the Ontario Farm Family Health Study (OFFHS) and investigated associations between reported pesticide use by males and pregnancy outcomes, specifically: miscarriage, pre-term delivery and small-for-gestational-age birth. Savitz *et al.* found that a number of specific pesticides had weak statistical associations with miscarriages and pre-term deliveries, but pesticides tended not to be associated with small for gestational age births. There were no statistically significant findings for glyphosate.

Epidemiology studies of this type differ from biomonitoring studies in that groups of people – some with illnesses and some without – are asked to recall what pesticides they may have used or come in contact with. Those studies depend on the ability of the person to recall accurately, but more importantly, they do not measure whether there actually was any internal exposure or the extent of such exposure.

There was no quantified exposure data in this epidemiologic study by Savitz *et al.* Exposures were assumed based on questionnaire responses by study subjects about farm activities and pesticide use. This type of information can be inaccurate. Exposure related to the professional use of glyphosate-based formulations, through the monitoring of the single active ingredient glyphosate, has been the subject of a number of studies. The most recent published study is that by Acquavella *et al.*(2004).

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[2] Savitz DA, Arbuckle, Kaczor D, Curtis KM. (2000) Male pesticide exposure and pregnancy outcome. *Am J Epidemiol* 146: 1025-36.

Aquavella *et al.* (2004) found that only sixty percent of the farmers were found to have detectable levels of glyphosate in their urine on the day of application and that the geometric mean concentration was 3.2 ppb. The limit of detection was 1 ppb. The distribution of detectable values was highly skewed to low exposure since most detectable values were close to the limit of detection; the highest observed concentration was 233 ppb. Based on estimates of systemic dose, a farmer who did 10 applications per year for 40 years with this highest level of exposure would receive an exposure approximately 31,938 fold below a lifetime systemic dose that corresponds to the US Environmental Protection Agencies reference dose (equivalent to the ADI) of 2 mg/kg/day.

The results of the Savitz *et al.* study do not meet generally accepted criteria from the epidemiology literature for determining causal relationships. First, the associations were very weak and not statistically significant. Secondly, control for potential confounding factors, including other pesticides, was not possible due to limited available information and small numbers of subjects. Thirdly, there was no indication in these studies of a dose-response relationship. Lastly, there was no biological plausibility, the experimental evidence from several studies with laboratory animals show that glyphosate is not a reproductive or developmental toxicant. (EU 2002; EPA 1993; Williams *et al.* 2000).

Therefore, based on the extremely low exposures expected for humans, the lack of biological plausibility, and the lack of statistical significance, the reported association of adverse health effects in epidemiologic studies are unlikely to be valid.

Response References

Acquavella JF, Doe J, Tomenson J, Chester G, Cowell J, Bloemen L. 2003. Epidemiologic Studies of Occupational Pesticide Exposure and Cancer: Regulatory Risk Assessments and Biologic Plausibility. Annals of Epidemiology 13: 1-7.

Acquavella JF, Alexander BH, Mandel JS, Gustin C, Baker B, Chapman P, Bleeke M. 2004. Glyphosate Biomonitoring for Farmer-Applicators and their Families: Results from the Farm Family Exposure Study. Environ Health Perspect 112:321-326.

EPA Reregistration Eligibility Decision: Glyphosate (September 1993):
Fact Sheet: http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf
Full RED: http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf

European Commission. 2002. Report for the Active Substance Glyphosate, Directive 6511/VI/99, January 21.
http://europa.eu.int/comm/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf

Williams GM, Kroes R, Munro IC. 2000. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. Regul Toxicol Pharmacol 31: 117-165.

Point 3. *"Prof. Eric-Giles Seralini and his research team from Caen University in France decided to find out more about the effects of the herbicide on cells from the human placenta. They have now shown that glyphosate is toxic to human placental cells, killing a large proportion of them after 18 hr of exposure at concentrations below that in agricultural use.* [3]*"*

Response:

- **This study by Richard *et al.* tells us nothing about real-world risks to humans. Instead, it tells us what we already know – substances can injure unprotected cells in a test-tube. In the real world, Roundup agricultural herbicides have been used safely by farm workers for more than 30 years. The conclusions of the authors are contradicted by extensive animal studies and by extensive human experience.**

  The following response document is available:

  > **Glyphosate: Response to "Differential effects of glyphosate and Roundup on human placental cells and aromatase"**
  > (http://www.monsanto.com/monsanto/content/products/productivity/roundup/bkg_richard_response_2005.pdf)

  Some of the financial support for this research came from CRII-GEN. Professor Seralini is a member of this anti-biotech organization. (http://www.crii-gen.org/)

  It is also of interest to note that one of the first public forums that Professor Seralini discussed this research was during an interview with The Pesticide Action Network (PAN). (http://www.pan-uk.org/pestnews/pn63/pn63p4.htm)

  PAN is an inappropriate reference source to use for credible scientific and/or medical information on glyphosate. PAN is a global network of over 600 participating nongovernmental organizations, institutions and individuals in over 60 countries working to replace the use of what they perceive as hazardous pesticides. PAN, at its Fifth International Conference in Dakar, Senegal on May 21, 2000, stated in "The Dakar Declaration": "We commit ourselves to fight for the elimination of pesticides, the termination of genetic engineering of organisms in food and agriculture, the end of corporate globalization and the realization of food sovereignty and sustainable agriculture worldwide" (http://www.pan-international.org/dakarDeclarationEn.html). The lead author of the glyphosate summary referenced by the authors is Meriel Watts. She is spokesperson for the Pesticide Action Network, Aotearoa, New Zealand (http://www.geocities.com/no_spray/meriel_rally_spch.htm).

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[3] Richard S, Moslemi S, Sipahutar H, Benachour N and Seralini G-E. (2005) Differential effects of glyphosate and Roundup on human placental cells and aromatases. *Environmental Health Perspectives*, in press. http://dx.doi.org/doi:10.1289/ehp.7728

Point 4. *"There is, indeed, direct evidence that glyphosate inhibits RNA transcription in animals at a concentration well below the level that is recommended for commercial spray application Transcription was inhibited and embryonic development delayed in sea urchins following exposure to low levels of the herbicide and/or the surfactant polyoxyethyleneamine. The pesticide should be considered a health concern by inhalation during spraying.[4] "*

Response:

- **This study by Marc *et al.* tells us nothing about real-world risks to humans. Instead, it tells us what we already know – substances can injure unprotected cells in a test-tube. In the real world, Roundup agricultural herbicides have been used safely by farm workers for more than 30 years. The conclusions of the authors are contradicted by extensive animal studies and by extensive human experience.**

  Marc and her colleagues conducted *in vitro* studies using sea urchins. They have now published a number of articles based on the faulty premise that Roundup is enhancing the ability of glyphosate to get into cells to disrupt the cell cycle. While they measure a variety of cellular/molecular endpoints in these studies, the results are not reflective of cellular effects in real-life systems since non-specific changes in cell membrane function have been shown to occur due to surfactants and may also result from other changes in the culture medium such as effects on pH and calcium levels Note that when the sea urchin embryos are placed back in normal medium they develop into normal sea urchins, indicating a lack of any permanent biological effect.

  When surfactants found in products such as bath gels and shampoos that humans put directly on their bodies everyday were tested in the sea urchin assay they produced the same results as Marc *et al.* did ...cell cycle delays; see http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=9828259).

  Other researchers have found that caffeine also alters cell division in sea urchin embryos (see http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=9276510).

  One could focus on these findings and claim a variety of threats to human safety from shampoo, coffee, tea, and chocolate. A more scientifically appropriate conclusion, knowing what we do about the safety of these consumer products, is that the sea-urchin test system is simply not relevant to predicting adverse effects on human health.

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[4] Marc J, Le Breton M, Cormier P, Morales J, Belle R, Mulner-Lorillo O. (2005) A glyphosate-based pesticide impinges on transcription. *Toxicology and Applied Pharmacology* 203: 1-8.

Point 5. *"New research shows that a brief exposure to commercial glyphosate caused liver damage in rats, as indicated by the leakage of intracellular liver enzymes. In this study, glyphosate and its surfactant in Roundup were also found to act in synergy to increase damage to the liver.* [5] *"*

Response:

- **No similar effects on the liver were found in rats tested at high doses in regulatory studies conducted according to international guidelines under Good Laboratory Practices. (EU 2002, EPA 1993 and Williams et al 2000)**

  Due to the poor conduct and reporting of this study as well as the lack of corroborative findings in studies conducted according to international guidelines under Good Laboratory Practices the findings and conclusions of these authors are not credible.

  A critical flaw is the authors never tested glyphosate alone they only tested dilutions of a glyphosate-based formulation even though they report "We showed that glyphosate and its formulation products may act in synergy on the liver metabolism and/or injury."

  In order to evaluate combined effects it is necessary to determine the response of each agent alone; synergism is noted if the combination of the two agents produces a response that exceeds the sum of the two responses. The only substance tested was the formulation and since the formulation already contains glyphosate the comparison does not hold true. The study design should have been with two groups to be tested; glyphosate alone and the formulation-minus glyphosate.

Response References

EPA Reregistration Eligibility Decision: Glyphosate (September 1993):
Fact Sheet: http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf
Full RED: http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf

European Commission (2002) Report for the Active Substance Glyphosate, Directive 6511/VI/99, January 21.
http://europa.eu.int/comm/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf

Williams GM, Kroes R, Munro IC. 2000. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. Regul Toxicol Pharmacol 31:117-165

[5] Benedetti AL, de Lourdes Vituri C, Trentin AG, Dominguesc MAC, Alvarez-Silva M. (2004) The effects of sub-chronic exposure of Wistar rats to the herbicide Glyphosate-Biocarb. *Toxicology Letters* 153: 227-232.

Point 6. *"Three recent case-control studies suggested an association between glyphosate use and the risk of non-Hodgkin lymphoma [6,7,8] while a prospective cohort study in Iowa and North Carolina that includes more than 54 315 private and commercial licensed pesticide applicators suggested a link between glyphosate use and multiple myoeloma [9]. Myeloma has been associated with agents that cause either DNA damage or immune suppression. These studies did not distinguish between Roundup and glyphosate, and it would be important for that to be done."*

Response:

- **Glyphosate is not carcinogenic or mutagenic. In June 1991, the US EPA placed glyphosate in the agency's most positive cancer classification (Category E) "evidence of non-carcinogenicity for humans--based on the lack of convincing evidence of carcinogenicity in adequate studies." There is no credible evidence that glyphosate or that Roundup herbicides cause cancer in humans.**

  Regulatory authorities and independent experts around the world agree that glyphosate, the active ingredient in Roundup brand agricultural herbicides, does not cause cancer, even at very high doses.

  The World Health Organization, in its 1994 review of glyphosate studies, states: "Animal studies show that glyphosate is not carcinogenic."

  The U.S. Environmental Protection Agency (EPA), after reviewing studies conducted for re-registration of glyphosate, stated in 1993: "Several chronic toxicity/carcinogenicity studies...resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study." EPA rates all pesticides according to their potential to cause cancer. In June 1991, EPA placed glyphosate in the agency's most positive cancer classification (Category E) "evidence of non-carcinogenicity for humans--based on the lack of convincing evidence of carcinogenicity in adequate studies."

  The most recent review was conducted by the European Commission's Health and Consumer Protection Directorate-General, after which glyphosate was re-registered for use in Europe (Jan. 21, 2002). The EC review, like others around the world, concluded that glyphosate is not carcinogenic. Reviews in Canada and Japan also found no evidence of cancer in glyphosate studies as well three independent scientists (Williams *et al.*, 2000)

  It is important to note that, in the most recent study by DeRoos *et al.* (2005), cancer rates were found to be the same for glyphosate users and non-users. Furthermore, no association was found between glyphosate users and all major types of cancers including the lymphopoetic cancers – non-Hodgkin's lymphoma (NHL), leukemia and multiple myeloma. Only in one analysis of a restricted subgroup of the study population, there was a weak association between frequency of glyphosate use and multiple myeloma. However, other

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[6] De Roos AH, Zahm SH, Cantor KP, Weisenburger DD, Holmes FF, Burmeister LF, Blair A. (2003) Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. *Occup Environ Med* 60: E11.

[7] Hardell L, Eriksson M, Nordstrom M. (2002) Exposure to pesticides as risk factor for non-Hodgkin's lymphoma and hairy cell leukemia: pooled analysis of two Swedish case-control studies. *Leuk Lymphoma* 43: 1043-1049.

[8] McDuffie HH, Pahwa P, McLaughlin JR, Spinelli JJ, Fincham S, Dosman JA, Robson D, Skinnider LF, Choi NW. (2001) Non-Hodgkin's lymphoma and specific pesticide exposures in men: Cross-Canada study of pesticides and health. *Cancer Epidemiol Biomarkers Prev* 10:1155-63.

[9] De Roos AJ, Blair A, Rusiecki JA, Hoppin JA, Svec M, Dosemeci M, Sandler DP and Alavanja MC. (2005) Cancer incidence among glyphosate-exposed pesticide applicators in the agricultural health study. *Environ Health Perspect* 113, 49-54.

analyses in the paper were conflicting in this matter. In any large study with hundreds of statistical analyses, occasional weak associations are expected by chance alone.

Regarding NHL, conflicting results have reported by De Roos *et al.* In 2003, De Roos *et al.* reported that there was an association with glyphosate and NHL. In 2005, De Roos *et al.* reported no association between glyphosate and NHL. Furthermore, it is important to point out that the De Roos *et al.* (2003) paper was a re-analysis of data from three studies in the 1980's, in which no association for glyphosate with NHL was observed.

The four references above are all epidemiologic studies. Epidemiology studies differ from biomonitoring studies in that groups of people – some with illnesses and some without – are asked to recall what pesticides they may have used or come in contact with. Those studies depend on the ability of the person to recall accurately, but more importantly, they do not measure whether there actually was any internal exposure or the extent of such exposure.

There was no measured exposure data in these epidemiologic studies by De Roos *et al.*, Hardell *et al.* and McDuffie *et al.*. Exposures were assumed based on questionnaire responses by study subjects about farm activities and pesticide use. This type of information can be inaccurate. Exposure related to the professional use of glyphosate-based formulations, through the monitoring of the single active ingredient glyphosate, has been the subject of a number of studies. The most recent published study is that by Acquavella *et al.*(2004).

When evaluating epidemiologic findings, it can be helpful to compare the range of likely exposure levels to the exposure levels of toxicologic significance (Acquavella *et al.* 2003). The cancer no-effect levels for glyphosate, based on rat and mouse lifetime feeding studies, are 1,000 and 1,500 mg/kg/day, respectively (Williams *et al.* 2000). Acquavella *et al.* (2004) reported results of a biomonitoring study in which 48 farmers collected all of their urine over 5 consecutive days (before, during, and for 3 days after a glyphosate application). In this study, the maximum systemic dose resulting from application of glyphosate to areas as large as 400 acres was 0.004 mg/kg. The geometric mean systemic dose was 0.0001 mg/kg. Accordingly, in the worst-case situation, had a farmer made a similar application every day for a lifetime, the systemic dose would be at least 250,000-fold lower than the cancer no-effect level in rodents. Indeed, this very large margin of exposure combined with the lack of evidence for genotoxicity must be factored into an assessment of biological plausibility.

Based on the consistent finding that glyphosate is not carcinogenic or mutagenic, the conflicting associations of glyphosate with NHL and multiple myeloma, and the extremely low exposures expected for humans, the reported association of adverse health effects in epidemiologic studies is unlikely to be valid.

Response References:

Acquavella JF, Doe J, Tomenson J, Chester G, Cowell J, Bloemen L. 2003. Epidemiologic Studies of Occupational Pesticide Exposure and Cancer: Regulatory Risk Assessments and Biologic Plausibility. Annals of Epidemiology 13: 1-7.

Acquavella JF, Alexander BH, Mandel JS, Gustin C, Baker B, Chapman P, Bleeke M. 2004. Glyphosate Biomonitoring for Farmer-Applicators and their Families: Results from the Farm Family Exposure Study. Environ Health Perspect 112:321-326.

EPA Reregistration Eligibility Decision: Glyphosate (September 1993):
Fact Sheet: http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf
Full RED: http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf

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Appendix

Following is the item that this response document is addressing:

From **Institute of Science in Society** website: http://www.i-sis.org.uk/GTARW.php
ISIS Press Release, March 7, 2005

Glyphosate Toxic & Roundup Worse

Dr. Mae-Wan Ho and Prof. Joe Cummins call for urgent regulatory review of the most widely used herbicide in the light of new scientific evidence

New research findings are raising serious concerns over the safety of the most commonly used herbicide, and should be sending shockwaves through proponents of genetically modified (GM) crops made tolerant to the herbicide, which now account for 75% of all GM crops in the world.

Worse yet, the most common formulation of the herbicide is even more toxic than the herbicide by itself, and is made by the same biotech giant that created the herbicide tolerant GM crops.

Broad-spectrum herbicide glyphosate (N-(phosphonomethyl)glycine), commonly sold in the commercial formulation Roundup (Monsanto company, St. Louis, Missouri USA) has been frequently used both on crops and non-crops areas world wide since it was introduced in the 1970s. Roundup is a combination of glyphosate with other chemicals including a surfactant (detergent) polyoxyethyleneamine that enhance the spreading of the spray droplets on the leaves of plants. The use of Roundup has gone up especially in countries growing Roundup-tolerant GM crops created by Monsanto.

Glyphosate kills plants by inhibiting the enzyme, 5-enolpyruvoyl-shikimate-3-phosphate synthetase (EPSPS), essential for the formation of aromatic amino acids such as phenylalanine, tyrosine and tryptophan; which leads onto vitamins and many secondary metabolites such as folates, ubiquinones and naphthoquines. It is believed to be rather specific in action and less toxic than other herbicides, because the shikimate pathway is not present in mammals and humans. However, glyphosate acts by preventing the binding of phosphoenol pyruvate to the active site of the enzyme, and phosphoenol pyruvate is a core metabolite present in all organisms; thus it has the potential to affect other metabolic pathways. This is borne out by many reports of toxicities associated with the herbicide reviewed in the Independent Science Panel Report, *The Case for a GM-free Sustainable World* [1].

An epidemiological study in the Ontario farming populations showed that glyphosate exposure nearly doubled the risk of late spontaneous abortions [2], and Prof. Eric-Giles Seralini and his research team from Caen University in France decided to find out more about the effects of the herbicide on cells from the human placenta.

They have now shown that glyphosate is toxic to human placental cells, killing a large proportion of them after 18 hr of exposure at concentrations below that in agricultural use [3]. Moreover, Roundup is always more toxic than its active ingredient, glyphosate; at least by two-fold. The effect increased with time, and was obtained with concentrations of Roundup 10 times lower than agricultural use.

The enzyme aromatase is responsible for making the female hormones estrogens from androgens (the male hormones). Glyphosate interacts with the active site of the enzyme but its effect on enzyme activity was minimal unless Roundup was present.

Interestingly, Roundup increased enzyme activity after 1 h of incubation, possibly because of its surfactant effect in making the androgen substrate more available to the enzyme. But at 18h incubation, Roundup invariably inhibited enzyme activity; the inhibition being associated with a decrease in mRNA synthesis,

suggesting that Roundup decreased the rate of gene transcription. Seralini and colleagues suggest that other ingredients in the Roundup formulation enhance the availability or accumulation of glyphosate in cells.

There is, indeed, direct evidence that glyphosate inhibits RNA transcription in animals at a concentration well below the level that is recommended for commercial spray application Transcription was inhibited and embryonic development delayed in sea urchins following exposure to low levels of the herbicide and/or the surfactant polyoxyethyleneamine. The pesticide should be considered a health concern by inhalation during spraying [4].

New research shows that a brief exposure to commercial glyphosate caused liver damage in rats, as indicated by the leakage of intracellular liver enzymes. In this study, glyphosate and its surfactant in Roundup were also found to act in synergy to increase damage to the liver [5].

Three recent case-control studies suggested an association between glyphosate use and the risk of non-Hodgkin lymphoma [6-8]; while a prospective cohort study in Iowa and North Carolina that includes more than 54 315 private and commercial licensed pesticide applicators suggested a link between glyphosate use and multiple myoeloma [9]. Myeloma has been associated with agents that cause either DNA damage or immune suppression. These studies did not distinguish between Roundup and glyphosate, and it would be important for that to be done.

There is now a wealth of evidence that glyphosate requires worldwide health warnings and new regulatory review. Meanwhile, its use should be reduced to a minimum as a matter of prudent precaution.

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ANNEXE B3: Monsanto Backgrounder, Glyphosate: Response to non-Hodgin's Lymphoma Allegations, July, 2002.

MONSANTO

Backgrounder
Glyphosate: Response to non-Hodgkin's Lymphoma Allegations
July, 2002

Monsanto Company

A 1999 epidemiologic study from Sweden asked people with non-Hodgkin's lymphoma (NHL) (a cancer typically associated with the lymph nodes) – to recall what pesticides they had used in past years (Hardell and Eriksson 1999). The Swedish authors reported weak, non-statistically significant associations between NHL and several herbicides, including glyphosate. The Swedish authors did not conclude that the glyphosate associations were causal, but merely expressed the opinion that further epidemiologic research on glyphosate was warranted. Nonetheless, the *New Scientist* periodical (Pierce and Mackenzie 1999) cited the Swedish study to raise questions about the potential for glyphosate to cause cancer in people.

Leading international experts from Karolinska Institute, Harvard, Yale and the University of Birmingham, UK do not consider the results to be credible evidence of a glyphosate cancer link. A review by world renowned epidemiologists concluded that uncontrolled risk factors, errors in exposure assessment, or chance (as indicated by the lack of statistical significance in this study) are likely explanations for the weak glyphosate / NHL association (Adami and Trichopolous, 1999; Cullen 1999; Jackson et al., 1999). Dr. Cullen of Yale University's School of Medicine indicated *"the evidence regarding glyphosate in relation to NHL is meaningless, and it would be highly inappropriate to construe this as a positive study in that regard."* Similarly, a review by Dr. Hans-Olav Adami of Karolinska Institute in Sweden and Dr. Dimitrios Trichopolous of Harvard University concluded, *"This is a study that has limited power, was inadequately designed, poorly analyzed and confusingly reported. "*

In addition, the results of the study do not meet well-established criteria from the epidemiology literature for determining causal relationships. First, the association was deemed very weak. Secondly, there was no control for exposure to other pesticides. Thirdly, no dose response relationship was demonstrated. Lastly, there is no experimental evidence from several long-term studies with laboratory animals that glyphosate is mutagenic or carcinogenic, so the biological plausibility of the glyphosate / NHL finding is dubious.

Glyphosate is widely considered by regulatory authorities to have no evidence that it might cause cancer in people (U.S. Environmental Protection Agency 1993, World Health Organization 1994). These assessments were based on thorough reviews of numerous toxicology studies conducted according to internationally accepted guidelines.

The most recent review was conducted by the European Commission's Health and Consumer Protection Directorate-General, after which glyphosate was re-registered for use in Europe (European Commission 2002). The EC review, like others around the world, concluded that glyphosate is not carcinogenic.

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[1] Unpublished references can be requested from Monsanto's Public Affairs Director for Agricultural Chemicals at 314-694-3546.

ANNEXE B4: Monsanto Backgrounder, Glyphosate: Response to Hairy Cell Leukemia Allegations, August, 2002.

MONSANTO

Backgrounder
Glyphosate: Response to Hairy Cell Leukemia Allegations
August, 2002

Monsanto Company

A 1998 epidemiologic study from Sweden investigated the potential or suspect occupational causes of hairy cell leukemia (HCL) (Nordstrom et al., 1998). HCL is a blood cancer that is manifest as the proliferation of a particular type of white blood cell. It has been classified by some as a variant non-Hodgkin's lymphoma (NHL), while others treat it as a related disorder with a likely different origin and disease process.

This HCL study preceded the widely publicized NHL and pesticides study from the same Swedish research group. In addition to agricultural chemicals, this HCL study also considered exposure to farm animals and numerous other factors (e.g. wood impregnating agents, petroleum derivatives, "exhausts", ultraviolet light, "mold dust", asbestos, etc.). The authors reported modest but statistically significant associations for all herbicides, all insecticides, all fungicides, impregnating agents, all animals, all solvents, and paint. Leading experts do not consider the results of this study to be credible evidence that any of the agricultural factors studied are causes of HCL. In fact, the study authors themselves recommended that caution be used when interpreting the results. According to Dr. Mark Cullen of Yale University's School of Medicine: *"the fact that virtually every tested factor proved positive -- inconceivable biologically -- speaks to simpler interpretation, namely differential reporting by cases and controls"* (Cullen, 1999).

In 2001, the HCL study was reviewed by several experts (Acquavella et al., 2001). These authors proposed that recall bias was the most likely explanation for the reported findings. Recall bias refers to the fact that ill people are more likely than well people to recall exposure to suspected substances. Acquavella et al. conclude: *"In view of the intrinsically weak measure of exposure, the multiple hypotheses being tested, the evidence for possible recall bias, the small numbers of cases and controls with exposure to any herbicide (16 and 22 respectively), and the inability to control for confounding factors, the validity of reported associations between HCL and specific agents is questionable."*

The results of the Nordstrom et al. study do not meet well-established criteria from the epidemiology literature for determining cause and effect. The associations were weak and there was no dose-response relationship. Finally, there is no experimental evidence from several long-term studies with animals that support the findings.

There is widespread agreement among regulatory and health organizations that there is no evidence that glyphosate might cause cancer in people (U.S. Environmental Protection Agency 1993, World Health Organization 1994). These assessments were based on thorough reviews of numerous toxicology studies conducted according to internationally accepted guidelines. The most recent review was conducted by the European Commission's Health and Consumer Protection Directorate-General, after which glyphosate was re-registered for use in Europe (European Commission 2002). The EC review, like others around the world, concluded that glyphosate is not carcinogenic.

Related Documents: Backgrounder: Glyphosate and Biomonitoring Studies

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[1] Unpublished references can be requested from Monsanto's Public Affairs Director for Agricultural Chemicals at 314-694-3546.

ANNEXE B5: Monsanto Backgrounder, Summary of Human Risk Assessment and Safety Evaluation on Glyphosate and Roundup® Herbicide, Update May, 2005.

MONSANTO
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Backgrounder
Summary of Human Risk Assessment and Safety Evaluation on Glyphosate and Roundup® Herbicide
Updated May, 2005

In 2000, three internationally recognized toxicologists published a peer-reviewed safety evaluation and risk assessment of glyphosate and the original Roundup herbicide formulation.[1] The authors reviewed Monsanto studies which had previously been reviewed by regulatory authorities around the world.[2] In addition, they reviewed regulatory and scientific organization reports as well as a wide array of studies conducted by independent researchers using information obtained from public literature. Over a two-year period, they examined and critiqued 188 documents to prepare a comprehensive evaluation of glyphosate.

For most agricultural and industrial uses, Roundup formulations are sold as a concentrated glyphosate solution (as either the isopropylamine salt or the potassium salt) and must be diluted with water before application. The reviewers conducted a risk assessment of the original Roundup formulation, the POEA surfactant, the active ingredient, glyphosate, and its major breakdown component, AMPA (aminomethylphosphonic acid). They considered exposures during both application of the product and consumption of treated food crops.

The article, "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans," by Gary M. Williams, Robert Kroes, and Ian C. Munro, was published in *Regulatory Toxicology and Pharmacology*, Volume 31, pages 117-165 (2000).

Key findings of this study include:

- **Glyphosate is not a carcinogen.** *"The chronic toxicity and oncogenic potential of glyphosate ... have been evaluated by a number of regulatory agencies and by international scientific organizations. Each of these groups has concluded that glyphosate is not carcinogenic." (p. 126)* This conclusion is based on long-term studies in which mice and rats were fed extremely high doses of glyphosate every day for two years. The U.S. EPA has placed glyphosate in Category E ("evidence of non-carcinogenicity for humans"), the most favorable carcinogenicity category possible.

- **Roundup herbicide, like glyphosate, has very low acute toxicity, which means very high exposure is required to cause an adverse effect.** The reviewers evaluated the potential short-term (acute) exposure and risk to herbicide applicators and children living on a farm. These two population groups have the maximal opportunity for exposure because they

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[1] In this Backgrounder, "Roundup" refers to the original Roundup agricultural herbicide (MON 2139), which contained the active ingredient glyphosate (as the isopropylamine salt), water and a surfactant (polyoxyethylene-alkylamine or POEA).

[2] *"Government regulatory agencies in several countries, international organizations, and other scientific institutions and experts have reviewed the available scientific data and independently judged the safety of glyphosate and Roundup. Conclusions from three major health organizations [Health Canada, United States Environmental Protection Agency (U.S. EPA), and World Health Organization (WHO)] are publicly available (Health and Welfare Canada, 1986, 1992; U.S. EPA, 1993, 1997a, 1998a; WHO 1994a). Those reviews, which have applied internationally accepted methods, principles, and procedures in toxicology, have discovered no grounds to suggest concern for human health." (pp. 118-119)*

are most likely to come in contact with herbicide sprays and residues. In addition, children age 1 to 6 are assumed to have the highest dietary exposure because they eat more of some foods per body weight than other age groups. In the exposure assessment, it was assumed that the child occasionally enters a recently sprayed farm field and stays there for up to five hours, playing or helping a parent. The authors compared the acute oral LD50s of glyphosate and POEA to a calculated acute exposure to these two subgroups. (LD50 is a standard for expressing the toxicity of a compound.) The calculated acute exposure of the two subgroups in the on-farm study that have maximal assumed opportunity for exposure were estimated to be 40,000 to 50,000 times lower than the LD50 of glyphosate and 7,360 to 13,200 times lower than the LD50 of POEA. *(p. 159-160)* Other studies showed that serious effects occurred only when large amounts of concentrated Roundup (e.g. ≥ 41%) were intentionally ingested. *(p. 149)*

- ***"Under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans."*** *"Roundup is placed in U.S. EPA's least toxic category (IV) for acute oral, dermal and inhalation toxicity. Thus, the Roundup formulation is considered to be practically nontoxic by all these routes of exposure. ... POEA is considered to be only slightly toxic and does not represent an acute toxicity hazard." (p. 129) "Results from several investigations establish that the acute toxicity and irritation potential of Roundup herbicide in humans is low." (p. 148)* With Roundup formulations containing the POEA surfactant, there is potential for eye irritation if the spray is misdirected or if splashing occurs during mixing with water. The surfactant POEA, in its concentrated form, is severely irritating to eyes, but the researchers reported that *"POEA is not used in concentrated form but rather is formulated at lower concentrations into an end-use product (Roundup) and later diluted to very low levels, rendering it significantly less irritating ... When diluted to a concentration commonly used for most spraying applications (~1%), Roundup was shown to be only minimally irritating to eyes and essentially non-irritating to skin." (p. 129)* The researchers also addressed a statistic commonly cited by pesticide activist groups, which identify Roundup as a leading cause of pesticide illness in California. *"Careful examination of the California data further indicates that the number of cases reported simply reflects greater use of the product relative to other herbicides and shows that glyphosate has relatively low toxicity among pesticides used in the State ... In 1994, for example, glyphosate exposure was reported in only 25 cases, of which only 13 were considered "definite or probable." Eleven of the 13 cases involved only minor and reversible eye irritation; the other two cases were a headache and an apparent misdiagnosis of reaction to hydrocarbon solvent, which is not an ingredient in Roundup."* The researchers noted that the California Department of Pesticide Regulation, which compiles pesticide illness figures, noted in its 1994 report that the majority of people reporting Roundup exposure experienced only irritant effects and that in 13 years of record keeping, there had been no hospitalization linked to Roundup. *(pp. 147-148)*

- **Glyphosate does not bioaccumulate.** *"The potential for systemic exposure is limited by the combination of poor absorption and rapid excretion of glyphosate after oral and/or dermal contact." (p. 124)* As glyphosate is not stored in the body, any exposure from skin contact or inhalation would be quickly eliminated by humans and animals.

- **Glyphosate does not adversely affect reproduction or development.** *"Results from several studies have established that glyphosate is not a reproductive or developmental toxicant." (p. 128)* In developmental toxicity studies, and in multi-generation animal studies in which high doses were fed to laboratory animals, *"there were no effects on fertility or reproductive parameters, and glyphosate did not produce birth defects." (pp. 127-128)* The developmental toxicity of the surfactant predominantly used in Roundup formulations worldwide (POEA) and its possible effects on the reproductive system have also been

evaluated in animal studies. *"There is no evidence that the surfactant or Roundup herbicide adversely impacts reproductive function." (p. 131)* The authors devoted several paragraphs to their critique of a rabbit study often cited by pesticide critics to imply sperm count reduction. (Yousef et al., 1995) *"There were a number of serious deficiencies in the design, conduct and reporting of this study which make the results uninterpretable. ... the data from this study cannot be used to support any meaningful conclusions." (p. 127-128)*

- **Children are not at greater risk.** *"The U.S. EPA has recently evaluated tolerance petitions under the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) which includes special provisions to protect infants and children. The U.S. EPA concluded that there is "reasonable certainty" that no harm will occur from aggregate exposure to glyphosate (U.S. EPA 1997a, 1998a)." (p. 128)* EPA also concluded that the currently applied safety factor of 100 is adequate to protect children. *"There was no suggestion of increased severity of effect in infants or children or of increased potency or unusual toxic properties of glyphosate in infants and children." (p.156)*

- **There is no evidence of endocrine disruption.** *"The endocrine-modulating potential of glyphosate has been evaluated in a variety of studies including* in vitro *assays and standard* in vivo *toxicology studies. The* in vivo *studies comprehensively assess endocrine functions that are required for reproduction, development, and chronic health. Glyphosate produced no effects in* in vitro *assays, and there was no indication of changes in endocrine function in any of the* in vivo *studies. Results from standard studies with AMPA, Roundup herbicide, and the POEA surfactant also failed to show any effects indicative of endocrine modulation. Therefore, it is concluded that the use of Roundup herbicide has no potential to produce adverse effects on endocrine systems in humans nor in other mammals." (p.143)*

- **There is no synergistic adverse effect.** Herbicides sometimes are applied in combination with other herbicides, raising the question of whether the combination creates a synergistic effect (more than an additive response). *"The toxicity of glyphosate has been evaluated in combination with several surfactants and/or other herbicides ... it is concluded that the simultaneous exposure of glyphosate and other materials does not produce a synergistic response." (p. 145)*

References in italics throughout this document refer to statements or concepts expressed by the authors of "Safety evaluation and risk assessment of the herbicide Roundup® and its active ingredient, glyphosate, for humans."

BIOGRAPHICAL DATA:

Gary M. Williams, M.D., is Director of Environmental Pathology and Toxicology and Head of the Program on Medicine, Food and Chemical Safety at New York Medical College, Valhalla., N.Y. He is a board-certified pathologist, physician and toxicologist in the United States and has also been certified as an Expert in Toxicology by the French Ministere des Affaires. He has served as an editor or editorial board member for more than 25 scientific journals and papers. Williams has also organized more than 20 scientific meetings and conferences around the world, many of which discussed safety assessments of pharmaceuticals and chemicals, and cancer screening tests and prevention.

Robert Kroes, Ph.D., is the Director of the Research Institute for Toxicology at Universiteit Utrecht in The Netherlands. He is board-certified in toxicology and pathology and specializes in toxicology, oncology and risk assessments. He served for seven years as Deputy Director General of the Dutch National Institute of Public Health and Environmental Protection. He

has served as a member of more than 20 international expert panels on toxicology, oncology and environment and health, including groups impaneled by the World Health Organization, the Food and Agriculture Organization of the United Nations, the Organization for Economic Cooperation and Development, and the European Union. He is an editorial board member of 13 scientific periodicals.

Ian C. Munro, Ph.D., is President of CANTOX Health Sciences International and a professor in the Department of Nutritional Sciences at the University of Toronto, Ontario, Canada. He is a Fellow at The Academy of Toxicological Sciences and the Royal College of Pathologists in London. He has more than 150 scientific publications in the fields of toxicology and risk assessment. He formerly held senior positions at Health and Welfare Canada as Director of the Bureau of Chemical Safety and Director General of the Food Directorate, Health Protection Branch. He also was Director of the Canadian Centre for Toxicology at Guelph, Ontario. Munro has served on more than 30 expert panels, nationally and internationally, including those of the World Health Organization, the International Agency for Research on Cancer and the U.S. National Academy of Sciences, where he chairs a subcommittee. He is a recipient of the "International Achievement Award" of the International Society of Regulatory Toxicology and Pharmacology. He has served on the editorial boards of Neurotoxicology, the Journal of the American College of Toxicology, and the Journal of Environmental Pathology and Toxicology.

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ANNEXE B6: Monsanto Backgrounder, Glyphosate: No Evidence of Carcinogenicity, September, 2005.

MONSANTO imagine

Backgrounder
Glyphosate: No Evidence of Carcinogenicity
September, 2005

Regulatory authorities and independent experts around the world agree that glyphosate, the active ingredient in Roundup® brand herbicides and other glyphosate-based herbicides, does not cause cancer, even at very high doses.

The World Health Organization, in its 1994 review of glyphosate studies, states: "Animal studies show that glyphosate is not carcinogenic..." (WHO 1994)

In 1993, the U.S. Environmental Protection Agency (EPA), after reviewing studies conducted for re-registration of glyphosate, stated: "Several chronic toxicity/carcinogenicity studies...resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study" (U.S. EPA 1993). EPA rates all pesticides according to their potential to cause cancer. In June 1991, EPA placed glyphosate in the agency's most positive cancer classification (Category E) "evidence of non-carcinogenicity for humans -- based on the lack of convincing evidence of carcinogenicity in adequate studies" (U.S. EPA 1997).

A regulatory review was conducted by the European Commission's Health and Consumer Protection Directorate-General, after which glyphosate was re-registered for use in Europe (European Commission 2002). The EC review, like others around the world, concluded that there was "no evidence of carcinogenicity". Reviews by Canadian regulators (Doliner 1991) also found no evidence that glyphosate causes cancer.

In 2004, the World Health Organization and Food and Agriculture Organization of the United Nations, in their report on pesticide residues in food, stated: "Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In the study of carcinogenicity in mice, no toxic effects were observed at up to the highest dose tested (1000 mg/kg bw per day), and there was no evidence of carcinogenicity" (WHO/FAO 2004).

In 2000, an international panel of toxicology experts published a peer-reviewed assessment of glyphosate studies (Williams *et al.*, 2000). They state: "Multiple lifetime feeding studies have failed to demonstrate any tumorigenic potential for glyphosate. Accordingly, it was concluded that glyphosate is noncarcinogenic."

A comprehensive human health risk assessment prepared for the U.S. Forest Service (Durkin 2003) stated: "Based on standard animal bioassays for carcinogenic activity *in vivo*, there is no basis for asserting that glyphosate is likely to pose a substantial risk."

EXTOXNET, a network of pesticide information provided by university extension toxicologists, reviewed several studies in which very high doses of glyphosate were administered to laboratory animals for up to two years. The EXTOXNET profile of glyphosate states: "Rats given oral doses of up to 400 mg/kg/day did not show any signs of cancer, nor did ... mice fed glyphosate at doses of up to 4500 mg/kg/day. It appears that glyphosate is not carcinogenic." The doses administered in those studies are thousands of times higher than the exposure that would be possible from expected use of the product.

Related Documents:

- Summary of Human Risk Assessment and Safety Evaluation on Glyphosate and Roundup® Herbicide
- Glyphosate: Response to non-Hodgkin's Lymphoma Allegations
- Glyphosate: Response to Hairy Cell Leukemia Allegations
- Glyphosate and Biomonitoring Studies

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[1] All internet links were functional on August 30, 2005.

ANNEXE B7: Monsanto Backgrounder,: Glyphosate and Reproductive Outcomes, January, 2004.

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Backgrounder
Glyphosate and Reproductive Outcomes
January, 2004

Monsanto Company

Glyphosate is one of many pesticides mentioned in three epidemiological reports that examine possible links between on-farm pesticide use and reproductive outcomes. All three reports--Savitz *et al.* (1997), Curtis *et al.* (1999), and Arbuckle *et al.* (2001) – use data from the Ontario Farm Family Health Study (OFFHS) (Arbuckle 1994). Savitz *et al.* (1997) investigated associations between reported pesticide use by males and pregnancy outcomes, specifically: miscarriage, pre-term delivery and small-for-gestational-age birth. Curtis *et al.* (1999) studied whether reported pesticide use by males or females was associated with delayed pregnancy, while Arbuckle *et al.* (2001) looked for associations between reported pesticide use and spontaneous abortion.

The OFFHS was a questionnaire-type study in which farm couples were asked to recall on-farm activities and pesticide usage on the farm during the previous 5 years. They were also asked to recall all pregnancy outcomes, 38% of which occurred more than 10 years before the survey. The farm couples lived year-round on a farm and the OFFHS investigators employed mail questionnaires to collect information about pregnancy outcomes from the mothers. Telephone follow-up was employed for non-respondents.

In the study by Savitz *et al.*, a number of specific pesticides had weak statistical associations with miscarriages and pre-term deliveries, but pesticides tended not to be associated with small for gestational age births. There were no statistically significant findings for glyphosate. In the study by Curtis *et al.*, for farms on which glyphosate was used, there was no significant association for women being engaged in pesticide activities. For men, glyphosate use was associated with a slight, but statistically significant, decrease in time to pregnancy. The authors dismissed this finding, which was contrary to their hypothesis that pesticide exposure delayed pregnancy, as probably due to uncontrolled factors or chance. Arbuckle *et al.* (2001) found that reported preconception use of phenoxyacetic acids, triazines, glyphosate, and thiocarbamates were weakly, but statistically significantly, associated with spontaneous abortions. Post conception reported use was not associated with increased risk. The authors characterized the associations between pesticides and spontaneous abortions as "hypothesis generating" pending confirmation from other epidemiologic studies.

These studies are not convincing evidence of a relationship between glyphosate exposure and adverse pregnancy outcomes for a number of reasons:

1. **Uncertainty about exposure**

   There was no actual exposure data per se in these three epidemiologic studies. Exposures were assumed based on questionnaire responses by study subjects about farm activities and pesticide use. This type of information can be inaccurate. For example, according to a study by the National Cancer Institute, self-reports of pesticide usage were found to be only 60 percent accurate when compared with purchasing records (Blair & Zahm 1993). Further increasing the potential for inaccuracy is the fact that study subjects were only asked about pesticide use for the 5 years before the OFFS survey. These responses were assumed to be applicable to the entire farming careers of study subjects, an assumption inconsistent with

changes in agricultural practice. Lastly, basing exposure estimation on questionnaire responses has the potential to be influenced by what epidemiologists call "recall bias." This refers to the likelihood that families that experienced an adverse reproductive outcome are more likely to remember use of certain pesticides than families that had only normal births. The most widely used pesticides, like atrazine, glyphosate, and 2,4-D, are most easily recalled and most likely to be over-reported.

2. **Low biological plausibility**

   Biologic plausibility is an important criterion for deciding whether a reported statistical association between a pesticide and a disease is likely to be valid. Glyphosate, even at very high doses in chronic feeding studies, does not cause adverse reproductive outcomes in laboratory animals (USEPA 1993, WHO 1994). This makes statistical associations from epidemiologic studies less plausible.

3. **Inaccuracy of reported pregnancy outcomes**

   The OFFHS study relied exclusively on maternal self-reports of adverse pregnancy outcomes with no medical or other validation. Generally, scientists place less confidence in reports of health outcomes that are not validated with medical records.

4. **Confounding**

   A confounding factor is a cause of a disease that is correlated with another exposure being studied. Failure to control confounding factors, especially those that are strong causes of a disease, can create spurious associations between benign exposures and diseases. In the Arbuckle study, there were at least three important potential confounding factors that were not controlled: history of previous spontaneous abortion, maternal age, and smoking. Even a weak correlation between these factors and use (or recall of use) of pesticides would produce spurious associations. In addition, in all three studies, the authors did not control the putative effect of one pesticide for the putative effects of other pesticides. So, for example, since farmers tend to use 4 or more pesticides each year, a disease that is associated with one pesticide will likely be associated with all, since their use patterns are correlated. In the absence of an analysis that controls for multiple pesticides, the best that can be said is that the findings for any individual pesticide might be due to its correlation with another pesticide.

In summary, three publications based on data collected in the OFFHS found associations between several pesticides and various adverse reproductive outcomes. There was no actual exposure data per se in these three epidemiologic studies. Exposures were assumed based on questionnaire responses by study subjects about farm activities and pesticide use. This type of information can be inaccurate. Glyphosate was not significantly associated with adverse reproductive outcomes in two of these studies (Savitz *et al.* 1997, Curtis *et al.* 1999). Glyphosate and other pesticides were weakly associated with spontaneous abortion in the study by Arbuckle (2001). However, the author did not control for important personal confounding factors or for multiple exposures and no actual exposure data was used, casting doubt on the validity of the findings in this study.

Biomonitoring data for glyphosate, collected as part of the Farm Family Exposure Study (FFES), provide assurance that human health effects related to glyphosate exposure are very unlikely. In the FFES, researchers from the University of Minnesota collected 5 days of urine samples from 48 farm families before, during, and after a glyphosate application (Mandel *et al.*, accepted for publication). Only 60% of farmers showed detectable exposure to glyphosate, with a 1 part per billion limit of detection, and the maximum estimated absorbed dose was 0.004 mg/kg (Acquavella *et al.*, 2004). For farmers who apply glyphosate 10 times per year for 40 years, this

maximum dose is more than 30,000-fold less than the EPA reference dose[1] of 2 mg/kg/day. For spouses, only 4% showed detectable exposures and the maximum systemic dose was 0.00004 mg/kg/day. Since glyphosate is not a reproductive toxic in high dose animal studies (USEPA 1993, WHO 1994) and since actual exposures on farms are so low, it is very unlikely that glyphosate would cause adverse reproductive outcomes for farmers or their spouses.

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[1] The reference dose is a numerical estimate of a daily oral exposure to the human population, including sensitive subgroups such as children, that is not likely to cause harmful effects during a lifetime. http://www.epa.gov/OCEPAterms/rterms.html (updated 5/22/03).

ANNEXE B8: Monsanto Backgrounder, Glyphosate and Reproductive Toxicology, September, 2002.

MONSANTO

Backgrounder
Glyphosate and Reproductive Toxicology
September 2002

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Regulatory authorities and independent experts around the world agree that glyphosate does not cause adverse reproductive effects in adults or birth defects in offspring of these adults exposed to glyphosate, even at very high doses. This conclusion is based on multiple studies in laboratory animals that have been conducted to examine the potential for such effects. These include studies in which laboratory animals, their offspring and the next generation of offspring have been examined for adverse effects.

An international panel of renowned toxicologists reviewed the extensive data for glyphosate (Williams et al., 2000). They concluded that the normal use of the original Roundup herbicide[1] "does not result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals." The World Health Organization (WHO 1994), the U.S. Environmental Protection Agency (US EPA 1993, 1997) and the European Commission (2002) also have reviewed the data and concluded that the use of glyphosate according to label directions would not result in adverse reproductive or developmental problems or birth defects.

The U.S. EPA has evaluated glyphosate data according to parameters established by the Food Quality Protection Act of 1996, which required special consideration of potential effects of pesticide use on children. The U.S. EPA (1997) concluded that "there is reasonable certainty that no harm will occur to infants and children from aggregate exposure to glyphosate". The following in vivo (live animal) toxicology studies have been conducted and reviewed by regulatory authorities, other scientific bodies and independent experts:

Three-Generation Rat Reproduction: Male and female rats were fed glyphosate at dosages of 0, 3, 10, and 30 mg/kg/day everyday throughout the production of three successive generations. No adverse treatment-related effects on reproduction were observed. Likewise, there were no other adverse effects as determined by gross and microscopic pathology examinations.

Two-Generation Rat Reproduction: Male and female rats were fed glyphosate at dose levels of 0, 2000, 10,000 and 30,000 parts per million (ppm; equivalent to approximately 0, 100, 500 and 1500 mg/kg body weight/day) everyday throughout the production of two successive generations. It was concluded that reduced body weights and soft stools occurred at 30,000 ppm (a very high dose representing approximately 3 percent of the diet). Glyphosate did not affect the ability of rats to mate, conceive, carry or deliver normal offspring at any dose and no treatment-related effects were seen at 10,000 ppm (1 percent of diet) and below.

Rat Teratology: No birth defects were observed in the offspring of pregnant rats given glyphosate by gavage at dose levels of 0, 300, 1000, and 3,500 mg/kg/day on days 6 through 19 of gestation. Only the highest dose caused adverse effects in the parent. No adverse effects were seen in either the parent or the offspring at 1,000 mg/kg/day.

[1] "Roundup" refers to the original single active ingredient Roundup herbicide formulation (also known as MON 2139).

Rabbit Teratology: No birth defects were observed in the offspring of pregnant rabbits given glyphosate by gavage at dose levels of 0, 75, 175 and 350 mg/kg/day on days 6 through 27 of gestation. Only the highest dose caused adverse effects in the parent.

Wildlife studies:

In reproduction studies with bobwhite quail and mallard ducks, glyphosate was fed to male and female birds at dietary concentrations of 0, 50, 200 and 1,000 ppm for 16-17 weeks. There was no effect on reproductive success in either species at any dose tested.

In a chronic fathead minnow study, fish were exposed to glyphosate concentrations of 0.7, 2.8, 7.0. 13.0 and 25.7 mg/l for 255 days. No treatment-related effects were reported on the survival, growth and egg production of first generation fish or on hatchability, survival and growth of second-generation eggs and fry.

In summary, the results of these studies indicate that glyphosate does not produce birth defects and is not a reproductive toxin.

Williams et al. (2000) also evaluated these studies to determine if glyphosate use had the potential to adversely affect the function of endocrine systems. They evaluated the active ingredient (glyphosate), its primary breakdown product (AMPA, aminomethylphosphonic acid), the original Roundup herbicide[1], and the polyethoxylated tallowamine (POEA) surfactant in the original Roundup herbicide[1]. The authors concluded:

> "The endocrine-modulating potential of glyphosate has been evaluated in a variety of studies including *in vitro* assays and standard *in vivo* toxicology studies. The *in vivo* studies comprehensively assess endocrine functions that are required for reproduction, development, and chronic health. Glyphosate produced no effects in *in vitro* assays, and there was no indication of changes in endocrine function in any of the *in vivo* studies. Results from standard studies with AMPA, Roundup herbicide, and the POEA surfactant also failed to show any effects indicative of endocrine modulation. Therefore, it is concluded that the use of Roundup herbicide has no potential to produce adverse effects on endocrine systems in humans nor in other mammals."

The U.S. EPA (1997) also concluded that there are no significant findings in other relative toxicity studies (*i.e.*, teratology and multigeneration reproduction studies) which would suggest that glyphosate produces endocrine effects.

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ANNEXE B9: Monsanto Backgrounder, Glyphosate: Response to "Differential effects of glyphosate and Roundup on human placental cells and aromatase", June, 2005.

MONSANTO imagine

Backgrounder

Glyphosate: Response to "Differential effects of glyphosate and Roundup on human placental cells and aromatase"

June 2005

In March 2005, Prof. Gilles-Eric Seralini's group in the University of Caen (Normandy, France) published the results of a study examining the effect of Roundup and glyphosate on cultured cells derived from a human placental cancer (choriocarcinoma) (Richard *et al.*, 2005).

The authors imply that Roundup (see Note) is an endocrine disruptor based on effects in human tumor cells originally derived from a cancer of the placenta. Aromatase activity, which is required for the production of certain steroid hormones, was decreased when these tumor cells were exposed to high concentrations of Roundup in a Petri dish for 18 hours.

The study, while interesting, has no relevance to a living animal. The implications of this *in vitro* experiment are contradicted by extensive live animal data and field studies reflecting real-world conditions.

The cells used in this study were taken from a human placental tumor, put into a Petri dish, and covered with culture media containing Roundup or other test materials. This direct exposure to high concentrations is vastly different than what would occur in a human or animal body, i.e. - the concentration of Roundup reported to have caused a reduction in aromatase activity was orders of magnitude greater than would result from the highest possible human exposure under real conditions. The direct exposure used in this study intentionally bypasses normal processes limiting absorption and cellular exposure and avoids normal metabolism, digestion and excretion that would protect cells from the minute amounts of chemical.

These cell lines are used as mechanistic research tools and are not recognized or accepted by any regulatory agency or other scientific body in the world for the assessment of human health risks.

Glyphosate has been tested extensively in higher order animals (Giesy *et al.* 2000; Williams *et al.* 2000). There is no evidence for developmental or reproductive effects in multiple species despite numerous high-dose tests by different manufacturers (EU, 2002). Furthermore, studies with surfactants in Roundup agricultural herbicides have demonstrated no target organ toxicity or effects on the embryos, fetus, or placenta (Williams *et al.* 2000).

Walsh *et al.* (2000) previously suggested that Roundup had endocrine disruption potential based on decrease in progesterone synthesis in mouse Leydig tumor cells exposed to supra-physiologic concentrations of formulated herbicide in a Petri dish. Monsanto and an academic collaborator (Levine *et al.* 2003; Heydens *et al.* 2003) repeated this experiment with the inclusion of a sensitive cytotoxicity assay that assessed mitochondrial membrane damage. This experiment demonstrated that decreased progesterone synthesis resulted from surfactant-induced

Note: The Roundup® product line consists of multiple agricultural and residential use products with varying ingredients and concentrations. Richard *et al.* have not specified the product or formulation used in their research. The term Roundup is used herein to refer generally to Roundup agricultural herbicides having glyphosate as the active ingredient.

mitochondrial membrane damage. In separate follow-up experiments, a number of surfactants commonly found in household products were tested. Each of these surfactants produced concentration-dependent decreases in progesterone synthesis and cytotoxicity comparable to that observed with concentrated Roundup formulation when tested in these mouse tumor cells. The results of these studies underscore: (1) the non-specific action of a variety of surfactants on cellular function in an *in vitro* test system; and (2) how this secondary activity can confound the results when surface-active agents are used in *in vitro* test systems.

Based on estimates of human exposure to Roundup herbicides from agricultural and residential uses by various routes, and based upon the non-specific metabolic effects of surfactants on tumor cells in Petri dishes, it is apparent that Roundup will not disrupt steroid synthesis *in vivo* under biologically relevant conditions.

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ANNEXE B10: Monsanto Backgrounder, Summary of Ecotoxicological Risk Assessment for Roundup® Herbicide, February, 2005

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Backgrounder
Summary of Ecotoxicological Risk Assessment for Roundup® Herbicide
February, 2005

In 2000, three internationally recognized experts in environmental toxicology published a peer-reviewed environmental safety evaluation of glyphosate and the original Roundup herbicide formulation[1] that has been used around the world for more than twenty years. The authors reviewed Monsanto studies that had been previously considered by regulatory authorities around the world[2]. In addition, they reviewed reports from regulatory and scientific institutions, as well as a wide array of studies conducted by independent researchers using information from the public literature. Over a two-year period, more than 250 documents were reviewed to evaluate the potential risk to wildlife (including mammals, birds, insects, soil invertebrates, microorganisms, fish, amphibians, and aquatic invertebrates) and non-target vegetation.

The article, "Ecotoxicological Risk Assessment for Roundup® Herbicide," by John P. Giesy, Stuart Dobson and Keith R. Solomon, was published in *Reviews of Environmental Contamination and Toxicology*, (2000) Volume 167, pages 35-120. The overall findings of this evaluation are described below.

Summary of Findings

The current state of knowledge on the ecological effects of Roundup® herbicide and its active ingredient, glyphosate, was reviewed. A comprehensive ecotoxicological risk assessment was conducted using a conservative hazard quotient method, in which a hazard quotient less than 1 indicates minimal risk of adverse effects. The no-effect-level for the most sensitive species was used as the toxicity endpoint in the assessment for aquatic and terrestrial organisms potentially exposed to Roundup or its components. Exposure levels were derived from environmental monitoring data or dissipation models. The predicted maximum acute and chronic hazard quotients were less than 1 for aquatic and terrestrial organisms following terrestrial Roundup uses, confirming that there is minimal risk of adverse effects. The acute assessment for honeybees also indicated minimal risk of adverse effects. Minimal risk of adverse effects was also indicated for beneficial arthropod populations in areas adjacent to treated areas. The authors concluded that expected vegetation change in treated areas can impact beneficial arthropod populations living there. The authors further concluded that Roundup use for aquatic habitat restoration can be conducted without unreasonable adverse effects on the environment, provided that factors such as application rate, depth of water, vegetation density, and overall rehabilitation goals are considered. This assessment indicates that application of Roundup in terrestrial and aquatic sites, including agriculture, forestry, residential, rights-of-way and habitat restoration, poses minimal risk to non-target species.

[1] In this Backgrounder, "Roundup" refers to the original Roundup agricultural herbicide (MON 2139), which contained the active ingredient glyphosate (as the isopropylamine salt), water and a surfactant (polyoxyethylenealkylamine or POEA).

[2] *"Formulations of glyphosate, including Roundup® Herbicide, have been extensively investigated for their potential to produce adverse effects in non-target organisms. Governmental regulatory agencies, international organizations, and others have reviewed and assessed the available scientific data for glyphosate formulations, and independently judged their safety. Conclusions from three major organizations are publicly available and indicate Roundup can be used with minimal risk to the environment (Agriculture Canada 1991; United States Environmental Protection Agency (USEPA) 1993a; World Health Organization (WHO) 1994)." (p. 36)*

Key Findings:

- **Glyphosate dissipates from soil and water.** Glyphosate has been shown to degrade in soil to naturally occurring products. *"Field studies indicate that glyphosate typically dissipates rapidly from both simple ecosystems, such as agricultural, and more complex ecosystems, such as forestry..." (p. 51)* Glyphosate has been shown to degrade in terrestrial and aquatic systems, predominantly via microbial processes. Field studies conducted in agricultural and forest soils (13 studies, 5 countries, 47 different sites) indicate an average half-life of 32 days. *"Both field and laboratory studies have reported microbial degradation of glyphosate to AMPA and CO_2 in aquatic environments and rapid dissipation from both flowing and standing surface waters."* (p.53). *"The results of field studies indicate that 50% of the concentration of glyphosate initially found in water dissipates within time periods ranging from a few days to 2 weeks."* (p. 53)

- **Contact with soil reduces bioavailability.** *"Once glyphosate enters the soil, it is essentially unavailable to plants due to its very high affinity for soil."* (p. 43)

- **Minimal leaching and runoff.** *"Although glyphosate is very soluble in water, its strong sorption to soils limits mobility."* (p. 48) *"Glyphosate is unlikely to leach into ground water or runoff significantly into surface water following application.* (p. 49) *"POEA* [the surfactant in Roundup] *strongly adsorbs to soil ... thus, the mobility of POEA in soil is expected to be less than 2%."* (p. 50)

- **Spray drift is well characterized.** *"Glyphosate has no significant vapor pressure; therefore, loss of glyphosate to the atmosphere via vaporization from treated surfaces is negligible."* (p.47) Spray drift can occur into non-target areas, but the drift levels have been well characterized. No long-term adverse effects are predicted for animals or soil microbes as a result of aerial spray drift. Non-target plants directly adjacent to the treated fields may be affected if present at a sensitive life stage; however, no effects are predicted at distances greater than 4 m. *"Aerial applications can result in increased drift relative to ground applications, but recent technological advances have significantly reduced aerial spray drift."* (p. 103)

- **No significant bioaccumulation in animals.** *"Neither glyphosate nor Roundup would be expected to bioaccumulate."* (p. 57) *"...glyphosate does not bioconcentrate in fish or other animals."* (p. 103).

- **Terrestrial applications pose little risk to:**
  Aquatic organisms (including amphibians) – *"[Hazard Quotient] values are considerably less than 1.0, indicating that Roundup poses minimal risk to aquatic organisms following terrestrial use."* (p. 89) *"...minimal risk from the application of Roundup would be expected for sediment dwelling organisms."* (p. 89)
  Soil organisms – *"...minimal acute hazard is predicted for populations of soil organisms."* (p. 94) *"The weight of evidence for effects of Roundup on soil microorganisms indicates that adverse effects would be unlikely as a result of application at normal field rates ... Earthworms are predicted to be at minimal risk from the use of Roundup or glyphosate."* (p. 95-96)
  Beneficial arthropods (insects) – *"...the literature supports the conclusion that non-target arthropods are at minimal risk from glyphosate and its formulations."* (p. 99) Most effects result from habitat change because of the decision to remove vegetation. *"Several studies have found that the application of glyphosate can increase populations of*

beneficial insects ... No effects on the number of common butterfly species were observed when glyphosate was used to control trees, shrubs and blackberry in wire zones; but numbers of individuals did increase." (p. 99) *"Honeybees are not affected by glyphosate formulations, either by ingestion or direct overspray, at maximum use rates."* (p. 103)
Birds – *"Several comprehensive field studies have observed birds in forest plots treated with Roundup ... In no case was there evidence of direct toxicity of Roundup or glyphosate to birds."* (p. 97)
Mammals – *"It has been concluded that there is minimal risk to small mammals from the application of glyphosate products and that the effects observed in the field studies are a result of changes in habitat."* (p. 98)

- **Aquatic applications help restore wildlife habitat.** *"Glyphosate has been used extensively to control aquatic weeds and restore ecosystems affected by introductions of exotic weeds."* (p. 101) The objective of an aquatic herbicide application is to remove weed species. *"It is inevitable that some short-term population level effects on plants and associated animals should occur in the pursuit of a long-term goal characteristic of restoration/rehabilitation projects."* (p. 100) Roundup[3] can be safely used for aquatic habitat restoration projects with knowledge of the water depth, vegetation density, and overall rehabilitation goal.

REFERENCES IN ITALICS THROUGHOUT THIS DOCUMENT REFER TO STATEMENTS OR CONCEPTS EXPRESSED BY THE AUTHORS OF "ECOTOXICOLOGICAL RISK ASSESSMENT FOR ROUNDUP® HERBICIDE."

BIOGRAPHICAL DATA:

John P. Giesy, Ph.D., is Distinguished Professor of Zoology at Michigan State University in East Lansing, Michigan, where he is also a Professor of Veterinary Medicine and on the faculties of the Center for Integrative Toxicology and a member of the National Food Safety and Toxicology Center. Prof. Giesy is a world leading ecotoxicologist with interests in many aspects of ecotoxicology, including both the fates and effects of potentially toxic compounds and elements, particularly in the area of ecological risk assessment. He has conducted research into the movement, bioaccumulation and effects of toxic substances at different levels of biological organization, ranging from biochemical to ecosystem. Currently, Prof. Giesy and his research group are actively studying the toxicity and reproductive effects of organic compounds, with special emphasis on herbicides, chlorinated dioxins and perfluorinated compounds. Prof. Giesy is an expert in ecological risk assessments of both industrial and agricultural chemicals. He has authored several books and more than 150 peer-reviewed publications, and has presented hundreds of lectures worldwide. He is the recipient of the Sigma Xi Meritorious Research Award, the CIBA-GEIGY Agricultural Recognition Award, and the Willard F. Shepard Award from the Michigan Water Pollution Control Association. Prof. Giesy is a Fellow of the Cooperative Institute for Limnology and Ecosystems Research, and is currently a member of the Executive Committee of the Board of Scientific Counselors (BOSC) of the US EPA's Office of Research and Development.

Stuart Dobson, Ph.D., is the head of the Research Station at Monks Wood, Centre for Ecology and Hydrology, Cambridgeshire, United Kingdom. He is a member of the Advisory Committee on

[3] Only certain Roundup-branded formulations in certain world areas are labeled for aquatic use. Other glyphosate herbicide products are labeled for aquatic use in other world areas. Use of a product inconsistent with its label is a violation of law and is strictly prohibited.

Toxic Substances, Health and Safety Executive, the chairman of the Core Assessment Group (Environment) of the Joint Meeting on Pesticides (WHO/FAO) and an advisor representing the United Kingdom Department of the Environment on the Advisory Committee on Pesticides for licensing new products. He is also a consultant to the International Programme on Chemical Safety (World Health Organization) and a consultant to the United Kingdom Department of Environment on toxic chemical effects on wildlife.

Keith R. Solomon, PhD., is Director for the Center of Toxicology, University of Guelph and is also a Professor in the Department of Environmental Biology. Professor Solomon teaches courses in toxicology and pesticides at the University of Guelph. He directs an active program of research into the fate and effects of pesticides in the environment as well as exposure of humans to pesticides. He currently serves on several advisory committees on matters related to environmental toxicology and pesticides in the USA and Canada and is an active member of the Society of Environmental Toxicology and Chemistry, the Entomological Society of American and the Toxicology Forum. He is the recipient of the 1993 Society for Environmental Toxicology and Chemistry-ABC Laboratories award for Environmental Education. He is a Graduate of Rhodes University in Chemistry and Zoology and holds M. Sc. degrees from Rhodes University and the University of Illinois as well as a Ph.D. from the University of Illinois. He has more than 25 years of experience in research and teaching in pesticide science and environmental toxicology and has contributed to more than 100 scientific publications in the fields of pesticides and environmental toxicology.

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ANNEXE B11: Monsanto Backgrounder, Glyphosate and Environmental Fate Studies, Updated April, 2005.

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Backgrounder
Glyphosate and Environmental Fate Studies
Updated April 2005

Monsanto Company

Before a herbicide can be registered for use, it must undergo rigorous studies to determine what happens to the compound after it is released into the environment, either from an intended use or an accidental release, such as a spill. These studies, referred to as "environmental fate" studies, are reviewed by the U.S. Environmental Protection Agency (EPA) and regulators in other world areas and are designed to provide answers to the following questions:

Does the herbicide:

- degrade after application? If so, what degradation products are formed after application?
- persist in soil?
- have residual herbicidal activity in soil?
- persist in water or sediment?
- leach through soil to reach groundwater?
- move from treated areas as runoff?
- move from treated areas as a vapor?
- accumulate in tissues of animals?

Laboratory and field studies have been conducted with glyphosate and glyphosate herbicides (such as Roundup UltraMax, Roundup Pro, and AquaMaster™) to address these questions. The overall results of these environmental fate studies are summarized below

Degradation processes and products

The processes by which a herbicide is degraded must be understood before the U.S. EPA and other regulatory agencies will register the herbicide. Some products break down by chemical processes, others through photodegradation, and others by microbial activity or a combination of several processes. Glyphosate is primarily degraded by microbes and fungi in the soil or in surface water. Photodegradation in water and soil are not expected to contribute significantly to glyphosate degradation.

The identity and characteristics of the compounds that are formed as a herbicide degrades must also be determined. The primary environmental degradate of glyphosate in soil and water is aminomethylphosphonic acid (AMPA). AMPA is further degraded to naturally-occurring substances such as carbon dioxide and phosphate. Acute oral and dermal toxicity studies with rats and mice in the laboratory demonstrate that AMPA has very low acute toxicity to mammals (Williams *et al.*, 2000). A number of ecotoxicology studies have been conducted to assess AMPA's toxicity to aquatic and terrestrial species. Based on the results, AMPA can be characterized as having little toxicity to non-target organisms (Giesy *et al.*, 2000).

Degradation in soil

Studies must also be performed to determine how much of the herbicide would be expected to remain in soil following normal use, and the rate of degradation. Research shows that glyphosate is degraded over time by soil microorganisms. The degradation rate of chemical

compounds is measured by their half-life (the time required for half of the applied compound to degrade). The average half-life for glyphosate, based on 47 agricultural and forestry studies conducted in diverse geographic locales, is 32 days (Giesy *et al.*, 2000). In most cases, over 90% of the applied glyphosate is expected to dissipate within six months after application.

Binding to soil

Glyphosate binds very tightly to most soils and sediments in the environment. Studies show that the soil-binding potential of glyphosate is stronger than that of nearly any other herbicide. A ratio known as the "soil adsorption coefficient" (K_{oc}) measures the soil-binding capacity of chemical compounds, with higher numbers meaning greater adsorption of the compound to soil.

The following table shows representative K_{oc} values for several herbicides, as reported by Wauchope *et al.* (1992):

Active ingredient	K_{oc} (L/kg)
2,4-D esters	100
Atrazine	100
Alachlor	170
Metolachlor	200
Pendimethalin	5,000
Trifluralin	8,000
Glyphosate	24,000
Oxyfluorfen	100,000

Herbicidal activity of residues in soil

Because of its strong soil-binding properties in most soils, glyphosate is not available for uptake by roots of nearby plants, and therefore poses negligible risk to non-target plants with roots in the application zone. Further evidence of this is provided by the fact that even susceptible, conventional crops may be planted directly into fields that were recently treated with a glyphosate herbicide. Studies also show that glyphosate herbicides, when used according to label directions, are not harmful to soil microbes, earthworms or other soil-dwelling organisms (Giesy *et al.*, 2000).

Degradation in water

Both field and laboratory studies have reported microbial degradation of glyphosate in aquatic environments (Giesy *et al.*, 2000). Analysis of available data representing many studies indicates that the typical aquatic half-life of glyphosate ranges from 7 to 14 days . Studies have established that microorganisms in surface waters break down glyphosate over time. Also, because of its strong affinity for soil, glyphosate binds to suspended sediment particles that are present in natural waters. As the particles settle to the bottom, microbial degradation continues. Toxicology studies show that glyphosate levels that might occasionally be detected in surface waters following terrestrial application are sufficiently low so that there is negligible risk to aquatic organisms. In situations where a glyphosate herbicide is applied to weeds growing in water, the exposure of non-target aquatic species is expected to be reduced due to interception by target vegetation and dissipation over time via binding to sediment and microbial degradation.

Leaching and runoff

Two primary factors determine whether a chemical is likely to leach through soil to groundwater or be subject to movement into surface water via runoff -- the rate of degradation in the soil, and the chemical's tendency to bind to soil. Slow degradation and a low tendency to bind to soil can result in leaching and runoff of a chemical, whereas higher degradation rates and tight binding to soil both limit the movement of a chemical by leaching and runoff.

With its combination of degradability and strong binding to soil, glyphosate has extremely low potential to move through the soil profile and has rarely been detected in groundwater. In addition, only limited amounts of glyphosate move to surface water as runoff. A three-year study of glyphosate transport from agricultural fields showed that less than 1 percent of glyphosate applied was typically lost as runoff. In one case, a loss of 1.85 percent of applied glyphosate was observed for a field treated at twice the recommended application rate, with more than 99 percent of the total runoff occurring during a severe rainstorm that occurred the day after application (Edwards *et al.*, 1980). If soil particles containing glyphosate are washed or blown into lakes or streams, the vast majority of the glyphosate will remain adsorbed to the soil and settle to the bottom as sediment. In sediment, glyphosate is degraded over time by microorganisms. Studies also show that sediment-dwelling organisms are not adversely affected by glyphosate (Simenstad *et al.*, 1996).

Bioaccumulation

Aquatic Species: In laboratory studies conducted with several aquatic species, glyphosate bioconcentration factors were less than or equal to 12, indicating that glyphosate has a low potential for bioaccumulation in aquatic animals (Giesy *et al.*, 2000). The low bioconcentration factors are a result of glyphosate being readily soluble in water, and therefore subject to rapid elimination from organisms in water.

Terrestrial Species: Studies conducted with laboratory mammals indicate that glyphosate is poorly absorbed when ingested; any absorbed glyphosate is rapidly eliminated, resulting in minimal tissue retention (Williams *et al.*, 2000). Feeding studies with chickens, cows and pigs have shown extremely low or non-detectable residues in meat and fat following repeated exposures. Negligible residues have also been reported in wild animals such as voles, chipmunks, hares and moose after feeding in treated areas.

Vapor and drift

The active ingredients in some herbicides are volatile, meaning that they can move as vapors to non-target areas after application. This can result in unintended consequences to sensitive plant species outside the treated area. Several laboratory studies show that glyphosate has extremely low vapor pressure and thus there is a negligible risk of glyphosate movement through volatility (Giesy *et al.*, 2000).

However, it is possible, as with any sprayed substance, that spray droplets could drift off-target during application. Research has demonstrated that application procedures and equipment can be optimized to significantly reduce spray drift in most circumstances. Spray drift can be minimized by taking into account spray droplet size, wind speed, other environmental factors and application equipment design. When drift does occur, there is a rapid decline in surface deposition with increasing distance from the target site for both ground and aerial applications.

Conclusions

The key properties of glyphosate that determine glyphosate's environmental fate are its:

- Microbial degradability in soil and water
- Strong binding to most soil types
- High water solubility
- Very low volatility

Glyphosate is microbially degraded over time to naturally occurring substances such as carbon dioxide and phosphate. There is minimal herbicidal activity from residues of glyphosate in soil, and glyphosate residues are not likely to move to groundwater. Glyphosate that reaches surface water either by intentional application, spray drift, runoff, or soil erosion is adsorbed to sediment and degraded over time. Glyphosate is unlikely to move offsite during or after application due to volatilization. Available data indicate that glyphosate is not likely to bioaccumulate in the tissues of non-target organisms.

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Related Documents:

- Backgrounder: Authoritative Sources for Glyphosate Information
- Backgrounder: Glyphosate Half-life in Soil
- Backgrounder: Glyphosate and Drift
- Backgrounder: Glyphosate and Water Quality
- Backgrounder: Formaldehyde is not a degradate of glyphosate
- Backgrounder: Summary of Ecotoxicological Risk Assessment for Roundup® Herbicide

ANNEXE B12: Monsanto Backgrounder, Formaldehyde is not a major degradate of glyphosate in the environment. May, 2005.

MONSANTO imagine™

Backgrounder

Formaldehyde is not a major degradate of glyphosate in the environment

May, 2005

Glyphosate, the active ingredient in Roundup® brand agricultural herbicides, is degraded over time in the environment, primarily by soil microbes and fungi. The primary environmental degradate of glyphosate in soil and water is aminomethyphosphonic acid (AMPA). AMPA is further degraded to naturally occurring substances such as carbon dioxide and phosphate.

The U.S. Environmental Protection Agency, in the September 1993 Glyphosate Reregistration Eligibility Decision (RED)[1], states: "Glyphosate is readily degraded by soil microbes to AMPA, which is degraded to carbon dioxide. Glyphosate and AMPA are not likely to move to ground water due to their strong adsorptive characteristics."

Anti-pesticide groups have, over the years, repeatedly and incorrectly implied that formaldehyde is the predominant final degradate of AMPA in the environment. This statement is quoted from a 1988 review of glyphosate data by Monroe[2]. However, the reviewer apparently misunderstood a reference he cited. Rueppel *et al.*[3] proposed that formation of carbon dioxide from the degradation of AMPA in soil may involve formaldehyde as a transitory precursor, a theoretical possibility that had not been confirmed experimentally. Since that possibility was suggested in 1977, detailed studies using radiolabeled glyphosate have uniformly failed to detect formaldehyde as a distinct intermediate or final decomposition product of either glyphosate or AMPA in soil, plants or aquatic environment.[4]

Similar to other amino acids and natural organic matter, glyphosate can be selectively oxidized under certain laboratory conditions to form aqueous formaldehyde. For instance, laboratory experiments have indicated that both aqueous formaldehyde and carbon dioxide are formed during glyphosate chlorination with sodium hypochlorite[5]. Similarly, under intense artificial light, glyphosate may convert to both aqueous formaldehyde and carbon dioxide via oxidative transformation induced by photochemical excitation of humic acids as reported for other pesticides[6].

Production of formaldehyde under certain laboratory conditions is not unique to glyphosate and would also be expected from oxidative fragmentation of many carbon containing small molecules, amino acids, and other natural organic compounds such as humic and fulvic acids[7]. However, in the field where glyphosate is used, there is overwhelming evidence that glyphosate is degraded by soil microbes primarily to AMPA, which is degraded over time to carbon dioxide and other naturally-occurring substances. There is no indication of any accumulation of formaldehyde in the environment as a result of glyphosate degradation.

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ANNEXE B13: Monsanto Backgrounder, No Restriction of Autumn Use of Glyphosate in Denmark, April, 2005

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Backgrounder
No Restriction of Autumn Use of Glyphosate in Denmark
April 2005

Monsanto Company

In June, 2003, following its environmental evaluation of glyphosate, the Danish Environmental Protection Agency proposed a restriction of certain uses of glyphosate occurring after September 15th. This proposed restriction was based primarily on the results of the Pesticide Leaching Assessment Programme (PLAP) which is run by GEUS (Geological Survey of Denmark and Greenland) for the Danish EPA[1]. Since then, the Danish EPA has evaluated additional information, and on December 14, 2004, they stated that they had no technical grounds for imposing restrictions on the autumn application of glyphosate in Denmark.

The PLAP is intended to serve as an early warning system for Danish Government to evaluate whether pesticides would leach to the groundwater at levels exceeding the maximum allowable concentration of 0.1 µg/l Drinking water quality in all European countries is governed by the requirements of the European Drinking Water Directive, which limits the maximum allowable concentration in drinking water to 0.1 µg/L for any single pesticide, regardless of toxicity. In comparison, the U.S. EPA has set a Maximum Contaminant Level of 700 µg/L for glyphosate in drinking water, based on a toxicological risk assessment.

As part of the Danish PLAP, a glyphosate herbicide was applied at five of the six locations utilized in the monitoring program. Glyphosate was applied in the autumn following crop harvest and at the maximum recommended rate, and water monitoring included sampling of water in both the unsaturated and saturated zones, using suction sampling cells and vertical and horizontal bore holes. In addition, at the four sites with clayey soil, field drainage water was sampled from the existing tile drainage systems.

In the samples collected following the glyphosate applications, there were no detections of glyphosate or its metabolite, aminomethylphosphonic acid (AMPA), exceeding 0.1 µg/L in any of the groundwater samples taken from the suction cells (1 and 2 meters below ground surface (m.b.g.s.)), the vertical bore holes (approx. 1.5 – 5.5 m.b.g.s.) and the horizontal bore holes (approx. 3.5 m.b.g.s.). The detections that were considered by the Danish EPA to represent an unacceptable risk to drinking water were found only in the field drainage water. The detections in the drainage water occurred primarily in the autumn. The highest measured concentrations were 5.1 µg/L for glyphosate and 5.4 µg/L for AMPA. The calculated average annual concentrations in drainage water of glyphosate and AMPA were 0.54 and 0.17 µg/L, respectively, at one location, and 0.12 µg/L and 0.06 µg/L, respectively, at a second location. At a third location, glyphosate and AMPA were detected but both average concentrations were below 0.1 µg/L. Based on these results, the Danish Minister of the Environment proposed a ban on glyphosate use after September 15th each year, on certain clay soils.

Three of the glyphosate manufacturers (Cheminova, Monsanto, and Syngenta) submitted a response to the Danish EPA that explained why the proposed restrictions on the use of glyphosate were unjustified. It was suggested that in poorly drained agricultural soils, sediment-laden water can flow to sub-surface tile drains and out of the field. Studies have shown that

[1] The Danish Pesticide Leaching Assessment Programme. Monitoring Results May 1999 – June 2002. 3rd Report. Editor: Jeanne Kjaer. Printed: June 2003. ISBN 87-7871-115-0. http://pesticidvarsling.dk/monitor_uk/2002_uk/index.html

glyphosate forms strong complexes with soil constituents. Thus, glyphosate bound to the suspended soil particles may reach the drains, but there is no indication that it will leach to any significant degree to groundwater. Hydrostatic pressures dictate that the soil water will preferentially flow to the drains rather than leach to groundwater.

Organizations such as the National Federation of Danish Agriculture, Danish Association for Conservation Agriculture, and the Royal Veterinary and Agriculture University of Denmark also suggested to the Danish government that the quality of the field drainage water could not be compared with the quality of the groundwater especially for soil particle-born substances such as glyphosate.

The issue of a special transport mechanism for glyphosate through drainpipes was evaluated in a scientific seminar held on September of 2004, organized by the Danish Institute of Agricultural Sciences. In this meeting, Danish expert scientists evaluated new research conceming the lack of detection of glyphosate below the drainpipes and confirmed the existence of a special transport mechanism for glyphosate bound to small soil particles through the drainpipes. As a result of this conference, the Danish Environmental Protection Agency concurred with the experts that field drainage water cannot be used as an indicator of leaching to groundwater for substances such as glyphosate that are strongly bound to soil particles.

In an updated evaluation status of glyphosate released on December 14, 2004, the Danish Environmental Protection Agency revoked the earlier proposal for restriction of glyphosate use and issued the following ruling in regard to the autumn application of glyphosate in Denmark (translated from Danish):

> "...the Danish Environmental Protection Agency believes that no unacceptable risk of pollution of the groundwater is associated with the currently approved agricultural use of glyphosate. The Agency thus does not consider that the updated state of our knowledge provides any technical grounds for the imposition of restrictions on the autumn application of glyphosate."

Related Documents:

- Backgrounder: Glyphosate and Water Quality

ANNEXE B14: Monsanto Backgrounder, Glyphosate and Water Quality, Updated November, 2003.

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Backgrounder
Glyphosate and Water Quality
Updated November, 2003

Glyphosate, the active ingredient in Roundup® agricultural herbicides and Roundup® turf and ornamental herbicides, sometimes is detected in surface waters, but historically, glyphosate has not been included among herbicides that cause concern in water supplies. Since glyphosate can readily be removed from water by conventional drinking water treatment methods (which include sand filtration and chlorination), it is highly unlikely that it would be detected in finished drinking water (Speth 1994). Because glyphosate binds tightly to most soils, it has a low potential to move through soil to contaminate groundwater (U.S. EPA 1993).

The World Health Organization reviewed water quality data for glyphosate and stated:

> "It was concluded that because of its low toxicity, the health-based value derived for glyphosate was orders of magnitude higher than glyphosate concentrations normally found in drinking water. Under usual conditions, therefore, the presence of glyphosate in drinking water does not represent a hazard to human health." (WHO 1997).

How glyphosate can enter surface water

Glyphosate can enter surface waters through three routes – direct application to aquatic vegetation, binding to soil that washes off treated terrestrial sites, or through drift from treated areas that are near water.

Specific glyphosate herbicides are used throughout the world to control emerged and floating vegetation in water. In the United States, AquaMaster™ herbicide is registered for application to emerged vegetation in water; in other countries, other glyphosate brands have approval for aquatic uses. Only a very few herbicides have the environmental and toxicological properties that make them suitable for application over water. Because glyphosate is approved for the control of unwanted vegetation in aquatic environments, including sources used for drinking water, it is expected that the glyphosate might occasionally be detected in surface water.

From terrestrial applications of glyphosate herbicide, it is expected that a small amount of the applied glyphosate may enter surface waters through runoff or attached to soil particles that wash off treated fields. Glyphosate residues in water resulting from such wash-off are typically seasonal and dissipate over time. In lakes or streams, glyphosate will remain attached to soil and sediment particles, which either are filtered out by drinking water treatment plants or settle to the bottom of waterbodies. In sediment, glyphosate is degraded over time by microorganisms.

When glyphosate applications are made near water, it also is possible that a small percentage of the sprayed material may reach the water during application. Once in contact with surface water, glyphosate is removed via several mechanisms, include binding to sediment and microbial degradation (U.S. EPA 1993).

Glyphosate effects on the aquatic environment

AquaMaster™ and other glyphosate herbicides approved for aquatic uses are designed for application to the exposed surfaces of emerged undesirable aquatic vegetation. Under normal

use conditions, there is little likelihood that aquatic application would result in concentrations in the water that would adversely affect sensitive non-target vegetation (Perkins 1997). There also is little likelihood under normal use conditions that concentrations in the water would exceed levels that would result in unreasonable adverse effects to fish and other species of aquatic wildlife (including sediment-dwelling organisms) (Giesy *et al.*, 2000).

In 2000, three internationally recognized experts in environmental toxicology published an ecotoxicological assessment of glyphosate (Giesy *et al.*, 2000). The authors wrote: "Glyphosate has been used extensively to control aquatic weeds and restore ecosystems affected by introduction of exotic weeds. During this period of use, there have been no documented cases of adverse effects on fish or aquatic invertebrates associated with glyphosate use for this purpose." Many wildlife organizations and state departments of conservation have used glyphosate herbicides to restore aquatic habitats (for example, in the Florida Everglades to remove invasive melaluca).

Drinking water standards

In the United States, the Environmental Protection Agency has established a federal drinking water standard known as the Maximum Contaminant Level (MCL) for selected pesticides. This is the dose that is deemed protective of public health if people were to consume that dose every day of their life. The establishment of an MCL for a pesticide does not imply that detections in drinking water are expected. Even though drinking water standards are in place, glyphosate detections in drinking water are not expected. Glyphosate binds to soil particles, including particles suspended in water which can be removed readily by filtration during water treatment processes. In addition, routine water disinfection processes such as ozonation and chlorination effectively remove glyphosate from water. Therefore, surface water that is used as a source for drinking water can be effectively treated to remove any glyphosate that may be present (Speth 1994). For glyphosate, the MCL is 700 parts per billion (ppb, or micrograms/L) (U.S. EPA Office of Ground Water and Drinking Water 2002). The California Environmental Protection Agency has established an even higher glyphosate standard of 1000 ppb (California EPA 1997). The U.S. EPA MCL, which is very high compared to most other pesticides, was set at a high level based on laboratory tests that demonstrated that glyphosate has very low acute and chronic toxicity to mammals and is not carcinogenic.

In Europe, the drinking water standard for any pesticide has been set at 0.1 ppb. This is not based on scientific toxicological testing, but instead is a regulatory standard for all pesticides, regardless of the toxicological profile. Even with such a low limit (10,000 times more restrictive than the California standard), there have been no confirmed instances of glyphosate in excess of the standard in finished drinking water.

Roundup Ready® Crops: A beneficial impact on surface water quality

When farmers engage in conservation tillage, leaving crop residue (leaves and stem stubble) on their fields instead of plowing it under, they can reduce runoff of soil and chemicals into streams by more than 90 percent (Hebblethwaite 1995; Fawcett *et al.*, 1995; Edwards *et al.*, 1988). The effect of crop residues on runoff reduction is influenced by several factors, including extent and type of crop residue, duration and intensity of rainfall, and the physical properties of the herbicidal active ingredient. The development of Roundup Ready® crops has had a significant role in enabling growers to include reduced tillage options in their farming practices. In a 2001 survey, 63 percent of U.S. soybean growers who increased the amount of crop residue left in their fields between 1996 and 2001 cited Roundup Ready® technology as the key factor that made it possible for them to reduce tillage (American Soybean Association, 2001).

Even if not used in conservation tillage, Roundup Ready® crops allow farmers to use Roundup agricultural herbicides for weed control in place of other herbicides that may have greater likelihood of moving to groundwater or surface water. Replacement of other herbicides with glyphosate is predicted by computer modeling studies to reduce the concentrations of pre-emergent herbicides in surface water in vulnerable watersheds (Wauchope *et al.*, 2001). In 2002, the U.S. Geological Survey conducted a monitoring study in which 51 streams in nine midwestern states were sampled to determine the presence of herbicides, their degradation products, or antibiotics (Scribner *et al.*, 2003). The authors reported that median concentrations of glyphosate were less than 0.10 ppb (the limit of detection), and AMPA median concentrations ranged from 0.1 to 0.27 ppb. These results indicate that glyphosate and AMPA residues in surface water in agricultural regions where Roundup Ready® crops are grown are not expected to approach levels that would be of toxicological concern to human health or of ecological concern for wildlife and other non-target organisms.

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ANNEXE B15: Monsanto Backgrounder, Glyphosate and Wildlife, December, 2002.

MONSANTO

Backgrounder
Glyphosate and Wildlife
December, 2002

Monsanto Company

Overview

Before any herbicide can be registered for use in the United States, the active ingredient must undergo a number of required studies to investigate the potential for unreasonable adverse effects to wildlife and other non-target organisms. The required studies are conducted with species representative of various forms of wildlife – small mammals, birds, fish, aquatic invertebrates, algae and aquatic plants, and honey bees. The results from these required studies indicate that glyphosate will not cause unreasonable adverse effects to wildlife when used according to label directions. In 1993, when glyphosate was reregistered in the U.S., the Environmental Protection Agency (EPA) stated: "Based on current data, EPA has determined that the effects of glyphosate on birds, mammals, fish and invertebrates are minimal" (U.S. EPA 1993).

In addition to studies required by the U.S. EPA and other regulatory bodies, many other wildlife-related studies have been conducted with glyphosate products during more than 30 years of use. The weight of evidence from these studies supports the conclusion from regulatory studies that no unreasonable adverse effects are predicted from the normal use of glyphosate herbicides (Sullivan and Sullivan, 2000). Glyphosate herbicides are commonly used as a tool to restore and protect habitat. For example, they have been used in protected habitats such as the Galapagos Islands and the Florida Everglades.

In 2000, three internationally recognized experts in environmental toxicology published an ecotoxicological assessment of glyphosate and the original Roundup[1] herbicide (Giesy et al., 2000). Using very conservative assumptions, the authors established hazard quotient (HQ) values for the various life forms that could be exposed to the formulation and glyphosate in the environment, for both acute and chronic exposures. An HQ lower than 1.0 indicates minimal risk of adverse effects, while HQ values greater than 10 suggest significant risk. The experts found that no terrestrial use of the formulated herbicide produced an HQ of 1.0 or greater. They also found that no aquatic use produced an HQ greater than 1.0, with the exception of glyphosate and surfactant applied directly to very shallow water (6 inches). The highest HQ in such shallow water was only 6.19. The authors point out that in actual use, aquatic vegetation would intercept at least 50 percent of the applied product. As a result, the authors concluded that direct applications of the original Roundup[1] herbicide to water could be carried out with minimal risk to aquatic organisms with consideration of the water depth, vegetation density, and overall rehabilitation goal.[2]

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[1] "Roundup" refers to the original single active ingredient Roundup herbicide formulation (also known as MON 2139).

[2] Only specific glyphosate formulations are labeled for aquatic use in certain world areas. Use of a product inconsistent with its label is a violation of law and is strictly prohibited. AquaMaster™ herbicide is labeled for aquatic uses in the United States.

Wild mammals

Glyphosate and Monsanto's glyphosate herbicides have been extensively tested for adverse effects on laboratory mammals, primarily rats, mice, and rabbits. In addition to laboratory studies, the scientific literature contains many field studies in which the effects of glyphosate use on wild mammals have been examined (Sullivan and Sullivan, 2000; Santillo et al. 1989; Hjeljord et al. 1988; Sullivan 1990; Hjeljord 1994; Cumming et al. 1996; Cole et al. 1998). These studies indicate that glyphosate and glyphosate herbicides, when used according to label directions, will not cause unreasonable adverse effects to mammals. An ecotoxicological risk assessment of glyphosate (Giesy et al. 2000) reported estimated exposures that various mammals might encounter from potential use of glyphosate. The authors concluded that mammals, including the tiny meadow vole, would not be expected to encounter harmful levels of glyphosate through multiple possible exposure routes, including food, water and direct contact.

Birds

Glyphosate has been evaluated for toxicity to bobwhite quail and mallard duck in laboratory studies. These species are surrogates for wild avian species that might be exposed to glyphosate through various exposure routes. In dietary studies conducted with bobwhite quail and mallard ducks, in which the birds consume treated diet for 5 days, glyphosate had no effects at the highest dose tested. Reproductive tests indicated that no adverse effects on avian reproduction or hatchling development would be expected from normal use of glyphosate. Exposure of birds to glyphosate in the environment is predicted to occur at much lower levels than the levels evaluated in the laboratory studies. In addition, glyphosate has been shown to rapidly dissipate from treated vegetation, and such vegetation becomes unpalatable within 1 to 3 weeks after treatment. Therefore, the proper use of glyphosate-containing herbicides is not expected to pose a significant risk to birds (U.S. EPA 1993). In addition to the laboratory studies, several comprehensive field studies have examined birds in natural settings where glyphosate products were used. These studies demonstrate that some species favored treated areas, while other species temporarily left treated areas because of changes in the vegetative habitat. No direct toxicity was reported in any of the studies (Giesy et al, 2000). Any form of vegetation removal would be expected to produce similar effects. Studies have shown that avian species abundance returns to pre-treatment levels when plant regrowth occurs (MacKinnon and Freedman, 1993).

A Technical Information Summary titled "Glyphosate and Avian Species" is available upon request from the Monsanto's Public Affairs Director for Agricultural Chemicals at 314-694-3546.

Aquatic animals (fish, shellfish)

Glyphosate and many of Monsanto's glyphosate formulations have been tested for toxicity to numerous aquatic animals, including invertebrate and vertebrate fresh and saltwater species. Results of these studies indicate that glyphosate has very low acute toxicity to aquatic animals (U.S. EPA 1993, WHO 1994) Levels required to produce adverse effects would not be expected from labeled use of glyphosate herbicides. It has also been shown that glyphosate does not bioconcentrate in tissues of aquatic organisms (WHO, 1994).

To work effectively, glyphosate must be mixed with a surfactant (a soap-like substance) that facilitates the uptake of glyphosate by the plant. Surfactants may be more toxic than glyphosate to aquatic organisms in laboratory tests. However, the level of surfactant present in a herbicide application is sufficiently low that no unreasonable adverse effects are expected to result from

the normal use of the products. A conservative aquatic risk assessment indicates that glyphosate and surfactant would not be expected to produce unreasonable adverse effects to aquatic organisms in water 6 feet deep (Giesy et al, 2000). In more shallow water, potential effects predicted by hazard quotients are unlikely to occur in the environment due to interception, sediment binding, and degradation of the herbicide components. The World Health Organization report on glyphosate states: "Fish and aquatic invertebrates would not be affected by glyphosate use" (WHO 1994).

Amphibians

Toxicity studies with amphibians are not included in the standard toxicity tests required for U.S. EPA registration. Toxicity studies with amphibians have shown that amphibians are not more sensitive than fish to herbicides (Mayer and Ellersieck, 1986; Birge et al., 2000). Since fish are included in the mandatory toxicity studies for pesticide active ingredients, amphibians are not. Nevertheless, the toxicity of glyphosate and some glyphosate formulations to several species of amphibians, including frogs, newts and salamanders, have been investigated. A risk assessment based on exposure of amphibians and other aquatic organisms demonstrates that normal use of glyphosate formulations are not expected to cause unreasonable adverse effects to amphibians, including tadpoles (Giesy et al., 2000).

Insects and other terrestrial arthropods

Glyphosate and the original Roundup[1] formulation have been tested for toxicity to honey bees in laboratory tests, using both oral and topical dosing. In these studies, glyphosate and Roundup were found to have no adverse effects to bees at rates much higher than would be present in treated areas. In addition, the original Roundup formulation has been evaluated in laboratory studies with terrestrial arthropods such as the parasitic wasp, predatory mite, carabid beetle, and green lacewing. These laboratory studies use artificial exposure conditions to simulate exposures in the field. When the results of these studies are compared to estimated residues of glyphosate that might occur in and adjacent to treated areas, it can be concluded that the risk of unreasonable adverse effects to terrestrial arthropods ranges from low to moderate. At the maximum use rate, no in-field effects are predicted for the carabid beetle and parasitic wasp, while in-field effects cannot be excluded for the predatory mite and green lacewing. However, no effects to the predatory mite and green lacewing are expected at more typical use rates.

Habitat change resulting from herbicide use (due to the decrease in vegetation) can have a significant influence on leaf-dwelling arthropod populations (e.g. wasp, mite, and lacewing). The primary effect to populations on-site are expected to result from herbicidal effects on vegetation. Therefore, direct effects on arthropod populations that might be observed after herbicide use are expected to be less significant than effects due to habitat change.

The effects of other glyphosate formulations on beneficial arthropods may vary from those observed for the original Roundup formulation. Generally, no effects are observed to beneficial arthropods at rates expected from herbicide drift to nontarget areas. In target areas, habitat change is expected to have the most influence on arthropod populations.

In a screening assay in which 18 different beneficial predators and parasites were exposed to the original Roundup[1] formulation on a synthetic surface, the formulation was found to be "harmless" to 13 species, "slightly harmful" to four species and "moderately harmful" to one species (carabid beetle) (Hassan *et al.* 1988)[a]. The authors did not believe that sufficient toxicity potential existed for the Roundup formulation to warrant semi-field and field tests that

were performed on some of the other compounds tested in the same program. A subsequent semi-field test with a similar glyphosate formulation indicated that even when carabid beetles were directly oversprayed at the maximum use rate, no mortality was observed. One reason for the difference between the laboratory and semi-field study results may be related to the artificial nature of the laboratory glass plate assays (e.g. potential stickiness of the formulation on the glass substrate).

After reviewing extensive research on glyphosate and arthropods, three experts in environmental toxicology wrote (Giesy et al., 2000):

> "In summary, the literature supports the conclusion that non-target arthropods are at minimal risk from glyphosate and its formulations in offsite areas. Within treated areas, applications of the herbicide can produce changes in species diversity and in population size and structure for beneficial insects through modifications of available food sources and habitat."

[a] Categories used by Hassan et al. to report mortality/reduction in beneficial capacity were as follows: "harmless": < 50%; "slightly harmful": 50-79%; "moderately harmful": 80-99%; "harmful": > 99%.

Earthworms

Numerous studies support the conclusion that normal use of glyphosate formulations, such as the original Roundup herbicide[1] and other glyphosate herbicides, will not result in adverse effects to earthworms. A comprehensive review of the effects of agricultural chemicals on earthworms reviewed the effects of glyphosate on earthworms (Edwards and Bohlen 1996). Glyphosate was ranked as zero on a scale of zero (relatively non-toxic) to 4 (extremely toxic). Monsanto and several independent researchers have conducted studies in which no adverse effects were observed when earthworms were exposed to glyphosate residues in soil at rates equal to or greater than labeled rates (Giesy et al., 2000). In field studies, it has been demonstrated that earthworms thrive under conservation-tillage cropping practices, which are facilitated by Roundup UltraMax and other glyphosate herbicides (Giesy et al., 2000).

A Technical Information Summary titled "Glyphosate and Earthworms" is available upon request from the Monsanto's Public Affairs Director for Agricultural Chemicals at 314-694-3546.

Soil microorganisms

Numerous laboratory and field studies have been published by independent researchers investigating the effects of glyphosate on soil microbes. The weight of evidence from these studies conducted using realistic exposure conditions indicates that no significant adverse effects to soil organisms are expected when glyphosate herbicides are applied according to label directions (Giesy et al, 2000). Experiments on glyphosate treated and untreated soil revealed no significant difference in the types or amount of microbes present (Rueppel et al. 1977). Studies also show that glyphosate does not interfere with the ability of microbes to decompose plant material, such as dead leaves, or convert inorganic nitrogen into an organic form needed for plant growth (Grossbard, 1985; Sullivan, 1990).

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